No. 21-55517

S273887

In the

United States Court of Appeals

for the

Ninth Circuit

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN;

Plaintiffs-Appellants,

vs.

SOMATICS, LLC,

Defendant-Respondent.

Appeal from an Order of the United State District Court for the Central District of California, Case No. 2:17-cv-06686-RGK- JCx
Hon. R. Gary Klausner

APPELLANTS' EXCERPTS OF RECORD
VOLUME 3 OF 6

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A. Once again, it was short-term memory loss due to ECT. There wasn't really a defined timetable on what short term meant. That was the big take-away that I can recall.

Q. And did you ask any questions about how long that duration would last?

A. No.

Q. Do you know if Michelle did?

A. Not really, no.

Q. At any point in time did anybody ever tell you how long to expect that short-term memory loss condition to last?

A. Not in -- in specifics. I mean, I -- I -- I think, you know, a question was posed in a conversation between Shelly and somebody; and -- and a speculative answer, sometimes a day to a couple weeks. Nothing really more than that.

Q. Do you know who that was? Was that Dr. Fidaleo?

A. I don't remember, sir.

Q. Did the video or Dr. Fidaleo during that next meeting go over any other risks or side effects of treatment?

A. They talked about the anesthesia, just that it would kind of incapacitate Shelly for -- for pretty

much the day. She wouldn't be able to drive a vehicle, that type of thing.

Q. Do you recall whether the video or Dr. Fidaleo discussed the possibility of confusion occurring after treatment?

A. That was something that I believe was said, yeah.

Q. Okay. And do you recall whether he gave you how -- whether the video or Dr. Fidaleo explained how long that confusion state would last?

A. I believe it was Dr. Fidaleo. It would have been just for the day, but more related to the anesthesia than anything.

Q. The pamphlets that you reviewed, were those provided to you from Dr. Fidaleo?

A. Yes, sir.

Q. And was that during that same visit when you saw the video as well?

A. I believe so, sir.

Q. Did he give you the pamphlets to take home?

A. I believe so. I think so.

Q. And do you have copies of those pamphlets?

A. No, sir.

Q. Do you recall what -- any of the contents that was on those pamphlets?

REPORTER'S CERTIFICATE

STATE OF IDAHO)
) ss.
COUNTY OF ADA)

I, MARYANN MATTHEWS, Certified Shorthand Reporter and Notary Public in and for the State of Idaho, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was duly sworn remotely by me to testify to the truth, the whole truth and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and that the foregoing transcript contains a full, true and verbatim record of said deposition.

I further certify that I have no interest in the event of the action.

WITNESS my hand and seal this 25th day of March, 2021.

MARYANN MATTHEWS
CSR and Notary
Public in and for the
State of Idaho.

My Commission Expires: 09-12-2025

EXHIBIT 4

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN, Plaintiffs, -vs- SOMATICS, LLC, Defendant.	CASE NO. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF
DANIEL BENJAMIN
TAKEN ON BEHALF OF THE DEFENDANT
VIA VIDEOCONFERENCE
ON MARCH 4, 2021

Job No. CS4482811

REPORTED BY: TRENA K. BLOYE, CSR

provided.

Q And what did you learn about that?

A Um, now, in retrospect there was maybe three positive reviews and one review that just criticized his bedside manner. And the positive reviews just said, "I felt better after the treatment." But, caveat, people within the -- immediately after I felt better.

Q And why did you add that caveat?

A Because, in retrospect, people who were posting reviews were right after they had had the treatment. I didn't -- I didn't care -- I didn't think to look into any long term or anything of that nature.

Q And were you also present for Mrs. Benjamin's consultation with Dr. Frankel?

A Yes.

Q And do you know if she did any research prior to meeting with Dr. Frankel about ECT?

A I think we -- no. I did most of the research and I shared it with her. Again, my objective was to get her well. We were provided this referral from a professional to another professional, and I was excited about the possibility of getting Marcia back to a full state of wellness.

Q All right. So when you met with Dr. Frankel, what did he tell you about the procedure?

A I -- not much, be honest. He asked a lot more questions of Marcia to, you know, I gathered he was trying to ascertain she was a candidate. And, obviously, we discussed the -- the connotation of having electric shock therapy. And, you know, he made it sound like it was pretty much a walk around the park with worst case scenario, you know, some short-term memory that doesn't last longer than three months.

Q Did he tell you that there were any other risks than potential short-term memory disturbances for three months?

A He did not.

Q Okay. Are you still there? It looks like we might have lost you for a second. Can you hear me?

A Yeah, no. You did lose me. I can hear you.

Q Okay. Great.

A My machine does this every hour or so.

MS. ALARCON: Can we -- can we actually take a quick break?

MR. BENKNER: Absolutely.

MS. ALARCON: Thank you.

VIDEO OPERATOR: The time is 10:34 and we are going off the record.

(A break was had.)

VIDEO OPERATOR: The time is 10:40 and we

Q Okay. And this was occurring while she was undergoing ECT treatment?

A At some point throughout the treatment, yes.

Q And did you express this concern to Dr. Frankel?

A I think most of my focus was on the memory aspects of the treatment.

Q Did you ever have a conversation with Dr. Frankel about Mrs. Benjamin exhibiting balancing issues?

A I believe, but I will not -- you know, I believe I did towards the end. I had kind of described to him where I thought things were not right.

Q And do you know what he said in response, if anything?

A The one thing that I remember that really upset me was he moved the goal post. He -- when we talked about memory he said, "Well, sometimes it can take six months, a year to get all your memory back."

Q And, now, the memory problems that you observed her having, was it that she was having trouble recalling events that occurred prior to ECT treatment?

A That is correct.

Q Do you know why Mrs. Benjamin stopped her ECT treatment in March of 2013?

A I do.
Q So why is that?
A I -- I stopped it. There -- there -- there's a story there.
We went to ECT because we were told medication wasn't working. When ECT was giving her all sorts of side effects and she was still not better, Dr. Frankel wanted her to use Lithium as a medication to go with ECT. At that point it was obvious to me that we got into this because medication wasn't working, and he was discussing medication in order to accommodate issues with ECT.
Q And so I understand she -- Mrs. Benjamin then went back to see Dr. Gudeman for transcranial magnetic stimulation; is that right?
A Not -- I don't recall it being immediate. It was sort of -- so there was some overlap when the ECT was providing her the side effect and it wasn't making her well, per se.
Q Were you also present when Dr. Gudeman explained what transcranial magnetic stimulation was?
A I was.
Q And what did -- what do you recall him saying about that procedure?
A That they had observed that people have EMRIs

Q (By Mr. Benkner) Yeah. Go ahead and let me know when you're ready.

A I'm ready.

Q Okay. So going back to my question, then, she indicated that prior to undergoing ECT she would engage in sexual relations with you approximately three to four times a week. Is that accurate?

A That's accurate.

Q Okay. And then a little bit further down this sentence says, "It took approximately three years after ECT before conjugal relations returned to the same frequency as they existed prior." Is that an accurate statement?

A That is accurate.

Q Do you know exactly when your -- the sexual relationship you had with your wife changed from three to four times to less?

A I cannot pinpoint exactly, but I have to say -- yeah, I can't pinpoint exactly. But I think -- I think in terms of a block of time before and after it's easier for me to see.

Q Sure. Were you having any problems with sexual relations while she was treating with Dr. Gudeman, first treating with Dr. Gudeman before undergoing ECT?

A No. I can expand on that if you like.

Q Sure.
A She had ups and downs in her -- with the medication Gudeman was giving her, so there were some ups where the relationship was quasi normal.
Q And in thinking -- thinking about the period of time after she underwent ECT, how did it change? It went from three to four times a week to approximately how often?
A There wasn't a lot of conjugal interaction during that time. If there was --
Q Can you give me any estimate?
A No. If there was a window here or there where things were, you know, relatively peaceful, maybe. But twice a year. I don't know. I really can't venture a guess.
Q Okay. And at any point did you seek the advice of a therapist or other healthcare provider to try to fix that problem?
A No. The problem of conjugal visits is what you are referring to?
Q This specific issue, yes.
A I don't really care for that question because the goal was to get her well. It was not -- to get the conjugal visits re-established was not the point.
Q Okay. So other than the conjugal relations

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C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, Trena K. Bloye, Certified Shorthand Reporter within and for the State of Oklahoma, certify that DANIEL BENJAMIN was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the witness chooses to read and sign the deposition; that the above and foregoing videotaped deposition was taken by me in shorthand and thereafter transcribed; that the same was taken on March 4, 2021, at 10:00 a.m. PST, via videoconference; that I am not an attorney for, nor a relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 8th day of March, 2021.

Trena K. Bloye, CSR
State of Oklahoma CSR No. 1522

EXHIBIT 5

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN, Plaintiffs, -vs- SOMATICS, LLC, Defendant.	CASE NO. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF
RAYMOND FIDALEO, M.D.
TAKEN ON BEHALF OF THE DEFENDANT
VIA VIDEOCONFERENCE
ON FEBRUARY 12, 2021

REPORTED BY: TRENA K. BLOYE, CSR
Job No. CS4452015

sort of like automatic. It works. You just have to set the setting. And then you -- if you have -- if they have the impedence right then the machine let's you treat it. If it isn't, if the impedence of the electrodes is not correct it won't let you treat. So there is a safety built in.

Q Okay. Do you recall reading the operator's manual for the Thymatron device?

A No, I don't recall that.

Q Okay. Do you know if the operator's manual is made available by the hospital?

A It's -- it's made available. The technician usually is the one that knows it. There's a technician that does all the ECT and he's the one that refers to the book if there is an issue, or we call the company if there is an issue, you know.

Q Okay. The technician that you're referring to, is that person a full-time employee of the hospital?

A Yes, he is.

Q Okay. The technician and -- if you know, do you know who the technician was for Sharp Vista Hospital in 2001 or 2002?

A Yeah. I'm pretty sure it was Dave Munden. I'm not accurate, but he's been there forever, so I think it was him. David Munden, M-u-n-d-e-n.

Q Okay. Is Mr. Munden still -- is he a doctor?
A No, no. He's a -- he's a nurse.
Q He's a nurse. Okay. Is Mr. Munden still employed at Sharp?
A He may be -- he was -- he may be retired. I haven't been to the hospital since COVID, so I don't know if he retired. He was getting close to retirement when I got COVID, so I backed out of the hospital since then.
Q Oh, okay. So since you have been in practice, you know, for quite a while, some things have changed in the practice of ECT; right, since you started practicing?
A Since I started, yes.
Q Yeah. One of them you've alluded to was, you know, obviously the use of an anesthesiologist as part of the procedure; right?
A Yeah.
Q Is there -- have you, um, relied on or used any kind of ongoing learning or educational programs to keep you updated on the advancement of ECT since you started practicing?
A Yes, yeah.
Q And what --
A If the AMA had some series on it. The machines

her life, her inability to take care of her child and she became paranoid. They treated her at Balboa and said they remitted it. But intermittently, you know, she just acknowledged that she really did believe that the formula had been tampered with, you know, and somebody was trying to kill her child.

Q Um-hum.

A So, you know, it was a serious case.

Q Do you recall if she voluntarily agreed to ECT?

A Yes.

MR. ESFANDIARI: Objection to form.

A She's voluntary. If you're involuntary ECT, you know, you needed to be able to document that she was not a voluntary patient in the hospital in the first place, and then you had to go to court and get permission from the court to do ECT if she's involuntary. That didn't take place.

Q (By Mr. Benkner) So it's your understanding that this particular hospitalization event, she voluntarily admitted herself?

A Yes.

Q Okay. So continuing on Exhibit No. 1 towards the bottom of page 1055, I want to focus your attention kind of on that last paragraph there.

A Yeah. She fully understands the --

Q Let me just blow it up so you can see it there. Do you see what I've highlighted there?
A Yes, I see it.
Q I'm going to take a quick quote on this. Quote, She fully understands side effects listed and gone over with her prior to admission and also finally after admission, end quote.
A Right.
Q Did you write that?
A Yes.
Q And are you referring to the side effects of ECT specifically?
A Yes.
Q Okay. The next sentence she says, quote -- or you say, quote, She has also researched it on her own, end quote.
A Yes.
Q Do you see that?
A See, she was at Balboa Hospital and they made the recommendation for ECT. So they had discussed it with her, and that's why she was sent here for ECT. Balboa was not doing the ECT. Not all of the hospitals in San Diego were doing ECT at that time.
Q Do you have a recollection of Ms. Himes telling you that she had researched ECT on her own?

know, it's like -- usually we talk about memory we're talking deficits, short-term and long-term memory. Okay.

Q Right.

A I'm trying to tell you there are going to be lapses of long-term memory. But in short-term memory, you know, that comes back.

Q And short-term memory, are you referring to the ability to learn and retain new information?

A Right, yes. And do your job. If you're a physician, your skills come back, you can work, you know. The physicians, they get the treatments, they are not -- they don't lose their skills. I mean, they still have them.

Q Gotcha. Did you advise Ms. Himes that she could experience brain damage from ECT?

A No. There is no literature that supports brain damage.

Q Okay. Have you ever been concerned in your own practice that brain damage could be a risk of treatment?

A No.

Q And why is that?

A Because people go back and function normally after ECT. ECT is, you know, used to say it's like a last resort. It doesn't have to be a last resort, but

we don't do ETC right off the bat. You try to get people better with medications and therapy.

If they can't get better and if they are profusely depressed and they are thinking of killing themselves then that's the treatment of choice. Okay?

Q Okay. I'm going to share my screen with you once more.

A You should know that, like, movies like "One Flew Over the Cuckoo's Nest," that's not an accurate picture. And we dont' do ECT every day. You know, it's a series and you do it three times a week, not every day.

This would be a treatment report, yeah.

Q Yeah, yeah. So I'm gonna mark this as Exhibit No. 2 I believe I'm on. Do you recognize this as a treatment report that you've completed, that you filled out?

A Yes, I did.

Q Okay. And, again, I will represent to you I got this from Sharp Hospital directly. And based on my review here it looks like ECT number 26 was the last date that you treated Ms. Himes with ECT.

A Right, right.

Q Does that comport with your recollection of that?

A Right.
Q Okay. And I think the date down here is 1/3/2012, January 3rd?
A Right.
Q Okay. I didn't see a discharge report. Would you typically generate a discharge report if you were treating someone outpatient ECT?
A No, not necessarily, not from the ECT report. It didn't require a discharge summary for the ECT.
Q Um-hum.
A For the hospital, when she had eleven treatments, I have a discharge report for that.
Q Yeah, and I have seen that. I was just trying it figure out if there was a discharge report after your final session of ECT?
A No, no.
Q Okay. Do you recall why Ms. Himes stopped treating with -- stopped --
A Well, she's doing well. If you see, she's on a monthly basis at that time. Okay. So she was doing well. Baby back with her.
You know, she had been separated from the baby, you know. So she was doing well with her baby at that point. The issue was because she was paranoid with respect to the baby, CPS was involved in the case.

Drs. Richard Abrams and Dr. Conrad Swartz. There may be others. Do those two names sound familiar to you at all, sir?

A No.

Q You mentioned you were board certified 1971?

A '71, yes.

Q In the field of psychiatry?

A Psychiatry, yeah. You get it in psychiatry and neurology, but it's basically psychiatry.

Q And how often do you have to recertify, sir?

A You don't have to with psychiatry. They don't require it.

Q Okay.

A They may change it. There's always new laws, but up until now they haven't required recertification.

Q You had mentioned that, in terms of training, that you believe that -- training with respect to the Somatics device, the Thymatron, that a Somatics personnel trained one of the technicians at the hospital that you're affiliated with, a gentleman by the name of Dave Munden you believe. And then Mr. Munden trained you and other users of the ECT device; is that correct?

A Correct, yeah.

Q Do -- do you know who from Somatics would have trained Mr. Munden?

alone or are there others in the room with you, sir?

A Well, the anesthesiologist is there. He has the anesthesia injected into the arm, person sleeps, and then he supersaturates them with oxygen. So there is another nurse in the room and a technician too. So you have a technician, a nurse, and an anesthesiologist. And then they go to recovery room and the nurses take care of them out there.

Q What is your role specifically during the procedure?

A My role is just kind of comfort the patient, you know, see I'm there. And I'm going to do it. I'm technically responsible, so I push the button that gets the seizure, and I set the settings. That's my role.

Q The settings on the machine?

A On the machine, yes.

Q Okay. And how long, start to finish, from the moment that anesthesia is administered to the moment that the person wakes up, how long is the procedure?

A Well, there is probably about three minutes. The seizure lasts about 60 seconds, give or take 20s second usually. You know, it can be different lengths.

And then, you know, then you have to wait until they recover and breathing on their own. That takes another minute. It takes a minute to get them out and

supersaturate. So it's about three minutes altogether, three to four minutes the actual procedure.

Q And I'll come back to that, dive into that in a little bit more detail.

So going back on the training. So you believe Somatics personnel trained Mr. Munden; he, in turn, trained you and other users of the ECT at the hospital. How many other users were there other than you? And when I say users I'm talking --

A Well, there are about six doctors that gave ECT, you know. It varies, but there are about six. Three or four do a lot, and there's probably another three. So seven all together.

Q And you had mentioned that some hospitals do not have ECT machines. Such as I think you mentioned Balboa, for example.

A Yeah. Balboa has one now. They didn't have one then. They wouldn't do it then.

Q Do you know why they wouldn't do it at that point?

A No. It's just technical. They didn't want to get involved with it. I don't know why they didn't do it. University wasn't doing it early and then they decided to do it. Now some hospitals can't do it in the city because they don't have anesthesia on staff, so

and antipsychotics?

A Yes.

Q Yes. Has it come in your practice where, for example, a manufacturer may learn of new safety risks or may learn that something that they had thought was effective is no longer effective based on new data, and they inform you of that fact either through sales representatives or dear doctor letters? Has that ever occurred?

MR. BENKNER: Objection. Incomplete hypothetical.

A Yeah. When -- if there is new stuff in the literature, they will tell you about it, yes. They will pull a drug if it's causing trouble, you know.

Q (By Mr. Esfandiari) And so you have had occasions where you've received, for example, a dear doctor letter or some -- some information from the manufacturer alerting you to a new safety risk?

A Yes, we get that. True.

Q And do you pay attention to those, Doctor?

A Yes.

Q Okay. Have you ever done consulting work for any pharmaceutical or medical device companies?

A No. I -- I gave a couple lectures -- no, I never -- no, I haven't even given lectures. Yeah, I

from Somatics?

A No, not to my recollection.

Q Doctor, you agree with me that the risk of brain injury is a serious risk?

A I don't think it's a risk with the treatment, no.

Q No. I'm asking -- I appreciate that. I'm asking a separate question, Doctor.

Assuming that a drug or a device causes brain injury, would you agree with me that is a serious risk.

A Well, if it causes brain injury then you would be reluctant to use it if we knew of it.

Q And would you agree with me that the risk of permanent memory loss is also a serious risk?

A Well, I was trying to explain to you. There is two kinds of memory losses. One kind is not serious. I mean, I can't remember a lot of things from my past now. If you say what happened 75 years ago, I don't remember. Okay. So long-term memory, you know, goes. That's for everybody.

Okay. This is a space or a period in a person's life where their memory is aborted. That memory loss is not significant. Okay? What would be significant is if the person can't remember and know how to function day-to-day, short-term memory like with

given because you are trying to --

Q Doctor, I'm asking a very simple question. I'm asking --

A It wouldn't stop me. You have to take the whole thing. All drugs and all things have memory loss. If you forgot your wedding date, but you knew how to function, I wouldn't consider that a reason not to give treatment.

Q I'm not asking whether you want to give treatment or not. I'm simply asking you if the manufacturer informed you that, "Our product carries with it a risk of permanent memory loss," is that information you would relay to the patient?

A We did that.

Q I'm asking you, wouldn't you?

A Yes, we do. That's the -- that's -- the consent form says that. That's what we do. We tell them that.

Q All right. We'll look at the consent form and we'll see what it says.

A Go ahead.

Q And if a medication or a procedure had a risk of the patient losing the ability to formulate new memories, is that a risk that you would have alerted patients to?

A Yeah. If you can't perform new memory, that would be a real problem. I mean, that means the person is functioning in a demented way. So that would not be a safe procedure. Okay.

Q And, in fact, you would relay that risk to a patient had a manufacturer --

A Well, I would have to make a decision whether or not I'm going to treat somebody if they -- if it disturbed their functioning. I have done treatments, you know, for 40 years, 50 years now. Okay. I had one patient that had serious memory loss that persisted, and over the course of a year she was able to regain her memory and begin functioning again and working again. So I have seen it once.

Now, does that mean the machine did it? Could. Could be the -- could have been anything for that matter. That was a different machine. So I don't know. Okay. It could have been anesthesia. It could have been anything that caused it.

So you don't have statistically enough cases to say that this is a major problem. All drugs and all things have problems. There is always outliers. Okay. But you have to see consistent outliers to say, This is a problem with this particular drug or machine.

Q And my simple question is: If that warning had

been provided to you by Somatics, you would have relayed that to your patients. Correct, Doctor?

MR. BENKNER: Objection. Incomplete hypothetical, calls for speculation.

A Yeah. It's like I do warn them they are going to have memory loss. Okay.

Q (By Mr. Esfandiari) No, no. Okay. Let me -- in light of the objection.

If Somatics had informed you that the use of their ECT device could potentially cause patients to lose the ability to formulate new memories, is that --

A That would be significant. But I would have to see it also myself.

Q But I'm asking you, Doctor, is that information you would have presented or at least informed your patients about?

A Yes, we would inform them.

Q Okay.

A If it was to this -- if the drug company is saying, Hey -- or if the machine company is saying, "Hey, guys, this is a problem we're getting.

You have to understand when we use the first machine we crank it up, they had severe memory losses. That was a problem. The MECTA cut that down. The Thymatron cut it down even more.

So, I mean, you know, you go by what you see clinically. Okay. Clinically is what you go by. If I see patients can't function after I give them ECT, that's going to concern me. I'm giving them ECT to get back functioning, the depression or psychosis is preventing it. If I give them a new disease, so to speak, if they can't remember anything, can't process life, I'm not helping them. Okay. I'm just -- I'm switching just -- I'm switching one for another one. That's no good.

I don't see that. That's what I'm trying to get across to you. You know, it's nice to say they have memory loss, some people do have spotty losses outside. That's true. But does that stop them from functioning and having new memories. That's not true. That's the issue.

If they told me the machine causes people to no longer be able to remember new information, that would be a serious concern, yeah, I would tell them. But I would be seeing that myself and I'm not seeing that with my patients. Okay. Patients that have ECT and have a recovery from it, they will come back and say, Doc, I need ETC again. I'm too seriously ill at this point. Help me. Okay. You save their lives. Okay. I'm not saving their lives to give them something else.

though, up there?
A That's my name.
Q All right. And we go to the bottom here. What's the date that appears at the signature line?
A The 13th. The 13th.
Q 13th. Okay. So we agree this form was signed on the 13th?
A Correct.
Q And is that your signature, Doctor, on the right?
A No. That's the nurse's.
Q That's the nurse's. All right. I assume this is Ms. Himes' signature? (Indicating)
A Right.
Q All right. So is this the consent form that you utilize with patients?
A Yes. It's a standardized form, yes.
Q Take a minute, Doctor, to just read the form and then I'm going to ask you some questions.
A I'm familiar with the form. Go ahead. Ask the questions.
Q All right. Anywhere in this form does it state that a patient can have permanent memory loss and use the word "permanent"?
A It says -- it says, Memory loss can last for an

hour or so after each treatment, spotty losses lasting for several months or years after a series of treatments, right.

Q The word "permanent" does not appear, though, correct, Doctor?

A If it lasts for years you can imply it's permanent. But go ahead. No, it doesn't say that.

Q Does the consent document warn of permanent brain injury?

A Does it do what?

Q Does it provide warning concerning permanent brain injury, Doctor?

A No, there is no evidence of permanent brain injury.

Q Does the consent document warn that a patient may have difficulty formulating new memories as a result of the ECT procedure?

A No, it doesn't say they are going to have --

Q And --

A -- forming new memories, no.

Q No. And we previously -- you testified that had Somatics provided you those warnings, you would have relayed those warnings to patients; correct?

A Well, we tell them that they are going to have difficulty. It will take a couple of weeks or a couple

of months until they start processing like they were before. That we tell them.

Q No. It's a simple question, Doctor. I'm just asking had it. And I think you already testified.

But you testified that had Somatics provided you warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories that you would have relayed those warnings to your patients as a good doctor would?

A They would -- they would be in the informed consent.

Q Yes.

A The hospital lawyers go over that. That's the -- that's the way. This is the consent we give them. Okay?

Q It would have appeared in this form; correct?

A It would appear in this form, yes.

Q Okay. Okay. All right.

Doctor, you agree with me that a patient who's voluntarily at the hospital can, after being adequately warned about the risks and benefits of a drug or a procedure, decide that they want to refuse that medication or drug. Correct, Doctor?

A I'm sorry. I had interference with the phone. Can you repeat that?

Q Absolutely. You agree with me that a patient who is present voluntarily in a hospital and is provided a medical option after being adequately informed, that patient has the right to refuse treatment if they feel the risks outweigh the benefits?

A Absolutely true.

Q Doctor, you mentioned that there is a video that is shown to patients; is that right?

A Yes.

Q Okay. Do you recall if there were also any -- because we have understood through the discovery we have done in this case from Somatics, that Somatics releases a patient information, kind of a brochure to give to doctors to give to patients. Do you recall if that was also provided to Ms. Himes or your patients?

A No, I don't think so. We're not -- I have never given them a document like that. We have given them some written documents on ECT they can read if they want, but not --

Q Let me show --

A Not a Somatics pamphlet, just our document.

Q I'm putting up as document that Somatics has produced in this case. Do you see it, Doctor?

(A document was displayed, which was later marked as Exhibit 7.)

And I believe you said you were subscribed to the "Journal of American Psychiatry." Is that right?

A Right.

Q Okay. So just talking about just that first category, did you receive any information in your practice from the manufacturer?

A Not that I'm aware of, no.

Q Do you find that strange that you didn't receive any information from the manufacturer?

A No, because it's not sold to the doctors. It's sold to hospital, you know.

Q Okay. Thanks. So you, yourself, never purchased an ECT machine?

A No.

Q Okay. Talking about the second category, your clinical observations. In your experience, Doctor, have you ever seen a patient who's treated with ECT experience short-term memory disruption that lasted longer than two months?

A Well, I say roughly two months. I said I saw one person that lasted a year with me. But most within two months, you know, maybe three at the most, you know, recovered the ability to get short-term memory functioning again.

Q Okay. So other than with one person you've --

C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, Trena K. Bloye, Certified Shorthand Reporter within and for the State of Oklahoma, certify that RAYMOND FIDALEO, M.D., was by me first duly sworn to testify the truth, the whole truth, and nothing but the truth, in the case aforesaid; that the witness chooses to read and sign the deposition; that the above and foregoing videotaped deposition was taken by me in shorthand and thereafter transcribed; that the same was taken on February 12, 2021, at 9:18 a.m. PST, via videoconference; that I am not an attorney for, nor a relative of any of said parties or otherwise interested in the event of said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 20th day of February, 2021.

Trena K. Bloye, CSR
State of Oklahoma CSR No. 1522

EXHIBIT 6

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC,

Defendant.

) Case No. 2:17-CV-06686-RGK-PJW

VIDEOTAPED DEPOSITION OF MICHAEL FRANKEL, M.D.

TAKEN FEBRUARY 19, 2021

REPORTED REMOTELY BY:

BEVERLY A. BENJAMIN, CSR No. 710

Notary Public

Q. And on average how many patients do you administer ECT on a yearly basis?

A. Well, we were before the pandemic hit, which really had a profound effect on our practice in a negative way, we were doing about 600 cases a year. That's not 600 patients but that would be 600 ECT treatments a year. And I would say maybe that would entail maybe 100 -- 100 to 150 patients or maybe more like 100 patients would be more accurate.

Q. And is that estimate fairly consistent with the amount of patients you would have seen back in 2012?

A. Yes.

Q. So turning back to the Thymatron device that you used at Northridge Hospital, was this the device that you would have used for treatment around September 2012?

A. Yes.

Q. Are there any other ECT devices made available by the hospital?

A. No.

Q. I should actually lay the foundation there. The device that you use, that's not a device that you purchase; right?

A. No.

Q. When you made the switchover to the Thymatron,

or I should say when the hospital made the switchover to the Thymatron, did they provide you any training on how to operate the new machine?

A. Basically just literature from the manufacturer.

Q. Do you remember what that literature was?

A. Just more or less an instruction manual, and the machine is pretty self- -- it's very straightforward. It doesn't take a great deal of training to learn to use the machine.

Q. And Doctor, are you aware that the operator's manual for the Thymatron System IV advises users to read the APA Task Force Report publication that was published in 2011 -- excuse me, strike that, 2001?

A. Yes. I think I did that, yes.

Q. Is that a publication that you rely on in your own practice?

A. I do refer patients to the American Psychiatric Association literature when they do want more information about ECT when we're doing our consultations.

Q. When was the last time you read the APA Task Force Report?

A. Several years ago.

Q. Do you know if the hospital makes that

A. Okay.

Q. I should ask you, do you have your clinical notes for Ms. Benjamin with you?

A. Yes, I do.

Q. Great. Let's make this a little easier.

A. Okay.

MR. BENKNER: Madam Court Reporter, can you allow me access to screen share?

(Exhibit 1 marked.)

Q. (BY MR. BENKNER) Doctor, do you see a document in front of you on your screen?

A. Yes, I do.

Q. I'll represent that this is a five-page document that we received from your office in response to a --

A. Correct. Yeah. Back 8 years ago we were doing handwritten consultation notes, which we've since changed to actual dictations. So this is an old way we were doing consultations back in 2012. But that is my initial consultation report on this patient.

Q. Perfect. That was going to be my next question.

And as you said, it is handwritten. So your handwriting is really not as bad as other doctors that I've seen. But I am wondering if you could help us out

by kind of reading into the record what you wrote to make sure there's no confusion.

A. Right. What I basically was indicating was the patient was complaining of symptoms ever since September of 2010. On March 5, 2011, she made a trip to the Los Robles Hospital emergency room. At that time she was having palpitations, discomfort in her left arm and face, she was on thyroid medication at that time, and had what we thought was somewhat of a toxicosis secondary to the hypothyroidism medication. She described nervousness, trembling, irritability, increased blood pressure, and dizziness.

And what was done in the emergency room was that she was taken off all her medications at one time.

Then do you want me to go on?

Q. Yes, please.

A. After that time the symptoms kept ongoing, she saw her cardiologist, who diagnosed it as having panic attacks, and prescribed Zoloft. On taking the Zoloft the patient became very ill, and she saw her GI doctor who placed her on another antidepressant named Cymbalta. That also made her quite ill.

Subsequent to that, the patient saw another psychiatrist who is well-known to me, a Dr. Kassman. He tried several medications with the benefit for severe --

with the patient for severe anxiety and depression. All the medications that he tried were without benefit or the patient could not tolerate the medications. He tried seven different medications. He did continue the patient on a low dose of Xanax.

At that point, the patient started complaining about being extremely weak. The patient subsequently saw a Dr. Gudeman. At that point, the patient says she couldn't even sit in a chair. She was prescribed another increased dose of Xanax, and then felt the Xanax was not helping. She was subsequently prescribed another low dose of Zoloft, up to 50 milligrams, which she could not tolerate.

She then developed a dependency on Xanax, getting up to 6 milligrams per day. And she was detoxified apparently in a Sao Paulo, Brazil, clinic to get her off the Xanax. In help to do that, she was given Valium up to 70 milligrams and Tegretol 600 milligrams. She says that now when I saw her for the consultation she was on 15 milligrams of Valium.

8 or 9 months till that, leading up to the consultation, the patient complained of being very tired and suddenly getting very irritated. She complained of "electrical things in my head," in quotation marks. She said she's very fearful in the mornings. She comes from

a background of homeopathy.

She talks about being an architect and a public designer, saying that she cannot concentrate. She describes crying spells. She said, I'm so scared. I'm scared of being alone, feared of having a myocardial infarction. She had both an echogram and an MRI of the head, both of which were within normal limits in terms of her workup.

Past psychiatric history: 1998, there was a great deal of stress when her father developed lymphoma. She couldn't sleep, she became depressed. She was placed on a different antidepressant, like Prozac she said, in the Paxil and Serzone group.

1984, she describes architecture school, where she experienced a great deal of anxiety, and was placed on Xanax. She said it resolved on its own though. She had lost quite a bit of weight at that time though in 1984.

Then going on to the past medical history, she describes as suffering from fibromyalgia. She's had a cholecystectomy, an appendectomy, emergency C-section, and LASIK to her eyes, she had surgery to remove adhesions.

The present medications at the time of the consultation include Valium 15 milligrams a day and

Q. Can you recall if Mrs. Benjamin ever expressed any reservations about the potential risks of treatment?

A. I don't remember.

Q. I'll show you another document I'll identify as Exhibit No. 4.

(Exhibit 4 marked.)

Q. (BY MR. BENKNER) Do you see that on your screen?

A. Yes, I do.

Q. Do you know what this document is?

A. I just looked it over before our session today. Yes, it was a note that I wrote, it is a progress note dated 1/21/13. "Met with patient" -- do you want me to read it?

Q. Sure.

A. Met with patient and husband. Patient's mood significantly improved. Her somatic anxiety remains less than before but still significant. Patient wants to discuss alternatives to maintenance ECT such as TMS, and I gave my opinion. We discussed medications nortriptyline and lithium again for maintenance purposes and patient did not want to be prescribed more medication.

She is having expected recent memory problems and naming difficulties. She attributes a lot of her

somatic symptoms to the ECT. Plan is I suggest monthly maintenance ECT with medication. Patient will think about it.

Q. So it was your understanding after reviewing this that -- strike that.

Is this a note you would have created after evaluating the patient?

A. Yes.

Q. In this case you indicate that Mrs. Benjamin was exhibiting signs of recent memory problems and naming difficulties; is that right?

A. Correct.

Q. And you didn't find that as odd because that's a risk of treatment that you had advised her of; right?

A. Absolutely.

Q. So the next sentence where it says, "She attributes a lot of her somatic" -- not an S, just "somatic" -- "symptoms to the ECT." Do you know what you're referring to specifically there?

A. You know, I honestly don't remember. It's been so long, I don't remember exactly what somatic symptoms the patient was having at that time.

Q. I'm going to show you a new document identified as Exhibit No. 5.

(Exhibit 5 marked.)

Q. (BY MR. BENKNER) Do you see that?
A. Yes, I do.
Q. Do you know what this document is?
A. Yes, it's a summary of the actual ECT treatment that we dictate each time we do a treatment.
Q. And I will represent to you I got this from Northridge Hospital pursuant to a subpoena request. And the date of procedure on this is March 4, 2013. Do you see that there?
A. Yes, I do.
Q. And based on the records that were produced by the hospital, this is the last date that we have showing that Mrs. Benjamin underwent ECT treatment under your care. Do you have any information that she underwent treatment at any point after March 4, 2013?
A. No, that was the last treatment I have as well.
Q. Okay. Do you know why Mrs. Benjamin stopped her ECT treatment at this time?
A. I don't fully remember, to be honest with you.
Q. Can you recall anything you might have discussed with her about it?
A. I don't recall.
Q. At the end of her treatment, did you observe any improvement in Mrs. Benjamin's condition?

A. I did, and actually we have a card which is missing from the chart. The problem is this chart was copied by so many attorneys over the last 8 years who have decided not to take the case, that it got lost somewhere. It was a note saying: Dr. Frankel, thank you for giving me my life back. And that was the follow-up to her treatment course.

And we always refer to maintenance therapy, which is like a booster shot, after the patient goes through what we call the index course, which is the actual first course of treatment.

But I don't know if you guys have a copy of that note because, again, some reason, as I say, the chart was copied by so many different attorneys who decided not to take the case, that it could have gone anywhere, but it's not present in the chart at this point in time. So the patient was very, very grateful that she had the treatment and had written us a note, a thank you note. So obviously she was doing very well.

MR. ESFANDIARI: Move to strike the entirety of the response just given lacks foundation.

Q. (BY MR. BENKNER) Now, Doctor, you indicated that your office has been contacted by multiple attorneys with respect to this patient over the years; is that right?

A. Yes, I just wanted to indicate --

MR. ESFANDIARI: Objection to form.

THE WITNESS: -- that we did find the records from a Mr. Iannaccone, from his law offices. This was dated back in 2016. That was the first request for records from an attorney's office.

And then we had another one from January of 2018, the following records were again requested from a Jason M. Yang, Esquire, and that was in May of 2018. And we have some others here. Again, the DK Law Group was 2020.

And that's all that I could find at this particular point in time.

Q. (BY MR. BENKNER) Thank you.

It appears you are referring to some documents. Is this part of the patient's medical chart that you have in front of you?

A. Yes, it is. Yes, that was copied from our office. Yes.

Q. I'm going to share my screen again with you.

Do you see a new document in front of you?

A. No -- yes, I do.

(Exhibit 6 marked.)

Q. (BY MR. BENKNER) Have you seen this document before, Doctor?

A. Yes, I have.

Q. And do you know what it is?

A. Yeah, it's a progress note that I had called the patient to see how she was doing several months after her treatment course, which I sometimes will do just to check up on the patient to see how they're progressing.

She said she was feeling better with the TMS maintenance, which she chose rather than doing, continuing with ECT maintenance which she started. She says she's complaining of continued memory problems, which she attributes to the ECT. She has not yet returned to work. I asked her to keep me posted on her condition.

Q. Do you have any other documents or progress notes in the medical chart in front of you indicating that you had evaluated or spoken to the patient about her condition at any point after July 1, 2013?

A. No, the situation is this, is that I'm an ECT consultant. So once I determine that the patient is a candidate for ECT, I perform the treatments, I do clinical observations throughout the treatment course, and then I return them to the care of their regular referring psychiatrist. I don't continue to follow them after the ECT course because that's not my position.

about an adverse event that a patient suffered?

A. No.

Q. You testified that you believe, to the best of your recollection, that the hospital Northridge bought the Somatics machine maybe 20 years ago or so; is that correct?

A. About that, yeah.

Q. And I think you testified that at that moment there was also some training that was provided by the manufacturer; is that correct?

MR. BENKNER: Objection; misstates prior testimony.

THE WITNESS: Yes.

Q. (BY MR. ESFANDIARI) Can you tell us a little bit more about the training that you do recall receiving, and I'm focusing right now about the new Somatics machine that you received two decades ago.

A. The training mostly was from the pamphlets that I received with the machine. And that was basically what I recall.

Q. Did --

A. Because I hadn't been doing ECT for years up to that point and I was familiar with the machine just from advertisements and other people using the machine. So there really wasn't that much that needed to be done

uncovered concerning drugs that were not previously known; correct?

A. Correct.

Q. And from time to time either doctors or sometimes the manufacturer will discuss these new risks either in the literature or at conferences or through labeling changes; correct?

A. Correct.

Q. And if you are alerted to new risks concerning a drug that you prescribe to patients or a device that you utilize, you would pay attention to that; correct, Doctor?

A. Correct.

Q. And if the manufacturer warned of a new serious risk, you would relay that risk to patients; correct?

A. Correct.

Q. You agree with me, Doctor, that if a drug or a device had a risk of brain injury, that that would be a serious risk?

A. Yes.

Q. And if a drug or a device had a risk of permanent memory loss, that would be a serious risk?

A. Yes. But again, we inform the patient --

Q. Doctor, there's no question pending.

specifically recall giving it to Mrs. Benjamin.

Q. Drawing your attention to Exhibit 9, does this appear to be the consent form that you utilized with patients?

A. Yes, it is.

Q. In 2012?

A. Yes. Uh-huh.

Q. And are these your handwritings, Doctor, or whose handwriting?

A. Yes, those are mine.

Q. Those are yours. Okay.

Now, does this consent form warn of permanent memory loss, Doctor?

A. I don't believe it does.

Q. And does this consent form warn of permanent brain damage, Doctor?

A. Not that I'm aware of.

Q. If Somatics had informed you that ECT could be linked to permanent brain damage in some patients, is that information that you would have advised patients about, Doctor?

A. If it were the case I would definitely advise patients in terms of giving informed consent.

Q. Thank you.

Bear with me one second, Doctor. I apologize.

Q. From a temporal point of view, what is that threshold of a seizure that exceeds your comfort level?

A. Well, I'd say anything over 100.

Q. 100 seconds?

A. 100 seconds, roughly, yeah. It's different in different patients. If it's a young healthy patient we don't get very alarmed; if it's an older patient we prefer not to have that length of seizure.

Q. I am going through the records here. So here we're looking at the ECT procedure from October 15, 2012. And again here, you're applying 100 percent energy level; correct?

A. Correct.

Q. And this one is a 52-second seizure; correct, Doctor?

A. Correct. Um-hmm.

Q. In the interest of time I'm not going to go through all of them. There's one that I did want to ask questions about. While I'm looking actually, let me ask a question.

You administered your first ECT I believe in September 28, 2012; is that correct?

A. Correct.

Q. When you began the ECT process, had you informed her how many sessions she was going to need?

A. No.

Q. Did you have a plan formulated that, I'm going to do 10 sessions or --

A. We generally look at 12 sessions as a complete course of treatment, we call it the index course. And then we usually recommend maintenance therapy, which is like booster shots, but not with the frequency of the index case. So in any particular patient it would vary in terms of how many treatments we would use in the index case based upon their improvement, based upon their clinical response to the treatment. But again, a complete course in many patients is what we would say would be about 12 treatments.

Q. And those index 12 treatments, what time frame are they administered over?

A. Usually three times a week for about 4 weeks.

Q. I believe this is the one that I wanted to ask questions about.

All right. So bringing you to the December procedures, Doctor, here we're looking at on page 25 of this exhibit, we're looking at the December 14, 2012, procedure; correct, Doctor?

A. Correct.

Q. And in this ECT session you administered again 100 percent of the current level for a seizure lasting

REPORTER'S CERTIFICATE

I, BEVERLY A. BENJAMIN, CSR No. 710, Certified Shorthand Reporter, certify:

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness was put under oath by me;

That the testimony and all objections made were recorded stenographically by me and transcribed by me or under my direction;

That the foregoing is a true and correct record of all testimony given, to the best of my ability;

I further certify that I am not a relative or employee of any attorney or party, nor am I financially interested in the action.

IN WITNESS WHEREOF, I set my hand and seal this _____ day of _____ _____.

Beverly A Benjamin

BEVERLY A. BENJAMIN, CSR

Notary Public

P.O. Box 2636

Boise, Idaho 83701-2636

BEVERLY A. BENJAMIN NOTARY PUBLIC MY COMMISSION EXPIRES 5-28-2019 STATE OF IDAHO COMMISSION NUMBER 36113

EXHIBIT 7

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA, DEBORAH CHASE, PLAINTIFFS,	)	
VS.	)	CAUSE NO. 2:17-CV-06686 RGK (PJWX)
SOMATICS, LLC; AND DOES 1 THROUGH 10, INCLUSIVE, DEFENDANTS.	)	

DEPOSITION OF RICHARD ABRAMS

BE IT REMEMBERED, THAT THE DEPOSITION UPON ORAL EXAMINATION OF RICHARD ABRAMS, M.D., APPEARING AT THE REQUEST OF PLAINTIFFS, WAS TAKEN AT THE BOARDROOM OF BANK OF BOZEMAN, 875 HARMON STREAM BLVD., BOZEMAN, MONTANA, ON THURSDAY, AUGUST 2, 2018, BEGINNING AT 9:56 A.M. SAID DEPOSITION WAS TAKEN PURSUANT TO THE CALIFORNIA RULES OF CIVIL PROCEDURE, BEFORE LAURINE BRINKMAN, A REGISTERED PROFESSIONAL REPORTER (RPR) AND NOTARY PUBLIC FOR THE STATE OF MONTANA.

11:23:50 for one of my ECT studies at Metropolitan Hospital. And
11:23:55 so, the three of us, Dr. Swartz, myself, and
11:24:01 John Pavel collaborated in the design and plan of the very
11:24:07 first Thymatron.
11:24:10 Q. In terms of your prior experience working with
11:24:14 John Pavel, what had you had him assist you with before
11:24:22 the Thymatron?
11:24:24 A. It was a research device for recording what is
11:24:30 called an electroencephalographic evoked potential for a
11:24:36 study I was doing, and he constructed what is called a
11:24:42 Schmitt, S-C-H-M-I-T-T, that turned the recording on and
11:24:49 off at the time of the seizure administration so you
11:24:57 didn't interfere with the recording. It was nothing to do
11:25:02 with therapy, it was a research tool, and that was it.
11:25:10 Q. All right. As I understand it, the Thymatron was
11:25:17 first produced by the company Somatics, LLC, correct?
11:25:21 A. Correct. Dr. Swartz and I formed that company in
11:25:25 1983, I think was the year we formed it.
11:25:30 Q. And was the purpose of forming Somatics expressly
11:25:36 to market Thymatron?
11:25:38 A. Correct.
11:25:39 Q. As opposed to any other purpose?
11:25:42 A. That is correct.
11:25:42 Q. And that remains its purpose today?
11:25:44 A. That is correct.

12:25:25 Are you aware of any changes that Somatics
12:25:32 undertook with regard to its marketing or disclosures
12:25:39 associated with the purchases of its device that addressed
12:25:44 Dr. Weiner's perspective that you had learned in the late
12:25:50 '80s?
12:25:52 A. No.
12:25:52 Q. Any reason why not?
12:25:54 A. I didn't agree with his study and it was one of
12:26:11 the reasons that it was only published in the proceedings
12:26:14 of the American Academy of Science, in the proceedings
12:26:19 which is a little book form and it was never published in
12:26:23 the peer-review journal. And even years afterwards it
12:26:27 never appeared in the peer-review journal which led me to
12:26:33 believe that the results could not be confirmed.
12:26:37 Q. At any time to the present has Somatics initiated
12:26:41 any studies or tests with regard to this issue of
12:26:47 long-term side effects associated with ECT?
12:26:51 A. No.
12:26:52 Q. Any reason why not?
12:26:56 A. That's not our business.
12:27:05 Q. Whose business do you believe it is?
12:27:08 A. Can you rephrase that, could you repeat that
12:27:13 question to me?
12:27:14 Q. I'll rephrase.
12:27:15 I believe I asked whether or not Somatics

Class II device, do you have any reason to believe Somatics ever submitted anything again after 2009 for reclassification?

A. No.

Q. Are you aware of whether or not Somatics has any practice of investigating verbal complaints that it's received as to adverse events associated with ECT?

A. From whom?

Q. Anybody.

A. No, I'm not aware of anything like that.

Q. Has Somatics ever conducted any studies to determine whether any brain injury could be caused by ECT?

A. Somatics has never conducted any studies of any kind.

Q. When was the last time you were aware that anyone has conducted any study as to whether or not any brain injury could be caused by ECT?

A. Probably those I cite in my book and maybe perhaps even somewhere -- yeah, the Patient Information pamphlet on chemicals released by brain cells during injury and the fact that such studies have been made on ECT and found no such chemicals in the blood after ECT and many similar reports. I think that was enolase was the particular compound that we mentioned.

Q. And so, that study was referenced in your book?

CERTIFICATE OF COMPLIANCE

I CERTIFY that the foregoing deposition transcript was prepared by the reporter designated herein; that a digital copy of the reporter's transcript was submitted by the reporter to Personal Court Reporters, Inc., for the purposes of preparing electronic and/or paper copies for the requesting parties; that the transcripts have been prepared, distributed and invoiced pursuant to the order on file with Personal Court Reporters, Inc.

I FURTHER CERTIFY that the production and distribution of the transcripts comply with all applicable regulations as well as CCP 2025 and Federal rule 30.

DATED at Van Nuys, California, this 20th day of August, 2018.

Lisa Carrier

Personal Court Reporters, Inc.
Vice President
Lisa Ann Carrier, CSR 6828

EXHIBIT 8

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; DIANE SCURRAH; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

vs.

No. 2:17-CV-06686-RGK-PJW

PORTIONS OF TESTIMONY MARKED CONFIDENTIAL

SOMATICS, LLC;

Defendant.

DEPOSITION OF CONRAD SWARTZ, M.D., 30(b)(6)/Individual

BE IT REMEMBERED that on the 1st day of April, 2021, at the hour of 10:00 a.m. PST, the deposition of CONRAD SWARTZ, M.D., 30(b)(6)/Individual via Zoom video conference, was taken at the request of the Plaintiffs, before Caryn E. Winters, CRR-RPR-CCR-CSR, Washington CCR No. 2496, Idaho CSR No. 237, at Vancouver, Spokane, Washington, pursuant to the Federal Rules of Civil Procedure.

EXAMINATION

Q (By Mr. Esfandiari) Good morning, Doctor. Can you please state and spell your name for the record.

A Conrad Swartz, C-O-N-R-A-D S-W-A-R-T-Z, Ph.D., M.D.

Q And, Dr. Swartz, you understand that you are here to give testimony both in your personal capacity today, as well as you've been designated as the person most knowledgeable by the company, Somatics, which I understand you're an owner of, to testify regarding various topics that we've identified. Is that your understanding, Doctor?

A No.

Q No?

A It's my understanding that I'm here to represent the views of Somatics both in terms of my office as member manager and as the PMK. I am not here in a personal capacity, as you suggested.

MR. POOLE: Dr. Swartz, just so you know, your deposition was noticed, actually, in two capacities; one as an individual, which has been limited by the court to three hours, and then four hours for the role as the person most qualified, actually, which is the Federal Court term. So you're actually here in two capacities today.

But I think it's important if you need to qualify any of your responses you can do so, but generally the deposition is covering both what you know as an

individual and what you may have -- what knowledge you may have gained as you prepared yourself to testify on behalf of the corporation. Do you understand that?

THE WITNESS: I thought it was covering my knowledge as an individual in an administrative capacity for Somatics, rather than as a private individual separate from Somatics.

MR. POOLE: Yeah, it's actually covering both. And so rather than have two completely separate depositions today where we just do three hours, that the court has allowed them to ask you in your individual capacity, and then four for PMQ. We've agreed to combine that.

THE WITNESS: So I'm to give my personal views and not just the views of Somatics?

MR. POOLE: Yes. I mean, really we're not so much looking for your views as your knowledge, and so I don't think there's going to be a significant distinction between the testimony you're going to give today. I think the -- the plaintiffs are seeking what you know in terms of knowledge.

If there's issues that involve your personal or professional opinions that you believe are distinct from those which are held by Somatics as an official position, you can certainly clarify that.

THE WITNESS: Okay.

A No reason.
Q Okay. So you're not under any medication that would impact your ability to recall facts and things of that nature?
A I'm free of influences.
Q All right. Very well, Doctor. Okay. With that said, --
MR. ESFANDIARI: David, did you want to add anything to the admonitions that I may have missed?
MR. POOLE: No, I think I've indicated that there is a court order with regard to the scope of today, that we're not repeating what has been covered in this case in the prior deposition of Mr. Swartz except as it may be impacted by additional documents that have been produced or developments since the date of that deposition in August of 2018.
MR. ESFANDIARI: Understood. And as I said before the depo, I may ask kind of like a foundational question just to build up, but I certainly don't intend to rehash old grounds.
Q (By Mr. Esfandiari) All right, Doctor. So I understand, Doctor, that you're one of the two owners of Somatics; is that correct?
A Yes, it is.
Q And the other owner is Dr. Richard Abrams; is that

correct?

A Yes, it is.

Q All right. And you have been an owner of Somatics since its formation in 1984, correct?

A Yes.

Q Between 1984 until the present, has the ownership of Somatics changed at all?

A No.

Q So it's always been the two of you at a 50/50 capacity?

A Yes.

Q And what type of business is Somatics involved in, Doctor?

A It's involved in the manufacture of electromedical devices and supplies for electroconvulsive therapy.

Q Anything else?

A There's a testing device we sell that is used to verify the electrical output of ECT devices. That's a testing device. It's not a medical device.

Q And other than those that you just described, any other products that your company manufactures or distributes?

A We have occasionally rebought and resold books concerning electroconvulsive therapy.

Q Fair to say then that your -- the business for

Somatics is exclusively devoted to ECT devices and products and pamphlets associated with ECT?

A Pamphlets? Products and supplies.

Q And supplies? When I said "pamphlets" I was referring to the books you were mentioning.

A Books, okay.

Q Books? All right. All right. And is one of the ECT machines that Somatics manufactures called a Thymatron machine, Doctor?

A No, the Thymatron is a brand name.

Q A brand name? What other brands of ECT machines does Somatics manufacture?

A No.

Q So Thymatron is the only one?

A The Thymatron is the only brand of ECT device but there are various models that have the name Thymatron in them.

Q And all those models are manufactured by Somatics?

A Yes.

Q All right. And I've seen references to Thymatron IV. What is that -- are you familiar with that phrase, Doctor?

A That refers to the latest model of Somatics ECT machine, the Thymatron System IV device.

Q Okay. And is that the most recent generation of the Thymatron devices, model?

A Yes.
Q All right. And I guess IV means -- I think you already answered this -- it's the fourth version of that device?
A It's one of two meanings.
Q Correct me if I'm wrong.
A The other meaning is it prints four channels of physiological observations. But, actually, it now prints five.
Q All right. The model IV, the Thymatron model IV, which as we get into was the machines that are implicated in my clients' procedures, when did that hit the market, Doctor?
A That was first sold in 1999.
Q '99. And it's predicated, though, on the very first Thymatron device, correct, the one from 1984?
A Yes.
MR. POOLE: I'm going to object to the term "predicated." Are you using the term "predicated" in the technical sense of the predicate as that nomenclature is used with the FDA or just talking in a general sense?
MR. ESFANDIARI: Very good objection. Let me rephrase and maybe back up to make it make more sense.
Q (By Mr. Esfandiari) So, Doctor, the -- in 1984 is when Somatics released its first ECT device, correct?

A Yes, but we reviewed all this in the previous deposition.

Q The reason I'm going over this is just in light of the objection to lay some foundation. So is that correct, Doctor?

A Yes.

Q All right. And that device, the 1984 device, was predicated upon, I believe you testified, a MedCraft device and a MECTA device; is that correct?

A Yes.

Q Okay. And at some point you obtained also clearance for the Thymatron IV device; is that correct?

A Yes.

Q All right. When you obtained clearance for the Thymatron IV device which is at issue in this litigation, did you have to submit an application identifying the predicate device?

A Richard Abrams submitted them, but I saw them, and the answer was it was a renaming.

Q It was a renaming? Okay. So the Thymatron IV device then is likewise predicated upon the MedCraft and the MedWatch, as was the case with the original Thymatron device?

A MedCraft and the MECTA.

Q MECTA? I'm sorry, it's MECTA. And since 1999 there

have been no further versions of the Thymatron machine, correct, Doctor?

A Right.

Q All right. Doctor, what role does Somatics play vis-a-vis the -- strike that. Who designed the Thymatron IV device?

A Elektrika, Incorporated.

Q And is that also true with respect to the original Thymatron device?

A Yes.

Q All right. Do you have any ownership interest in Elektrika, Doctor?

A I reviewed this in the previous deposition.

Q I don't recall. Do you or do you not, Doctor? I don't recall if you did or didn't.

A No ownership.

Q No ownership? All right. And, Doctor, is my understanding correct that the Elektrika is owned by the Pavel family, I guess, for better say?

A I don't know the ownership of Elektrika, but I believe the owners are, to the best of my ability, John and Jesse Pavel. But I do not know this for a fact.

Q And the relationship between John and Jesse is what? Brothers or father and son?

A Father and son.

videotape, the manual, and the service manual, what else would Sharp Hospital have received from Somatics?

A In terms of written materials, they probably received a catalog, which illustrates the various products Somatics sells such as the Thymatron device and the supplies.

Q I have seen not only in this litigation but in other litigation -- that's a poorly worded way of doing this. I've seen documents produced that appear to be kind like a patient information pamphlet with Somatics' logo on them. Are you familiar with those types of documents, Doctor?

A I have seen that, yes.

Q Okay. Is that something that Somatics created?

A It's something Somatics had printed, something Richard Abrams and I had created.

Q All right. Would that have been sent to a new purchaser of the ECT devices back in 2002?

A No.

Q When were those sent out?

A According to David Mirkovich, he told me they were sent out for a period of about a year around 2007.

Q Okay. So only --

A Maybe a year and a half.

Q But only between, let's say, 2007 and 2008, 2009 was the time period where those patient information pamphlets would have been distributed?

A Yes.
Q And would they have been distributed to only new customers who purchased a device in that 2007 through 2009 time period or would it have been sent to all existing customers of Thymatron devices?
A Only new devices and those Thymatron users, who are very few, who called up to ask for copies.
Q All right. In your investigation for today's deposition, are you aware if Sharp Hospital was provided with the patient information pamphlet that Somatics had prepared?
A David Mirkovich said they were not.
Q Okay. Have we covered all materials that Sharp would have received with the -- with their ECT machine in 2002?
A Taking the broader view, we had sent out the Thymatron DGx manual in mass mailings, no doubt to Sharp, during the 1990s without their request.
Q What is the DGx manual, Doctor?
A Oh, it's -- it's the -- it's called the ECT instruction manual, and it shows a picture of the Thymatron DGx on it. We sometimes call this the DGx manual because it was provided with the Thymatron DGx. But it's a perfect bound book, as you see (indicating). It's not a loose-leaf production.
Q Is DGx the predecessor model to the Thymatron IV?

risks and adverse effects of ECT without reading any materials that Somatics sends to them. And this is because of something called the standard of practice of psychiatry and ECT. This is not merely a standard to practice by. It's the standard of practice by which if you don't do it you are negligent.

And it's a certainty that every ECT doctor in the U.S.A. has met requirements that demonstrate his knowledge, experience and expertise in ECT and in understanding its benefits, side effects and adverse effects, and has demonstrated this knowledge to a committee of peers at his hospital.

These hospitals control these ECT devices and own them. In order to give ECT, it's necessary for a doctor to receive ECT privileges from a hospital that attests to his knowledge and experience and expertise.

MR. ESFANDIARI: I'm going to move to strike that answer as non-responsive.

Madam Court Reporter, can you read back my original question, please?

(Record Read Back as Requested)

Q (By Mr. Esfandiari) Doctor, that's a simple "Yes" or "No" answer. Does Somatics have a responsibility to warn doctors concerning the risks associated with the use of Somatics' ECT device?

MR. POOLE: Actually, I object to your assertion that it's a simple "yes" or "no." I think he gave an answer which encompasses the context with regard to their responsibility. But you can go ahead and answer, Dr. Swartz.

Q (By Mr. Esfandiari) Well, let me put some time frames on it. In 2002 did Somatics, at the time when these devices were sent to -- or, strike that. In early 2000, at the time that these devices were sent to either Northridge Hospital or Sharp, did Somatics have a responsibility to provide warnings to the doctors concerning risks associated with Somatics' Thymatron ECT devices? "Yes" or "no"?

A I believe the answer is more complex than a "yes" or a "no" could provide.

Q Did Somatics provide any warnings concerning risks associated with its ECT devices to Sharp Hospital in 2002 when it sent over its manual, as well as the new ECT device?

A No doubt Sharp received warnings in the form of the DGx manual prior to 2002.

Q My question was different. The manual that accompanied the ECT device for the Thymatron IV, did that manual contain any warnings about the risks associated with the Thymatron IV ECT device?

A I believe it did not.

Q And how about the manual that Northridge Hospital

would have received from Somatics concerning the Thymatron IV ECT device?

A I believe that did contain some warnings.

Q All right. So let's go put some meat to the bones, as they say. Share screen.

Doctor, are you able to see this document?

A Yes.

Q Okay. Doctor, I'll represent to you that this is a document that was sent to us by Sharp in response to a subpoena. Can you identify -- And we're going to mark this as Exhibit --

MR. ESFANDIARI: Madam Court Reporter, are we at 4 or 3? Where are we at?

REPORTER: We're at number 3.

MR. ESFANDIARI: Number 3? Thank you.

Q (By Mr. Esfandiari) Doctor, looking at the first page of this Exhibit 3, what does this document appear to be?

A It's an operational manual for the Thymatron System IV.

Q Okay. And it identifies both you and Dr. Abrams; is that correct?

A That's what it appears.

Q All right. And this appears to be the sixth version of that manual; is that correct, Doctor?

A That's what it says.
Q And dated October 2001; is that correct?
A Yes.
Q All right. Do you have any reason to dispute that this is the manual that Sharp Hospital would have received when they purchased the Thymatron IV ECT device in 2002?
A I understand this is the copy that was furnished by Sharp, and, therefore, they received it.
Q All right. Do you have this document or this version of the manual in Somatics' possession?
A I first received it yesterday evening from counsel.
Q Okay. So when you looked at your production -- or, your documents, Somatics does not have version six of its manual in its custody, correct?
A Correct.
Q Okay. But now you do because it was produced by Sharp, correct?
A Yes.
Q All right. Do you have any reason to dispute the veracity of the document, Exhibit 3?
A No.
Q Okay. And does this appear to be the manual that was indeed in existence at that time?
A It appears to be, but I don't know.
Q Now, I've gone through this manual, and I could not

find any section that discusses adverse events or risks associated with the use of the Thymatron ECT device. Is that your understanding as well, Doctor? That was a horrible question. Let me strike that.

Doctor, you reviewed this document, correct?

A Yes. I admit that there were two documents, and the -- that you had -- that counsel provided me last night, and the later one of the two had no warnings in it. The earlier one had warnings.

Q And that is my -- well, I don't know if they were warnings or not, but this is, we'll say, the later one of the two. So this is the one version six. We'll look at version five when we talk about Northridge.

But version six, Doctor, if I asked you to point me to the page that contains the warnings and adverse events associated with the use of ECT, what page would I have to go to in this manual, Exhibit 3?

A There is no such page.

Q Okay. Doctor, do you believe warnings are important?

A Sometimes.

Q Why are they important, Doctor?

A To --

MR. POOLE: I'm going to object as vague and ambiguous and hypothetical, without necessary facts. But you can go ahead and answer, Dr. Swartz.

A Well, they're to inform people who don't know them.
Q (By Mr. Esfandiari) Inform people about what, Doctor?
A Inform people of the content of the warnings who do not know the content of these warnings already.
Q Is one of the purposes of warnings to inform users concerning the risks that may be associated with the device?
A Sometimes.
Q And do you believe it's important for a manufacturer to issue warnings concerning risks associated with its device?
MR. POOLE: Objection. Again, incomplete hypothetical. You can go ahead and answer, Dr. Swartz.
A If the recipient does not already know the content of the warnings, then it's important. If the recipient already knows, then the warnings are not doing anything.
Q (By Mr. Esfandiari) Doctor, the ECT machines that Somatics sells are used by hundreds, if not thousands, of medical professionals; is that correct?
A Yes.
Q And you're telling me that you know for a fact what the thousands of different medical professionals who are using the Somatics ECT device already know about the risk of the Thymatron ECT device?
A They already know about the risks of ECT.

Q And you know this because you've spoken with every single one of them?

A I know it because it is a -- a very important standard of practice.

Q Have you personally spoken with every single user of the Thymatron ECT device, Doctor?

A Of course not.

Q Okay. Has anyone, to your knowledge, at Somatics spoken with every single user of the Thymatron ECT device to find out what that individual knows about the risks associated with the Thymatron ECT device?

A That is not the job of Somatics.

Q Did you assume that all of these users already know of all the risks associated with the Thymatron ECT device, and, therefore, Somatics' chose not to provide any warnings in its manual concerning the risks associated with the ECT device?

MR. POOLE: I'm going to object as vague and overbroad. I assume you're referring specifically to the manual that we're looking at, Exhibit 3?

MR. ESFANDIARI: That is correct, Exhibit 3, the manual that was given to Sharp Hospital.

A I assume nothing. I know.

Q (By Mr. Esfandiari) But you just told me you haven't spoken with every single user of the ECT device, so how do

you know?

A I know --

Q How do you know what's in their head?

A I know because they have privileges to give ECT, and to get these they must have passed examination and credentialing by their hospital. If you're -- this is analogous to asking a scalpel maker if surgeons know how to use the scalpel.

Q I don't think it is. I mean, if you believe that all physicians already know about the risks associated with the use of Somatics' ECT device, then why is it in late 2018 Somatics updated its warnings and provided a whole list of new risks, leading with burns, headaches, cognitive impairment, brain injury, brain damage? Why did you update those lists if you feel that everybody already knew them?

MR. POOLE: Objection. Misstates his prior testimony that all physicians knew that. But you can go ahead and answer the question, Dr. Swartz.

A We are hoping and trying to avoid litigation.

Q (By Mr. Esfandiari) So you only gave the warnings because you're trying to avoid litigation?

MR. POOLE: Objection. Misstates his testimony. Go ahead. You can answer.

Q (By Mr. Esfandiari) Did I misstate your testimony?

A We gave the warnings because we are trying to avoid

litigation.

Q Okay. And that's the only reason Somatics decided to update its warnings concerning brain injury, cognitive issues and so forth in late 2018?

A Yes.

Q Were you required by the FDA to provide the updated warnings which you now provide concerning brain damage, cognitive issues and memory loss, permanent memory loss?

A No brain damage. Concerning -- the various warnings and cautions that are in the manual were written to fulfill the FDA's requirements.

Q And why did the FDA require Somatics to provide enhanced warnings concerning the permanent memory loss and all these various updated warnings that you now provide?

MR. POOLE: Objection. Misstates his testimony. You can answer.

A I don't know why these -- I don't know why the -- there's a feedback here. I don't know why the FDA does what it does.

Q Was there anything prohibiting you or preventing you from providing the warnings that you now provide concerning permanent memory loss and cognition issues, to have provided those back in 2001?

A It seemed to serve no purpose.

Q But there was nothing preventing you from doing that,

correct, Doctor?

A Nothing preventing that I know of.

Q What is the expense to Somatics for issuing enhanced warnings if you chose to issue enhanced warnings?

A It's not a substantial expense, whatever it is.

Q Okay. Doctor, what modes of communication do you utilize to communicate with your current customers, as well as potential customers? And let me place this in the time frame of, let's say, between 2002 and 2012? What were the modes of communication?

A There were mass mailings. There were meetings at trade shows, specifically the American Psychiatric Association and the Association of Convulsive Therapy. That -- and there may have been a number of emails.

Q How about a website? Did you have a website between 2002 and 2012?

A I don't know when the website began. Richard Abrams took care of that. But I think it's fair to say it began in the 2000s.

Q Okay. So certainly the website would have been around in, let's say, 2011?

A Was it around 2002?

Q No, no, strike that. Would the website have been in existence, let's say, in approximately 2011?

A Probably.

difficult. Just softball questions.

A I was trained as a scientist. I'm just telling you --

Q I understand. This one is a softball question.

All right. Now, this document was sent to us by Somatics, and it's Bates numbered 905. Do you have any reason to dispute the authenticity of this document, Doctor?

A No reason.

Q All right. And does this appear to be the type of document that Elektrika would use to test new devices prior to sending them to Somatics?

A Yes.

Q All right. And you identified the serial number as 40186; is that correct, Doctor?

A Yes.

Q And based upon preparing for today's deposition, is it your understanding that this is the serial number of the device that was sold to Northridge Hospital?

A Yes.

Q All right. Based upon the documents you have reviewed, Doctor, can you tell me a rough estimate as to when you believe this device was sold to Northridge Hospital?

A In 2001.

Q Okay. And we discussed previously what information

A Yes.

Q But you're saying that the current manual for whatever reason has nothing about the GENIE software?

A I don't know -- well, let's see. I think the manual for the GENIE is separate, and it's possible that it may exist only on a disc or a download.

Q Okay. Did Elektrika play any role in between 1984 and the present, any role in the marketing of the ECT devices that Somatics sold?

A Well, back in the first year or two John Pavel represented Somatics devices at the trade shows. This is before Somatics actually hired a salesman to do this. Because that was long, long ago. As I say, it was probably 1986 that he was no longer involved in any sales for Somatics.

Q Okay. All right. I'm trying to think if we should take a break now or if we should ask questions about -- well, let me ask some questions, and then we'll take our break in a couple of minutes.

So, Doctor, previously you testified that the manual that was given to Sharp Hospital which was version six did not contain any warnings or risks regarding adverse events associated with the Thymatron. And then I stated, but you believe that this version, the one that Northridge Hospital received, version five, did contain some warnings;

is that correct?

A Yes.

Q All right. What warnings did this Exhibit 4, which is version five of the manual, contain?

MR. POOLE: Objection. The document speaks for itself. But if you want him to --

A If you can scroll to the top of the document?

What's -- we -- I think you just went past it. Go up a little bit, please.

Q (By Mr. Esfandiari) All right.

A Stop.

Q Okay.

A Well, it looks like you got it in highlighter.

Q Yeah, is that -- so trying to make it easy for you, Doctor. Easier for both of us. So this was -- is this the language you were talking about, Doctor?

A Yes.

Q Okay. Now, I read this, and basically from what I understood from this language is Somatics was talking about risks associated with sine wave ECT stimulation; is that correct?

A It was talking about several things. That's one of them. There were several comparisons made by the text in this document, not just between sine wave and brief pulse.

Q So is it your -- now, you testified about this, I

think, previously, the distinction between sine wave and brief pulse, correct?

A Yes.

Q So I don't need to rehash that. We have that in the record. But is the Thymatron device, Thymatron IV, a sine wave device?

A No.

Q No? Okay. However, the Thymatron device is predicated on a sine wave device; is that correct?

A One of the two predicative devices is a sine wave, the other is a brief pulse.

Q Which one was the sine wave? Was it the MedCraft one?

A Yes.

Q Okay. All right. And then is what Somatics' stating here that sine wave is associated with more risks of cognition than brief pulse?

A That's one thing it's stating.

Q Okay. What else does it say?

A It says that with right unilateral ECT, memory and cognitive side effects are much less than bilateral ECT, which is the other method.

Q Okay. Now, does this provide any warnings about permanent memory loss, Doctor?

A Not in specific, but in general it just talks about

so, like, memory and cognitive side effects. So it doesn't say they're just short term. It doesn't limit them.

Q I'm -- I don't know if my reception went bad. I did not hear the full answer, Dr. Swartz. Can you repeat that?

A The sentence is not limited to short term side effects. It addresses side effects in general without limitation of their duration.

Q Okay. In reading this, Doctor, and let's say you were going to be a user of the Thymatron IV device, which is a brief pulse device, will you -- is this telling you that the Thymatron ECT device is associated with memory loss?

A When given with bilateral ECT, yes.

Q And how about when given unilaterally? Is it providing any warnings about memory loss?

A It says it's undetectable. There were reports that it's undetectable, which doesn't mean that it's entirely undetectable.

Q And you agree with me that there is -- the words permanent memory loss do not appear anywhere in this manual, correct, Doctor?

A Did not rule out, but they don't appear.

Q Okay. Will you agree with me that Exhibit 4 has no warnings concerning brain damage, correct, Doctor?

A It does not specifically mention brain damage, but it does not identify a cause of memory and cognitive side

effects.

Q And, Doctor, you agree with me when looking at Exhibit 4, which is version five of the ECT manual, that there is no reference to the patient suffering from permanent retrograde and anterograde memory loss, correct?

A This is version five we're looking at, right?

Q Correct.

A There's no direct reference, but it's not disqualified.

Q And, in fact, you'd agree with me that actually what this -- what you refer to as a warning here that we've highlighted is in reality giving assurance to doctors that, hey, our Thymatron device, which is a brief pulse device, actually does not cause cognitive issues, that those issues are more related with the sine wave devices, as well as the bilateral use of the devices, correct?

A I disagree with that. It warns about bilateral with brief pulse. It warns about brief pulse bilateral ECT, beyond any doubt.

Q Where? Point me to the sentence that you're talking about, Doctor.

A "When brief pulse stimuli are administered via right unilateral treatment electrodes." Right there, that is a specific identification that says that the rest of the sentence does not apply when brief pulse stimuli are

administered by some other method.

Q I'm reading this. I don't see anywhere in here where it tells me if I'm using bilateral brief pulse that I have a risk of cognitive side effects.

A That's a matter of your interpretation, I guess.

Q But, I mean, can you point to me where a sentence that says if you use brief pulse in a bilateral fashion you're going to have cognitive, permanent cognitive side effects?

A The last sentence of that paragraph says it's a possibility.

Q And the last sentence being this sentence, "In contrast, when brief pulse stimuli are administered via right unilateral treatment electrodes, memory and cognitive side effects are reported to be undetectable, even with stimuli administered at high charge." Is that the sentence you're talking about?

A Yes, it warns in effect against bilateral ECT and high dose bilateral ECT as possibly causing memory and cognitive side effects of unknown cause, unknown brain cause.

Q We're going to have to let a jury figure that one out. But would you agree with me at least that the warnings that Somatics currently provide are certainly a lot more prominent concerning the risks of brain damage and permanent

memory loss, correct, Doctor?

A Yes, but they're redundant.

Q All right. Doctor, let's take a 30-minute break. 30, 40 minute break for lunch. Maybe we'll reconvene 12:45?

MR. POOLE: 12:45?

MR. ESFANDIARI: Yeah, 12:45, 12:50.

MR. POOLE: Great.

VIDEOGRAPHER: Off the record. The time is 12:07 p.m.

(Lunch recess taken)

VIDEOGRAPHER: Back on the record. The time is 1:05 p.m.

Q (By Mr. Esfandiari) Dr. Swartz, we took a lunch break. We're back on. Do you have any change to the testimony you've given so far, Doctor?

A Well, I can say the patient information brochure may well have been distributed to these hospitals with a new Thymatron because it was before Mr. Mirkovich began working for Somatics. So his recall does not apply to these two hospital purchases.

Q Okay. So is it your testimony that the patient information was actually sent to both Sharp and Northridge or is it that you just -- you think it may have been sent?

A It may have been sent.

Q It may have been sent? And how would you -- if you

wanted to corroborate that and confirm that, is there anything you could do on your end?

A No.

Q No? You don't -- Somatics has no records of that transaction or occurrence?

A It -- those records were not kept of who it was sent to.

Q I see. All right. And what -- why is it that you think it may have been sent?

A Because it existed. It -- the 2002 edition was the latest edition of several editions. So that illustrates that Richard Abrams and I were interested in the brochure and that it was distributed to somebody.

Q Okay. Do you have any recollection when you would have been sending it, for example, to the hospitals? Would it have been as part of the new device you were selling?

A I expect it would be part of a new device so that they could see it and ask for it if they wanted.

Q And would you be sending, like, multiple copies or would you just be sending one copy with the expectation that the hospital makes copies to hand out to patients?

A One or two copies with the expectation that they would either make their own copies or they would ask us for more.

Q Okay. And was this something that was -- you

Q Okay. Now, previously today when I asked you why there were no warnings included in version six of the manual that Sharp received, you stated that there were no warnings necessary because it was your expectation that all doctors knew about the warnings and side effects of ECT, the risks and side effects of ECT.

So did this experience in 2006 then lead you to conclude that perhaps not every single doctor knows about these side effects and risks of ECT?

A No, it did not change. I was just anxious and concerned. It was more because of my feelings of fear and anxiety. Well, of anxiety. Not really a fear. Of anxiety about the practices of my colleagues that led me to express my anxiety this way.

Q Right. But, I mean, why -- why -- you know, I mean, so they were -- colleagues were providing ECT to patients who you felt was not indicated and who you felt were at an increased risk of having cognitive difficulties. So that indicates to me that perhaps all doctors of ECT are not as well-versed concerning the risks of ECT as you, the manufacturer.

So given that you've become enlightened with that information, why not then be forthright with all the risks and benefits and side effects of ECT that you were aware of and outline them in your manual?

MR. POOLE: Objection. Misstates his testimony. But you can go ahead and answer, Dr. Swartz.

A Well, I can say it wasn't indicated. These elderly patients with Alzheimer's disease had what could easily be identified and diagnosed as agitated depression on top of their dementia. Depression and dementia is a very common and notable problem, and so is agitated depression. I did not say that it was not indicated. I said something very different. I said I was anxious about it.

Q (By Mr. Esfandiari) You were anxious about the risks that the patients were being exposed to, correct?

A I was anxious about the risks that the hospital staff was being exposed to, as well as the patients being exposed to, because of confusion that these patients are likely to show.

Q Okay. And isn't that something that could be remedied, those risks potentially remedied if Somatics had provided adequate warnings on the use of its device and the risks associated with its device?

A Oh, not at all. These doctors were desperate for something to assuage the agitation and -- and depression shown by these patients. They were totally desperate. They tried everything else. They tried antipsychotic tranquilizers. They said, "If not ECT, then what?" In other words, "We don't have anything."

Q All right. And did you issue any warnings to deal with your anxiousness, as you put it?
A Well, we issued the statement in the 2006 manual. That's what we issued.
Q Yeah, and in your own words in the e-mails that have been produced in this litigation you didn't deem this disclaimer to be a warning at all, correct?
A It was redundant for warnings that were already made.
Q Doctor, the 2006 manual we looked at had no warnings whatsoever, so how could it be redundant of something that is never warned about?
A It did indeed have warning. It said heed what is in the APA ECT Task Force report of 2002. Be familiar with it.
Q That's not a warning, correct, Doctor?
A It is a warning. It embodies all the content of the APA task force report, including the warnings within.
Q So if your label had said "Go to medical school," and that's your warning, is that sufficient?
A If we were -- well, that warning is in there too. It said this treatment is only for administration by a licensed M.D. It requires going to medical school, doesn't it?
Q All right. Doctor, going back to Exhibit 5, which is the version six of the label or the manual, as you have previously noted all doctors are aware about the risks associated with ECT. Why did you need to include this

antipsychotic tranquilizers. In one of them I noted that antipsychotic tranquilizers cause cancer. I received notice from several pharmaceutical manufacturers. They had seen my report and were unhappy with it. So I had notified them.

Q Okay. So you were notifying them of risks that were not contained in their promotional literature or in their labeling but that you were -- had experienced or seen in your own patients?

A Oh, you're right, it was actually in their labeling. Oh, there was another one, yes, where I --

MR. POOLE: Dr. Swartz, I think we're kind of going far afield from the question. He was just -- he was really making an argument in the form of a question. I think you answered his question. There may be other instances, but let's just move on to the next question.

THE WITNESS: Okay.

MR. POOLE: All right.

Q (By Mr. Esfandiari) I think that's sound advice.

All right. Doctor, can you see this document that I've popped up?

A Oh, yes.

Q All right. I believe we are at Exhibit 6. Can you identify Exhibit 6 for the record, Doctor?

A This is one of the series of e-mails between Richard Abrams and me in 2006 concerning adding an additional

warning statement to the Thymatron System IV manual.

Q And it wasn't a warning as much as it was a disclaimer, correct?

A No, it was a warning. It was entitled "Disclaimer."

Q Okay. In your email -- this is your email that we're looking at, correct?

A Yes.

Q And Dick is -- I assume you're referencing Dr. Abrams?

A Yes.

Q Okay. So in this email --

First of all, can you just read the highlighted section on there?

A "The goals of the warning statement we need to make are to prevent lawsuits and not alienate psychiatrists. All warnings that are written are stated in the form that this product can or may cause XXX. We should conform to this" -- there's some words underneath this video strip that I can't see.

Q Can you see it now?

A No, the video strip shows faces of people --

Q Right.

A -- participating in this conversation.

Q I understand. Are you able to move the strip on your end, Doctor, to be able to --

Q (By Mr. Esfandiari) All right. Doctor, let me get the next exhibit going here, Doctor. Okay.

(Pause in proceedings)

Q I should have had this ready during the break.

MR. POOLE: So stipulated.

MR. ESFANDIARI: I know. I know.

Q (By Mr. Esfandiari) Doctor, can you see this document?

A Yes.

Q Okay. We're going to mark this the next exhibit in line, which I believe is Exhibit 7, and it's titled "Regulatory Update to Thymatron System IV Instruction Manual." Do you see this, Doctor?

A Yes.

Q And I will represent to you, Doctor, that our office pulled this off of your website. Do you recognize this document, Doctor?

A It looks like it's something that Somatics published on the website.

Q Okay. And what was the purpose of this document?

A Somatics is put -- it's to avoid litigation.

Q What do you mean by that?

A You sued us. We are trying to avoid more lawsuits.

Q All right. Now, this, from my understanding, went off shortly after we settled the Riera and Chase case. Is

that your understanding as well, Doctor?

A I'm not sure when the settlement was done.

Q Okay. Do you recall if this update to your website occurred around the time of the settlement of the initial batch of cases?

A No, I don't recall.

Q Do you recall when you put this information on the website, this document we're looking at, Exhibit 7? So I have the date at 10-19-18, October 19th, 2018. Do you have any idea when it went on the website?

A I expect it went on in 2018.

Q Okay. All right. And you agree with me that this does provide warnings and certain adverse events that are associated with ECT and the Thymatron device, correct?

A Yes.

Q All right. And including you've put in here now cognition and memory impairment, as well as brain damage; is that correct?

A Yes.

Q All right. And why was this not included in the warnings and manuals that were submitted to Sharp and Northridge back in the 2002-2001 time period?

A It's the learned intermediary theory and practice where the doctors already are fully expected to be expert and familiar with all -- all of the actual possible --

possible side effects of ECT and the risks. And so this would merely be redundant.

Q So you knew back in 2002 that ECT causes brain damage, but yet you chose not to warn?

A That is not what I said.

Q What did you --

A And nor does ECT cause brain damage. That's a false and incorrect statement of fact because it is not supported by science or studies of patients. It is put in there purely to discourage litigation. We are put in a position of having to warn of adverse effects that have never been proven to occur in large studies with numerous patients. These effects such as brain damage have not been found to occur, but yet we are put in a position of having to warn -- of having to warn of such things to decrease the risk of litigation.

MR. ESFANDIARI: David, I hate to do this. My -- I froze out, and I'm again logged out of my network. I'm going to need, like, a minute or two to have my people --

MR. POOLE: Sure, if it's a minute or two, let's just hold and let you work through it. We can go off the record, but I don't think we need to take another --

MR. ESFANDIARI: No, no, at least go off the record.

MR. POOLE: Sure.

MR. ESFANDIARI: But you all can stay.

MR. POOLE: Yeah.

MR. ESFANDIARI: I'm just -- I'm going to mute myself.

VIDEOGRAPHER: We're off the record. The time is 2:17 p.m.

(Off the Record)

VIDEOGRAPHER: We're back on the record. The time is 2:26 p.m.

Q (By Mr. Esfandiari) All right. Doctor, we were looking at Exhibit 7, which was the regulatory update you had put up on your website some time in 2018. Do you recall that, Doctor?

A Yeah.

Q Okay. So you agree with me that in this regulatory update on your website you now provide a number of warnings associated with ECT and the Thymatron machine, correct, Doctor?

A Yeah.

Q All right. But is your claim that all of these warnings that are identified in Exhibit 7, that they're not really risks and you're just adding all of this in order to avoid litigation?

MR. POOLE: Objection. Compound. But you can go ahead and respond, Dr. Swartz.

A These are risks already known to the physicians, and warning of them is merely redundant because they already knew it.

Q (By Mr. Esfandiari) And is that also true with respect to the reference to brain damage that we saw previously?

A Well, in the -- the full truth of that is we are warning of something that doesn't -- that is not known or proven to occur.

Q All right. And I understand that is -- that is your opinion and Somatics' opinion, correct?

A Yes.

Q All right. With respect to the other side effects that are listed here on page three of seven, page three of Exhibit 7, in addition to brain damage do all of the other side effects also encompass that universe of things that you just don't believe exist or happened?

A Some of them are true. Most of them have been reported to occur.

Q All right. So on this -- you see this paragraph on page three?

A Yes.

Q Which ones are you saying occur and which ones are not true risks?

A Would you please stop moving it around?

Q Sure. Let me know when you want me to move it.
A Move it up. Oh, I see. The most common -- the most common reported effects occur -- the mortality estimate is reasonable. The cognition and memory impairment are temporary except for spotty retrograde amnesia, which is sometimes permanent. The brain damage is not true. Not proven to occur, put it that way. General motor dysfunction. I don't honestly understand that and can't comment on it.
(Pause to review document)
A I'm not aware of homicidality. I'm not aware of data supporting that. I'm not aware of substance abuse as a consequence of ECT. And so I'm going to throw those in with the brain damage. And that's it.
Q Okay. But everything else you believe is something that could potentially arise as a result of ECT and the Thymatron device?
A Yes.
Q Okay. And you agree with me that yet none of those risks were ever identified in the manual that existed in 2002 and 2001?
A Yes.
MR. POOLE: Again, I'm going to object as compound. But you can go ahead and answer.
Q (By Mr. Esfandiari) Correct, Doctor?

A Yes.

Q All right. And were those -- is your opinion were you or Somatics aware of these risks back in, let's say, early 2000, 2002-2001 time period?

MR. POOLE: Again, objection. Compound. Make sure you specify in your answer what risks you're testifying you were aware of.

Q (By Mr. Esfandiari) Let me -- so you identify that every -- with the exception of, for example, brain damage and homicide, and you reiterated that a few items on Exhibit 7 that you don't agree with can happen as a result of ECT, but everything else that you didn't specifically identify you believe can occur as a result of ECT treatment, correct?

A Yes. And has been reported somewhere.

Q All right. And I'm asking were Somatics aware of those risks occurring as of 2002?

MR. POOLE: Again, same objection. Compound. But go ahead and answer.

A Sometimes it's improper to call an extremely unlikely event a risk. But am I aware that these events are possible, although some of them are extremely unlikely outside of the brain damage and homicidality, the answer is yes.

MR. POOLE: Dr. Swartz, I just want to clarify, your response is in the present tense. The

that administers electricity up to a hundred joules into human brains is the equivalent of essentially a scalpel or basically a surgical knife?

MR. POOLE: Objection.

Q (By Mr. Esfandiari) You're equating those two devices?

MR. POOLE: Objection. Argumentative. You can answer.

A It's an analogy. It's not an equivalence. There's a big difference.

Q (By Mr. Esfandiari) And is Prozac the equivalent of a scalpel, Doctor?

MR. POOLE: Same objection. You can answer.

A It's an agent. It's not equivalent, no. We're talking about analogies, not equivalences.

Q (By Mr. Esfandiari) And I'm saying is it more appropriate to refer to ECT and its risks to other dangerous pharmaceutical agents and other pharmaceutical therapies as opposed to simply a scalpel?

MR. POOLE: Objection. Argumentative. You can answer.

A I don't understand the question anymore.

Q (By Mr. Esfandiari) Okay. Who wrote Exhibit 7?

A Richard Abrams.

Q Did you have any part of it, Doctor?

A I don't recall.
Q And this was posted on your website; is that correct?
A Yes.
Q Did you take any effort to also mail this or email it to your current customers?
A Yes.
Q Was this emailed to Sharp Hospital in 2018?
A What Mr. Mirkovich told me it was printed and mailed to all owners of a Thymatron System IV. A -- in about 2018.
Q Do you --
A What was sent may or may not have been exactly this, but it resembled it.
Q Do you have what was sent?
A No.
Q Do you have a copy a document that I would identify all the customers that received this warning in Exhibit 7, or whatever formatting it was displayed in?
A This would be a confidential list of our customers.
Q I understand. But do you have the list?
A We have a list of customers. We have a list of customers as of 2018. We have the data to produce such a list. We may or may not have a list.
Q Okay. In the past when a company has issued new warnings to customers, they do it sometimes through a Dear Doctor letter. Have you ever received a Dear Doctor letter

from a manufacturer?

A Yes.

Q Okay. Did the information that you relayed to your current customers concerning Exhibit 7, was it accompanied with a cover letter, something Dear Doctor or Dear Hospital, something like that?

A I expect it was.

Q Do you have a copy of that cover letter?

A No.

Q Why not?

A I don't have it. I have no explanation. I expect it was produced.

MR. POOLE: Bijan, maybe Jason -- I mean, Jason has knowledge of what was produced recently, which included an addendum. And are you on the line, Jason?

MR. ESFANDIARI: And, David, we can explore that on a break.

MR. POOLE: All right. No worries.

A If Somatics has it, it was produced.

Q (By Mr. Esfandiari) If you had it, it would have been produced? Okay. And in other litigation that I've seen, the companies would actually have a list where it identifies all their customers and has, like, a check off saying -- to confirm that every customer received the new warning.

Does Somatics have such a document that kind of just in case anybody asks for confirmation "Hey, did Northridge Hospital get the update, regulatory update?" that you can go and consult and say, "Yeah, they did. See? I checked off this box"?

A I expect Somatics does not have a list.

Q So if you were asked to confirm if Sharp or Northridge ever received this regulatory update, you would have no way to confirm that in-house?

A I can confirm that it was sent to them because we have a record that we sold a Thymatron IV to them, and we sent out the 2018 letter to all purchasers of the Thymatron IV up to that point.

Q But in terms of a document to confirm that it was sent out, you don't have that?

A Right.

Q Okay. And who did the -- and was it sent by mail or email, Doctor?

A Mail.

Q And who did that? Who physically did that?

A Somatics' staff, including David Mirkovich.

Q Okay. And when did the mailer go out? Did it go out around toward end of 2018 or early 2019?

A It went out in 2018.

Q 2018? And I understand, Doctor, that in around this

Q All right. I'm going to go through a few documents that were produced in this case just for authentication purposes, and, just, I have some brief questions.

Moving to Exhibit -- what we're going to mark as Exhibit --

MR. ESFANDIARI: I believe we're on 14, Miss Court Reporter?

REPORTER: I'm showing 15.

Q (By Mr. Esfandiari) All right. So Exhibit 15, Dr. Conrad, can you tell us what is Exhibit 15?

A It looks like a computer list of files.

MR. POOLE: Yeah, Bijan, we're not --

MR. ESFANDIARI: Oh, are you -- what? You're not seeing --

MR. POOLE: We're seeing your screen, which has a list of documents. I'm literally looking at your computer screen.

MR. ESFANDIARI: Oh, no, that shouldn't be it.

MR. POOLE: It was up before, but --

MR. ESFANDIARI: It disappeared. Okay. Let's see if this helps.

Q (By Mr. Esfandiari) There we go. Doctor, are you able to see this document?

A Yes.

Q Okay. What is Exhibit 15, Doctor?

A It's the 510(k) approval of the Thymatron ECT device initial model, Thymatron 1 we call it now, from 1984.

Q Okay. And it's the clearance, not the approval, correct?

A That's just the -- right, it's the clearance. The approval for marketing.

Q Okay. But the FDA has never approved Thymatron, correct?

A Yes, it's only approved for marketing and sales. That's all.

Q Cleared for marketing and sales?

A Okay. Yes.

Q Yes? Okay. And, in fact, in this very letter in Exhibit 15, and I'll read this into the record, it says "This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding." Did I read that correctly, Doctor?

A Yes.

Q Okay. All right. And moving on to Exhibit 16, what is Exhibit 16, Doctor?

A That's 510(k) approval for the device that became the Thymatron System IV.

Q And, again, you used the word approval. You meant clearance, correct, Doctor?
A It's a habit. It's hard to break.
Q I know.
A It's clearance. And, you know, I can't tell you how many times I've lectured other doctors on this same exact topic.
Q Okay. And this is -- and this is for the Thymatron IV, correct, Doctor?
A Yes.
Q All right. Now previously you testified that the Thymatron IV hit the market in 1999. This document is dated 1995. Is this more the correct date when the Thymatron IV hit the market?
A It's when it was approved. We didn't market it until later.
Q It was -- okay.
A Again, I did it again. When it was cleared.
Q All right. But you -- all right. But you didn't start sending it out to hospitals until 1999? That's still your testimony?
A Yes, that's the truth.
Q Okay. No, it's fine. I just was -- you know, we're talking about -- that's fine.
And, again, you've seen, Doctor, that I've

highlighted -- this also contains the same admonition that this is a clearance, it does not constitute approval, and you may not promote or in any way represent your device or labeling as being approved by the FDA? Do you see that, Doctor?

A Yes.

Q All right. Did Somatics comply with these instructions from the FDA, that you're not allowed to represent that your device is approved by the FDA?

A We may have made the error a few times.

Q Okay. And where were those few times, Doctor?

A I have a recollection of something on a website.

Q Anything else?

A I have other recollection of that error. It was definitely an error.

Q Okay.

A I repent. I repent.

Q All right. It's rare to get repentance, Doctor, in a witness.

Let me draw your attention to Exhibit 17. This appears to be an image from your website; is that correct, Doctor? Does this look familiar to you at all?

A Based on what it says on the left, yes, the website.

Q Its catalog?

A Downloads, distributors, yeah.

Q Yeah. And I think we got this about a year or so ago, March 11, 2020. Do you see that, Doctor, right here on the top right-hand corner?

A It's right under your picture. I don't see it.

Q Okay. All right. All right. And is this a picture of the Thymatron IV machine, Doctor, this image we're looking at?

A Yes.

Q All right. And is this how the machine currently looks as well?

A Yes.

Q Okay. And then there's some specifications. And then do you see here you have a section called "Approvals," Doctor?

A Yeah.

Q And then you put down that the FDA has provided approval. Do you see that, Doctor?

A Yeah.

Q All right. Has anyone told you that this constitutes misbranding, as indicated by the FDA letters that we just took a look at?

A Anyone told me? I can see it's wrong. It's an error.

Q All right. Prior to me informing you, has anyone else informed you of this error, Doctor?

A I probably saw it. I don't know.
Q Okay. And is the current website, is this representation currently made by Somatics on its website, that the FDA has approved the Thymatron device?
A I don't know.
Q Okay.
A The website speaks for itself.
Q Okay. Assuming it does include that information, are you going to take any steps to remove those false representations?
A Yes, sir.
Q All right. Other than this website, do you have any recollection of making similar representations concerning approval of this Thymatron device in any other document, venues, anywhere else?
A I have no recollection of it.
Q Okay. All right. Doctor, I'm drawing your attention to what we're going to call Exhibit 18 to your deposition. Have you seen this document before, Doctor? It's a one-paged --
A I think so.
Q What is this document, Doctor?
A It's a sales flyer or it's the front page of the eight-paged brochure, catalog. I'm not sure which it is. It looks like the front page of the eight-paged catalog.

Q All right. Let me -- moving on to Exhibit 19, Doctor, this is probably -- do you see Exhibit 19, Doctor?

A Yes.

Q What is Exhibit 19?

A That looks like the back page of the eight-paged catalog or it could be the back page of a two-paged flyer.

Q All right. And do you have any -- you know, this statement right here where it says "Thymatron System IV, the most advanced ECT device technically and operationally with demonstrated superior safety and clinical effectiveness," do you see that, Doctor?

A Yeah.

Q All right. What is -- what's the basis for this representation, Doctor?

A The safety is superior to the previous Thymatron DGx because it has internal monitoring and testing. The effectiveness -- well, -- well, "demonstrated superior clinical effectiveness." Hmm. Well, they were the core studies showing -- no, let's see. "Clinical effectiveness"? Oh, okay.

So we have the study of Chanapatana, Awarak Chanapatana, showing that the Thymatron had a lower seizure threshold than the MECTA device. So with a lower seizure threshold you can use lower electrical stimuli, and so that -- using lower electrical stimuli is the basis for saying --

is a basis for saying superior safety and clinical effectiveness in -- in inducing an electrical seizure.

Q Why -- why is it beneficial to have a lower electrical stimuli?

A I discussed that in the previous deposition.

Q Well, just briefly explain to me.

MR. POOLE: Briefly.

A Greater efficiency.

Q (By Mr. Esfandiari) What does that mean? I mean, is there a safety component associated with having lower electrical stimuli?

A Less chance of burns.

Q Anything else?

A Generally also, yes, higher electrical stimuli have been shown to produce more temporary cognitive side effects. So using lower electrical stimuli, more efficient stimuli should be safer. It's -- as I explained in the previous deposition, it's the reason that brief pulse is safer than sine wave ECT.

Q Now, did you conduct -- and when I say "you," Doctor, I'm talking about Somatics as a whole, did Somatics conduct any clinical trials on the Thymatron devices?

MR. POOLE: This was clearly gone into before with this witness.

MR. ESFANDIARI: I just -- we're looking at a

document here that's making representations, and I want to see if there were any clinical trials that are --

A I have nothing -- I have nothing to add.

Q (By Mr. Esfandiari) All right. So it's true that Somatics has never conducted any clinical trial regarding the Thymatron ECT devices, correct?

A Correct.

Q All right. So there are no clinical trials performed by Somatics to support the representations made here in Exhibit 19, correct?

A Correct.

Q Okay. Now, moving on to Exhibit 20, Doctor, do you see Exhibit 20, Doctor?

A I see a Thymatron.

Q Yeah. And this is Bates number -- and I'm starting to have the same problem you did, Doctor. The faces start covering the document. This I believe we took from your website. Well, why don't you authenticate this document for us, Doctor? What does this document appear to be?

A This appears to be the eight-paged catalog which is downloadable from the website.

Q Okay. Perfect. I want to draw your attention to the very last page of this document. Are you there? Do you see this highlighted section, Doctor?

A This looks identical to what you previously showed

me.

Q Okay. So read this sentence. Do you see it? "Thymatron, the most advanced ECT device technically and operationally," correct?

A So it is a little different, yes.

Q Yes, yes. And so going to Exhibit 19, it looks like for Exhibit 20 the new operation -- the new manual -- or, the new brochure you eliminated the reference to "superior safety and clinical effectiveness." Is that correct?

A Yes.

Q Do you know why that occurred?

A Because the statement about effectiveness is not necessary.

Q How about safety? Is that also not necessary?

A It's not necessary.

Q And why is it not necessary?

A Because the previous words are sufficient.

Q Do you know who made the decision to remove the references to "superior safety and clinical effectiveness" from your marketing brochure?

A Richard Abrams and me.

Q And why -- and other than what you just testified to, was there any other reason as to why these representations were removed?

A Not in my mind.

Q Did anybody -- how about in other people's minds?
A Did anybody?
Q Other people? You said not in your mind. I'm asking maybe did Dr. Abrams or others have any concerns that led to this statement being removed?
A Well, Dr. Abrams agreed it wasn't necessary.
Q Were you ever concerned that maybe these statements were misleading and could potentially result in litigation concerning making false representations concerning safety and efficacy?
A No.
Q That was not a concern?
A No.
Q Did anyone else inform you that you should remove the representations concerning superior safety and clinical effectiveness?
A Nobody informed me of it.
Q Okay. Do you know when the language was deleted?
A I don't know for sure. I will -- I can imagine it was in 2018.
Q In 2018? So that's around the same time that you advised your revised your manual to warn of adverse events; is that correct?
A Yes, but I am not sure it was 2018. I think it was 2018.

CORRECTIONS

Page	Line	
87	5	Vaclav not Vishra
87	13	It may not I may
139	8	Flurothyl not fluorofil
158	21+22	Chanpattana, Worrawat Chanpattana
172	4	Thymatrons not Thymatron's
202	22	Megsinet.net

I have read the foregoing 206 pages of my testimony and believe the same to be true except for correction (s) noted above.

DATED: 4/10/2021

CONRAD SWARTZ, M.D.

STATE OF WASHINGTON)
: ss: REPORTER'S CERTIFICATE
COUNTY OF SPOKANE)

I, Caryn E. Winters, a certified court reporter in and for the states of Washington and Idaho, do hereby certify:

That the foregoing deposition of CONRAD SWARTZ, M.D. 30(b)(6)/individual, via Zoom video conference, was taken on the date and at the time and place as shown on Page 1 hereto;

That the witness was sworn upon his oath to tell the truth, the whole truth and nothing but the truth, and did thereafter make answers as appear herein. The final page count of this transcript is 208.

That the foregoing is a true and correct transcription of my shorthand notes of the requested deposition transcribed by me or under my direction;

That the witness' signature was reserved.

WITNESS my hand this 5th day of April, 2021.

CARYN E. WINTERS, CRR, RPR
WA CCR No. 2496, ID CSR 237

(This transcript and billing have been prepared/submitted for final preparation and delivery in accordance with all Washington state laws, rules and regulations, including WAC 308-14-130, WAC 308-14-135, RCW 18-35, and applicable Court Rules regulating formatting and equal terms requirements. Alterations, changes, fees or charges that violate any of these provisions are not authorized by me and are not at my direction or with my knowledge.)

EXHIBIT 9

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CASE NO.: 2:17-CV-06686 RGK(PJWX)

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN AND DANIEL BENJAMIN, INDIVIDUALLY, AND ON BEHALF OF ALL OTHERS SIMILARLY SITUATED,

PLAINTIFFS,

VS.

MECTA CORPORATION; SOMATICS, LLC; AND DOES 1 THROUGH 10, INCLUSIVE,

DEFENDANTS.

VIDEOTAPED DEPOSITION OF: DAVID L. MIRKOVICH, PMK

DATE: JULY 12, 2018

TIME: 10:15 A.M. TO 4:55 P.M.

PLACE: MICHAEL MUSETTA & ASSOCIATES
201 NORTH FRANKLIN STREET
SUITE 3400
TAMPA, FLORIDA

BEFORE: CAROLYN R. LOUDEN, RPR
NOTARY PUBLIC, STATE OF FLORIDA AT LARGE

PAGES 1 - 236

JOB NO. 132834

don't know."

THE WITNESS: I can't answer because I do not recall.

BY MR. KAREN:

Q. All right. So, for example, during the course of your employment with Somatics, would you have ever maintained a file where you would have printed and kept any source material that you utilize to assist you in understanding your responsibilities to report adverse events to the FDA?

A. Yes.

Q. Okay. When was the first time that you started to maintain that file?

A. The MedWatch file, in '03, '04, '05.

Q. All right. And at that point in time -- apologies for going backwards a little bit -- the MedWatch events that came to your attention during that period of time were which? Which events from MedWatch did you become aware of?

A. The vast, vast majority were the minor skin burns that were reported. There was one other wacko -- that's a bad term to use. There was one other listing that was not a minor skin burn.

Q. And what was that?

11:29:18 A. That's where a no-named individual, with
11:29:23 no medical information or hospital information,
11:29:28 posted that she had suffered memory loss and things
11:29:33 along those lines, but without any credible evidence
11:29:39 of events. It was just -- in today's language, she
11:29:45 posted a blog.
11:29:46 Q. Okay. And was this the approximate 2005
11:29:51 time frame?
11:29:51 A. Somewhere back in those days, yes.
11:29:53 Q. All right. How did, if you recall, those
11:29:59 initial MedWatch reports come to you?
11:30:04 A. They were mailed by the FDA.
11:30:10 Q. And I think you referenced earlier that
11:30:12 you reported with regard to the skin burn MedWatch
11:30:18 reports that you received from the FDA at about that
11:30:21 time; is that correct?
11:30:22 A. Yes.
11:30:25 Q. And when you use that phrase "reported,"
11:30:28 what do you mean?
11:30:29 A. I responded to them in writing the
11:30:41 sequence of events that we investigated, getting
11:30:44 back to investigating reports. We would obtain the
11:30:46 electrodes, if possible. We would check with the
11:30:49 medical people to see if they followed procedures.
11:30:52 Some did, some didn't.

14:41:25 A. I'm done.
14:41:25 Q. Have you ever, either in your sales
14:41:29 conversations or your marketing materials -- ever
14:41:32 inferred that the Somatics devices are FDA approved?
14:41:38 A. No.
14:41:38 Q. They're not FDA approved, are they?
14:41:40 A. They are not FDA approved. They are FDA
14:41:43 registered. Very big difference, and thank you for
14:41:47 bringing that up. The FDA does not approve medical
14:41:50 devices. They register them.
14:41:52 Q. Well, if it had premarket approval, it
14:41:55 would be approved, wouldn't it?
14:41:56 A. I have no idea.
14:41:57 Q. Okay. But you do know that Somatics' ECT
14:42:00 devices have never had premarket approval, correct?
14:42:04 A. To my knowledge, correct.
14:42:09 Q. I was looking at, I think, the web page of
14:42:14 Somatics, and there were some frequently asked
14:42:19 questions. And one of them dealt with TMS,
14:42:27 Transcranial Magnetic Stimulation.
14:42:30 Are you familiar with what's on the web
14:42:32 page?
14:42:33 A. To some degree, yes, but go ahead with
14:42:35 your question.
14:42:36 Q. Who's responsible for the web page? Is

CERTIFICATE OF COMPLIANCE

I CERTIFY that the foregoing deposition transcript was prepared by the reporter designated herein; that a digital copy of the reporter's transcript was submitted by the reporter to Personal Court Reporters, Inc., for the purposes of preparing electronic and/or paper copies for the requesting parties; that the transcripts have been prepared, distributed and invoiced pursuant to the order on file with Personal Court Reporters, Inc.

I FURTHER CERTIFY that the production and distribution of the transcripts comply with all applicable regulations as well as CCP 2025 and Federal rule 30.

DATED at Van Nuys, California, this 26th day of July, 2018.

Lisa Carrier

Personal Court Reporters, Inc.
Vice President
Lisa Ann Carrier, CSR 6828

EXHIBIT 10

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; MICHELLE HIMES; DIANE SCURRAH; DEBORAH CHASE; MARCIA BENJAMIN and DANIEL BENJAMIN, individually, and on behalf of all others similarly situated,

Plaintiffs,

v.

MECTA CORPORATION; SOMATICS, LLC; and DOES 1 through 10, inclusive,

Defendants.

Case No.: 2:17-cv-06686 RGK(PJWx)

DECLARATION OF PETER BREGGIN, MD IN SUPORT CLASS CERTIFICATION

I, Peter Breggin, declare under penalty of perjury as follows:

1. I am a medical doctor (physician) with a specialty in psychiatry. I am licensed to practice medicine in New York State and since 2002 I have an active practice of psychiatry in Ithaca, New York. I also have inactive licenses in Virginia, Maryland, and Washington DC, the area where I practiced until 2002.

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2. I graduated from Harvard University with honors in 1958 and Case Western Reserve School of Medicine in 1962, where I conducted four years of psychopharmacology lab research with controlled animal trials under a grant from the National Institute of Mental Health, resulting in the first two published papers in the field of psychopharmacology. In 1963, I earned the highest grade in the country on the psychiatry portion of the National Board of Medical Examiners used to qualify for medical licenses. I completed a mixed internship in medicine and psychiatry at the State University of New York Upstate Medical Center (SUNY). I completed my first year of residency at Harvard's main teaching hospital, working in the Massachusetts Mental Health Center, and a teaching fellowship at Harvard Medical School. I finished my second and third year of psychiatric residence at SUNY. Following that I was a full-time Consultant with the National Institute of Mental Health (NIMH) in Washington, DC while a commissioned officer in the U.S. Public Health Service (1966-1968).

3. Throughout my career, I have taught as a faculty member or adjunct professor at multiple universities, including the University of Maryland (1968-1970), Washington School of Psychiatry (1968-1972), George Mason University (1990-1996), Johns Hopkins University (1996-1999), and the State University of New York at Oswego (2007-2008, 2010-2014).

4. From 1998 to 2002, I was the Founder and Editor-in-Chief of *Ethical Human Sciences and Services: An International Journal of Critical Inquiry* (now titled *Ethical Human Psychology and Psychiatry*). I currently serve as an editorial consultant to numerous other publications, including the *International Journal of Risk and Safety in Medicine*.

5. I have written numerous publications on the practice of electroconvulsive therapy ("ECT"). A true and correct copy of my Resume is attached as Exhibit A which includes my complete bibliography. Dating back to 1979, I wrote the medical book, *Electroshock: Its Brain-Disabling Effects* (New York: Springer), which remains the only medical textbook that focuses on the harms caused by ECT. Since then I have written many medical articles on electroshock treatment, including "Electroshock Therapy and Brain Damage: The Acute Organic Brain Syndrome as Treatment" in *Behavior and Brain Sciences* (1984), "Neuropathology and Cognitive Dysfunction from ECT" in *Psychopharmacology Bulletin* (1986), "Electroshock: Scientific,

ethical, and political issues" in *International Journal of Risk & Safety In Medicine* (1998), "The FDA should test the safety of ECT machines" in *International Journal of Risk & Safety in Medicine* (2010) and "The Utmost Discretion: How Presumed Prudence Leaves Children Susceptible to Electroshock" in *Children & Society* (2014).

6. I have also written many books chapters on ECT and have discussed it in detail in a series of my medical textbooks, most recently, *Brain-Disabling Treatments in Psychiatry: Drugs, Electroshock and the Role of the FDA, Second Edition* (New York: Springer Publishing Company, 2008).

7. In 1985, the National Institutes of Health (NIH) invited me to be the scientific presenter on the subject of "Neuropathology and Cognitive Dysfunction from ECT" at its *Consensus Development Conference on Electroconvulsive Therapy, June 10-12, 1985.* Consensus Conferences are significant scientific and media events in which acknowledged, well-known experts make presentations on controversial topics and a panel without conflicts of interest renders a consensus from the presentations. The Consensus Conference final statement regarding ECT were published in *JAMA* ("Consensus Conference: Electroconvulsive Therapy," *Journal of the American Medical Association, No. 15, October 1986.*). My scientific presentation, along with others, was individually published ("Neuropathology and Cognitive Dysfunction from ECT" in *Psychopharmacology Bulletin*, 1986).

8. Electroconvulsive therapy is the practice of inducing a grand mal motor seizure through application of electricity to the head and brain. It began in 1938, when Ugo Cerletti and Lucio Bini observed the shocking pigs to render them manageable before slaughter. It has been in widespread use across the States, including California for decades.

9. ECT is primarily used on patients seeking treatment for major depression. It is also liberally prescribed for a broad range of psychiatric conditions including bipolar disorder, schizophrenia and catatonia. I believe the practice has become more widespread since 1979, when I estimated that 100,000 people received ECT per year in the United States. A report by the California Department of Mental Health indicates that over 18,000 people underwent ECT treatment in California in 2001 alone. While there is no formal record of the exact number of

patients who undergo ECT in California each year, my estimate is that it would amount to several thousand per year, perhaps tens of thousands.

10. Early in my career, I administered ECT and supervised a ward upon which ECT was performed. Throughout my career I have observed the effects of ECT. Based upon all my education, experience, training and study of ECT to date, it is my opinion, as to a reasonable medical certainty, that ECT inherently causes damage to the brain, causing symptoms such as severe permanent memory loss, cognitive impairment, and apathy and indifference towards oneself and others.

11. Prior to 1979, the psychiatric community acknowledged that the purpose of ECT was to damage the brain. In 1979, the year that the FDA first ordered the submission of all safety and effectiveness data relating to ECT treatment, I published my aforementioned medical textbook, *Electroshock: Its Brain-Disabling Effects*. In the book, I quoted from the scientific literature the statements of many leading advocates of ECT that brain damage was the intended effect of ECT. Around this time, because of the negative publicity, the dialogue surrounding ECT shifted away from brain damage, and ECT proponents instead began to assert that ECT is a way of correcting chemical imbalances in the brain. There is no scientific foundation for this recent claim that ECT corrects biochemical imbalances. In fact, by causing widespread dysfunction and harm throughout the brain ECT causes biochemical imbalances, as well as other pathological results.

12. ECT universally damages the brains of patients who receive it, and the mechanism of trauma is identical among all ECT victims. Some patients are fortunate enough to escape grossly obvious dysfunctionality, enduring relatively minor cognitive impairment and loss of memory for the days, weeks or months surrounding the treatment. Other patients will experience severe memory losses covering prior decades, as well as continuing memory dysfunction and over all cognitive dysfunction with emotional apathy, disinterest or blunting. Although the degree of harm varies, the nature of the harm caused by ECT is consistently the same, specifically including: (1) retrograde memory loss (past memories injured or destroyed) with the worst losses nearer to the ECT treatments; (2) especially severe memory loss surrounding the ECT itself; (3) anterograde memory loss (a broad term referring to persisting memory and cognitive

dysfunction); and (4) degrees of apathy or disinterest.

13. The reason that all ECT patients endure similar injuries is that the treatments attempt to provide a suitable amount of current to the brain to produce a seizure. The current and the seizures then produce most of the harm, including through the breakdown of the blood brain barrier, hypertension, anoxia, exhaustion of energy sources, heat injury, and electrical injury.

14. **The result in all cases without exception is a concussive-like traumatic brain injury from every single effective treatment.** The immediate result of this injury is a total disruption of the brain's electrical pattern, driving the recording needle on the EEG strip into a series of explosive, jagged peaks. This is often followed by flat-lining, with a straight line on the EEG indicating that the brain has temporarily stopped functioning, at least in respect to this gross measurement of activity. If the ECT treatment proceeds routinely, the patient is immediately driven into a comatose state. Recovery from the coma then requires several minutes or more in a specialized recovery room under constant supervision. The individual then awakens in a confused state, usually with apathy, and with no memory of what has happened. As the ECTs increase in number, the patient typically awakens from the coma with increasing amounts of brain dysfunction and injury, often with headaches and nausea. There can be no legitimate doubt that ECT damages the brain and mind—no more than there can be about repeated blows on the head that render and individual comatose and then confused and disoriented on awakening. The only question is how much recovery occurs—and anyone who claims that such repeated assaults on the brain are harmless is ignoring the fact that repeated severe traumatic injuries to the brain that cause coma will inevitably leave persistent negative aftereffects to the brain and mind.

15. No mechanism of action by which ECT "treats" depression has been identified or proven to this day by the advocates of the treatment; but there is considerable evidence that the apathy and disinterest caused by the treatment is mistaken for improvement by some patients, families and physicians.

16. Some ECT advocates claim that ECT reduces the risk of suicide. This is an easy claim to test, because the endpoint, suicide, can be easily measured and recorded. Yet there is no sound scientific evidence that ECT reduces the risk of suicide while there is some evidence that it

increases the risk, probably because of the despair patients feel when they realize they have been harmed.

17. The "newer" and allegedly "modified" forms of ECT are not different or less harmful than the original form, as both apply enough electricity to the head of a patient to induce a major motor seizure. It is impossible to induce a major motor seizure through application of electricity to the cranium without causing traumatic brain injury. Indeed, contemporary ECT is more damaging to the brain because it requires much higher energy doses in order to produce a seizure in patients who given prior sedatives for sleep or anxiety, and then anesthesia during the ECT treatments. Sedatives and anesthesia increase the seizure threshold, requiring these more traumatic doses of electricity. In previous years 200 milliamps of electrical current were commonly used in humans as well as in animal experiments to produce seizures as a part of ECT, while today the doses produced by the machines are over 1,000 milliamps.

18. The clinical markers of brain damage and chronic traumatic encephalopathy resulting from ECT include pinpoint hemorrhages, neurogenesis, scattered cell death in the regions beneath the electrodes, vascular wall damage, gliosis, nerve cell abnormalities, dilated blood vessels, and other markers. Brain damage caused by ECT to an individual patient can sometimes be documented by brain scans, electroencephalograms, and autopsy studies. The most sensitive methods for detecting the extent of brain damage from any cause, including ECT, are a clinical interview by an experienced and well-informed clinician who involves the family and neuropsychiatric testing by an experienced and well-informed psychologist. It is my opinion, that the application of a large enough electric current to induce a grand mall or generalized seizure with unconsciousness causes brain injury is well supported by the medical community and findings developed over a significant time in scientifically reliable publications. The following publications confirm pathology damage in the brain or memory and cognitive dysfunction to indicate an underlying physical damage:

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19. Memory impairment such as that observed after ECT does not occur naturally, nor is it caused by depression or other psychiatric disorders. The memory loss follows the typical, expected pattern following a discrete, traumatic physical injury to the brain and in fact is similar in its clinical effects to other forms of injury to the head and brain. The possible exception is that ECT seems to produce an especially drastic impact upon personal memories of one's experiences in life, such as family celebrations, holidays, work accomplishments, and educational experiences. For this reason, the harm caused by ECT is particularly destructive to personal identity.

20. Based upon my active involvement in this industry, my experience, training and review of all relevant materials including the nature of the "informed consent" that is generally discussed in the medical communities that offer ECT treatment, physicians that administer ECT do not generally acknowledge or advise of any risk of brain damage, permanent memory loss, or the loss of self that ECT victims frequently report. This is often very discouraging to patients who do not understand why their cognitive abilities have been so severely affected following ECT. Many health professionals tell patients injured by ECT that it is harmless and that their perceived dysfunction in the brain and mind is a "mental illness."

21. The psychiatric profession is keenly influenced by device manufacturers' research and required FDA reporting. The Manufacturer and User Facility Device Experience ("MAUDE") database houses medical device reports submitted to the FDA by mandatory reporters and serves as a primary source of information for psychiatrists and other medical professionals to rely on in evaluating and informing patients of the relative risk and safety of utilizing medical devices.

22. If the manufacturers fully performed their reporting and testing requirements, the psychiatric community would be informed of all risks of ECT through the required mandatory reporting of any adverse events required to be reported and/or addressed by manufacturers in the MAUDE database.

23. If the ECT device manufacturers had reported upon any adverse events associated with the administration of ECT in the use of their devices to the FDA as required so that they appear within the MAUDE database, the psychiatric community would have utilized the MAUDE database reporting as an avenue to become informed of such untoward events. Such reporting associated with ECT provides the medical community as a whole with information regarding the risks of utilizing the ECT procedures and in informing our patients of known risks, the dangers and the inherent damages known to be universally caused by ECT. Had there been reporting over the years as required, physicians administering ECT would have been apprised of the grave dangers inherent in ECT in time to prevent injury.

24. I have served as the expert witness in numerous actions where adverse events, such as brain damage, have occurred as a result of ECT. Despite these actions where adverse events were alleged and did occur, I am not aware that the manufacturers of ECT devices, including MECTA Corporation and Somatics, LLC investigated or reported to the FDA those adverse events and understand they have continued to manufacture, sell and distribute their ECT machines. I am not aware of any reporting of any such known adverse ECT events reported by any ECT manufacturer within the FDA's MAUDE database.

25. In the previous litigation actions that I have been involved addressing the injuries caused by ECT, the defense has often portrayed the individual plaintiffs' injuries as stand-alone events, rather than the remarkably uniform result of an invariably injurious psychiatric practice that has repeated itself continuously over the years that ECT has been utilized in the psychiatric community.

26. I believe ECT is still available as a treatment methodology and remaining on the market today because of the substantial influence and power of the psychiatric lobby which gains from and supports ECT. Based upon my experience and involvement, it is not uncommon for

psychiatrists to typically charge whatever the insurance will cover for a session of ECT. In addition, anesthesiologists and the facility, as well as others, are all compensated from an ECT practice where hospitals charge considerably for the procedure. The proceeds from ECT, typically paid by Medicare, are often sufficient to support the profitability of individual psychiatrists and the entire psychiatric department at healthcare facilities.

27. Typical consent forms that patients sign before receiving ECT are routinely and uniformly inadequate by not disclosing the known risks of long-term damage that occurs from ECT. Typical consent forms provided to most ECT patients that I have reviewed, including the standard APA consent forms, do not inform the patient that ECT inherently damages the brain, nor do they warn of the risk of permanent memory loss and the probable long-term cognitive impairment that can occur. These consent forms generally warn only of risks such as nausea, headaches, and short-term memory loss which would not discourage patients and their families from ECT treatment.

28. The adverse events that have occurred following the administration of ECT over the past several decades have clearly demonstrated that the certainty of damage to the brain from ECT, the risk of permanent memory loss and the probable long term cognitive impairment are risks that should have been disclosed to any patient receiving ECT. Had Defendants populated the MAUDE database with reports of reasonably known adverse events by filing adverse event reports with the FDA as required, the treating psychiatrists of members of the putative class would have been in a position to warn members of the putative class of the latent dangers inherent in ECT treatment in time to prevent their injuries.

29. All of the information I have provided here is documented in my dozens of peer-reviewed articles and scientific books. I also provide the profession and the public with a free ECT Resource Center on my website, www.breggin.com which contains more than a hundred scientific documents, including my entire book, *Electroshock: Its Brain-Disabling Effects*. The Resource center can also be reached directly at www.123ECT.com.

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I declare under penalty of perjury the foregoing is true and correct. Executed this 4th day of December, 2017 at Ithaca, New York.

EXHIBIT 11

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA; DEBORAH CHASE;

Plaintiffs,

v.

SOMATICS, LLC

Defendants.

Case No.: 2:17-cv-06686 RGK(PJWx)

Assigned to Hon. R. Gary Klausner, Court Room 850

DECLARATION OF KENNETH CASTLEMAN, PHD IN SUPPORT OF OPPOSITION TO MOTION FOR SUMMARY JUDGMENT

Action Filed: September 22, 2017
Trial Date: October 2, 2018

I, KENNETH CASTLEMAN, Ph.D., declare under penalty of perjury as true of my personal knowledge as follows:

1. I have Bachelor and Master's degrees in electrical engineering and a Ph.D. in Biomedical Engineering. The latter involves application of engineering techniques to problems in medicine and biology. My entire professional career has been dedicated to scientific research and technology development. With over 45 years of experience, I hold image analysis and image processing patents and have served on various university and government advisory committees. I have served on

the faculty at Caltech, as the Visiting Committee Chairman for the Department of Electrical and Computer Engineering, and as an Adjunct Professor of Biomedical Engineering at The University of Texas, and as a Research Fellow at both USC and UCLA. I have also been a member of the Scientific Working Group on Imaging Technology for the Federal Bureau of Investigation. I was a Senior Scientist at NASA's Jet Propulsion Laboratory for 15 years, and I was subsequently called in to assist NASA in their investigations of both the Space Shuttle Challenger and Columbia disasters. In 1994, I was inducted into the United States Space Foundation's Space Technology Hall of Fame, and I am a Fellow of the American Institute of Medical and Biological Engineering. I have also served as a technical expert in legal cases ranging from the JFK assassination to bank robberies and over thirty patent infringement cases. I have published three college-level textbooks, including the seminal textbook Digital Image Processing (1979 and 1996), which has been translated into Japanese and Chinese. I have also published more than 60 articles in scientific journals. My education and experience in scientific research and in the fields of electrical and biomedical engineering qualify me to explain how electricity works and the effects it can produce on human tissue. A true and correct copy of my current curriculum vitae is attached hereto as **Exhibit A**.

2. I have reviewed the scientific literature relating to the effects of electric fields and electric currents on human tissue. In addition, I have reviewed the body of literature relating to the history of, and to the past and current practice of ECT, and the literature relating to brain trauma resulting from electric shock. The latter includes reports of post mortem microscopic studies of brain tissue from ECT patients and other studies of brain damage caused by ECT.

3. Electroconvulsive therapy ("ECT") is a procedure that induces a seizure in a patient by passing an electric current through the brain. It has the intended purpose of initiating a grand mal seizure, which is believed to produce therapeutic effects in some cases of mental illness.

4. ECT devices, such as the Thymatron machine manufactured and sold by Somatics, LLC, are utilized by placing electrodes on the patient's head, and supplying a stimulus in the form of a series of brief or ultra brief electrical pulses. These devices commonly deliver two to six times the amount of electrical charge that is required to induce a seizure. "the recommended dosing level for unilateral ECT is 4-6 times that threshold value." See **Exhibit B**, Thymatron System IV Instruction Manual, page 21. The induced seizures continue for 30 to 60 seconds beyond the duration of the electrical stimulus.

5. According to Somatics, LLC's Thymatron System IV Instruction Manual, the Thymatron System IV ECT device of Somatics, LLC, can deliver a stimulus current to patients of 0.9 amperes at a voltage as high as 450 volts. See **Exhibit B**, Thymatron System IV Instruction Manual.

6. In electrical science, voltage is the force that causes charged particles, such as electrons, to move through an object. It is analogous to the pressure that causes water molecules to flow through a hose. Applying a voltage to an object tends to pull positively charged particles in one direction while pushing negatively charged particles in the opposite direction.

7. An applied voltage causes a current to flow. The current is the rate at which the electrons are passing through an object. It is analogous to the rate at which water is flowing through a hose. Water flow can be measured in gallons per minute. Current flow is commonly measured in amperes, or "amps." One amp is a flow rate of approximately six billion billion electrons per second.

8. The amount of electrical energy that is delivered to the patient's head can be specified in several ways. At this time it is customary to specify the "dose" of an ECT treatment as the total number of electrons that are forced through the patient's head during one treatment. The dose is specified in "coulombs." One coulomb consists of six billion billion electrons. A typical dose size (the "charge") is about one-third of a coulomb. The dose is delivered at a pulse frequency of 70

Hertz (70 positive and 70 negative pulses every second, delivered in alternation) for a period of 7.2 seconds, for a total of 1008 pulses. Each pulse is 0.3 milliseconds in duration, with 6.84 milliseconds of dead time (where the current is not flowing) between pulses. See the example in **Exhibit C**, attached true and correct copy of the Thymatron System IV Brochure.

9. The Somatics Thymatron device is a constant-current pulse generator. That is, it automatically and continuously adjusts the voltage, as necessary, to maintain the current at a specified level. The current is typically set at 0.9 amps. See the example in **Exhibit C**, Thymatron System IV Brochure. Thus the patient's brain is subjected to over a thousand alternating positive and negative current pulses of almost one amp each.

10. The Somatics Thymatron machine accomplishes this by applying an alternating voltage of whatever intensity is required to produce the specified 0.9 amp current. From Ohm's law we know that voltage equals current times resistance (E=IR). The resistance of the patient's head varies from one individual to the next and with the details of electrode attachment. Typical values are 1,440 ohms prior to treatment, dropping to 260 ohms during the pulses. See the example in **Exhibit C**, Thymatron System IV Brochure. In this case the voltage would settle to 0.9 x 260 or 234 volts during each pulse. By contrast, individual brain cells operate normally with less than one-half of a volt and a current of less than 0.001 amp.

11. During each pulse, one electrode becomes positively charged, and the other electrode becomes negatively charged, establishing a value of 234 volts between them. This creates an intense pull on all of the charged particles inside the head. This includes not only free electrons in the tissue, but also the charged molecules that reside within the cell membranes (cell walls) of the brain cells. Then, on the next pulse, the polarity is reversed, and all of the charged particles are instantly pulled in the opposite direction.

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12. This process of alternately pulling and tugging on the cell membrane creates a jackhammer effect that can tear holes in the cell walls. This process is called "electroporation," the creation of pores (holes) in the cell wall by electrical means. At low voltage levels the forces are not strong enough to damage the cell membrane. At medium voltage levels small holes are produced, but the cells can repair them before too much damage is done. Higher voltage levels, however, produce more and larger holes, the repair mechanism becomes overwhelmed, foreign substances leak into the cell, and the cell dies. Electroporation at medium voltage levels is used in biological research to force experimental drugs inside cells. It is used at higher voltage levels in cancer therapy to kill malignant cells.

13. The degree of electroporation effect on any particular cell depends on the local electric field strength and the size of the cell. Red blood cells, for example are quite small and thus less likely to be seriously affected by an electric field. Brain cells, however, which can extend more than halfway across the head, are many times more vulnerable to damage by electroporation. Further, the scientific literature gives little or no guidance regarding how ECT electric field strength is distributed throughout the head. Thus it is presently impossible to assess the risk of this type of brain damage that ECT imposes.

14. Two things happen when an electric current, such as that from Defendant's ECT device, is caused to flow through the brain. The first is the electrodynamic effect discussed above in relation to electroporation. The second is heating. The internal temperature of the human body is regulated within narrow limits to maintain the health and proper functioning of the cells. As the temperature rises, the cells can suffer dysfunction, temporary injury, permanent damage, and even death. This is particularly true in the brain, where the electrical energy supplied by an ECT device is converted into heat, thereby raising its temperature. The larger the current, the more heat is produced. In fact, the amount of power transferred into the brain is proportional to the square of the current ($P = I^2R$). For

the example that is cited in the Somatics brochure (**Exhibit C**), this works out to 0.9 amps squared times 260 ohms or 210.6 watts during each pulse. Since the current is actually flowing only 4.2% of the time, the average power is just under nine watts. The total current is unevenly distributed throughout the brain, and some cells, particularly the larger ones, will get more heating than others. Thus brain heating is a potential source of cell damage and cell death.

15. ECT-induced structural brain trauma can be detected objectively by direct microscopic examination of brain cells following treatment. Such damage is often too subtle to be detected by indirect methods. But the majority of published scientific studies seeking to evaluate ECT-induced brain damage use indirect methods such as computed tomography brain imaging, magnetic resonance imaging, proton magnetic resonance spectroscopic imaging, cerebrospinal fluid levels of markers of neuronal or glial cell degeneration, and serum levels of markers of brain tissue damage. These techniques have limited resolution, do not look at brain cells directly, and thus can detect only relatively large changes in the brain.

16. Regarding direct microscopic examination of the brains of ECT patients, a recent research paper says “Only 2 prior reports of postmortem gross and microscopic evaluation of brain in ECT patients have appeared in the last 3 decades,” and “In summary, it seems that there have been only 3 relatively recent reports of postmortem studies of patients who received large numbers of ECT treatments, and only 2 in which modern techniques were used exclusively.” See **Exhibit D** Anderson, et. al., "Neuropathological Evaluation of an 84-Year-Old Man After 422 ECT Treatments," *Journal of ECT*, Volume 30, Number 3, September 2014, pages 249 and 250. This means that a sensitive study looking directly at brain cells for ECT-induced damage has been conducted only about once per decade, and then using only a single patient each time. Studying only three patients in 30 years is hopelessly inadequate to evaluate ECT-induced brain damage on a cellular level.

17. Most of the studies evaluating ECT-induced brain damage are conducted by researchers who have a vested interest in the outcome and who openly state their preconception that ECT is safe and effective. Thus the subtle, often unintentional, influence of investigator bias on the interpretation of experimental data cannot be ruled out.

18. In summary, ECT has the potential to injure or kill brain cells by at least two different mechanisms, heating and electroporation. The scientific literature has demonstrated brain damage in earlier times and, despite the claims of ECT advocates, it fails to show that damage, at least on a cellular level, is not continuing with modern ECT devices. Further, even the most basic studies to evaluate the risk of electroporation by ECT have not been done. Despite its widespread use, ECT puts patients at risks of brain damage that have not been evaluated. The opinion of "authorities in the field" has been substituted for hard scientific data.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10th day of August, 2018 at League City, TX.

Kenneth R Castleman

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Kenneth R. Castleman, Ph.D.

EXHIBIT 12

Expert Report on Electroconvulsive Therapy

by

Kenneth R. Castleman, PhD

Introduction

Electroconvulsive Therapy (ECT) treats mental illness by running an electric current through a patient's brain. [1] This report addresses the question of whether ECT risks brain damage in patients to whom it is administered. The medical practitioners who prescribe and administer ECT assert that it is a safe and effective treatment for certain types of mental illness, such as severe depression. [2] Yet patients often report serious degradation of their quality of life following ECT treatment. For example, "At times, patients are so neurologically impaired following ECT that they will remain prone and apathetic for days at a time, … and unable to communicate or to carry out routine self-care. [3]

And even those who practice ECT have concerns. "ECT is one of the most controversial treatments in medicine, particularly because of still unknown mechanism of action and uncertainty about cognitive side effects." [1] A large number of scientific studies and published articles over at least seven decades have failed to satisfy critics that serious brain damage is not resulting from routine ECT treatments [3, 4].

In this report we examine the physics of ECT and the biology of electrical stimulation of brain tissue. We look at the basics of electrical science as it applies to ECT, and examine the related factors of cell biology to elucidate the potential risk of this controversial treatment. This report also looks at the science that is used to support the contention that ECT is safe.

The author is an electrical engineer with a PhD in Biomedical Engineering and fifty years of experience in scientific research and technology development. His qualifications are detailed at the end of this report.

A Brief history of ECT

The beginnings of the medical reasoning that led eventually to the widespread use of ECT are explained in a recent Scientific American article. "In the 1930's, Hungarian neuropathologist Ladislaus Meduna observed that a certain type of brain cells, called glial cells, increased greatly in tissue taken from people with epilepsy. But samples from patients with schizophrenia and depression had far fewer glial cells in the cerebral cortex than normal. … Meduna speculated that schizophrenia and depression might result from a deficiency of glial cells, so he reasoned that by inducing a seizure, he could increase their numbers and cure his patients." [5]

Based on Meduna's reasoning, a number of different methods were used to induce seizures in mental patients. [6] "Ugo Cerletti and Lucio Bini in Italy used electricity to induce a seizure by applying electrodes they had obtained from a pig slaughterhouse to the head of one of their mental patients on April 11, 1938." [5] Eventually electric shock proved to be the most reliable and least messy way to induce seizures.

Early ECT devices applied alternating current (AC) from the power lines to the patient. These are called “sine wave” machines because a plot of the voltage variations over time takes the smoothly varying form of the sine function used in trigonometry. With such a machine the current flow smoothly reverses itself 120 times per second. In the 1950’s ECT moved toward “square wave” devices that reverse the current flow direction abruptly rather than smoothly.

The next innovation came two decades later. “In 1976, Blatchley demonstrated the effectiveness of his device that used constant current and brief pulse ECT. At this time a report from the American Psychiatric Association (APA) endorsed the use of ECT in the treatment of depression.” [7] Brief pulse ECT devices deliver the current to the brain in short pulses separated by a longer period during which the current is not flowing. [8, 9] Since the same total amount of current is delivered, the treatment is simply spread out over a longer period of time. Beginning in the 1980s this type of device has largely replaced earlier devices. [10]

Brief pulse ECT machines deliver current pulses as short as one millisecond. Newer ECT machines are called “ultrabrief pulse” devices because they can deliver pulses lasting less than one millisecond. [8, 9] The newer machines are able to produce seizures using smaller doses of electricity. [8] In spite of this, a minority of US practitioners still use sine wave stimulation. [11]

The Practice of ECT

ECT is not usually administered as only a single treatment or even as a few treatments delivered over a short period of time. Instead “maintenance ECT is continuing with ECT beyond 6 months.” [1] This is done because "... studies show a high rate of relapse after discontinuation of ECT." And "... without active treatment, virtually all remitted patients relapse within 6 months of stopping ECT." [12] Some patients receive hundreds of ECT treatments during their lifetimes. [13]

A recent clinical review article sheds light on the current practice of ECT. The study found that “some clinicians may consider 6–10 treatments and then consider medication maintenance, while others will continue prescribing ECT only for months or even years.” Also “After acute series of ECT, the ECT long-term treatment may be considered, although this practice may vary significantly between countries or even within the same country, because there is no universal consensus about its indications, duration and frequency of administration.” In addition, “it is not rare in a clinical practice to see patients who are receiving maintenance ECT weekly or biweekly for an extended period of time … .” [1]

As the patient ages the ECT doses become larger. “In general, older patients, particularly elderly patients, require higher stimulus intensities than younger patients.” [8] Also larger doses are required as the patient continues to receive more ECT treatments, “seizure threshold usually increases markedly during the ECT course.” [8]

Side Effects of ECT

ECT can produce what are called “adverse cognitive effects” in patients who are treated. [4] Side effects of ECT include amnesia (substantial and permanent memory loss), confusion, disorientation, apathy, disinterest, headaches, nausea, slowed reaction time, and lowered intellectual function. [11, 14-18] These are side effects of treatment that impair the mental capacity of the patient. “Cognitive side effects are usually dependent on factors such as electrode

placement, electrical dosage, stimulus parameter configuration and frequency of treatment sessions." [1]

Retrograde amnesia is the inability to remember things that happened before the treatment. This type of memory loss can extend back to childhood. Anterograde amnesia is the inability to retain new memories for more than a short time. [14] Most ECT patients experience retrograde and anterograde amnesia following ECT treatment. [3, 4, 11, 15, 18-20,] "ECT patients often lose memory of part or all of their previous lives. Anterograde amnesia may last for a couple of weeks or couple of months after treatment. However, retrograde amnesia for autobiographical information is a potentially persistent cognitive side effect of ECT. (21)" [1] Also, "The loss of autobiographical memory has not been adequately investigated." [1] Further, "permanent amnesia is one of possible, frequent and serious side effects of ECT which affects at least one-third of patients." [1] In addition, "Patients should be clearly told that ECT may have serious and permanent effects on both memory ability and non-memory cognition. ... 'the ability to plan and organise and get things done'" [22]

Other side effects can be debilitating as well. "Cognitive side effects of ECT are sometimes underestimated and may last much longer after completed treatment than it is usually expected. These cognitive impairments associated with ECT may cause significant functional difficulties and prevent patients to return to work." [1]

There is even a concern that existing procedures for evaluating patients for cognitive side effects and rehabilitating them are inadequate, "Neuropsychological assessment should be a part of good clinical practice in the ECT units." And, "The lack of neuropsychological services available to ECT psychiatrists may have negative impact on identifying and assessing cognitive effects of ECT. This may also significantly delay the process of post-ECT cognitive rehabilitation." [1]

The Mechanism of Therapy

No one can explain how electric shock could reduce any of the symptoms of mental illness. "…the mechanism of therapeutic action of ECT has not yet been established." [1] And "The efficacy of any medical treatment depends on scientific understanding of the disorder, and how the treatment is applied. But that insight is largely lacking with ECT" [5] As mentioned above, the seizure is commonly thought to be the therapeutic agent. But ECT treatments typically use six times the amount of electricity that is required simply to initiate a seizure. This suggests that whatever ECT is doing, it must be more than simply inducing a seizure. The effects of electric currents on the human body are well known, [23-27] and the electric current levels that ECT produces in the head are so high (approximately one ampere) that direct, possibly damaging, electrical effect on the brain is an obvious possibility.

The Basics of Electricity

In electrical science, we work with three basic quantities: voltage, current, and resistance. **Voltage** is the pressure that puts a force on charged particles (such as electrons) and causes them to move through an object. It is analogous to the pressure that causes water molecules to flow through a hose. Applying a voltage to an object tends to pull positively charged particles in one direction while pushing negatively charged particles in the opposite direction.

Applying a voltage to an object causes a **current** to flow through it. Because of the force of an applied voltage, electrons will jump from one atom to the next. This causes a general migration

of electrons through the object. This migration is the current flow that results from the applied voltage. The current is measured by the rate at which the electrons are passing through the object. It is analogous to the rate at which water is flowing through a hose. Water flow can be measured in gallons per minute. Current flow is commonly measured in amperes, or "amps." One amp is a flow rate of approximately six billion billion electrons per second.

Resistance is the amount of opposition that an object presents to current flow. In metals such as copper, the electrons are only loosely attached to the atoms. Since only a small applied voltage is required to produce a large current flow, copper is said to have a low resistance. Insulating materials, such as glass, have their electrons tightly attached to their atoms. Since a large applied voltage is required to produce only a small current flow, glass has a high resistance. Resistance is measured in units of ohms. In the human body the resistance depends greatly upon the nature of the physical contact made between the body and the source of electricity.

The relationship among there three quantities is specified by **Ohm's law**. This law of physics states that the current (in amps) that will flow through an object is equal to the applied voltage (in volts) divided by that object's resistance (in ohms). The familiar formula is $I = E/R$, where E is the voltage in volts, R is the resistance in ohms, and I is the current in amps. If any two of these quantities are known, the third will be determined by Ohm's law. For example, modern ECT devices are constant current sources. That is, the operator sets the desired value of current, and the machine uses Ohm's law to adjust the voltage, as necessary, to produce that amount of current flow.

ECT Dose

The amount of electricity that is delivered to the patient's head during an ECT treatment can be specified in several ways. In the past it was common to specify the total amount of electrical **energy** that is transferred into the patient's head during one treatment. This energy is measured in "joules." One hundred joules is the amount of electrical energy that is converted into heat and light by a 100 watt light bulb every second.

More recently it has become customary to specify the dose of an ECT treatment as the "**charge**." This is the total number of electrons that are forced through the patient's head during one treatment. The charge is specified in "coulombs." One coulomb consists of approximately six billion billion electrons. It is the result of one amp of current flowing for one second.

A typical ECT dose size is about one-third of a coulomb. [8, 9, 28, 29] In one example the dose is delivered at a pulse frequency of 70 Hertz (70 positive and 70 negative pulses every second, delivered in alternation) for a period of 7.2 seconds, for a total of 1008 pulses. Each pulse is 0.3 milliseconds in duration, with 6.84 milliseconds of dead time (where the current is not flowing) between pulses. [30]

Modern ECT machines (in the USA) can deliver up to 100 joules of energy or one-half coulomb of charge (200 joules and one coulomb in Europe, Asia, and elsewhere). The pulse frequency can be set between 10 and 70 cycles per second, and the pulses can be as brief as 0.3 milliseconds. The current can be set up to 0.9 amp, and the voltage can go as high as 460 volts as needed to overcome the patient's resistance. [8, 29, 30]

Dose Determination

ECT device manufacturers suggest two methods for setting the ECT stimulus intensity for individual patients. These are based on recommendations of the American Psychiatric Association Task Force on ECT. [2] Both methods are based on the seizure threshold, which is the minimum stimulus intensity (electrical dose) that is required to induce an adequate seizure (convulsions lasting 30 to 60 seconds after the shock). [2, 31-33] It is to the patient's benefit to keep the level of electrical stimulus as low as possible, "By reducing the strength of electrical stimulus, however, we may greatly reduce cognitive side effects (20)." [34]

The seizure threshold varies greatly from one patient to the next, and it increases as the patient receives more treatments. [32] "There is marked variability among patients in seizure threshold. Seizure threshold may be influenced by concurrent medications. Further, seizure threshold usually increases markedly during the ECT course." Also "seizure threshold is greater in males than females. ... In general, older patients, particularly elderly patients, require higher stimulus intensities than younger patients." And "Degree of oxygenation, dosage and type of anesthetics, concomitant psychotropic medication, quality of electrodes, site preparation, and a variety of other factors influence seizure threshold." [8] Thus determining the seizure threshold, upon which to base the treatment dose, is not simple.

One method of determining the seizure threshold is called **empirical titration**. According to the Mecta Spectrum manual, "This method, termed EMPIRICAL TITRATION, involves administration of subconvulsive intensities in the first treatment, finding the intensity level that produces an adequate seizure in that session, and in subsequent sessions administering an intensity that is a fixed amount above the seizure threshold identified in the first session." [8] The practitioner gives the new patient a series of shocks of gradually increasing intensity until a suitable seizure is induced. "… the great majority [of patients] have an adequate seizure before or following the third stimulation. However, the range in seizure threshold is great and exceptional patients may have very high thresholds. If the third stimulation does not produce a seizure, a fourth or fifth stimulation should be attempted. The final stimulation is at maximal device dosage." [8] This process is used to establish the patient's initial seizure threshold.

That patient's regular treatment dose is then set at four to six times the seizure threshold. For example, "In subsequent treatments you plan on delivering a dose that will be approximately 6 times this initial seizure threshold." And "Thus, the goal with unilateral ECT is to administer stimulation that is at least 4 times the seizure threshold, with an upper limit of 6.0 times the seizure threshold." [8] Also, "Once the seizure threshold is determined for a specific PERCENT ENERGY setting, the recommended dosing level for unilateral ECT is 4-6 times that threshold value." [9]

The second method of dose determination involves picking a stimulus intensity value off a chart, "An alternative to the titration method is to use the known predictors of seizure threshold (electrode placement, age, and gender) and preselect a dosage that on a probabilistic basis is likely to be in the appropriate range relative to seizure threshold. … This approach is termed the PRESELECTED DOSAGE METHOD." [8] Notice that this method is more of a gamble than anything precise.

But seizure threshold is not well correlated with age and gender, [8] and use of the charts and tables can lead to overdosing patients and creating more serious side effects. According to the MECTA manual, "However, current research indicates that there is only a weak relationship

between patient age and seizure threshold." And, "This circumstance means that dosing based on age will intrinsically result in the oldest patients receiving the greatest excess of electrical stimulation." Also, "In general, none of the formula-based or preselected dosage methods yet devised provide the level of accuracy that is achieved with empirical titration. Accurate determination of dosage is one of the key aspects of … minimizing side effects." In addition, "If acute cognitive side effects become excessive and clinical progress is acceptable, dosing at later treatments may be reduced." [8] Notice that cognitive side effects are both expected and tolerable.

Using the dosing tables increases the risk for the patient, "It is important to note that the treatment methods and stimulus parameter settings presented here are only suggestions." And, "Further, the suggested settings in the Titration tables and Pre-selected Dosage table are likely to be overestimates of the stimulus intensity necessary to produce adequate seizures." [8] Thus an ECT patient will likely get even more electrical stimulus than American Psychiatric Association (APA) and manufacturer guidelines call for.

In spite of these operational guidelines, approximately half of US practitioners do not adjust dosage relative to the patient's seizure threshold. [11] Some simply set the "% Dose" knob according to the patient's age. According to the Somatics Thymatron instruction manual, "Satisfactory therapeutic results can be obtained with right unilateral ECT by simply setting the PERCENT ENERGY dial to approximate the patient's age in years (e.g., 75% for a 72 year-old patient). … Once a patient obtains a satisfactory seizure with a given PERCENT ENERGY stimulus dose with unilateral ECT, we *do not* recommend administering subsequent treatments with progressively lower settings in an attempt to deliver the smallest stimulus that will still induce a seizure." [9] This technique is almost certain to set the stimulus intensity well above 6 times seizure threshold.

ECT Device Operation

A modern ECT device is a constant-current pulse generator. That is, it automatically and continuously adjusts the voltage, as necessary, to maintain the current at a specified level. The current is typically set at 0.9 amps. See the example in [30] mentioned above. Thus the patient's brain is subjected to over a thousand alternating positive and negative current pulses of almost one amp each.

An ECT machine accomplishes this by applying an alternating voltage of whatever intensity is required to produce the specified 0.9 amp current. From Ohm's law we know that voltage equals current times resistance (E = IR). The resistance of the patient's head varies from one individual to the next and with the details of electrode attachment. Typical values are 1,440 ohms prior to treatment, dropping to 260 ohms during the treatment. See the example in [30]. In this case the voltage would settle to 0.9 x 260 or 234 volts during each pulse. By contrast, individual brain cells operate normally with less than one-half of a volt and a current of less than 0.001 amp. [39]

Heating in the Brain

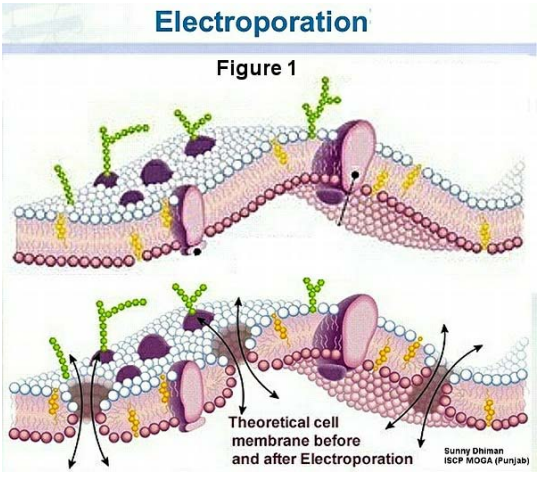
Two things happen when an electric current, such as that from an ECT device, is caused to flow through the brain. The first is heating. The internal temperature of the human body is regulated within narrow limits to maintain the health and proper functioning of the cells. As the temperature rises, the cells can suffer dysfunction, temporary injury, permanent damage, or even cell death. [35] This is particularly true in the brain, where the electrical energy supplied by an

ECT device is converted into heat, thereby raising its temperature. The larger the current, the more heat is produced. In fact, the amount of power transferred into the brain is proportional to the square of the current ($P = I^2R$). For the example that is cited in the Somatics brochure [30], this works out to 0.9 amps squared times 260 ohms or 210.6 watts during each pulse. Since the current is actually flowing only 4.2% of the time, the average power is just under nine watts. The total current is unevenly distributed throughout the brain, and some cells, particularly the larger ones, will get more heating than others. Thus brain heating is a potential source of cell injury and cell death. [23-27]

Electroporation

The second effect results from the pulsing nature of the voltage applied by ECT machines. [8, 9] During each pulse, one electrode instantly becomes positively charged, and the other electrode becomes negatively charged, establishing a value of up to 240 volts between them. This creates a sudden and intense pull on all of the charged particles inside the head. This includes not only ions in the tissue, but also the charged molecules that reside within the cell membranes (walls) of the brain cells. [36-38] Then, on the next pulse, the polarity is reversed, and all of the charged particles are instantly pulled in the opposite direction.

This process of alternately pulling and tugging on the cell membrane creates a jackhammer effect that can tear holes in cell walls. This process is called "electroporation," the creation of pores (holes) in the cell wall by electrical means. [36-41] "Electroporation involves applying electric field pulses to cells, leading to the alteration or destruction of cell membranes." [42] Electroporation is illustrated graphically in Figure 1, and Figure 2 shows a laboratory example at 60,000X magnification [from 43].



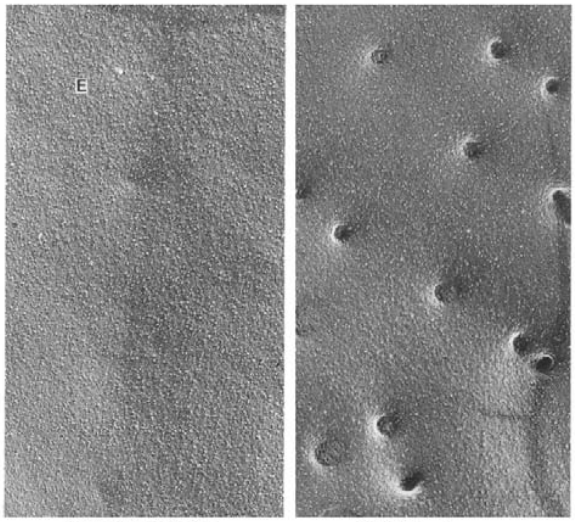


Figure 2

At low voltage levels the forces are not strong enough to damage the cell membrane. At medium voltage levels small holes are produced, but the cells can repair them before too much damage is done. Higher voltage levels, however, produce more and larger holes, the repair mechanism

becomes overwhelmed, foreign substances leak into the cell, and the cell dies. [41, 42] "Irreversible electroporation (IRE) creates permanent defects in cell membranes and induces cell death." [42]

Electroporation at medium voltage levels is used in biological science to force experimental drugs inside cells for research purposes. "The electropermeabilization [using electricity to make them permeable] of biological cell membranes by the application of an external field occurs whenever an applied field exceeds a threshold value. For fields above this threshold value but less than another critical value, the pores formed in the membrane are transient or reversible." [39] Thus if the electric field is not too strong, then the cell can repair the holes before too much damage is done.

It is used at higher voltage levels in cancer therapy to kill malignant cells in the brain. [42] "This study identified N-TIRE pulse parameters that can be used to safely create circumscribed foci of brain necrosis while selectively preserving major vascular structures." [41]

The degree of electroporation effect on any particular cell depends on (1) the local electric field strength and (2) the size of the cell. [36, 38, 40] Red blood cells, for example are quite small and thus less likely to be seriously affected by an electric field. Brain cells, however, which can extend more than halfway across the head, are many times more vulnerable to damage by electroporation.

Further, the scientific literature gives little or no guidance regarding how ECT electric field strength is distributed throughout the head. As little as one volt across the cell membrane can open holes. "While the mechanism of electroporation is not completely understood, numerous experiments show that electroporation occurs for short pulses when the transmembrane voltage reaches approximately 1 V. The electric field pulses causing the electroporation of cells are typically of magnitude 1-20 kV/cm and have duration of 10 μs to 10 ms." (2 – 22 mC) [39] Notice that ECT pulse durations fall in the middle of that range.

Although electroporation has been used in biological research and cancer therapy for more than a decade, there have been no published studies assessing the risk of ECT pulses causing brain cell death by this well-documented mechanism. Further, the distribution of electric field strength inside the head during ECT treatment has not been mapped, or even estimated. Thus it is presently impossible to assess the level of risk of this type of brain damage that ECT imposes and therefore to accurately assess the safety of ECT devices.

Voltage and Current Levels

As stated above, voltage is the pressure that causes current to flow. Resistance is the property of an object that impedes the flow of current. The electrical resistance of the human body is not easily predicted. It depends on where the two points of contact are located on the body and the size and nature of those contacts. Dry skin has a much higher resistance than wet skin. [44] The salty fluids inside the body have a relatively low resistance. The path that the current will take through the body is likewise difficult to predict. The overall current flow will be from one electrode to the other, but the path it follows through the body will depend on the resistance of the different organs and channels that exist in the intervening tissue.

During ECT treatment a typical value for the resistance of the head is 1,440 ohms prior to initiation, dropping to 260 ohms during treatment [30]. Modern ECT devices automatically and continuously adjust the voltage, as necessary, to maintain the current at a specified level of

between one-half and one amp. [8, 9] While the voltage may be different from one patient to the next, from one treatment to the next, and may even fluctuate during one treatment, the current is the quantity that is held constant.

A current flow through the body of less than 0.01 amp (10 milliamperes) can produce a painful shock. Currents above about 10 milliamperes become dangerous. “The severity of an electrical shock is determined by the amount of current (amperes, A) and the duration of the current flow. In medical terms, electrical shocks are usually divided into two categories. Macroshock refers to larger currents (typically more than 10 mA) flowing through a person, which can cause harm or death.” [44]

Stun gun (Taser) devices are used by law enforcement to subdue suspects and by citizens for self-defense. They incapacitate a person by inducing massive muscle contractions. A stun gun can develop up to 50,000 volts in order to penetrate clothing, initiate a spark, and make contact with the body. But the amount of current that it actually forces through the victim’s body is only about 0.002 amps. “The [Taser] X26—the model commonly used by police departments—delivers a peak voltage of 1200 V to the body. Once the barbs establish a circuit, the gun generates a series of 100-microsecond pulses at a rate of 19 per second. Each pulse carries 100 microcoulombs of charge, so the average current is 1.9 milliamperes.” [49] Notice that these pulse parameters are similar to those of ECT devices, (0.1 millisecond, 19 per second) but the charge delivered by a Taser (0.1 millicoulombs per pulse) is considerably less.

Cattle prods also deliver about 0.002 amps, and an electric fence can turn a cow around with only about 0.012 amps. Automotive spark plugs also operate with currents of just a few milliamperes, despite their high voltage ratings. As with Tasers, cattle prods and electric fences, once current begins to flow, the voltage drops significantly because these devices simply are not designed to deliver high currents.

The National Electric Code specifies that Ground Fault Circuit Interrupter (GFCI) circuit breakers must be used anywhere electrical outlets are located outdoors or near plumbing pipes. These are circuit breakers that sense when more current is flowing out of the main circuit than is flowing back in, such as when current is leaking through a short circuit to ground. This is a safety feature since that leakage current could be flowing through a human body. In the USA, GFCI breakers are required to shut off the circuit any time the leakage current exceeds 0.005 amps. This value of 0.005 amps was chosen as an upper limit to prevent accidental injury or death by electrocution. [45]

Slaughterhouses use a one-second electric shock to the head to “stun” animals (knock them unconscious) before slaughter. Some slaughterhouses also run the electric current through the entire body so that it stops the heart and kills the animal. The recommended current for stunning sheep is one amp, and for 200 pound pigs it is 1.25 amps [46]. Notice that one amp (about the same current that ECT uses) flowing for one second is equivalent to a one-coulomb ECT dose.

Electrocution has been used to carry out death sentences on convicted criminals. Sponges soaked in saltwater are clamped by metal electrodes to the convict’s shaven head and ankles. A current as high as five amps is run through the inmate’s body for several seconds. In addition to unconsciousness and cardiac arrest, this produces severe heating of the tissues. The brain is heated to between 138 and 148 degrees Fahrenheit. The bodies often show severe burns at the electrode sites and the flesh appears “cooked.” The current produces violent contraction of muscles, sometimes breaking bones. [47]

So, to put this all in perspective, the amount of electric current that an ECT machine puts through a patient's head is about 200 times what is considered dangerous for ground fault leakage, approximately 100 times what Tasers, cattle prods, and electric fences use, about the same as what is used for stunning pigs, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. Clearly this amount of electricity has the potential to cause injury to the brain.

The Science Behind ECT

ECT-induced structural brain trauma can be detected objectively by direct microscopic examination of brain tissue following treatment. Such damage is often too subtle to be detected by indirect methods. But the majority of published scientific studies seeking to evaluate ECT-induced brain damage use indirect methods such as computed tomography brain imaging, magnetic resonance imaging, proton magnetic resonance spectroscopic imaging, cerebrospinal fluid levels of markers of neuronal or glial cell degeneration, and serum levels of markers of brain tissue damage. [13] These techniques have limited resolution, do not look at individual brain cells directly, and thus can detect only relatively large changes in the brain, not the loss of individual neurons.

Regarding direct microscopic examination of the brains of ECT patients, a recent research paper says "Only 2 prior reports of postmortem gross and microscopic evaluation of brain in ECT patients have appeared in the last 3 decades," and "In summary, it seems that there have been only 3 relatively recent reports of postmortem studies of patients who received large numbers of ECT treatments, and only 2 in which modern techniques were used exclusively." [13] This means that a sensitive study looking directly at brain tissue for ECT-induced damage has been conducted only about once per decade, and then only on a single patient each time. Studying only three patients in 30 years is hopelessly inadequate to evaluate ECT-induced brain damage at the cellular level. Thus it would be improper to omit this risk from informed consent discussions with patients.

Most of the studies evaluating ECT-induced brain damage have been conducted by researchers who practice ECT themselves. Thus they have a vested professional or financial interest in the outcome of the study. They often state their preconception that ECT is safe and effective at the outset in their publications. Since these studies are seldom done under the rigorous scientific conditions of a clinical trial, the influence of investigator bias in the interpretation of experimental data cannot be ruled out.

ECT and the FDA

The United States Food and Drug Administration (FDA) was given authority to regulate medical devices in 1976. [48] ECT devices were already in use by then, so they were automatically approved ("grandfathered in") without any testing for safety or effectiveness. In response to public pressure to ban ECT, the FDA has held several hearings over the years. Each time, after hearing horror stories from ECT patients, they continued to allow ECT devices to be sold without requiring any further testing by the device manufacturers.

Normally when an FDA-approved device is modified it must be re-tested before the new design can be sold. The exception comes when the new device is considered to be "substantially equivalent" to the older model. ECT's advocates acknowledge that earlier machines did cause

brain damage and serious side effects, but they claim the newer brief and ultrabrief pulse machines eliminate that problem. Yet they simultaneously argue to the FDA that the newer machines do not require testing because they are “substantially equivalent” to the older ones. In other words, they are different from, but yet they are the same as, other devices that have not been tested either. Remarkably, the FDA has accepted this pair of contradictory arguments.

The FDA normally sets a high standard for approving drugs and medical devices for public use. They require stringent clinical trials with double-blind experiments, large sample sizes, accurate statistics, and thoughtful interpretation of results. Regarding ECT, however, they are much quicker to conclude, without such evidence, that the practice is safe and effective. They tend to discount the testimony of ECT patients claiming harm as being “anecdotal” and thus unscientific. Instead they rely on the opinion of psychiatry experts where timely scientific evidence is unavailable or incomplete.

Device Classification

Under the Food, Drug, and Cosmetic Act, the U.S. Food and Drug Administration recognizes three classes of medical devices, based on the level of control necessary to assure safety and effectiveness. [48]

The FDA currently places ECT devices in Class III (“potential unreasonable risk of illness or injury”), along with automated cardiac defibrillators, for example. But they are currently considering moving electroshock devices into Class II (“safe and effective with special controls”). [51] Class II includes less risky things such as powered wheelchairs, acupuncture needles and condoms. Further, the manufacturers have never been required to conduct clinical trials to evaluate the risk of injury. This reclassification would permit greatly expanded use of ECT. But since the FDA does not regulate psychiatry or medicine, if the ECT devices were reduced in risk classification, practitioners would be free to administer electroshock more widely and for less severe conditions that the FDA has not cleared it to treat.

The Economics of ECT

The cost of ECT treatment is high. It is used on over 100,000 people each year in the USA. [5] “With 5 to 15 treatments per initial course and 10 to 20 maintenance treatments per year, the annual cost of ECT can exceed $10,000." [52] When hospital expenses are added the cost is even higher. “The cost of ECT runs upwards from $35,000 per series. Patients generally receive 6 treatments during an inpatient stay at a hospital and get up to seven follow up ECTs on an outpatient basis. Generally patients may receive up to thirty treatments in a year. ECT treatments cost $800-$1000 per treatment plus hospital stay ($600- 800 per day) which is generally a series of 8-12 and 25-30 days in a hospital.” And “It is estimated at being a $2-3 billion dollar a year industry (53)." [54]

ECT provides a significant source of income for psychiatrists as well as revenue for hospitals. “The attending psychiatrist may charge $300 and up for a session of ECT and may easily perform five to six ECT treatments within one hour ($1,800/hour). … ECT appears to be an important moneymaker for both hospital and psychiatrists in a time when costs are high and reimbursements are scarce.” [54]

Thus this is a multi-billion dollar business in the United States alone. If the FDA were to reclassify ECT devices as proposed, that business would boom.

Summary - ECT and Brain Damage

"ECT is one of the most controversial treatments in medicine, particularly because of still unknown mechanism of action and uncertainty about cognitive side effects." [1]

ECT attempts to treat mental disorders by using a high voltage to send a large electric current through the brain, inducing a seizure that lasts 30 to 60 seconds. Based on research reports, it gives only temporary results on only a percentage of those treated, while still requiring maintenance on psychiatric drugs and/or additional ECT treatments. [51] Its practitioners admit to moderate side effects, [34, 50] but some patients complain of much more devastating damage to their lives [3].

No one can explain how or why ECT "works." The scientific literature fails to establish a mechanism of therapy or to support the belief that the seizures produced by ECT are therapeutic. Further, the amount of electricity that is used in practice is routinely at least six times what is required to produce a seizure. [8, 9] The existing research also fails to show that cell damage and cell death are not still occurring, even with modern ECT equipment and practice.

ECT uses electric current levels approximately one hundred times what is considered safe in the human body and at very dangerous voltage levels. In so doing it risks brain cell damage from both heating and electroporation. Modern Brief-Pulse and Ultrabrief Pulse ECT devices are much more likely to cause electroporation than those used in the past. Adequate scientific studies to fully assess the risk of ECT-induced brain damage at the cellular level have not been done. In spite of all this, instead of requiring testing of these devices, the FDA is considering allowing them to be used much more widely than ever before. [51]

In summary, ECT has the potential to injure or kill brain cells by at least two different electrical mechanisms, heating and electroporation. The scientific literature has demonstrated brain damage in earlier times, and recent studies using high magnet-strength MRI show ECT-induced changes in the sizes of certain brain structures [55-58]. Little is known about whether damage on a cellular level is continuing to occur with modern ECT devices and practice. Further, studies to evaluate the risk of electroporation by ECT have not been reported. Despite its widespread use, ECT exposes patients to risks of brain damage that have not been thoroughly evaluated. The opinion of "authorities in the field" is being substituted for scientific fact.

The Author's Qualifications

I have Bachelor and Master's degrees in electrical engineering and a Ph.D. in Biomedical Engineering. The latter involves application of engineering techniques to problems in medicine and biology. My entire professional career has been dedicated to scientific research and technology development.

With over 45 years of experience, I hold image analysis and image processing patents and have served on various university and government advisory committees. I have served on the faculty at Caltech, as the Visiting Committee Chairman for the Department of Electrical and Computer Engineering, and as an Adjunct Professor of Biomedical Engineering at The University of Texas, and as a Research Fellow at both USC and UCLA. I have also been a member of the Scientific Working Group on Imaging Technology for the Federal Bureau of Investigation.

I was a Senior Scientist at NASA's Jet Propulsion Laboratory for 15 years, and I was subsequently called in to assist NASA in their investigations of both the Space Shuttle

Challenger and Columbia disasters. In 1994, I was inducted into the United States Space Foundation's Space Technology Hall of Fame, and I am a Fellow of the American Institute of Medical and Biological Engineering.

I have also served as a technical expert in legal cases ranging from the JFK assassination to bank robberies and over thirty patent infringement cases. I have published three college-level textbooks, including the seminal textbook Digital Image Processing (1979 and 1996), which has been translated into Japanese and Chinese. I have also published more than 60 articles in scientific journals.

I have reviewed the scientific literature relating to the effects of electric fields and electric currents on human tissue. In addition, I have reviewed the body of literature concerning the history of, and to the past and current practice of ECT, and the literature relating to brain trauma resulting from electric shock. The latter includes reports of post mortem microscopic studies of brain tissue from ECT patients and other studies of brain damage caused by ECT.

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EXHIBIT 13

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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

JOSE RIERA and DEBORAH CHASE,

Plaintiffs,

v.

SOMATICS, LLC,

Defendant.

Case No.: 2:17-cv-06686 RGK-PJW

Assigned to Hon. R. Gary Klausner, Court Room 850

DECLARATION OF JANET ARROWSMITH IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Date: September 4, 2018
Time: 9:00 a.m.

Trial Date: October 2, 2018

I, Janet B. Arrowsmith, M.D., declare under penalty of perjury as follows based on my own personal knowledge, and if called to testify I could and would testify competently thereto:

1. I am an FDA regulatory and epidemiology expert providing regulatory consultation and assistance to companies and clients subject to or affected by the

laws and regulations promulgated by and on behalf of the U. S. Food and Drug Administration (FDA).

2. I assisted in drafting aspects of the Food, Drug and Cosmetic Act's (FD&C) postmarket surveillance regulations applicable to medical devices, including those codified in 21 C.F.R. § 820 *et seq.* and 21 C.F.R. § 803 *et seq.* As acting Director of the Office of Surveillance and Biometrics, Center for Devices and Radiological Health, I worked with regulated industry and FDA to refine aspects of the Medical Device Reporting (MDR) regulations to assure that compliance with the final regulations would help produce postmarket surveillance data useful to FDA and industry in monitoring the safety and performance of medical devices and radiation-emitting devices marketed in the U.S.

3. These regulations are designed to help identify and assess root causes of medical device and radiation emitting device problems following market introduction, including detection of unforeseen and unlabeled risks and product failures. The law and regulations are intended to provide "a mechanism for FDA and manufacturers to identify and monitor significant adverse events involving medical devices. The goals of the regulation are to detect and correct problems in a timely manner."
(www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/postmarketrequirements/reportingadverseevents/ucm127985.htm accessed 07/21/2018). Manufacturers and FDA are to use problem reports and adverse event reports to correct real and potential device-related problems to better serve the public health. Information from medical device reports is used by manufacturers, user facilities, and providers to help insure that patients and other stakeholders are properly informed of all material risks associated with use of medical devices.

4. These regulations require medical device manufacturers to investigate and report to the FDA reports of death or serious injury potentially related to the use of a marketed device upon becoming aware of such reports.

5. Within the FDA's MDR postmarket surveillance framework, medical device manufacturers have a duty to investigate and evaluate complaints of death or serious injury potentially associated with the use of their devices. These complaints or reports may arise *from any source*, including public dockets opened by the FDA.

6. Manufacturers are required to investigate deaths or serious injuries reported in association with their device to determine a possible causal association with the use of their device. The requirement for investigation is triggered by the report of death or serious injury and does not require prior corroboration by a healthcare provider or user facility.

7. The FDA's postmarket surveillance scheme is designed to detect unexpected risks associated with use of marketed medical products, including risks potentially associated with the use of medical devices. Identification and assessment of previously unreported or unrecognized risks are important functions of postmarket surveillance. A paucity or absence of similar reports in the scientific or medical literature does not invalidate the importance of information received in MDR or other postmarket report. The duty to investigate and assess relatedness to the medical product is initiated by the report itself.

8. To be clear, there is no exception to the requirement for investigation of allegations of injuries potentially associated with the use of a medical device due to the absence of such reports in the current scientific or medical literature. If a complaint alleges a death or a specific type of serious injury associated with the use of a device, the manufacturer is required to thoroughly investigate the allegation. It is of no importance whether similar reports have or have not been previously reported in the literature. Again, one of the most important functions of postmarket surveillance is to detect previously unknown risks of death of serious injury potentially related to the use of a medical product.

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9. If a report of a skin or scalp burn meets the regulatory definition of a serious injury, that single report triggers the manufacturer's obligation to investigate. There are two exceptions to a manufacturer's obligation to report a death or serious injury to FDA. First in in the case in which the death or serious injury is clearly duplicative of one or more previously reported incidents concerning the same patient and the same event. The second exception to the reporting requirement is in the circumstance that investigation of the report indicates that the event is clearly not related to the use of the device. The second circumstance clearly requires investigation of the report and data from that investigation must be retained by the manufacturer as per 21 C.F.R. §803.18(e).

10. If the manufacturer's investigation cannot discover evidence demonstrating that there is either no link between the complaint and use of their device or that the report is a duplicate as noted above, the manufacturer must file an adverse event report with the FDA, containing any "reasonably known" information. This information will then become publicly available in the FDA's MAUDE database.

11. "Reasonably known" information includes information that can be obtained from any reporter, including a patient, a patient's medical records or user facility, or any information that can be obtained through investigation, analysis, testing, or other evaluation of the manufacturer's device.

12. Upon receiving information from manufacturers, the scientific and regulatory personnel at FDA have the capability and the duty to evaluate trends, conduct signal analyses, and draw conclusions regarding risks potentially associated with use of specific medical devices. As has been noted, that while most signals arise from more than one report, there are occasions when a single well documented adverse event report can constitute a signal of a potential new safety concern.

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13. If data from and analysis of the MAUDE database suggest that, to a reasonable degree of medical certainty, a significant risk may be associated with use of a medical device, FDA may require that the manufacturer notify health care providers or make changes to labeling or instructions for use to inform users of the new risk information.

14. If data from and analysis of the MAUDE database suggest that, to a reasonable degree of medical and regulatory certainty, a significant risk may be associated with use of a medical device, once that information becomes publicly available, health care providers have a duty to communicate that risk to patients before use of the device.

15. Neither FDA nor health care providers can execute their public health duty to protect patients if manufacturers fail to timely and appropriately evaluate and report significant health risks potentially associated with the use of their device as MDRs, as required under the previously cited regulations.

16. The FDA's Section 510(k) "premarket notification" or "clearance" of a medical device does not necessarily assure that, in all cases, the clinical use of a product has been found specifically safe or effective for a particular intended use. The 510(k) clearance process indicates that the proposed device has been found to be "substantially equivalent" to a "predicate" device. The predicate device is a device legally marketed in the United States and not found to be in violation of the FD&C Act; e.g. not removed from the market for safety reasons. A 510(k) clearance order means that the proposed device is "cleared" for marketing in the U.S. Unlike devices that are marketed under a Premarket Application (PMA), or prescription pharmaceutical products, a device cleared through the 510(k) process may have limited or no clinical data submitted to FDA in support of marketing for a specific intended use. Many medical devices with U.S. market clearance through the 510(k) process have not undergone evaluation of clinical safety and/or effectiveness

directly via clinical trials, but rather by having been determined to be substantially equivalent to a predicate device, including a device available on the U.S. market prior to May 28, 1976.

17. In my opinion, the 510(k) premarket notification process may not provide specific assurance of safety and effectiveness for an intended use which has not been itself studied via the clinical trials process. Thus, the public may not be fully apprised of potential risks nor assured of potential clinical benefit associated with some marketed medical devices, including some devices classified as Class III, when such devices have gained market access through the 510(k) process.

18. Attached hereto as Exhibit "A" is a true and correct copy of my curriculum vitae.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th day of August, 2018; Corrales, New Mexico.

/s/ Janet B. Arrowsmith

Janet B. Arrowsmith, M.D.

directly via clinical trials, but rather by having been determined to be substantially equivalent to a predicate device, including a device available on the U.S. market prior to May 28, 1976.

17. In my opinion, the 510(k) premarket notification process may not provide specific assurance of safety and effectiveness for an intended use which has not been itself studied via the clinical trials process. Thus, the public may not be fully apprised of potential risks nor assured of potential clinical benefit associated with some marketed medical devices, including some devices classified as Class III, when such devices have gained market access through the 510(k) process.

18. Attached hereto as Exhibit "A" is a true and correct copy of my curriculum vitae.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 11th Day of August, 2018; Corrales, New Mexico.

Janet B. Arrowsmith, M.D.

Janet B. Arrowsmith, M.D.

EXHIBIT 14

1/22/13 Met c pt. and husband.
- Pt's mood sig. improved
- Her somatic anxiety remains, less than before, but still sig.
- Pt wanted to discuss alternatives to maintenance ECT such as rTMS and I gave my opinion -
- We discussed meds, nortriptyline + Li. Pt did not want more meds -
- She is having expected recent memory problems and naming difficulties -
- She attributes alot of her somatic SXS. to the ECT.

Plan: I suggest mo. maintenance ECT c meds - Pt will think about it.

M. Frankel

EXHIBIT 4

EXHIBIT 15

DO NOT SIGN THIS FORM UNTIL YOU HAVE READ IT THOROUGHLY, YOUR PHYSICIAN HAS EXPLAINED TO YOU THE MATTERS MENTIONED BELOW, AND YOU HAVE ALL THE INFORMATION THAT YOU DESIRE CONCERNING ELECTROCONVULSIVE TREATMENT.

The nature of electroconvulsive therapy has been fully explained to me by Dr. [signature] and I am satisfied with that explanation. I understand all of the following:

1. The nature and seriousness of my mental condition.
2. The reason for using this treatment, which involves passing a controlled electrical current through my brain while I am under general anesthesia.
3. The frequency (generally 3 time per week for 4 weeks, but not to exceed 30 days from the first treatment).
4. There exists a division of opinion as to the efficacy of this treatment, but it is known to include a brief episode of unconsciousness and a form of convulsion which, since the 1930's has been known to result in a change of brain functioning, which may end or reduce depression, excitement, or agitation, and disturbing thoughts.
5. The improvement associated with this treatment has sometimes been permanent and has sometimes lasted for only a few months. However, without such treatment, my present condition might continue with little or no change for many weeks or months, thereby endangering my health and even my life.
6. Alternatives to this treatment are no treatment, psychotherapy and medication individually or in various combinations. These alternatives are not preferable to the proposed electroconvulsive therapy because
   other Tx's not effective
7. This treatment may have the following side effects and risks:
   a. Headache, nausea, and sore muscles lasting from an hour or so to several weeks after a treatment.
   b. Confusion lasting from an hour or so after each treatment to several weeks after a series of treatments.
   c. Memory loss lasting from an hour or so after each treatment to spotty losses lasting for several months or years after a series of treatments.
8. There may be serious complications of heart, lung, or brain functioning as a result of the treatments or of procedures used with the treatment.
9. I have the right to accept or refuse this treatment and the right to revoke my consent for any reason at any time prior to or between treatments.
10. The special circumstances that apply to my case are (Indicate "none" if there are no special circumstances):
    none

I HAVE CAREFULLY READ AND UNDERSTAND THE FOREGOING. I HEREBY CONSENT TO THE PERFORMANCE OF ELECTROCONVULSIVE THERAPY, FOLLOWING ADMINISTRATION OF A SHORT ACTING ANESTHETIC. I UNDERSTAND THAT THE REQUIRED 24 HOURS HAVE ELAPSED BETWEEN MY SIGNATURE AND THE TIME THE ABOVE INFORMATION WAS PROVIDED TO ME.

Date 9-28-12 Time 0915 X [signature] (Patient Signature)

Date 9-28-12 Time 0915 [signature] (Witness Signature)

Northridge Hospital Medical Center
A Dignity Health Member

INFORMED CONSENT FOR ELECTROCONVULSIVE TREATMENT

UNR-6340-31 (09/06)

PATIENT IDENTIFICATION

BENJAMIN, MARCIA S [redacted]

EXHIBIT 3

EXHIBIT 16

RECEIVED 09/04/2015 14:56

9/4/2015 2:21 PM FROM: Fax TO: +1 (818) 345-2848 PAGE: 001 OF 002

Medical Diagnostic Imaging
300 Lombard St
Thousand Oaks, CA 91360
Phone: (805) 495-1220
Fax: (805) 496-1790

Copy To

MICHAEL HIRT, MD
5620 WILBUR AVE, STE 220
TARZANA CA, 91356

FAX: (818) 345-2848

BENJAMIN, MARCIA
[redacted]

Date of Service: 06-19-2013
Exam: MRI BRAIN WITHOUT CONTRAST [BR-MBRS]

EXAM: MRI BRAIN WITHOUT CONTRAST

HISTORY:

The patient is a 52-year-old female with a history of a perineal cyst seen on the previous MR study dated 5/8/2012. The patient has right-sided parietal headaches.

TECHNIQUE:

Multiple MR sequences were obtained on a 1.5 Tesla high field MR scanner.

COMPARISON:

Study is compared to the prior MRI scan dated 5/8/2012.

FINDINGS:

Ventricular System: Normal.

Gray and White Matter: Normal.

Central Gray Structures: Normal

Brainstem: Normal.

Cerebellum: Normal.

Vasculature: Normal flow void phenomena seen of visualized vessels.

Subarachnoid/Extraaxial Spaces: Normal.

Sella/Pineal Regions: Again demonstrated is a small cyst on the pineal gland measuring 1 cm x 0.5 cm in size unchanged from the prior study.

Visualized Orbits: Normal.

Visualized Paranasal Sinuses: Clear.

Visualized Mastoid Regions: Clear.

Visualized Soft Tissues Inferior to Skull Base: Normal.

Osseous Structures: Normal.

Miscellaneous Findings: None.

IMPRESSION: 1. Stable MR scan of the brain demonstrating a small probable incidental pineal cyst measuring

Confidential

Medical Diagnostic Imaging
300 Lombard St
Thousand Oaks, CA 91360
Phone: (805) 495-1220
Fax: (805) 496-1790

1 cm x 0.5 cm. The study is otherwise unremarkable.

End of diagnostic report for accession: 26045312BR1
Dictated by: Roy Gottlieb, D.O. 6/19/2013 6:33:00 PM
Signed by: Roy Gottlieb, D.O. 6/19/2013 6:48:39 PM
Exam requested by:DAVID GUDEMAN MD

Confidential

EXHIBIT 17

Marcia Stefanon Benjamin, CID, AIA Associate
[redacted]

September 23, 2016

Michael Frankel, MD
22144 Claredon Street
Suite 300
Woodland Hills, CA 91367

Dear Dr. Frankel,

On July 16, 2015 – fourteen months ago - I faxed a personal written and signed formal request to your attention, asking for the release and full disclosure of all electronic convulsive treatments given to me from September, 2012 through March, 2013, compiling all specifics including all medications, anesthetics, muscle paralyzing agents, machine model, voltage used, the number of seizures per treatment, seizure length, post ECT recovery details, and any audio-visual materials from the procedures. In addition, I have requested a list disclosing how often, including the specific dates, maintenance and calibration of the shock device has been done during my treatment.

Subsequently, I spoke on the telephone with your front office assistant, Jason, twice inquiring the status of my formal request. During the first call, Jason acknowledged being in receipt of my fax with my first request, expressed that "my medical file was huge", despite my offering to pay for any professional copy services, that "no other patients of yours have ever made such request", that he was going to follow up on it, and get back to me. After not hearing back from Jason a month after, I made a second call to your office, in which Jason expressed that "you did not have the information regarding the machine model used during my treatments", that "only the hospital keeps that information", and that "he was going to contact Northridge Hospital to obtain such information", and that "he would get back to me with a status of my request". It has been over six months since my second call to your office, and Jason has not returned my call to this date.

EXHIBIT
7

Three months ago, Dr. Drorit Gaines, PhD, my Neuropsychologist, also requested a copy of all my medical records from your office with my permission, and has not received a response to this day.

Please be informed that this is my last formal attempt requesting you for a copy of all my records as described above prior to me elevating this matter to the Medical Board and to my attorney.

Sincerely,

Marcia

Marcia S. Benjamin, CID, AIA Associate

[redacted]

EXHIBIT 18

Marcia Stefanon Benjamin, CID, CCIDC
[redacted]

July 16, 2015

Michael Frankel, MD
22144 Claredon Street
Suite 300
Woodland Hills, CA 91367

Dear Dr. Frankel,

This is a personal formal request for the release and full disclosure of all electronic convulsive treatments given to me from September 2012 through March 2013. Please incorporate all specifics including all medications, anesthetics, muscle paralyzing agents, machine model, voltage used, the number of seizures per treatment, seizure length, and post ECT recovery details. In addition, please include any audio-visual materials from the procedures.

Thank you very much for your time and attention.

Sincerely,

Marcia Stefanon Benjamin

EXHIBIT
8

Michael Frankel, M.D. Inc.
22144 Clarendon Street #300
Woodland Hills, CA 91367
(818) 999-1144

Authorization For Release of Information

By signing this document, I (name of patient) MARCIA STEFANON BENJAMIN (hereinafter "Patient") hereby authorize Michael Frankel, M.D. (hereinafter "Provider") to disclose mental health treatment information and records obtained in the course of Provider's treatment of patient, including, but not limited to, Provider's diagnosis of Patient, to (name and functions of the person or entity to whom disclosure is made) MARCIA STEFANON BENJAMIN, CID, CCIDC # 6424. ENVIRONMENTAL DESIGNER AND ARCHITECT PROFESSIONAL

I understand that I have a right to receive a copy of this authorization. I understand that any cancellation or modification of this authorization must be in writing. I understand that I have the right to revoke this authorization at any time unless Provider has taken action in reliance upon it. And, I also understand that such revocation must be in writing and received by Provider at 22144 Clarendon Street #300, Woodland Hills, CA 91367 to be effective.

This disclosure of information and records authorized by Patient is required for the following purpose:

PERSONAL INFORMATION

The specific uses and limitations on the types of medical information to be discussed are as follows:

NONE

Such disclosure shall be limited to the following specific types of information:

FULL DISCLOSURE OF ELECTRIC CONVULSIVE TREATMENTS (ECTs) INCLUDING ALL SPECIFICS (MEDS, MACHINE USED, VOLTAGE, SEIZURE LENGTH, ETC)

Provider shall not condition treatment upon Patient signing this authorization.

Patient has the right to refuse to sign this form.

Patient understands that information used or disclosed pursuant to this authorization may be subject to re-disclosure by the recipient and may no longer be protected by the Federal Privacy Rule, although applicable California law may protect such information.

This authorization shall remain valid until: PERMANENT

Patient MARCIA STEFANON BENJAMIN Signature

Date 07/16/2015

EXHIBIT 19

Please do not sign this form until you have read it thoroughly, your physician has adequately explained to you the matters mentioned below, and you have all the information that you desire concerning electroconvulsive treatment.

The nature of electroconvulsive therapy has been explained fully to me by R. Fidalgo, M.D., and I am satisfied with that explanation. I understand all of the following:

1. The nature and seriousness of my mental condition.
2. The reason for using this treatment, which involves passing a controlled electrical current through my brain.
3. The frequency (probably 3 times per week, for 30 weeks, but not to exceed 15 treatments and not to exceed 30 days from the date of the first treatment).
4. There exists a division of opinion as to the efficacy of this treatment, but it is known to induce a brief episode of unconsciousness and a form of convulsion which, since the 1930's has been known to result in a change in brain functioning, which may end or reduce depression, excitement, or agitation and disturbing thoughts.
5. The improvement associated with this treatment has sometimes been permanent and has sometimes lasted for only a few months. However, without such treatment, my present condition might improve or might continue with little or no change for many weeks or months, thereby endangering my health and even my life.
6. Alternatives to this treatment are: no treatment, psychotherapy and medications, individually or in various combinations. These alternatives are not preferable to the proposed electroconvulsive therapy because:

   Not effective
7. This treatment may have the following side effects and risks:
   (a) headache, nausea and sore muscles lasting from an hour or so to several weeks after a treatment.
   (b) confusion lasting from an hour or so after each treatment to several weeks after a series of treatments.
   (c) memory loss lasting from an hour or so after each treatment to spotty losses lasting for several months or years after a series of treatments.
   (d) minor dental problems (chipped or broken teeth).
8. There may be serious complications of heart, lung or brain functioning as a result of the treatments or of procedures used with the treatment.
9. I have the right to accept or refuse this treatment and the right to revoke my consent for any reason at any time prior to or between treatments.
10. The special circumstances that apply to my case are: ☐ None

    Specify: _____

I HAVE CAREFULLY READ AND UNDERSTAND THE FOREGOING. I HEREBY CONSENT TO THE PERFORMANCE OF ELECTROCONVULSIVE THERAPY. I UNDERSTAND THAT THE REQUIRED TWENTY-FOUR (24) HOURS HAVE ELAPSED BETWEEN MY SIGNATURE AND THE TIME THE ABOVE INFORMATION WAS PROVIDED TO ME:

Michelle Himes 4/13/11
PATIENT'S SIGNATURE DATE

RN 4-13-11
WITNESS' SIGNATURE DATE

_____ ,needed if patient unable to sign
RELATIVE/GUARDIAN/CONSERVATOR DATE

Check appropriate box:

☐ I hereby request that no relative be notified of my treatment by electroconvulsive therapy.
☐ I hereby authorize and agree that a relative be notified of my treatment by electroconvulsive therapy.

_____ _____
PATIENT'S SIGNATURE DATE

_____ _____
WITNESS' SIGNATURE DATE

INFORMED CONSENT FOR ELECTROCONVULSIVE TREATMENT

PT. IDENTIFICATION

[redacted] 04/12/2011
HIMES,MICHELLE [redacted]

0-44-0232 (Rev 9-01)

EXHIBIT 20

26 Jun 2013 2312 GMT at Mike O'Callaghan Federal Medical Center, Emergency Department Encounter Note by GOODEN, CHERYL A

Title:	REVIEW CLINICAL NOTE-HOSPITAL MEDICAL RECORDS 04/2013 PART 1 OF 5	Original Date:	26 Jun 2013 2312 GMT
Document Type:	Emergency Department Encounter Note	AHLTA Entry Date:	26 Jun 2013 2313 GMT
Facility:	Mike O'Callaghan Federal Medical Center	Document ID:	5799084029
Clinician:	GOODEN, CHERYL A		

Jun. 26. 2013 2:28PM No. 2679 P. 4

SEVEN HILLS BEHAVIORAL INSTITUTE **DISCHARGE SUMMARY**

PATIENT NAME: Michelle Himes **MEDICAL RECORD #: 1000973**

DATE OF ADMISSION: 04/03/13 **DATE OF DISCHARGE: 04/06/13**

REASON FOR ADMISSION: The patient is a 27-year-old female with a voluntary admission to the Adult Services Unit on 04/03/13 and discharged on 04/06/13 [redacted] **The patient was admitted secondary to increased** [redacted] **reports increasing depression for the past three or four days. She has had increased suicidal thoughts. She reports being overwhelmed with news of medical issues. She reports she has an elevated prolactin level and her primary care physician told her she needs to have a CAT scan or an MRI scan to rule out a pituitary tumor. She has seen her ob-gyn doctor as she has not had a period for one and a half years. She** [redacted]

04/04/13: Seen by M.D. Goals are reviewed with the patient. She is feeling less depressed since being here. We discussed the likelihood that all of her issues are related to the Risperdal

Medical Record

SEVEN HILLS BEHAVIORAL INSTITUTE **DISCHARGE SUMMARY**

PATIENT NAME: Michelle Himes **MEDICAL RECORD #: 1000973**

PAGE 2

and it is unlikely she has a pituitary tumor. We reviewed the various medications. She has been on mostly antipsychotics. [redacted]

[redacted]

KEITH A. BREILAND, M.D.
Dictated by Joanie Blum, RN ADN

KAB/JB/cg12
#0504-044 @ 10:38 a.m.
DT: 05/04/13

RMC: Signed @ 26 Jun 2013 1613 PDT

Name: CHERYL GOODEN

Date/Time:
Transcription Date/Time: 26 Apr 2013 15:08:00
Provider: GAARDE, SARA H
Requesting Location: [redacted] NELLIS FEDERAL HOSPITAL
Status: COMPLETE
Result Code: SEE RADIOLOGIST'S REPORT
Interpreted By: WHITE, DOUGLAS W
Approved By: WHITE, DOUGLAS W
Approved Date: 26 Apr 2013 14:55:00

Report Text

COMPARISONS: None available.

FINDINGS: Multiplanar MR images are obtained through the brain and sella as part of a dynamic MRI pituitary protocol, and demonstrate a normal appearing pituitary gland measuring 11 mm in AP dimension. There is a concave superior surface of the pituitary.

This was portions of the brain are unremarkable. Clivus is within normal limits. The upper cervical spine is also unremarkable.

There is no evidence of delayed nor persistent enhancement to suggest a microadenoma. The infundibulum is normal.

There is some paranasal sinus disease involving the right maxillary sinus.

IMPRESSION: NO MRI EVIDENCE OF MICROADENOMA.

NOTE: MICROADENOMAS SMALLER THAN 2 MM CANNOT BE DETECTED ON MRI. RECOMMEND CORRELATION WITH LABORATORY DATA.

MRI Sella Turcica/Pituitary With And Without Contrast Report on Unknown

Procedure: MRI Sella Turcica/Pituitary With And Without Contrast Report
Order Comment:
Reason for Order:
Exam #: 13022611
Exam Date/Time: Unknown
Transcription Date/Time: Unknown
Provider: GAURON, MICHAEL R
Requesting Location: 99MDG FAMILY HEALTH CLINIC B NELLIS FEDERAL HOSPITAL</PRE>
Status:
Result Code:
Interpreted By:
Approved By:
Approved Date: Unknown

Report Text

EXHIBIT 21

Wednesday, September 12, 2018 **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, September 5, 2018 **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, August 29, 2018 **CPT: QNote** **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, August 22, 2018 **CPT: QNote** **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, August 15, 2018 **Note By: Charlotte Myers, LICSW**
CPT code: [redacted]
Appointment Time: 10:00 AM through 10:50 AM on 8/15/2018
Notes: Individual Psychotherapy to address emotional, social and behavioral difficulties due to depression and anxiety. Processed current life circumstances involving family and support system. Worked through feelings related to cleint's belief she is brain damaged from ECT treatments. Validated and encouraged client to focus on today not what happened in the past. Practiced mindfulness exercises.

Wednesday, August 8, 2018 **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, August 1, 2018 **Note By: Charlotte Myers, LICSW**

[redacted]

Wednesday, July 25, 2018 **Note By: Charlotte Myers, LICSW**

[redacted]

EXHIBIT 22

Keep

THYMATRON™ SYSTEM IV INSTRUCTION MANUAL

Richard Abrams, M.D.

Conrad M.Swartz, Ph.D., M.D.

(Sixth Edition, October 8, 2001)

Technical Support

Tel. 1(800) 642-6761
Fax (847) 234-6763
e-mail: somatics@megsinet.net

SPECIFICATIONS

STIMULUS OUPUT:

Current: 0.9 amp constant, limited to 450 volts, isolated from line current.

Frequency: 10 to 70 Hz in 10 Hz increments (to 140 Hz with "LOW 0.25" program)

Pulsewidth: 0.25 to 1.5 ms in 0.25 ms increments

Duration: 0.14 to 7.99 sec in increments of equal charge.

Maximum output: Standard maximum output across 220 ohms impedance, 504 mC, 99.4 joules. Output with double-dose option (where available) across 220 ohms impedance: 1008 mC, 198.8 joules.

Actual (delivered) treatment output shown in printed report (mC).

RECORDING :

4 recording channels: channels 1 & 2 , EEG; channel 3, EMG; channel 4 , ECG.

8 user-selectable gain positions for each channel: 10, 20, 50, 100, 200, 500, and 2000 uV/cm

REQUIREMENTS: 100-130 volts (120 volts) AC, 60 Hz, single phase. 150 VA. (220-240 volt, 50/60 Hz switchable).

STIMULUS GENERATION

Waveform: bipolar brief pulse square wave

IMPEDANCE

Static Impedance Test: 0 to 3000 ohms static (+/- 100 ohms) at 1000 Hz (L.E.D. and printed report)

Dynamic Impedance Measure: 0 - 500 ohms (printed report)

SEIZURE MONITORING

Channel specifications:

Maximum gain: EEG (2 channels), 10uV/cm; EMG, 100 UV/cm; ECG, 100 UV/cm
Common mode rejection: 80 dB

Isolation: full, opto-electronic
Chart recorder speed: user-selectable: 5 - 50 mm/sec

Seizure Quality Measures:

Postictal Suppression Index (EEG): range, 0-100%
Maximum Sustained EEG Power and Time to Peak EEG Power
Maximum Sustained EEG Coherence and Time to Peak EEG Coherence
Postictal Coherence reduction Index
Duke University EEG Measures
Power Spectral Analysis by fast Fourier transform
Peak Heart Rate : beats/min

Computer Seizure Endpoint Estimates by: EEG, EMG, and ECG

Dimensions

Weight:	**22 lb**
Height:	**5.5"**
Width:	**17.5"**
Depth:	**13.0"**

OPERATING INSTRUCTIONS

Front Panel Layout

The new Thymatron™ System IV features two front-panel controls for display and selection of all treatment choices: the PERCENT ENERGY stimulus dose dial, and the FLEXDIAL™ option selector.

In addition, you will see a POWER switch (power on/off), an IMPEDANCE TEST button, a START/STOP button (to manually control the 4-channel printer), a TREAT button (to deliver the treatment stimulus), two alphanumeric L.E.D.s (the left one with 8 characters, the right one with 4 characters), and 4 individual dot L.E.D.s (to indicate activation of the *FlexDial*™ selection mode, activation of the *Safety Monitor* alarm, and whether a *preset* or a *user*-set program is in effect).

POWER ON/OFF

Be sure the power cable is plugged into a grounded, 3-prong hospital-grade socket. Press the top half of the front-panel POWER switch (labeled "I") to turn the unit on; press the bottom half of the POWER switch (labeled "0") to turn the unit off.

SELF TEST

The Thymatron™ System IV incorporates an automatic self-test feature that tests the integrity of all circuits. When the unit is first powered on, a flashing nonsense symbol first appears for several seconds in the 8-character L.E.D., followed by the flashing message "SELFTEST" for a few more seconds, after which a self-test confirmation report is printed and the words "NO BASE" appear in the 8-character L.E.D., indicating that baseline EEG collection still has to be accomplished. (See IMPEDANCE TEST procedure below for initiating baseline EEG collection.)

The printed SELF TEST confirmation report will appear on the paper strip as follows:

Thymatron System IV S/N [*serial number here*]

Date Time S-IV version [*software version here*]/[*the number 60 or 50, depending on the wall current frequency*]

PERCENT ENERGY DIAL

This dial-and-button combination has two functions.

1. **Rotation of the dial displays the PERCENT ENERGY settings for each stimulus dose, followed by a 1-second display of the corresponding stimulus charge in mC.**
2. **A press of the dial displays an abbreviated reminder in the 4-character *FlexDial*™ L.E.D. of the stimulus program currently in effect (the one most recently selected via the *FlexDial*™).**

To Set Stimulus Dose

Rotate the PERCENT ENERGY dial to display the available stimulus settings (range: 5% to 100% ENERGY in 5% increments). Stop rotating the dial at the desired PERCENT ENERGY setting. A 1-second display then appears of the charge in millicoulombs (mC) that corresponds to the PERCENT ENERGY setting, followed by a return to the PERCENT ENERGY display.

To display the corresponding charge again, briefly rotate the PERCENT ENERGY dial in either direction and back to the desired setting.

Press and hold the PERCENT ENERGY dial at any time to display an abbreviated 4-character L.E.D. identification of the *FlexDial*™ stimulus program currently in effect. Release the dial to return to the PERCENT ENERGY display.

Because stimulus duration is limited to a maximum of 8 sec, the higher PERCENT ENERGY settings may not be available when using the lower range of pulsewidth and frequency values. Whenever the PERCENT ENERGY setting for a given

pulsewidth and frequency would cause the stimulus duration to exceed 8 sec, the message > 8s will briefly appear in the display, followed by a display of the *maximum PERCENT ENERGY* available for the particular stimulus parameters or program chosen.

LIGHT-EMITTING FUNCTION DISPLAYS

The Thymatron™ System IV front panel has two alphanumeric L.E.D.s (the left one, with 8 characters, and the right one with 4 characters), plus 4 individual dot L.E.D.s

8-character L.E.D

Located directly above the IMPEDANCE TEST button, this L.E.D. has the following functions:

1. **It displays the message "SELFTEST" immediately the unit is powered on.**
2. **It displays the message "NO BASE" following completion of the self-test procedure and before baseline EEG collection has been initiated.**
3. **It displays the message "TESTING" for 1 sec when the IMPEDANCE TEST button is pressed.**
4. **It then displays the static impedance value in Ohms, and maintains it until the button is released.**
5. **It displays the message "BASELINE" when the IMPEDANCE TEST button is released, during which display baseline EEG collection proceeds (about 4 sec).**
6. **It displays the message "READY" when baseline EEG collection has been successfully accomplished.**
7. **After the "TREAT" button is pressed and released, it shows the *time elapsed in sec* since the end of the stimulus.**
8. **It displays the flashing message "REPORT" when the START/STOP button is pressed to terminate recording and the end-of-treatment report is being printed.**
9. **It displays the designations and values of all *FlexDial*™-selectable variables during their setup.**

4-character L.E.D.

Located directly above the PERCENT ENERGY dial this L.E.D. has the following functions:

1. **It displays the PERCENT ENERGY choices as the PERCENT ENERGY dial is rotated.**
2. **It briefly displays the millicoulombs of *charge* corresponding to each PERCENT ENERGY dial setting.**
3. **It displays a reminder of the *stimulus program in effect* when the central button of the PERCENT ENERGY dial is pressed.**

Dot L.E.D.s

1. **The one labeled "FLEXDIAL" flashes whenever the *FlexDial*™ is in use.**
2. **The one labeled "SAFETY MONITOR ACTIVATED" flashes when *the Safety Monitor* has been activated.**
3. **The one labeled "SETTING" lights when a *factory preset FlexDial*™ program is in effect.**
4. **The one labeled "USER SET" lights when a *user-set FlexDial*™ program is in effect.**

SAFETY MONITOR CIRCUIT ALARM TEST

The Thymatron™ System IV has a special *Safety Monitor Circuit* test button on the back panel labeled "ALARM TEST". The *Safety Monitor Circuit* can be tested as follows:

1. **Turn power to Thymatron™ System IV on; do not connect cables.**
2. **Set PERCENT ENERGY dial to any setting.**
3. **Connect ECT treatment cable clips to 200 ohm, 10 watt load.**
4. **Press and hold down rear panel "ALARM TEST" button while pressing the TREAT" button as if giving a real treatment.**
5. **Continue pressing "ALARM TEST" and "TREAT" buttons while the Thymatron™ System IV goes through the full cycle of stimulus warning signal and stimulus indicator tones, then release both buttons.**

At the end of the stimulus indicator tone the "SAFETY MONITOR ACTIVATED" front panel indicator light will go on and a high-pitched, continuous signal tone will sound until the unit is powered off. *This shows the alarm signal is operating correctly*. If the indicator light and alarm signal tone do not occur, do not use the unit to treat patients until it has been examined and cleared by authorized biomedical personnel.

FRONT PANEL JACKS

ECT Stimulus jack

This 9-pin jack labeled "ECT" is located directly below and to the *left* of the IMPEDANCE TEST button. It accepts the plug from the *ECT Stimulus Cable.*

EEG/EMG/ECG Recording Jack

This 4-pin jack labeled "EEG/EMG/ECG" is located directly below and to the *right* of the IMPEDANCE TEST button. It accepts the plug from the *EEG/EMG/ECG recording cable.*

[NOTE: It is impossible to insert the plug from the stimulus cable into the recording jack, and vice versa]

FLEXDIAL™ OPERATION

There are 16 different Thymatron™ System IV user-selectable functions, all of which can be displayed and set by alternate *turns* and *presses* of the FlexDial™, according to the following general principles:

1. **Rotating the *FlexDial*™ in either direction provides a continuous-loop display of all functions and options assigned to a particular level. That is, from any function or option you can reach any other function or option in the same level by turning the dial in *either* direction.**
2. **Pressing the *FlexDial*™ selects the function displayed in the 8-character L.E.D. and advances to the next choice.**

To enter Flexdial™ mode:

After power up, press the *FlexDial*™ to enter *FlexDial*™ selection mode. The *FlexDial*™ dot L.E.D. flashes and the most recently-set function (e.g., "SETTING") will appear in the 8-character alphanumeric L.E.D.. This indicates that you are now in the *FlexDial*™ "shell"—the primary, or entry-level, layer for selecting *FlexDial*™ options.

These initial headings (e.g., "SETTING", "PROGRAMS", "PRINTOUT", "INDEXES", etc.) do not themselves change a particular setting, but are the *FlexDial*™ locations (the *FlexDial*™ shell entry-points) for a range of related specific selections. For example, selecting the "PROGRAMS" heading leads you to a related series of choices enabling you to duplicate the traditional Thymatron™ DGx stimulus settings, select among three *Low Charge Rate* programs, and choose the *Pulse Volley* stimulus mode, and the *Double Dose* mode (where available).

[NOTE:* Once a variable is set with the *FlexDial*™ *it remains in effect until changed, even when the unit is powered off.]

To exit FlexDial™ mode:

There are two ways to exit *FlexDial*™ mode: pressing the START/STOP button of the printer, and pressing the IMPEDANCE TEST button.

1. **Pressing the START/STOP button generates a printed report of the status of the 11 *FlexDial*™ -selectable settings that control stimulus parameters and printing, and advances you to TREAT mode.**
2. **Pressing the IMPEDANCE TEST button immediately advances you to TREAT mode without first generating a printed report of the FlexDial™ settings.**

MODEL PROCEDURE FOR ACCOMPLISHING ALL FLEXDIAL™ CHANGES

To change any FlexDial™ variable proceed as follows:

1. **Press the *FlexDial*™ to display the most recently-adjusted *FlexDial*™ function in the 8-character L.E.D.**
2. **Rotate the *FlexDial*™ in either direction until the function you seek is displayed.**
3. **Press the *FlexDial*™ to flash-display the existing setting for that function.**
4. **Turn the *FlexDial*™ in either direction to flash-display other choices for that function.**
5. **Press the *FlexDial*™ to select the desired choice and advance to the next choice (if there is one) or return to *FlexDial*™ entry level.**
6. **Press the "IMPEDANCE TEST" button to exit *FlexDial*™ mode and advance directly to TREAT mode.**

or,

7. **Press the "START/STOP" button to generate a printed report of the status of all *FlexDial*™-selectable settings, exit *FlexDial*™ mode, and advance to "TREAT" mode.**

For the remainder of this manual, selection of *FlexDial*™ options will be shown by the following shorthand notation:

FLEXDIAL™→[*function*]→[*choices*]

Where [*function*] = the particular *FlexDial*™ function that you wish to change, and [*choices*] = the range of available choices for that function.

For example, the notation

FLEXDIAL™→CH 3-4→EMG-ECG, EEG-EEG

Means "enter FlexDial™ mode, turn to the channel 3-4 options, and select from EMG-ECG or EEG-EEG".

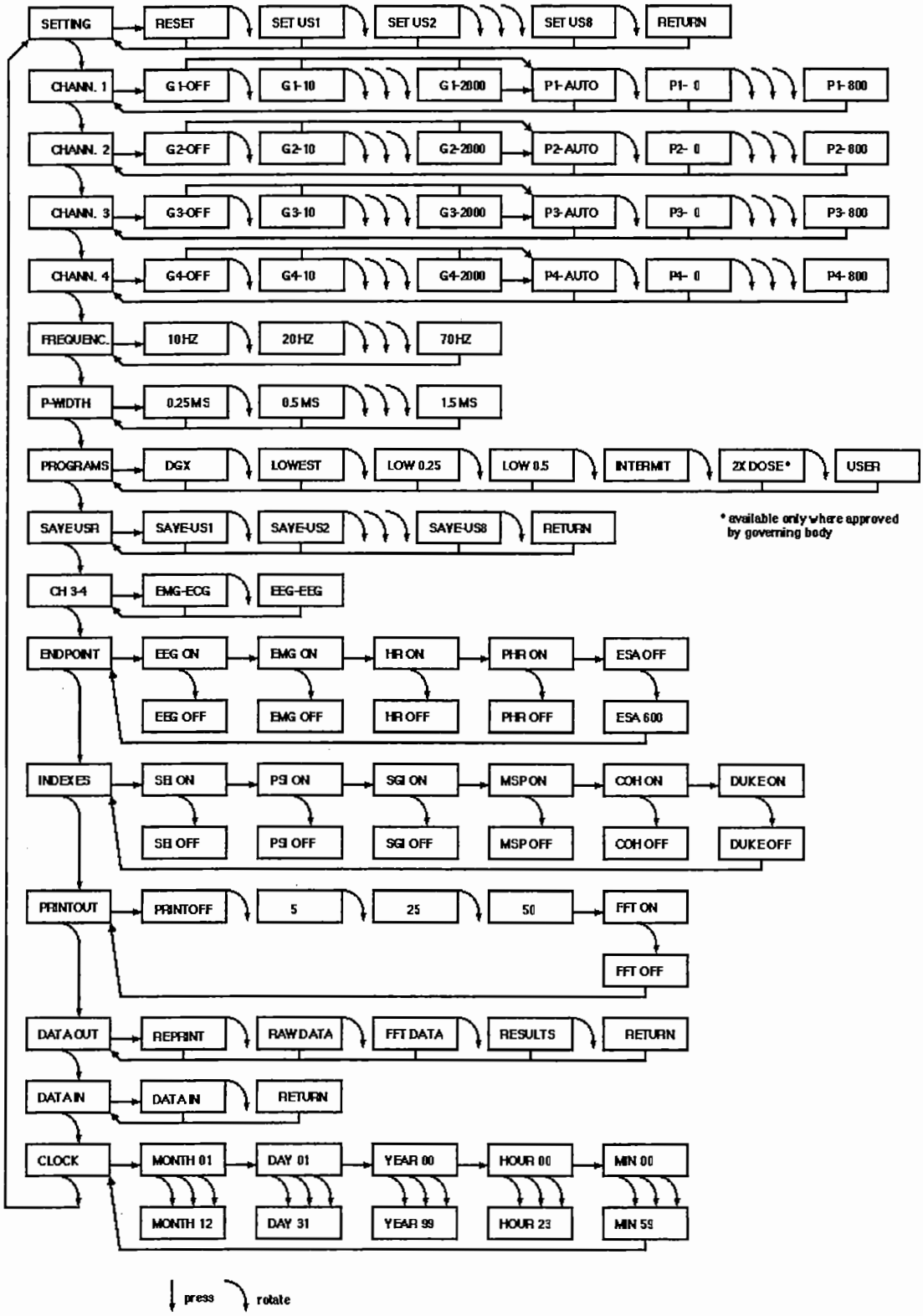
THE 16 FLEXDIAL FUNCTIONS AND WHAT THEY CONTROL

FLEXDIAL FUNCTION	SELECTS WHAT OPTIONS?
SETTING	Resets to factory specifications, selects up to 8 user-set programs
CHANN. 1	Channel 1 gain and position settings
CHANN. 2	Channel 2 gain and position settings
CHANN. 3	Channel 3 gain and position settings
CHANN. 4	Channel 4 gain and position settings

FREQUENC	**Stimulus frequency (10 Hz – 70 Hz in 7 steps)**
P-WIDTH	**Stimulus pulsewidth (0.25 mS – 1.5 mS in 5 steps)**
PROGRAMS	**Selects from 5 factory-preset stimulus delivery programs**
SAVE USR	**Stores up to 8 user-set stimulus programs**
CH 3-4	**Assigns channels 3-4 to record either EMG-ECG or EEG-EEG**
ENDPOINT	**Enables endpoint detection, HR measures, long seizure alert signal**
INDEXES	**Enables seizure quality measures**
PRINTOUT	**Enables/disables printer and FFT printout, sets paper speed**
DATA OUT	**Reprints treatment just given; sends complete treatment data to PC**
DATA IN	**Accepts data from PC**
CLOCK	**Sets month, day, year, hour, & minute in printed report**

FLEXDIAL™ FLOW-CHART:

RELEASE 5.20 8/V01



LOADING PRINTER PAPER

The Thymatron™ System IV printer paper holder is located just below the Somatics logo on the front panel. Press the arrow on the printer cover release bar just above the printer cover to open the paper holder and view the instructions for loading the fan-fold paper.

CONNECTING THE ECT STIMULUS CABLE

Connect the plug of the *black* ECT stimulus cable to the jack labeled "ECT", located on the front panel, just beneath the triangular symbol containing an exclamation point.

CONNECTING THE EEG/ECG/EMG RECORDING (PATIENT CONNECTION) CABLE

Connect the plug of the *gray* EEG/ECG/EMG recording (patient connection) cable to the jack labeled "EEG/ECG/EMG", located on the front panel, just to the right of symbol of the human figure inside a box.

[NOTE: For safety, it is impossible to insert the plug from one cable into the jack for the other, and vice versa.]

CONNECTING EEG/ECG/EMG RECORDING LEAD WIRES

[See figure below]

The Thymatron™ System IV is shipped with 9 standard-length lead wires: 4 red, 4 black, and 1 green; plus 2 extra-length brown lead wires for recording the channel 4 EMG from the leg, if desired.

Plug the 4 red lead wires into the 4 receptacles (for channels 1,2,3 & 4) indicated by red dots on the lead wire holder attached to the end of the gray cable, and plug the 4 black lead wires into the corresponding 4 receptacles (for channels 1,2,3 & 4) indicated by black dots. Plug the green lead wire into the green receptacle marked "*Iso Gnd*". If you are using the extra-length brown lead wires for recording EMG in the leg, insert them in the channel 4 receptacle (in any order) instead of the red and black lead wires.

RECORDING ELECTRODE APPLICATION

Somatics' stick-on recording electrodes [Cat. # EEDS] supplied with the Thymatron™ System IV are ideal for EEG, ECG, and EMG. They are easy and quick to use, and their small size and narrow rectangular shape facilitate bifrontal and fronto-mastoid application without interfering with stimulus electrode

placement. Instantly and firmly adherent, they remain in place throughout the seizure.

EEG: You can choose to monitor up to 4 channels of EEG. Rub the skin over the monitoring sites with an alcohol swab and wipe dry.

***For 1-channel EEG recording* from the traditional bifrontal position, place a stick-on electrode just above each eyebrow. For fronto-mastoid placement, place one recording electrode just above an eyebrow, and the other recording electrode over the ipsilateral mastoid bone (a single fronto-mastoid placement over the non-stimulated hemisphere when giving unilateral ECT helps confirm generalization of the seizure.) Apply a recording electrode to either shoulder as a patient ground.**

Connect the channel 1 lead wire clips to the EEG recording electrodes in any order of polarity (black or red); connect the green recording wire clip to the ground electrode.

2-channel EEG recording, as follows, provides more specific evidence for interhemispheric seizure generalization.

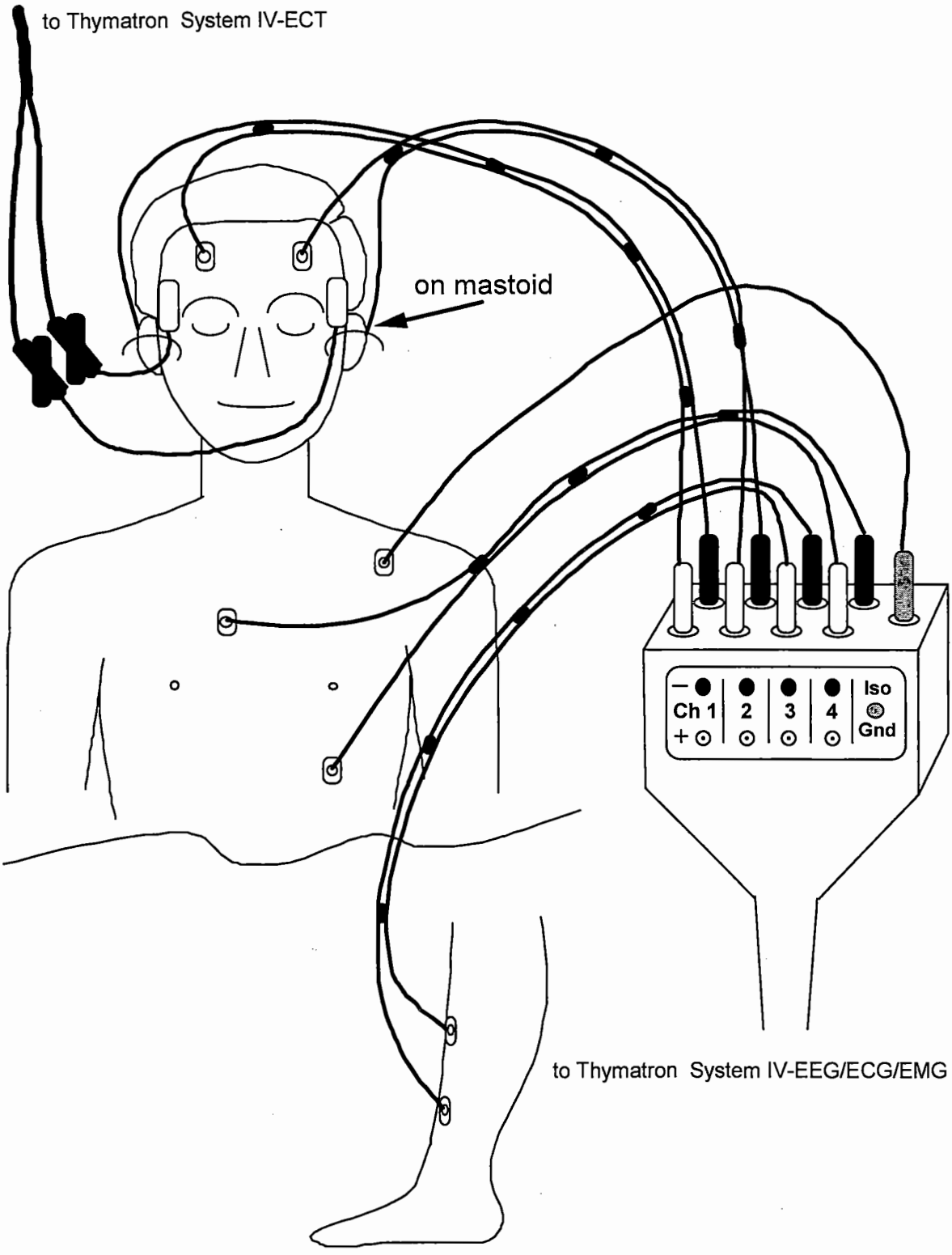
***For 2-channel EEG recording*, fronto-mastoid placements are recommended, on each side of the head. Place a recording electrode just above an eyebrow and another electrode over the ipsilateral mastoid bone. Repeat this for the other side of the head. Connect the channel 1 lead wire snaps to the first pair of EEG recording electrodes in any order (red or black), and then connect the channel 2 lead wire snaps to the second pair of EEG recording electrodes *in the same order* (e.g., if a red snap is connected to the channel 1 supra-orbital recording electrode, connect a red snap to the channel 2 supra-orbital recording electrode, and so forth). Apply a recording electrode to either shoulder as a patient ground and connect it to the green lead wire snap.**

***For 3- or 4-channel EEG recording*, use the electrode placements of your choice, remembering to keep the polarity (relationship of red and black lead wires) consistent for corresponding channels on each side of the head (e.g., if you connect the red and black lead wires to frontal and temporal recording electrodes, respectively, on the *left* side of the head, be sure to maintain the same polarity relationship when connecting the corresponding pair of frontal and temporal recording electrodes on the *right* side of the head).**

ECG: You can monitor ECG from channel 3. Apply two monitoring electrodes over the anterior chest above and below the heart, spaced about 8" apart. Connect the two channel 3 leads from the recording cable to the precordial electrodes in any order of polarity (red and black). The ground lead used for EEG as described above is also the ground for the ECG. (If only EEG is being monitored then a separate ground lead must still be connected to a shoulder electrode.)

EMG: You can monitor EMG from channel 4. Apply 2 monitoring electrodes spaced about 3" apart to a limb that has been cuffed to prevent the effects of the muscle-relaxant drug used (see next paragraph). Connect the channel 4 lead wires in any order of polarity (red and black). Use the pair of brown 60" leads for recording from the foot. If you are already recording from another channel, the same ground lead will serve for EMG as well. If you are not recording other channels, then apply a separate green ground lead to a shoulder electrode.

The "cuffed limb" method relies on observing the motor manifestations of the cerebral seizure activity in a limb that has been blocked from the effects of the muscle-relaxant agent (e.g., succinylcholine) by inflation of a blood pressure cuff over the biceps or calf to just above systolic pressure immediately prior to succinylcholine administration. As soon as the seizure ends, the blood pressure cuff is deflated. With this method, the EMG electrodes are applied over the forearm or dorsum of the foot, as needed.



Electrode connections for channel 1-2 EEG, channel 3 EMG, channel 4 ECG recording

SETTING CHANNEL 3 & 4 RECORDING OPTIONS

EEG is always recorded in channels 1 & 2; they are not user-selectable. To select the recording options for channels 3 & 4 (EEG-EEG for 2 additional channels of EEG, or EMG-ECG):

***FlexDial*™→CH 3-4→EMG-ECG; EEG-EEG**

STIMULUS ELECTRODE APPLICATION

Apply the Thymapad™ adherent stimulus electrodes [Cat. #EPAD] supplied with the Thymatron™ System IV.

For conventional *bitemporal* stimulus electrode placement, clean the skin over the temples by rubbing vigorously with a *saline*-moistened swab (do not use solvents with Thymapad™ disposable stimulus electrodes), and pat dry. Remove a Thymapad™ from its wrapper, peel it from its plastic backing, and apply it firmly to the bare skin over one temple. Apply a second Thymapad™ to the other temple.

For *bifrontal* placement simply place the centers of each Thymapad™ 5 cm above the lateral angle of each orbit, about 14-15 cm apart. Before peeling the Thymapads™ from their backing, bend them to match the shape of the skull at the electrode site.

For Swartz' *left-anterior right-temporal* (LART) placement, the left-sided Thymapad™ is placed above the left eye, with its lateral edge bordering the bony ridge between the forehead and the temple. Before peeling the left Thymapad™ from its backing, bend it to match the forehead's curve. Place the right frontotemporal electrode exactly as described above for bitemporal ECT.

For *right unilateral* stimulus electrode placement:

The d'Elia placement is recommended. Clean and dry the skin over the patient's right temple as above. Remove a Thymapad™ from its wrapper, peel it from its plastic backing, and apply it firmly to the bare skin over the temple (this is the lower electrode site). Part the hair on the right side of the head near the vertex, moisten the scalp thoroughly with a saline-soaked gauze pad or saline solution spray (patients with dense, wiry hair may require full saline saturation of the hair and scalp area directly under the electrode), and apply a Thymapad™ to the site, holding it firmly in place with the special unilateral electrode handle supplied. If the patient is bald at the near-vertex site the Thymapad™ can be applied directly to the bare scalp after cleaning and drying it as described above.

Insert the plug from the ECT stimulus cable into the plastic electrode receptacle at the end of each Thymapad™'s wire until the entire conducting surface of each

plug is covered and no metal shows. Press firmly once more on the Thymapads™ to ensure that they are properly applied, and test impedance as described below.

IMPEDANCE TEST (FOR *STATIC* IMPEDANCE)

To do nothing more than simply test the patient's static impedance, turn the front panel "POWER" button on. With both ECT treatment electrodes firmly applied (as for either bilateral or unilateral ECT), press the front panel "IMPEDANCE TEST" button and observe the impedance value in ohms in the 8-digit L.E.D..

CAUTION: DO NOT PRESS THE "TREAT" BUTTON WHEN TESTING THE IMPEDANCE

BASELINE EEG COLLECTION

Most users will want to collect a baseline EEG sample at the same time they test the patient's static impedance. To accomplish this, the automatic EEG endpoint detection feature of the Thymatron™ System IV must be enabled, the EEG recording electrodes applied to the patient, the EEG recording cable with attached lead wires connected to the front panel recording jack of the Thymatron™ System IV, and the EEG lead wires clipped to the recording electrodes.

When the IMPEDANCETEST button is then pressed, the word "TESTING", followed by a number ranging from 0 to 3000 ohm representing the static impedance in ohms, will appear in the 8-digit L.E.D. and disappear when it is released. The message "BASELINE" will appear for several seconds after the IMPEDANCE TEST button is released, indicating that collection of the baseline EEG sample is in progress. When baseline EEG collection has been accomplished, the word "READY" will appear in the L.E.D.

[NOTE: *Moving the patient's head or touching or moving the recording electrodes, lead wires, or recording cables during baseline EEG collection will prolong the process by introducing EEG artifact. The less you move and touch the patient and recording connections during baseline EEG acquisition, the sooner you will be ready to treat.*]

Repeatedly checking impedance does not prevent ongoing monitoring or processing of baseline EEG, or in any way affect the quality of the data collected.

Checking the static impedance tests the quality of the skin-to-electrode contact. With the Thymatron™ System IV, the static impedance should be at least 100 ohms and less than 3000 ohms before the treatment stimulus is administered. An impedance of under 100 ohms suggests the possibility a short circuit, probably in the recording cable. An impedance of 3000 ohms should be reduced by the following steps:

a) Try pressing firmly on the Thymapad™ again while testing the impedance; this is especially important for the vertex electrode with unilateral ECT, which should be pressed vigorously in place with the rubber cupped handle provided with Thymapads™. Also for unilateral ECT, make sure that the hair and scalp under the vertex electrode are thoroughly moistened with a saline-soaked pad.

b) If necessary, remove the Thymapad™, lightly moisten the entire solid gel surface of with the tip of a finger dipped in water, and reapply. Rarely, the impedance will remain over 3000 ohms despite these efforts—in such instances, try applying a small amount of fluid gel [e.g., Somatics' EGEL] just under the edge of the Thymapad™ perimeter while leaving the central portion attached to the skin.

c) Check to be sure the electrodes have not slipped or twisted.

d) Reposition electrodes to minimize the amount of hair underneath.

e) Increase pressure on the treatment electrodes by pressing harder with the unilateral electrode handle.

f) Gently rub the skin under the stimulus electrodes with a fine emery board or Skin Prep tape (3-M) just enough to remove the top layer of dead cells and sebum and reattach the stimulus electrodes exactly as before. (Alternatively, rub an abrasive gel [e.g. Omniprep] into the skin before reapplying the stimulus electrodes coated with conductive gel.)

If the impedance reading remains at 3000 ohms after the above procedures have been carried out, try replacing the Thymapads™, electrode wires, or the ECT cable, in that order.

STIMULUS SELECTION

The Thymatron™ System IV is shipped with the 0.5 ms *Low Charge Rate* program ("LOW 0.5") already enabled. This is the recommended choice for the first treatment in all patients for whom there is no prior information concerning their response to ECT or their seizure threshold. (Where such prior information exists, the *FlexDial*™ can be used to select stimulus parameters specifically tailored to the patient's established requirements, or to select from among several preset stimulus programs.) As a general rule, however, we recommend use of the 0.5 ms *Low Charge Rate* program wherever possible, because it provides a broadly effective stimulus well within in the physiological range for most patients.

TO SELECT A FACTORY-PRESET STIMULUS PROGRAM--HOW TO SELECT

There are 6 factory pre-set stimulus programs:

DGX	**Reproduces the the standard stimulus of theThymatron™ DGx**
LOWEST	**Automatically adjusts parameters to provide the lowest charge rate**
LOW 0.5	**Uses 0.5 ms pulsewidth and adjusts frequency to maximize duration**
LOW 0.25	**Ultrabrief 0.25 ms pulsewidth in a special low charge rate program**
INTERMIT	**Approximates intermittent pulse-volley stimulus of the *Konvulsator***
2X DOSE	**Double-dose stimulus proram (*not available in USA*)**

FLEXDIAL➔PROGRAMS➔DGX, LOWEST, LOW 0.5, LOW 0.25 , INTERMIT, 2X DOSE

TO SELECT STIMULUS FREQUENCY

For those who prefer to select a specific stimulus frequency:

FLEXDIAL™➔FREQUENC➔10, 20, 30, 40, 50, 60, 70 Hz

TO SELECT STIMULUS PULSEWIDTH

For those who prefer to select a specificpulewidth:

FLEXDIAL™➔P-WIDTH➔0.25, 0.5, 0.75, 1.0, 1.25, 1.5 MS

STIMULUS DOSE FOR *BILATERAL* (BITEMPORAL, BIFRONTAL) ECT:

For the initial treatment the dial labeled PERCENT ENERGY should be set to approximate one-half the patient's age (e.g., 25% for a 50 year-old). If no seizure activity results the PERCENT ENERGY setting should be increased to 100% and the patient restimulated within 30-60 seconds to maximize the likelihood of obtaining a therapeutically satisfactory seizure during the first treatment session. If this does not work, consider giving an additional stimulus at 100% ENERGY using the *FlexDial*™ to select a 70 Hz, 0.5 ms combination (which will deliver an 8 second pulse train).

Before the next treatment day, the patient's history and records should be reviewed to ensure that dehydration or ingestion of sedative-hypnotic or anticonvulsant medications have not contributed to the difficulty in obtaining seizures, and consideration should be given at the next scheduled treatment session to administering a stimulus at maximum charge and duration.

STIMULUS DOSE FOR *UNILATERAL* ECT:

Satisfactory therapeutic results can be obtained with right unilateral ECT by simply setting the PERCENT ENERGY dial to approximate the patient's age in years (e.g., 75 for a 72 year-old patient). If a satisfactory seizure is not obtained to the initial stimulus with right unilateral ECT, proceed as described in the paragraphs above for bilateral ECT.

Note: Once a patient obtains a satisfactory seizure with a given PERCENT ENERGY setting, we do *not* recommend administering subsequent treatments with progressively lower settings in an attempt to deliver the smallest stimulus that will still induce a seizure. This is because

minimum stimulus dosing has been associated with inadequate therapeutic efficacy for both bilateral and right unilateral ECT.

Table 2 at the end of this manual shows all the standard dosages and stimulus parameters corresponding to each PERCENT ENERGY dial setting.

EASY STIMULUS TITRATION WITH THE THYMATRON™ SYSTEM IV

For those who prefer to set the initial stimulus dose relative to the seizure threshold, a simple and effective stimulus titration schedule for unilateral ECT starts with an initial setting of 5% ENERGY, followed by restimulations at 5% ENERGY increments as needed, to a maximum of 4 stimulations in a treatment session (on average, fewer than three stimuli are required). Once the seizure threshold is determined as a specific % ENERGY figure, the recommended dosing level for unilateral ECT is 4-6 times that threshold value (e.g., 60% to 90% ENERGY for a threshold value of 15% ENERGY).

Because seizure thresholds for bitemporal and bifrontal ECT are higher than those for right unilateral ECT, the initial dose for stimulus titration with bitemporal ECT should be 10% Energy, with 5% ENERGY increments as described above. Subsequent treatments should be administered at doses that approximate 2 times threshold (e.g., 40% ENERGY in a patient with a 20% ENERGY seizure threshold).

NOTE: ***The charge dose in mC that corresponds to any % ENERGY figure shown in the L.E.D. can be viewed for 1 sec by turning the PERCENT ENERGY dial one click to either side and then back again; repeat as often as you wish.***

"BENCHMARK" METHOD FOR SETTING AND ADJUSTING THE ECT STIMULUS

Because neither seizure duration nor seizure threshold are systematically related to the clinical efficacy of an ECT treatment, you may wish to consider regulating the stimulus dose according to a physiological measurement that has been reported to correlate with treatment response (the "target measurement"). Possible target measurements include postictal EEG suppression (PSI), mean peak ictal EEG power (MSP), or peak heart rate (peak HR).

Unlike stimulus threshold titration, the target method does not administer consecutively increasing sub-threshold stimulus doses until a seizure is obtained. Rather, at the first ECT a stimulus dose is given that is high enough to induce a vigorous and effective seizure in virtually all patients. The value for the target measurement in the end-of-treatment report for the first ECT is then used as a goal for all subsequent treatments.

Selection of this initial stimulus dose can be made by the fixed-dose method or an age-based method. A fixed dose of 75-90% Energy should be high enough for virtually all patients, regardless of treatment electrode placement. Alternatively, the % Energy dial can be set to the patient's age for unilateral ECT, or to 50-75% of the patient's age for the various bilateral placements: bitemporal, bifrontal, or LART.

Dosage should be adjusted for subsequent treatments to maintain the selected variable (PSI, MSP, peak HR) within about 5% of the benchmark, keeping in mind the often dramatic rise in seizure threshold across a course of treatment. Lower values for the target measurement suggest increasing likelihood that the treatment was less than fully effective; this might be acceptable for selected patients, but is clearly a matter of medical judgment.

Of course, as everywhere in medicine, clinical response is overriding: patients whose EEG or peak heart reflect a high seizure quality at lower dosage levels, but who are not showing clinical improvement, might benefit from higher doses; those who are enjoying a satisfactory clinical response despite apparently poor-quality seizures may require no dose adjustment.

DOUBLE DOSE STIMULUS PROGRAM (NOT AVALABLE IN USA)

The double-dose stimulus program is selected as follows:

FLEXDIAL→PROGRAMS→2X DOSE

When the double-dose stimulus program is in effect, the charge delivered at all PERCENT ENERGY dial settings is automatically doubled (e.g., at the 50 PERCENT ENERGY dial setting 504 mC is delivered instead of 252 mC; at the 100 PERCENT ENERGY dial setting, 1008 mC is delivered instead of 504 mC). Table 1 at the end of this manual shows the dosage values, pulsewidths, and frequencies that correspond to all PERCENT ENERGY dial settings for the double-dose stimulus program.

ADMINISTRATION OF THE TREATMENT STIMULUS

The clear plastic hinged cover over the "TREAT" button is flipped up and the button pressed and held down until the treatment light comes on and then goes off again. While the "TREAT" button (or remote pedal button) is being held down, the following events will occur in order:

a. A one-second continuous clear tone warning signal sounds, during which the current will not be on.
b. The "TREAT" button lights up and a buzz tone sounds while the current is on. Both remain on for the full duration of the treatment stimulus.

c. The "TREAT" button light and buzz tone turn off when the treatment stimulus ends.
d. When the "TREAT" button is released the *Audible EEG*™ seizure monitor is automatically activated and the 4-channel monitor-recorder automatically provides a continuous written display beginning at the end of the stimulus. If the 4-channel monitor-recorder is already printing physiological activity when the ECT stimulus is delivered, the stimulus will appear on the paper, followed immediately by resumption of the physiological record.
e. The 8-digit L.E.D. on the front of the Thymatron™ System IV automatically shows the number of seconds elapsed since the end of the stimulus.

[NOTE: It is important to continue pressing the "TREAT" button until the light and buzzer stop automatically, as earlier release of the button immediately terminates the stimulus and delivers a smaller charge than intended.]

Keeping pressure on the "TREAT" button after the stimulus ends will not deliver additional current because no further stimulation will occur without first releasing the button, then pressing it again, and holding it down for longer than one second.

SEIZURE MONITORING

The Thymatron™ System IV allows the physician to monitor any or all of the physiological variables of EEG, ECG, and EMG.

EEG Monitoring: As described above, the Thymatron™ System IV provides 4 methods to monitor the EEG seizure:

1) The *Audible EEG*™
2) The paper EEG
3) The Ictal Line™
4) The computer-automated EEG monitor-analyzer with printout of seizure duration estimate.

1) Audible EEG Seizure Monitor

This feature is always enabled and operates automatically when the TREAT button is pressed and released. The knob marked "VOLUME" on the back panel of the Thymatron™ System IV controls the volume of the tone for the Audible EEG seizure monitor. The volume should be set near the minimum level that can be comfortably heard, and left at that setting for all patients.

The pitch of the *Audible EEG*™ signal varies with the amplitude of the EEG; it will waver and warble intensely and rapidly during the initial tonic phase. It becomes increasingly irregular, with superimposed staccato bursts, during the clonic phase, and tends to correspond to each muscular contraction. Seizure

termination is marked by a change to a nearly steady tone with little modulation or variability

Each Thymatron™ System IV is supplied with a cassette tape guide to the interpretation of the *Audible EEG*™ monitor.

2) Paper EEG Tracing

This can be activated before or after stimulus administration, as follows.

a) ***Paper EEG recording prior to the stimulus*** **(or without any intent to administer stimulation) can be initiated after the EEG recording electrodes are applied as described above by pressing the "START/STOP" button on the front panel. EEG recording continues throughout stimulus administration, ictal, and postictal periods, until terminated by pressing the "START/STOP" button again, generating the end-of-treatment report.**
b) ***Automatic paper EEG recording*** **begins when the "TREAT" button is pressed and then released and continues until the "START/STOP" button is pressed again, generating the end-of-treatment report.**

[Note: The baseline paper EEG record should not be confused with *the computer-derived* baseline EEG sample described below, which must be collected to activate the automatic EEG seizure endpoint detection program]

3) The Ictal Line™ EEG Seizure Indicator

If the *computer-determined baseline EEG sample* has first been obtained as described below, a thin black line is printed along the top of the paper recording strip when the EEG amplitude exceeds a specified baseline value determined individually for the patient being treated. An unbroken, solid black line reflects continuous seizure activity; a broken or intermittent line reflects waxing and waning, or intermittent seizure activity; and complete cessation the black line reflects EEG seizure termination.

4) Computer-Automated Seizure Duration Monitoring

A unique feature of the Thymatron™ System IV (U.S. patents 4873981, 4878498, 5269302, and 5871517) allows the physician to automatically monitor and print up to 3 computer-determined estimates of the duration of the induced seizure, derived from EEG, EMG, and ECG.

Automatic printout of EEG seizure duration

The Thymatron™ System IV continuously monitors the EEG for the endpoint of seizure activity and prints the seizure duration, in seconds, in the end-of-treatment report.

The Automatic EEG endpoint detection feature requires the initial collection of a computer-analyzed EEG baseline, which is accomplished as described above following the IMPEDANCE TEST instructions.

NOTE: If the ECT stimulus is administered to the patient after the message "READY" appears in the display, EEG analysis and reporting—including *Ictal Line*™ and seizure length determination—will proceed automatically.

***If the ECT stimulus is administered before the message "READY" appears, however, automatic EEG analysis will not occur*, and the end-of-treatment report will carry the message "EEG baseline not determined." During the several seconds until "READY" appears it is advisable to avoid touching or moving the patient's head, the recording electrodes, or the wire leads, to minimize EEG artifacts.**

In about 10-20% of ECT treatments, the EEG endpoint is not readily determined from the paper strip (Abrams, 1997). This typically occurs when paroxysmal activity decreases too gradually to provide a clear visual endpoint, or when the immediate post-seizure EEG contains high amplitude resting activity. In such circumstances, inability to detect a precise endpoint is expected with any method of examination; the Ictal Line™ might show an "on-again-off-again" broken line pattern, and the end-of-treatment report might state "EEG endpoint not determined."

Automatic printout of motor seizure duration estimate by EMG

The Thymatron™ System IV is shipped with the EMG monitor enabled in channel 3. When EMG recording electrodes have been properly applied and connected as described above, the EMG tracing automatically appears on the paper record after the TREAT button is pressed and released.

The Thymatron™ System IV continuously monitors the EMG for the endpoint of motor seizure activity and prints the EMG seizure duration, in seconds, in the end-of-treatment report. Baseline EMG collection is not required—or possible—for this measure, just a pair of EMG recording electrodes and a ground electrode, properly applied as described above, and correctly connected to the recording cable.

Automatic printout of ECG seizure duration

The Thymatron™ System IV is shipped with the ECG monitor enabled in channel 4. When ECG recording electrodes have been properly applied and connected as described above, the ECG tracing automatically appears on the paper record after the TREAT button is pressed and released.

The Thymatron™ System IV continuously monitors the ECG for the endpoint of motor seizure activity and prints the ECG-based seizure duration estimate, in seconds, in the end-of-treatment report. Baseline ECG collection is not required—or possible—for this measure, just a pair of ECG recording electrodes and a ground electrode, properly applied as described above, and correctly connected to the recording cable.

The Thymatron™ System IV is shipped with the computer-automated ECG endpoint detection feature already enabled.

[*CAUTION: The computer-derived seizure duration measures and estimates of the Thymatron™ System IV, including the Ictal Line™ indicator, are derived solely by calculation and are provided to aid, not replace, the physician's judgment. It is possible for seizure activity to continue in the brain after any or all of the computer report s indicate seizure termination. It is also possible for artifact to be interpreted by the computer programs as seizure activity*]

GAIN AND POSITION SETTING OF RECORDING TRACES

The factory preset GAIN and POSITION settings are likely to produce the best all-around results.

For those who prefer individualized settings, please note that POSITION is *always* set following GAIN, because positioning of the tracing on the recording paper depends on the amplitude, or GAIN, of the signal. Thus, it is always necessary to set the GAIN in a specific channel before setting the POSITION.

The choices for *gain* are as follows:

G[*n*]-OFF	**Turns off printing in channel [*n*]**
G[*n*]-10 to G[*n*]-2000	**Adjusts channel [*n*] gain (in microvolts)**

The choices for *position* are as follows:

P1-AUTO	**Selects auto-positioning of recording trace (*recommended*)**
P1-0 to P1-800	**Adjusts position on strip from 0 (bottom) to 800 (top).**

To set GAIN and POSITON in Channel 1, for example:

FLEXDIAL™→CHANN. 1→G1-10 to G1-2000>P1-AUTO, P1-0 to P1-800

TO TURN OFF PRINTING IN CHANNEL 1

FLEXDIAL™→CHANN. 1→G1-OFF

Follow the same procedures for the remaining channels as desired.

SEIZURE QUALITY MEASURES

The Thymatron™ System IV provides 8 *Seizure Quality Measures* under the INDEXES heading that can be individually enabled/disabled. Their names and *FlexDial*™ designations are as follows:

Postictal Suppression Index	**PSI ON/OFF**
Seizure Energy Index	**SEI ON/OFF**
Seizure Generalization Index	**SGI ON/OFF**
Maximum Sustained Power and Time to Peak Power	**MSP ON/OFF**
Maximum Sustained Coherence and Time to Peak Coherence	**COH ON/OFF**
Duke University Amplitude Measures	**DUKE ON/OFF**

The POSTICTAL SUPPRESSION INDEX (PSI) measures the percentage decrease in ictal EEG amplitude immediately following seizure termination.

The SEIZURE ENERGY INDEX (SEI) integrates the total ictal EEG power across the entire seizure.

The SEIZURE GENERALIZATION INDEX (SGI) measures the statistical concordance among 3 independent estimates of seizure duration: EEG endpoint, EMG endpoint, and ECG endpoint.

The MAXIMUM SUSTAINED POWER (MSP) measure reports the mean value of the 10-second EEG segment with the highest average power recorded during the seizure.

TIME TO PEAK POWER is the time elapsed from stimulus termination to the point of maximum EEG power.

The MAXIMUM SUSTAINED COHERENCE (MSC) measure reports the mean value of the 5-second EEG segment with the highest average coherence recorded during the seizure.

TIME TO PEAK COHERENCE is the time elapsed from stimulus termination to the point of maximum EEG coherence.

TO ENABLE/DISABLE ANY OF THE SEIZURE QUALITY MEASURES:

FLEXDIAL™➔INDEXES➔PSI, MSP, COH, PCSI, DUKE

***NOTE*: From INDEXES, repeatedly pressing the *FlexDial*™ will show a sequential flashing display of the status ("ON" or "OFF") of the PSI, MSP, COH, PCSI, and DUKE measures in that order. Turning the dial left or right at each flashing display allows the user to enable or disable each index as desired (and proceed to the next index) by pressing the *FlexDial*™. When the last of the indexes (DUKE) is enabled/disabled by pressing the *FlexDial*™, the display returns to INDEXES once again.**

TO SET PAPER (CHART DRIVE) SPEED, OR TURN PRINTING OFF

The choices are:

PRINT 5	**5 mm/sec**
PRINT 25	**25 mm/sec (*as shipped)***
PRINT 50	**50 mm/sec**
PRINTOFF	**Disables printing of monitoring traces (EEG, ECG, EMG)**

The Thymatron™ System IV is shipped with the paper speed set to 25 mm/sec. Alternate paper speeds of 5 mm/sec and 50 mm/sec may be selected, *or the printing of the monitoring traces turned off entirely,* as follows.

TO CHANGE PAPER SPEED

FLEXDIAL™➔PRINTOUT➔PRINT 5, PRINT 25, PRINT 50

TO TURN OFF PRINTING ENTIRELY

FLEXDIAL™➔PRINTOUT➔PRINTOFF

After the above selection is made, you will advance to the FFT print option:

TO TURN OFF PRINTING OF THE POWER SPECTRAL ANALYSIS (FFT)

The Thymatron™ System IV is shipped with the power spectral analysis printout enabled; to disable this feature:

FLEXDIAL™➔PRINTOUT➔FFT OFF

TO SAVE USER-SPECIFIED CONFIGURATIONS OF PRESENT FLEXDIAL™ SETTINGS

Choices:

SAVE-US1 through SAVE-US8
RETURN (TO SAVE USR)

This feature is used to store up to a total of 8 user-specified FlexDial™ configurations in memory (e.g., up to 8 individual doctors' personally-preferred settings for *all* the FLEXDIAL variables; up to 8 special-purpose FlexDial™ configurations, etc.) After they have been set, these user-specified configurations can be selected from the "SETTING" location of the *FlexDial*™ shell by selecting from"SET US1" through "SET US8".

TO STORE THE PRESENTLY-SELECTED FLEXDIAL™ SETTINGS

FLEXDIAL™→SAVE USR→SAVE US1-SAVE US8

Thus, if you have chosen to save the present *FlexDial*™ settings as US1, for example, you can then reproduce them exactly any time later by:

FLEXDIAL™→SETTING→SET US1

TO RESET ALL OPTIONS TO FACTORY-DETERMINED VALUES

The factory-determined values for the 11 *FlexDial*™ -selectable settings that control stimulus parameters and printing appear as follows in the printed report when the START/STOP button is pressed while theunit is in *FlexDial*™ mode:

Chann. 1.....G1--200 uV; P1--AUTO
Chann. 2.....G2--200 uV; P2--AUTO
Chann. 3.....G3--200 uV; P3--AUTO
Chann. 4.....G4--200 uV; P4—AUTO
FREQUENC.....10Hz
P-WIDTH.....0.5mS
PROGRAMS....LOW 0.5 CHARGE RATE
CH. 3-4.....EMG-ECG
ENDPOINT.....EEG-ON;EMG-ON; HR-ON;PHR-ON;ESA-OFF
INDEXES.....PSI-ON;MSP-ON;COH-ON;PCSI ON; DUKE-ON
PRINTOUT.....PRINT-25;FFT-ON

To reset all options to the above specifications:

FLEXDIAL™→SETTING→RESET

TO SELECT FROM UP TO 8 DIFFERENT USER-SPECIFIED CONFIGURATIONS OF ALL FLEXDIAL™ SETTINGS

FLEXDIAL™→SETTING→SET-US1 to SET-US8

When a user-specified stimulus configuration is in force, the word "USER" will appear in the L.E.D.

TO INPUT TREATMENT DATA PREVIOUSLY COLLECTED WITH THE THYMATRON™ SYSTEM IV AND STORED IN A PC

The Thymatron™ System IV allows the operator to download previously-stored treatment data from a personal computer file back into the Thymatron™ System IV, when the PC has been properly set up with the correct software. The procedure is as follows (the treatment data must already have been collected with the Thymatron™ System IV and uploaded to a PC using the DATA OUT utility of the Thymatron™ System IV):

1. **Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial until "DATA IN" is displayed.**
3. **Press the dial once; "DATA IN" will begin flashing. Now is the time to connect the PC to the rear-panel RS232 (serial) port.**
4. **Press the dial again; "IN ←" will start to flash in the display. Now is the time to initiate data transfer from the PC.**
5. **Data transfer is complete when the display stops flashing. Press the *FlexDial*™ or START/STOP button to return to the DATA IN level.**

TO SELECT DATA OUTPUTTING OPTIONS

The Thymatron™ System IV allows the operator several options for outputting the data of the treatment just given, as follows:

TO REPRINT A COMPLETE RECORD, INCLUDING RECORDING TRACES, OF THE TREATMENT JUST GIVEN (whether or not an end-of-treatment report has already been printed)

FLEXDIAL™→DATA OUT→REPRINT

(NOTE: *The following choices require the GENIE ™ IV software to be installed on a PC and connected to the Thymatron™ System IV as described in the Addendum at the end of this manual. It is also possible to use a PC that has been set up to receive data with a suitable commercially-available program, such as the modem program "Procomm".)*

RAW DATA Sends the digitized EEG data, including all FFT points and EEG indices, through the serial port to a PC.

FFT DATA Sends all FFT points and EEG indices through the serial port to a PC.

RESULTS Sends ASCII files of treatment results through the serial port to a PC.

EXIT Returns to the FLEXDIAL shell

1. Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.
2. Rotate the dial left or right until "DATA OUT" is displayed.
3. Press the *FlexDial*™; "REPRINT" will flash. Rotate the *FlexDial*™ to display the alternate choices listed above.
4. When your choice is flashing in the display (e.g., "RAW DATA") , press the *FlexDial*™ to initiate printing or data output, according to your selection. *[NOTE: If no treatment data is stored in memory the message "EMPTY" will flash and no data transfer will occur]*
5. To EXIT and return to DATA OUT, turn the dial until "EXIT" is flashing and press the dial,

or,

6. Press the IMPEDANCE TEST button to exit the *FlexDial*™ shell.

TO SAVE DATA IN EXCEL™ - FRIENDLY FORMAT:

1. Select either the *text* output or the *graph* window in GENIE IV™. It is not necessary to replay the data. If you select *text* the output will be saved as alphanumeric data. If you select *graph* (you will then be asked if you want to save all the data or only a specified segment), the data points will be saved in ASCII format.

2. Select the FILE button on the top menu, then select "Save as Text" and type in the new file name you want.

TO SET DATE & TIME IN PRINTED REPORT

The FlexDial™ "CLOCK" mode choices are as follows:

MONTH 01 - 12

DAY	**01 - 31**
YEAR	**00 - 99**
HOUR	**00 - 24**
MIN	**00 – 60**

FLEXDIAL™➔CLOCK➔MONTH>DAY>YEAR>HOUR>MIN

TABLE 1: STANDARD DOSE STIMULUS PARAMETERS: STIMULUS DURATION (SEC), CHARGE (mC), AND JOULES (AT 220 OHMS IMPEDANCE) AT EVERY PERCENT ENERGY DIAL SETTING FOR ALL PW AND FREQUENCY COMBINATIONS

FREQ = 10 PW= .25

DIAL	DURATION	mC	JOULES
5 %	5.60	25.2	5.0

FREQ = 20 PW= .25

DIAL	DURATION	mC	JOULES
5 %	2.80	25.2	5.0
10 %	5.60	50.4	10.0

FREQ = 30 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.87	25.2	5.0
10 %	3.73	50.4	10.0
15 %	5.60	75.6	15.0
20 %	7.47	100.8	20.0

FREQ = 40 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 50 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.12	25.2	5.0
10 %	2.24	50.4	10.0
15 %	3.36	75.6	15.0
20 %	4.48	100.8	20.0
25 %	5.60	126	24.9
30 %	6.72	151.2	29.9
35 %	7.84	176.4	34.9

FREQ = 60 PW= .25

DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 70 PW= .25

DIAL	DURATION	mC	JOULES
5 %	0.80	25.2	5.0
10 %	1.60	50.4	10.0
15 %	2.40	75.6	15.0
20 %	3.20	100.8	20.0

25 %	4.00	126	24.9
30 %	4.80	151.2	29.9
35 %	5.60	176.4	34.9
40 %	6.40	201.6	39.9
45 %	7.20	226.8	44.9
50 %	8.00	252	49.9

FREQ = 10 PW= .5

DIAL	DURATION	mC	JOULES
5 %	2.80	25.2	5.0
10 %	5.60	50.4	10.0

FREQ = 20 PW= .5

DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 30 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 40 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.70	25.2	5.0
10 %	1.40	50.4	10.0
15 %	2.10	75.6	15.0
20 %	2.80	100.8	20.0
25 %	3.50	126	24.9
30 %	4.20	151.2	29.9
35 %	4.90	176.4	34.9
40 %	5.60	201.6	39.9
45 %	6.30	226.8	44.9
50 %	7.00	252	49.9
55 %	7.70	277.2	54.9

FREQ = 50 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.56	25.2	5.0

10FREQ = 10 PW= .25

DIAL	DURATION	mC	JOULES
5 %	5.60	25.2	5.0

FREQ = 20 PW= .25

DIAL	DURATION	mC	JOULES
5 %	2.80	25.2	5.0
10 %	5.60	50.4	10.0

FREQ = 30 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.87	25.2	5.0
10 %	3.73	50.4	10.0
15 %	5.60	75.6	15.0
20 %	7.47	100.8	20.0

FREQ = 40 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 50 PW= .25

DIAL	DURATION	mC	JOULES
5 %	1.12	25.2	5.0
10 %	2.24	50.4	10.0
15 %	3.36	75.6	15.0
20 %	4.48	100.8	20.0
25 %	5.60	126	24.9
30 %	6.72	151.2	29.9
35 %	7.84	176.4	34.9

FREQ = 60 PW= .25

DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 70 PW= .25

DIAL	DURATION	mC	JOULES
5 %	0.80	25.2	5.0
10 %	1.60	50.4	10.0
15 %	2.40	75.6	15.0
20 %	3.20	100.8	20.0
25 %	4.00	126	24.9
30 %	4.80	151.2	29.9
35 %	5.60	176.4	34.9
40 %	6.40	201.6	39.9
45 %	7.20	226.8	44.9
50 %	8.00	252	49.9

FREQ = 10 PW= .5

DIAL	DURATION	mC	JOULES
5 %	2.80	25.2	5.0
10 %	5.60	50.4	10.0

FREQ = 20 PW= .5

DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0

10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 30 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 40 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.70	25.2	5.0
10 %	1.40	50.4	10.0
15 %	2.10	75.6	15.0
20 %	2.80	100.8	20.0
25 %	3.50	126	24.9
30 %	4.20	151.2	29.9
35 %	4.90	176.4	34.9
40 %	5.60	201.6	39.9
45 %	6.30	226.8	44.9
50 %	7.00	252	49.9
55 %	7.70	277.2	54.9

FREQ = 50 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.56	25.2	5.0
10DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 50 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.37	25.2	5.0
10 %	0.75	50.4	10.0
15 %	1.12	75.6	15.0

20 %	1.49	100.8	20.0
25 %	1.87	126	24.9
30 %	2.24	151.2	29.9
35 %	2.61	176.4	34.9
40 %	2.99	201.6	39.9
45 %	3.36	226.8	44.9
50 %	3.73	252	49.9
55 %	4.11	277.2	54.9
60 %	4.48	302.4	59.9
65 %	4.85	327.6	64.9
70 %	5.23	352.8	69.9
75 %	5.60	378	74.8
80 %	5.97	403.2	79.8
85 %	6.35	428.4	84.8
90 %	6.72	453.6	89.8
95 %	7.09	478.8	94.8
100 %	7.47	504	99.8

FREQ = 60 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.31	25.2	5.0
10 %	0.62	50.4	10.0
15 %	0.93	75.6	15.0
20 %	1.24	100.8	20.0
25 %	1.56	126	24.9
30 %	1.87	151.2	29.9
35 %	2.18	176.4	34.9
40 %	2.49	201.6	39.9
45 %	2.80	226.8	44.9
50 %	3.11	252	49.9
55 %	3.42	277.2	54.9
60 %	3.73	302.4	59.9
65 %	4.04	327.6	64.9
70 %	4.36	352.8	69.9
75 %	4.67	378	74.8
80 %	4.98	403.2	79.8
85 %	5.29	428.4	84.8
90 %	5.60	453.6	89.8
95 %	5.91	478.8	94.8
100 %	6.22	504	99.8

FREQ = 70 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.27	25.2	5.0
10 %	0.53	50.4	10.0
15 %	0.80	75.6	15.0
20 %	1.07	100.8	20.0
25 %	1.33	126	24.9
30 %	1.60	151.2	29.9
35 %	1.87	176.4	34.9
40 %	2.13	201.6	39.9
45 %	2.40	226.8	44.9
50 %	2.67	252	49.9
55 %	2.93	277.2	54.9
60 %	3.20	302.4	59.9
65 %	3.47	327.6	64.9
70 %	3.73	352.8	69.9

75 %	4.00	378	74.8
80 %	4.27	403.2	79.8
85 %	4.53	428.4	84.8
90 %	4.80	453.6	89.8
95 %	5.07	478.8	94.8
100 %	5.33	504	99.8

FREQ = 10 PW= 1

DIAL	DURATION	mC	JOULES
5 %	1.40	25.2	5.0
10 %	2.80	50.4	10.0
15 %	4.20	75.6	15.0
20 %	5.60	100.8	20.0
25 %	7.00	126	24.9

FREQ = 20 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.70	25.2	5.0
10 %	1.40	50.4	10.0
15 %	2.10	75.6	15.0
20 %	2.80	100.8	20.0
25 %	3.50	126	24.9
30 %	4.20	151.2	29.9
35 %	4.90	176.4	34.9
40 %	5.60	201.6	39.9
45 %	6.30	226.8	44.9
50 %	7.00	252	49.9
55 %	7.70	277.2	54.9

FREQ = 30 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 40 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.35	25.2	5.0
10 %	0.70	50.4	10.0
15 %	1.05	75.6	15.0
20 %	1.40	100.8	20.0
25 %	1.75	126	24.9
30 %	2.10	151.2	29.9

35 %	2.45	176.4	34.9
40 %	2.80	201.6	39.9
45 %	3.15	226.8	44.9
50 %	3.50	252	49.9
55 %	3.85	277.2	54.9
60 %	4.20	302.4	59.9
65 %	4.55	327.6	64.9
70 %	4.90	352.8	69.9
75 %	5.25	378	74.8
80 %	5.60	403.2	79.8
85 %	5.95	428.4	84.8
90 %	6.30	453.6	89.8
95 %	6.65	478.8	94.8
100 %	7.00	504	99.8

FREQ = 50 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.28	25.2	5.0
10 %	0.56	50.4	10.0
15 %	0.84	75.6	15.0
20 %	1.12	100.8	20.0
25 %	1.40	126	24.9
30 %	1.68	151.2	29.9
35 %	1.96	176.4	34.9
40 %	2.24	201.6	39.9
45 %	2.52	226.8	44.9
50 %	2.80	252	49.9
55 %	3.08	277.2	54.9
60 %	3.36	302.4	59.9
65 %	3.64	327.6	64.9
70 %	3.92	352.8	69.9
75 %	4.20	378	74.8
80 %	4.48	403.2	79.8
85 %	4.76	428.4	84.8
90 %	5.04	453.6	89.8
95 %	5.32	478.8	94.8
100 %	5.60	504	99.8

FREQ = 60 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.23	25.2	5.0
10 %	0.47	50.4	10.0
15 %	0.70	75.6	15.0
20 %	0.93	100.8	20.0
25 %	1.17	126	24.9
30 %	1.40	151.2	29.9
35 %	1.63	176.4	34.9
40 %	1.87	201.6	39.9
45 %	2.10	226.8	44.9
50 %	2.33	252	49.9
55 %	2.57	277.2	54.9
60 %	2.80	302.4	59.9
65 %	3.03	327.6	64.9
70 %	3.27	352.8	69.9
75 %	3.50	378	74.8
80 %	3.73	403.2	79.8
85 %	3.97	428.4	84.8

90 %	4.20	453.6	89.8
95 %	4.43	478.8	94.8
100 %	4.67	504	99.8

FREQ = 70 PW= 1

DIAL	DURATION	mC	JOULES
5 %	0.20	25.2	5.0
10 %	0.40	50.4	10.0
15 %	0.60	75.6	15.0
20 %	0.80	100.8	20.0
25 %	1.00	126	24.9
30 %	1.20	151.2	29.9
35 %	1.40	176.4	34.9
40 %	1.60	201.6	39.9
45 %	1.80	226.8	44.9
50 %	2.00	252	49.9
55 %	2.20	277.2	54.9
60 %	2.40	302.4	59.9
65 %	2.60	327.6	64.9
70 %	2.80	352.8	69.9
75 %	3.00	378	74.8
80 %	3.20	403.2	79.8
85 %	3.40	428.4	84.8
90 %	3.60	453.6	89.8
95 %	3.80	478.8	94.8
100 %	4.00	504	99.8

FREQ = 10 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	1.12	25.2	5.0
10 %	2.24	50.4	10.0
15 %	3.36	75.6	15.0
20 %	4.48	100.8	20.0
25 %	5.60	126	24.9
30 %	6.72	151.2	29.9
35 %	7.84	176.4	34.9

FREQ = 20 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.56	25.2	5.0
10 %	1.12	50.4	10.0
15 %	1.68	75.6	15.0
20 %	2.24	100.8	20.0
25 %	2.80	126	24.9
30 %	3.36	151.2	29.9
35 %	3.92	176.4	34.9
40 %	4.48	201.6	39.9
45 %	5.04	226.8	44.9
50 %	5.60	252	49.9
55 %	6.16	277.2	54.9
60 %	6.72	302.4	59.9
65 %	7.28	327.6	64.9
70 %	7.84	352.8	69.9

FREQ = 30 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.37	25.2	5.0

10 %	0.75	50.4	10.0
15 %	1.12	75.6	15.0
20 %	1.49	100.8	20.0
25 %	1.87	126	24.9
30 %	2.24	151.2	29.9
35 %	2.61	176.4	34.9
40 %	2.99	201.6	39.9
45 %	3.36	226.8	44.9
50 %	3.73	252	49.9
55 %	4.11	277.2	54.9
60 %	4.48	302.4	59.9
65 %	4.85	327.6	64.9
70 %	5.23	352.8	69.9
75 %	5.60	378	74.8
80 %	5.97	403.2	79.8
85 %	6.35	428.4	84.8
90 %	6.72	453.6	89.8
95 %	7.09	478.8	94.8
100 %	7.47	504	99.8

FREQ = 40 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.28	25.2	5.0
10 %	0.56	50.4	10.0
15 %	0.84	75.6	15.0
20 %	1.12	100.8	20.0
25 %	1.40	126	24.9
30 %	1.68	151.2	29.9
35 %	1.96	176.4	34.9
40 %	2.24	201.6	39.9
45 %	2.52	226.8	44.9
50 %	2.80	252	49.9
55 %	3.08	277.2	54.9
60 %	3.36	302.4	59.9
65 %	3.64	327.6	64.9
70 %	3.92	352.8	69.9
75 %	4.20	378	74.8
80 %	4.48	403.2	79.8
85 %	4.76	428.4	84.8
90 %	5.04	453.6	89.8
95 %	5.32	478.8	94.8
100 %	5.60	504	99.8

FREQ = 50 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.22	25.2	5.0
10 %	0.45	50.4	10.0
15 %	0.67	75.6	15.0
20 %	0.90	100.8	20.0
25 %	1.12	126	24.9
30 %	1.34	151.2	29.9
35 %	1.57	176.4	34.9
40 %	1.79	201.6	39.9
45 %	2.02	226.8	44.9
50 %	2.24	252	49.9
55 %	2.46	277.2	54.9
60 %	2.69	302.4	59.9

65 %	2.91	327.6	64.9
70 %	3.14	352.8	69.9
75 %	3.36	378	74.8
80 %	3.58	403.2	79.8
85 %	3.81	428.4	84.8
90 %	4.03	453.6	89.8
95 %	4.26	478.8	94.8
100 %	4.48	504	99.8

FREQ = 60 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.19	25.2	5.0
10 %	0.37	50.4	10.0
15 %	0.56	75.6	15.0
20 %	0.75	100.8	20.0
25 %	0.93	126	24.9
30 %	1.12	151.2	29.9
35 %	1.31	176.4	34.9
40 %	1.49	201.6	39.9
45 %	1.68	226.8	44.9
50 %	1.87	252	49.9
55 %	2.05	277.2	54.9
60 %	2.24	302.4	59.9
65 %	2.43	327.6	64.9
70 %	2.61	352.8	69.9
75 %	2.80	378	74.8
80 %	2.99	403.2	79.8
85 %	3.17	428.4	84.8
90 %	3.36	453.6	89.8
95 %	3.55	478.8	94.8
100 %	3.73	504	99.8

FREQ = 70 PW= 1.25

DIAL	DURATION	mC	JOULES
5 %	0.16	25.2	5.0
10 %	0.32	50.4	10.0
15 %	0.48	75.6	15.0
20 %	0.64	100.8	20.0
25 %	0.80	126	24.9
30 %	0.96	151.2	29.9
35 %	1.12	176.4	34.9
40 %	1.28	201.6	39.9
45 %	1.44	226.8	44.9
50 %	1.60	252	49.9
55 %	1.76	277.2	54.9
60 %	1.92	302.4	59.9
65 %	2.08	327.6	64.9
70 %	2.24	352.8	69.9
75 %	2.40	378	74.8
80 %	2.56	403.2	79.8
85 %	2.72	428.4	84.8
90 %	2.88	453.6	89.8
95 %	3.04	478.8	94.8
100 %	3.20	504	99.8

FREQ = 10 PW= 1.5

DIAL	DURATION	mC	JOULES

5 %	0.93	25.2	5.0
10 %	1.87	50.4	10.0
15 %	2.80	75.6	15.0
20 %	3.73	100.8	20.0
25 %	4.67	126	24.9
30 %	5.60	151.2	29.9
35 %	6.53	176.4	34.9
40 %	7.47	201.6	39.9

FREQ = 20 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.47	25.2	5.0
10 %	0.93	50.4	10.0
15 %	1.40	75.6	15.0
20 %	1.87	100.8	20.0
25 %	2.33	126	24.9
30 %	2.80	151.2	29.9
35 %	3.27	176.4	34.9
40 %	3.73	201.6	39.9
45 %	4.20	226.8	44.9
50 %	4.67	252	49.9
55 %	5.13	277.2	54.9
60 %	5.60	302.4	59.9
65 %	6.07	327.6	64.9
70 %	6.53	352.8	69.9
75 %	7.00	378	74.8
80 %	7.47	403.2	79.8
85 %	7.93	428.4	84.8

FREQ = 30 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.31	25.2	5.0
10 %	0.62	50.4	10.0
15 %	0.93	75.6	15.0
20 %	1.24	100.8	20.0
25 %	1.56	126	24.9
30 %	1.87	151.2	29.9
35 %	2.18	176.4	34.9
40 %	2.49	201.6	39.9
45 %	2.80	226.8	44.9
50 %	3.11	252	49.9
55 %	3.42	277.2	54.9
60 %	3.73	302.4	59.9
65 %	4.04	327.6	64.9
70 %	4.36	352.8	69.9
75 %	4.67	378	74.8
80 %	4.98	403.2	79.8
85 %	5.29	428.4	84.8
90 %	5.60	453.6	89.8
95 %	5.91	478.8	94.8
100 %	6.22	504	99.8

FREQ = 40 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.23	25.2	5.0
10 %	0.47	50.4	10.0
15 %	0.70	75.6	15.0

20 %	0.93	100.8	20.0
25 %	1.17	126	24.9
30 %	1.40	151.2	29.9
35 %	1.63	176.4	34.9
40 %	1.87	201.6	39.9
45 %	2.10	226.8	44.9
50 %	2.33	252	49.9
55 %	2.57	277.2	54.9
60 %	2.80	302.4	59.9
65 %	3.03	327.6	64.9
70 %	3.27	352.8	69.9
75 %	3.50	378	74.8
80 %	3.73	403.2	79.8
85 %	3.97	428.4	84.8
90 %	4.20	453.6	89.8
95 %	4.43	478.8	94.8
100 %	4.67	504	99.8

FREQ = 50 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.19	25.2	5.0
10 %	0.37	50.4	10.0
15 %	0.56	75.6	15.0
20 %	0.75	100.8	20.0
25 %	0.93	126	24.9
30 %	1.12	151.2	29.9
35 %	1.31	176.4	34.9
40 %	1.49	201.6	39.9
45 %	1.68	226.8	44.9
50 %	1.87	252	49.9
55 %	2.05	277.2	54.9
60 %	2.24	302.4	59.9
65 %	2.43	327.6	64.9
70 %	2.61	352.8	69.9
75 %	2.80	378	74.8
80 %	2.99	403.2	79.8
85 %	3.17	428.4	84.8
90 %	3.36	453.6	89.8
95 %	3.55	478.8	94.8
100 %	3.73	504	99.8

FREQ = 60 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.16	25.2	5.0
10 %	0.31	50.4	10.0
15 %	0.47	75.6	15.0
20 %	0.62	100.8	20.0
25 %	0.78	126	24.9
30 %	0.93	151.2	29.9
35 %	1.09	176.4	34.9
40 %	1.24	201.6	39.9
45 %	1.40	226.8	44.9
50 %	1.56	252	49.9
55 %	1.71	277.2	54.9
60 %	1.87	302.4	59.9
65 %	2.02	327.6	64.9
70 %	2.18	352.8	69.9

75 %	2.33	378	74.8
80 %	2.49	403.2	79.8
85 %	2.64	428.4	84.8
90 %	2.80	453.6	89.8
95 %	2.96	478.8	94.8
100 %	3.11	504	99.8

FREQ = 70 PW= 1.5

DIAL	DURATION	mC	JOULES
5 %	0.13	25.2	5.0
10 %	0.27	50.4	10.0
15 %	0.40	75.6	15.0
20 %	0.53	100.8	20.0
25 %	0.67	126	24.9
30 %	0.80	151.2	29.9
35 %	0.93	176.4	34.9
40 %	1.07	201.6	39.9
45 %	1.20	226.8	44.9
50 %	1.33	252	49.9
55 %	1.47	277.2	54.9
60 %	1.60	302.4	59.9
65 %	1.73	327.6	64.9
70 %	1.87	352.8	69.9
75 %	2.00	378	74.8
80 %	2.13	403.2	79.8
85 %	2.27	428.4	84.8
90 %	2.40	453.6	89.8
95 %	2.53	478.8	94.8
100 %	2.67	504	99.8

TABLE 2: DOUBLE DOSE STIMULUS PARAMETERS*: STIMULUS DURATION (SEC), CHARGE (mC), AND JOULES (AT 220 OHMS IMPEDANCE) AT EVERY PERCENT ENERGY DIAL SETTING ABOVE 50%, FOR ALL PW AND FREQUENCY COMBINATIONS.

*(Not available in USA)

FREQ = 60 PW= .75

DIAL	DURATION	mC	JOULES
110 %	6.84	554.4	109.7
120 %	7.47	604.8	119.7

FREQ = 70 PW= .75

DIAL	DURATION	mC	JOULES
110 %	5.87	554.4	109.7
120 %	6.4	604.8	119.7
130 %	6.93	655.2	129.7
140 %	7.47	705.6	139.7
150 %	8	756	149.6

FREQ = 40 PW= 1

DIAL	DURATION	mC	JOULES
110 %	7.7	554.4	109.7

FREQ = 50 PW= 1

DIAL	DURATION	mC	JOULES
110 %	6.16	554.4	109.7
120 %	6.72	604.8	119.7
130 %	7.28	655.2	129.7
140 %	7.84	705.6	139.7

FREQ = 60 PW= 1

DIAL	DURATION	mC	JOULES
110 %	5.13	554.4	109.7
120 %	5.6	604.8	119.7
130 %	6.07	655.2	129.7
140 %	6.53	705.6	139.7
150 %	7	756	149.6
160 %	7.47	806.4	159.6
170 %	7.93	856.8	169.6

FREQ = 70 PW= 1

DIAL	DURATION	mC	JOULES
110 %	4.4	554.4	109.7
120 %	4.8	604.8	119.7
130 %	5.2	655.2	129.7
140 %	5.6	705.6	139.7
150 %	6	756	149.6
160 %	6.4	806.4	159.6
170 %	6.8	856.8	169.6
180 %	7.2	907.2	179.6
190 %	7.6	957.6	189.6
200 %	8	1008	199.5

FREQ = 40 PW= 1.25

DIAL	DURATION	mC	JOULES

110 %	6.16	554.4	109.7
120 %	6.72	604.8	119.7
130 %	7.28	655.2	129.7
140 %	7.84	705.6	139.7

FREQ = 50 PW= 1.25

DIAL	DURATION	mC	JOULES
110 %	4.928	554.4	109.7
120 %	5.376	604.8	119.7
130 %	5.824	655.2	129.7
140 %	6.272	705.6	139.7
150 %	6.72	756	149.6
160 %	7.168	806.4	159.6
170 %	7.616	856.8	169.6

FREQ = 60 PW= 1.25

DIAL	DURATION	mC	JOULES
110 %	4.11	554.4	109.7
120 %	4.48	604.8	119.7
130 %	4.85	655.2	129.7
140 %	5.23	705.6	139.7
150 %	5.6	756	149.6
160 %	5.97	806.4	159.6
170 %	6.35	856.8	169.6
180 %	6.72	907.2	179.6
190 %	7.09	957.6	189.6
200 %	7.47	1008	199.5

FREQ = 70 PW= 1.25

DIAL	DURATION	mC	JOULES
110 %	3.52	554.4	109.7
120 %	3.84	604.8	119.7
130 %	4.16	655.2	129.7
140 %	4.48	705.6	139.7
150 %	4.8	756	149.6
160 %	5.12	806.4	159.6
170 %	5.44	856.8	169.6
180 %	5.76	907.2	179.6
190 %	6.08	957.6	189.6
200 %	6.4	1008	199.5

FREQ = 30 PW= 1.5

DIAL	DURATION	mC	JOULES
110 %	6.84	554.4	109.7
120 %	7.47	604.8	119.7

FREQ = 40 PW= 1.5

DIAL	DURATION	mC	JOULES
110 %	5.13	554.4	109.7
120 %	5.6	604.8	119.7
130 %	6.07	655.2	129.7
140 %	6.53	705.6	139.7
150 %	7	756	149.6
160 %	7.47	806.4	159.6
170 %	7.93	856.8	169.6

FREQ = 50 PW= 1.5

DIAL	DURATION	mC	JOULES
110 %	4.11	554.4	109.7
120 %	4.48	604.8	119.7
130 %	4.85	655.2	129.7
140 %	5.23	705.6	139.7
150 %	5.6	756	149.6
160 %	5.97	806.4	159.6
170 %	6.35	856.8	169.6
180 %	6.72	907.2	179.6
190 %	7.09	957.6	189.6
200 %	7.47	1008	199.5

FREQ = 60 PW= 1.5

DIAL	DURATION	mC	JOULES
110 %	3.42	554.4	109.7
120 %	3.73	604.8	119.7
130 %	4.04	655.2	129.7
140 %	4.36	705.6	139.7
150 %	4.67	756	149.6
160 %	4.98	806.4	159.6
170 %	5.29	856.8	169.6
180 %	5.6	907.2	179.6
190 %	5.91	957.6	189.6
200 %	6.22	1008	199.5

FREQ = 70 PW= 1.5

DIAL	DURATION	mC	JOULES
110 %	2.93	554.4	109.7
120 %	3.2	604.8	119.7
130 %	3.47	655.2	129.7
140 %	3.73	705.6	139.7
150 %	4	756	149.6
160 %	4.27	806.4	159.6
170 %	4.53	856.8	169.6
180 %	4.8	907.2	179.6
190 %	5.07	957.6	189.6
200 %	5.33	1008	199.5

ADDENDUM: GENIE™ IV MANUAL

COMPUTER-ASSISTED EEG ANALYSIS SOFTWARE FOR THYMATRON™ SYSTEM IV

(WINDOWS 95-98)

John Pavel

Richard Abrams, M.D.

DESCRIPTION

The Genie™ IV 4-channel computer-assisted EEG analyzer-analyzer is an accessory to the Thymatron™ System IV ECT instrument that enables the user to acquire, process and display 4 channels of EEG, EMG and ECG data on a PC computer via the rear-panel RS232 serial port.

A *Patient Information* window allows the operator to enter patient identifying data and clinical information using the computer keyboard.

The system was designed and engineered to minimize training time and allow "hands on" use almost immediately. It is *Windows 95-98* compliant, enabling the operator to use all the features of the *Windows* environment.

A certain amount of redundancy has been built in to the program to make it easier to operate (e.g., playback speed can be adjusted from the CONTROL window, the *Tools* drop-down menu, or by the B key on the computer keyboard)

INSTALLATION & SOFTWARE OPERATION

Connect the Thymatron™ System IV to an IBM™-compatible (desktop or laptop) PC computer, using a 9-pin serial cable: *Connect one end of the cable to the rear-panel serial port (labeled RS232) of the Thymatron™ System IV, and the other end of the cable to a 9-pin serial port on your computer.*

Insert the program diskette in your floppy drive a:
Create a new folder named "GENIE" on your hard drive (preferably on the *Desktop*) for the Genie™ IV EEG analysis program and your data files.
Copy the file *Genie IV.exe* from the floppy disk to the new folder you have just created.
Using the program *Genie IV.exe*, copy the sample patient data file *Sample.dat* into the same folder.

Open your GENIE™ folder and click on the Genie IV icon to view the menus and utilities, as follows:

[NOTE: See under the REPORT section below for instruction on how to create a patient data file in GENIE™ IV by direct transfer of treatment results from the Thymatron™ System IV]

Title Bar Headings:

File **Used to open existing files, set up data for printing, print, and exit.**

Connect **Sends and receives data to and from the Thymatron; sends user's name to Thymatron™ System IV as the heading of the printed treatment report; selects parallel port.**

PatientInfo **Used to enter patient identifying information and comments.**

Spectrum ***Appears only when FFT, BANDS, or SPECTRUM windows are open.*** **Used to select pairs of EEG channels for analysis; to specify whether the analysis will cover the entire EEG or just the current segment; and to assign numerical values to frequency bands.**

Tools ***Appears only when a window is open.*** **Used to open/close the SETTING window for adjusting *scale* and *artifact rejection* settings for all the channels; to set the playback *speed*; and to initiate *playback, reset,* and *reject* functions (these last 3 can also be accessed from the CONTROL window, as described below).**

Window

Used to display a copy of the printed report [when a patient data file is open]; to open/close the CONTROL window for *playback, reset, reject,* and *data collection* functions; to close all windows; and to open and close various display windows, as follows:

***Graph*:** **Replays raw EEG, ECG, and EMG as continuous tracings**

***FFT*:** **Displays bar graphs of the frequency composition of the data.**

***Bands*:** **Displays frequency bands of the data.**

Spectrum: **Displays each individual frequency band.**

***"HOT" KEYS*: You can also use accelerator ("hot") keys on the computer keyboard to facilitate data replay. Pressing these keys produces the same effects as clicking on the display.**

Use the B key to control PlayBack
Use the R key to control Reset
Use the J key to control Reject

***FOCUS* feature*:* A border appears around the most recently-used button to *focus* your attention; use the *Space* bar on the computer keyboard to control whichever button is in Focus.**

EEG ANALYSIS

The Genie™ IV features 5 different display windows: REPORT,GRAPH, BANDS, FFT, and SPECTRUM, as follows.

REPORT

The report window duplicates the final report as printed on the thermal printer of the Thymatron™ System IV. It will not change with artifacting or time limitation.

To open the REPORT window with the demo patient file that accompanies this program, click on
File→Open→Hh6.dat [logo]→Open

(If a patient data file is already open, you can also open the REPORT window from *Window* on the title bar.)

To open the REPORT window using a patient data file of your own, you must first have stored your patient's data using the *Connect* utility of the GENIE™ IV program in conjunction with the DATA OUT utility of the Thymatron™ System IV, as follows:

[NOTE: The following assumes you have administered an ECT treatment with the Thymatron™ System IV properly configured to collect EEG and other physiologic data as described in the Thymatron™ System IV Instruction Manual, and have neither turned off the POWER switch nor unplugged the unit prior to attempting to transfer the treatment results]

Make sure your PC is connected to the rear-panel RS232 (serial) port of the Thymatron™ System IV with a 9-pin male to 9-pin female (modem extension) cable, and that you have opened your GENIE™ folder and clicked on the *Genie IV* program as described above under INSTALLATION & SOFTWARE OPERATION).
Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.
Rotate the dial left or right until "DATA OUT" is displayed.
Press the *FlexDial*™; "REPRINT" will flash. Rotate the *FlexDial*™ until "RAW DATA" flashes in the display.
Click *Connect* in the title bar of the GENIE™ IV program on your PC, then click on *Receive data* in the pull-down menu.
Press the *FlexDial*™ to initiate data output to the PC. *[NOTE: If no treatment data is stored in memory the message "EMPTY" will flash and no data transfer will occur]*
To EXIT and return to DATA OUT, turn the dial until "EXIT" is flashing and press the dial,

or,

6. Press the START/STOP button to exit the *FlexDial*™ shell.

To close the patient data file close the REPORT window by clicking on X in the upper right-hand corner. [If you made any changes to the data you will be prompted to save the changed file using different file name.]

GRAPH

This window serves as a 4-channel analyzer, displaying 2 channels of EEG plus either EMG & ECG, or 2 additional channels of EEG, in 1.28 second epochs. A patient data file (e.g., the *Sample.dat* file on the accompanying diskette) must first be opened as described above in order to display the tracings in the GRAPH window.

When you click on *Graph,* the GRAPH window will open, together with the CONTROL and SETTING windows as described below (the CONTROL and SETTING windows can also be opened/closed directly from *Window* and *Tools,* respectively, on the title bar).

The GRAPH window can be moved and resized using standard Windows 95 procedures, but the CONTROL and SETTING windows can only be moved, not resized.

To view a real-time graphic display of the 4-channel recording, click on:

***Window*→*Graph*→*PlayBack* button (in CONTROL window)**

Select playback speed (100%, 200% or 500% of real time) from the CONTROL window or by clicking on *Speed* in the drop-down menu from *Tools* in the title bar. [The CONTROL window can also be opened/closed by clicking on *Play control* in the drop-down menu from *Window* in the title bar.]

If you wish to playback and analyze only *part* of the tracing (e.g., the portion from 10 to 20 sec), select the time using the *time set* feature in the CONTROL window, following the format xx-xx (e.g., 10-20) in seconds. The exact number of seconds elapsed as shown on the CONTROL window timer may differ slightly from your setting because of the 1.28 sec epoch length.

You can stop playback any time by clicking on *StopBack* in the CONTROL window.

To reject an epoch, click on the CONTROL window *Reject* button (or the J key on the keyboard) during playback of the epoch in question, and the 1.28 second segment will be dropped from the analysis.

For each channel, the *scale* (10 to 2000 microvolts) and the automatic *artifact rejection level* (20 to 1000 microvolts) are selected from the SETTINGS window (accessed by clicking *Channels setting* on the pull-down menu from *Tools* in the title bar). A segment will be rejected either automatically when the amplitude exceeds

the preset amplitude value selected, or manually when the user clicks the *Reject* button in the CONTROL window.

Click on the *Reset* button in the CONTROL window (or the R key on the keyboard) to "rewind" the recording back to the beginning.

Click on the *Collect* button to receive and store patient data from the Thymatron™ System IV, using its DATA OUT utility.

FFT

This feature provides a continuously updated, real-time, 32 bar, graphic display of the FFT analysis of the EEG in channels 1 & 2 only.

Clicking on *Spectrum* in the title bar provides a choice of viewing a static graphic display of either the entire (*Accumulated spectrum*) power spectral analysis, or the analysis for the *Current segment* only.

The CONTROL and SETTING windows have the same functions as described earlier.

BANDS

BANDS provides numeric values for *absolute EEG power*, *relative EEG power*, *% interhemispheric coherence*, and *% interhemispheric asymmetry*, for each of the 4 standard frequency bands (*delta, theta, alpha, beta*), using either preset or user-defined values, plus 2 additional user-assignable bandwidths. These variables are used to assess the relative inter-hemispheric symmetry in EEG *amplitude* and *phase* .

NOTE: The user can choose to view a continuously-updated real-time display for these and other variables described below by clicking on *Accumulated Spectrum* in the pull-down menu from *Spectrum* in the title bar, or view the analysis of the current segment only, by clicking on *Current segment* in the pull-down menu.

The mean EEG frequency is also displayed for each channel.

To change the EEG frequency band limits select from the title bar and pull-down menus as follows:

Spectrum→Set bands→[choose band]→click on displayed value→enter new value→click OK

You may set up us many BANDS windows as needed by selecting from the title bar and drop-down menu:

Window→Bands

If 4 EEG channels are being analyzed you may click on *Spectrum* in the title bar to select any combination of 2 of the four channels (e.g., 1&2, 2&4, etc.) to compare against each other by clicking *Spectrum* on the title bar and then selecting the desired channel pair(s) from the pull-down menu:

Spectrum→EEG [channel]&[channel]

The BANDS window can also be set to display a continuously-updated real-time display, or a display of the current segment only, using the *Accumulated spectrum* and *Current segment* choices in the pull-down menu from *Spectrum* in the title bar.

SPECTRUM

This window provides a complete array of numeric values for *absolute power, relative power, asymmetry,* and *coherence* for each of 32 frequency points, in steps of 0.78 Hz each. *[NOTE: The SPECTRUM window must be opened from the pull-down menu of Window in the title bar—it is not the same as Spectrum in the title bar, which is described above]*

If 4 EEG channels are being analyzed you may select any combination of 2 of the four channels for analysis, as described above under BANDS.

As for BANDS, the SPECTRUM window can also be set to display a continuously-updated real-time display, or a display of the current segment only, using the *Accumulated spectrum* and *Current segment* choices in the pull-down menu from *Spectrum* in the title bar.

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EXHIBIT 23

THYMATRON™ SYSTEM IV INSTRUCTION MANUAL

by

Richard Abrams, M.D.

and

Conrad M. Swartz, Ph.D., M.D.

(Fifth Edition, September 20, 2000)

RICHARD ABRAMS, M.D. is Professor in the Department of Psychiatry and Behavioral Sciences at University of Health Sciences/The Chicago Medical School. He has conducted clinical and basic science research on ECT since 1965 and has authored over 70 articles on the subject, as well as dozens of additional research papers and textbook chapters on psychopharmacology, and on the diagnosis, classification, and familial transmission of manic-depressive illness and schizophrenia. His books include *Electroconvulsive Therapy: Biological Foundations and Clinical Applications* (Spectrum Publications, 1982), *General Hospital Psychiatry* (The Free Press, 1985), and *Electroconvulsive Therapy* (Oxford University Press, 1988; 1992; 1997), long the standard text for the field. He has been a member of the editorial board of *The Journal of ECT* of since its inception as *Convulsive Therapy*.

CONRAD M. SWARTZ, Ph.D., M.D. is Professor of Psychiatry and Chief, Division of Psychiatric Research at Southern Illinois University School of Medicine. Relevant to his Ph.D. in Chemical Engineering and Mathematics, he has authored over 100 original clinical and laboratory research papers on ECT, pharmacokinetics, hormone kinetics, and psychosomatics. He received two Clinical Research Awards from the American Academy of Clinical Psychiatrists for his research on ECT. He is on the editorial boards of *The Journal of ECT*, *Annals of Clinical Psychiatry*, and *The Journal of Clinical Pharmacology*, and served as President of the Association for Convulsive Therapy, 1990-1992.

ACKNOWLEDGEMENTS

John Pavel of Elektrika, Inc. collaborated in the design of the Thymatron™ System IV.

REPAIR AND MAINTENANCE

There are no user-serviceable parts in the Thymatron™ System IV. If the device does not operate as indicated in the instructions, it must be returned to Somatics, Inc., for repair. All returns must be accompanied by a Return Authorization Number obtained from Somatics in advance and clearly marked on the outside of the shipping carton.

SPECIFICATIONS

STIMULUS OUPUT:

Current: 0.9 amp constant, limited to 450 volts, isolated from line current.

Frequency: 10 to 70 Hz in 10 Hz increments

Pulsewidth: 0.25 to 1.5 ms in 0.25 ms increments

Duration: 0.14 to 8.0 sec in increments of equal charge.

Maximum output: Standard maximum output across 220 ohms impedance, 504 mC, 99.4 joules. Output with double-dose option (where available) across 220 ohms impedance: 1008 mC, 188.8 joules.

RECORDING:

4 recording channels: channels 1 & 2 , EEG; channel 3, EMG; channel 4 , ECG.

8 user-selectable gain positions for each channel: 10, 20, 50, 100, 200, 500, and 2000 uV/cm

REQUIREMENTS: 100-130 volts (120 volts) AC, 60 Hz, single phase. 150 VA. (220-240 volt, 50/60 Hz switchable).

STIMULUS GENERATION

Waveform: bipolar brief pulse square wave

IMPEDANCE

Static Impedance Test: 0 to 3000 ohms static (+/- 100 ohms) at 1000 Hz (L.E.D. and printed report)

Dynamic Impedance Measure: 0 - 500 ohms (printed report)

SEIZURE MONITORING

Channel specifications:

Maximum gain: EEG (2 channels), 10uV/cm; EMG, 100 UV/cm; ECG, 100 UV/cm
Common mode rejection: 80 dB
Isolation: full, opto-electronic
Chart recorder speed: user-selectable: 5 - 50 mm/sec

Seizure Quality Measures:

Seizure Energy Index (EEG): integrated ictal wide-band EEG voltage
Postictal Suppression Index (EEG): range, 0-100%
Seizure Concordance Index (EEG, EMG, ECG): range, 0-100%
Maximum Sustained EEG Power and Time to Peak EEG Power
Maximum Sustained EEG Coherence and Time to Peak EEG Coherence
Duke University EEG Measures
Power Spectral Analysis by fast Fourier transform
Peak Heart Rate : beats/min

Computer Seizure Endpoint Estimates by: EEG, EMG, and ECG

Dimensions

Weight:	**22 lb**
Height:	**5.5”**
Width:	**17.5”**
Depth:	**13.0”**

DESIGN CONSIDERATIONS

The Thymatron™ System IV was constructed to achieve specific quality goals: stimulus characteristics based on systematic data for efficiency in generating effective treatments; rational, straightforward stimulus control; reliable seizure induction; conformity with independent testing laboratory standards for quality of construction; easy-to-use comprehensive monitoring capabilities.

The following research data on the nature of the ECT stimulus determined the choice of specifications for the Thymatron™ System IV.

SINE WAVE vs. BRIEF PULSE STIMULI

The sine wave stimulus is a continually waxing and waning stream of electrons that reverses direction 120 times per second. Because each cycle consists of one negative and one positive wave, the cycle frequency is 60 per second and the corresponding pulsewidth is 8.3 ms. Because this fixed-voltage wave-form is supplied by commercial wall mains it was the first to be used for ECT (Cerletti and Bini, 1938).

In sharp contrast, the brief pulse, square wave stimulus rises and falls abruptly and delivers its charge typically in about 1 ms. Because the current is off during most of the stimulus train, brief pulse square wave stimuli deliver a fraction of the charge per second of sine wave stimuli of equal current, yet have the same therapeutic quality (Valentine et al, 1968; Weaver and Williams, 1982; Weiner et al, 1986b; Scott et al, 1992).

The gradual rise and fall of the sine wave current to its peak delivers a substantial fraction of the stimulus charge below the minimum required for neural depolarization. The brief pulse, square wave stimulus was early found to be more efficient because its abrupt rise and fall delivers all charge above this minimum (Merritt and Putnam, 1938; Maxwell, 1968; Gordon, 1981).

The excess electrical dosage of the sine wave stimulus does not contribute to therapy, rather, it only produces adverse cognitive and electroencephalographic (EEG) effects. Compared with brief pulse ECT, sine wave ECT is associated with slower return of orientation (Valentine et al, 1968; Daniel and Crovitz, 1983;1986), greater retrograde amnesia for events shortly before treatment (Daniel et al, 1983), and more personal memory loss (Weiner et al, 1986a). In contrast, when brief pulse stimuli are administered via right unilateral treatment electrodes, memory and cognitive side-effects are reported to be undetectable (Weiner et al, 1986a), even with stimuli administered at high (336 mC) charge (Squire and Zouzounis, 1986).

The prevalence of ECT-induced EEG abnormalities (e.g., slowing, dysrhythmia, asymmetry) is also greater with sine wave than brief pulse stimuli (Bayles et al, 1950; Weiner et al, 1986b; Abrams et al, 1992).

Besides excessive side-effects, sine wave ECT has shown disappointing efficacy with right unilateral electrode placement (Abrams et al, 1983; Abrams, 1986; Mattes et al, 1990). In contrast, brief pulse right unilateral ECT can be given with efficacy comparable to bitemporal ECT (Abrams et al, 1991; Sackeim et al, 1992). Weaver et al (1982) reported that 3 patients who failed to obtain seizures with right unilateral sine-wave ECT at maximum stimulus dose were then treated successfully with brief pulse ECT. Thus, brief pulse ECT provides a double savings in cognitive effects by facilitating effective use of right unilateral ECT.

For the reasons detailed above, use of the constant voltage sine wave stimulus for ECT has been prohibited or discouraged by government agencies and professional associations in several countries. The British government required all its National Health Service Hospitals to replace their sine wave devices with brief pulse instruments (Department of Health, 1982), a decision emphasized by the Royal College of Psychiatrists (1989). In the U.S., the American Psychiatric Association Task Force on ECT (1990) recommends brief pulse instead of sine wave ECT. Similar recommendations have been made by the Ontario Psychiatric Association (Position Paper, 1985), and the Danish Psychiatric Association (Bolwig, 1987).

- *The Thymatron™ System IV employs a brief pulse square wave stimulus.*

CONSTANT CURRENT vs. CONSTANT VOLTAGE

Yet another substantial disadvantage of sine wave devices for patients is that the constant voltage they deliver makes the stimulus dose susceptible to variation with impedance (McClelland and McAllister, 1988; Weiner and Coffey, 1988). Low patient impedance (e.g., as with closely-spaced electrodes or sweaty skin) can elicit such high currents (Weiner and Coffey, 1986) as to cause second-degree skin burns (Abrams and Taylor, 1973). High patient impedance (e.g., in the elderly) cuts the charge and energy of the stimulus; not only does this remove control of the stimulus dose from the doctor, but it increases the likelihood of missed or ineffectively brief seizures.

- *The Thymatron™ System IV employs a constant-current stimulus.*

PULSE WIDTH

Perhaps the most important contrast between sine wave and brief pulse stimuli is in the pulse width. The 60 Hz sine wave of 8.3 ms. is about ten times wider than the 0.5 to 1.0 ms that is optimal for ECT (Swartz and Larson, 1989). Pulsewidths exceeding 1 ms. are inefficient because "longer pulses...produce satisfactory responses...only at a markedly higher total energy level" (Weaver et al, 1974), needlessly increasing cognitive side-effects and the risk-to-benefit ratio. The

electrophysiology of ECT suggests that pulse durations are most efficient when they do not substantially exceed the chronaxie of cerebral neurons (Liberson, 1945; Sackeim, 1994), estimated to be in the range of about 0.2 ms (Lapicque, 1926; Malmivuo and Plonsey, 1995).

Using a constant charge, Manly and Swartz (1977) found that seizures were easier to induce with a 0.5 ms pulsewidth than with wider pulses, and in a review of the relation of stimulus parameters to efficiency of seizure induction, Devanand et al (1998) concluded that "Basic research data suggest that increasing pulse width may be particularly inefficient in eliciting a seizure."

Thus, for treatment efficacy and efficiency, especially in older patients, it is necessary for a brief pulse device to be able to deliver its maximum stimulus dose using a pulsewidth in the physiologic range below 1 ms. Brief pulse machines that can only deliver their maximum charge at pulsewidths in the 1 -2 ms range are inefficient, causing missed seizures and attenuating the important cognitive advantage of the brief pulse stimulus.

- ***The Thymatron™ System IV is unique in providing pulsewidths as short as 0.25 ms. Equally important, the Thymatron™ System IV allows the maximum charge to be delivered with a pulsewidth as short as 0.5 ms).***

STIMULUS TRAIN DURATION

Of the various strategies for manipulating the stimulus in order to maximize the likelihood of obtaining a seizure, the most effective one is to increase the number of pulses (Weaver et al, 1977; Swartz and Larson, 1989; Swartz, 1993; Rasmussen, Zorumski and Jarvis, 1994; Isenberg et al, 1996; Devanand et al, 1998) and, therefore, the total duration over which the stimulus is applied (i.e., to increase the length of the stimulus train).

In preliminary studies, Swartz and Larson (1989) found that a 2 sec stimulus train duration was more likely to elicit seizures than a 1 sec duration, stimulus charge remaining constant, and Rasmussen, Zorumski and Jarvis (1994) found that the seizure thresholds they obtained with stimulus train durations as high as 2.8 sec were significantly lower than those previously reported using shorter stimulus trains. In the largest sample studied to date, Isenberg et al (1996) found a short pulsewidth, long pulse-train stimulus to be more than twice as effective as a wide pulsewidth, short-duration pulse train stimulus. Using a 1 ms pulsewidth Devanand et al (1998) have confirmed these views, finding that stimulus titration performed by varying pulse train duration was more efficient (i.e., resulted in lower seizure thresholds) than by varying pulse frequency.

In two studies of the clinical efficacy of brief pulse ECT given at a mean stimulus dose of about 2.5 times the minimum required for a seizure, investigators

employing a 3 sec stimulus duration (Abrams et al, 1991) reported substantially greater therapeutic efficacy than those using a 1 sec stimulus duration (Sackeim et al, 1992, 1993; Abrams and Swartz, 1992a,b). Still greater efficacy was reported by Pettinati et al (1990) using a stimulus duration between 3 and 4 seconds, suggesting the likelihood of additional benefit for even longer stimulus trains.

- *The Thymatron ™ System IV can deliver stimulus trains up to 8 sec, longer than any other brief pulse device. Equally important, the 8 sec stimulus train can be delivered using a pulsewidth as low as 0.25 ms.*

STIMULUS FREQUENCY

The interval between pulses is another crucial parameter for the efficacy and efficiency of ECT because neuronal depolarization and recovery take about 6 ms (Kandel et al, 1991). Stimulus frequencies above 83.3 Hz impinge on this 6 ms period, delivering about half the pulses during refractory phases. It is as important for brief pulse devices to be able to deliver the maximum stimulus at frequencies below 83.3 Hz as to deliver the maximum stimulus at pulsewidths below 0.5 ms. Brief pulse machines requiring a 90 Hz frequency to deliver the maximum stimulus are less efficient at inducing seizures than the Thymatron™ (Nilsen et al, 1986)

- *The Thymatron™ System IV has a 10-70 Hz frequency range in which even the lowest frequency (10 Hz) can be used to deliver the maximum charge.*

RELIABILITY IN PRODUCING SEIZURES

According to data collected by the Task Force on ECT Device Standards of the American Psychiatric Association (APA, 1982), both impedance and stimulus energy affect success in seizure induction.

a) In a sample of 756 treatments the dynamic impedance ranged from 120 to 520 ohms (mean = 220 ohms); 95% of measurements fell between 155 and 340 ohms (R. Weiner, M.D., personal communication).
b) In a sample of 2,044 treatments given with a brief pulse stimulus, 70 joules (joules = volts x Coulombs of charge) produced a seizure in every case.

Together these observations suggest that to maximize the likelihood of obtaining a seizure in every patient, a brief pulse ECT device must be capable of delivering at least 70 joules to a patient of 155 ohms impedance. This is the lowest impedance ordinarily encountered, and low impedance patients have the shortest seizures.

Although the relative contributions of voltage and charge to stimulus efficacy remains to be defined, the combination of a very small charge with a very high

voltage—e.g., as used for ultra-brief stimuli (Hyrman et al, 1985)—is ineffectual (Cronholm and Ottosson, 1963).

- ***At maximum setting, the Thymatron™ System IV will deliver 70 joules to a patient of 155 ohms impedance.***

At Gracie Square Hospital in New York City, the Thymatron™ was virtually 100% reliable in producing seizures in over 1100 consecutive ECT sessions (Mouzon, 1986), a result that was confirmed by DiMichele et al (1989), who reported 99% seizure induction in 557 consecutive treatments.

STIMULUS CHARGE vs. STIMULUS ENERGY

Sackeim et al (1987a) reported that the smallest charge to induce a generalized seizure of specified minimum duration was 36 to 459 mC (mean = 154 mC). They found a strong inverse relation between this charge and dynamic impedance (about twice as much variance in the minimum dose was accounted for by charge as energy). Energy was insensitive to sex differences, whereas men required a substantially higher minimum charge than women. These findings concur with preferences already expressed (Gordon, 1982; Gangadhar et al, 1985) for quantifying stimulus dose in units of charge (mC) rather than energy (joules).

- ***The Thymatron™ System IV allows the physician to directly set the stimulus charge with the "Percent Energy" dial, which always provides stimulus increments of 25.2 mC each, regardless of the pulsewidth, frequency, or stimulus mode selected.***

SEIZURE THRESHOLD & DURATION VS. TREATMENT RESPONSE

The seizure threshold is multi-determined and dependent on the methods used to measure it. Several investigators have used a method-of-limits stimulus titration procedure with different stimulus parameters and seizure criteria to obtain widely differing seizure threshold estimations (Weaver et al, 1978; Weiner, 1980; Sackeim et al, 1987a,1987b).

Sackeim et al (1987a; 1993) recommended a particular method of estimating the seizure threshold prior to stimulus selection. However, because of limitations on the ECT device they used (Sackeim et al, 1992), these investigators chose to maintain the stimulus train duration constant at 1 sec, and to titrate dosage by varying the stimulus frequency to as high as 140 Hz; this strategy yielded a mean minimum dose of 154 mC in their patients (Sackeim et al, 1987a,b).

Approaching the problem from a different perspective, Swartz and Larson (1989) found that a constant 144 mC charge was more effective in producing seizures of at least 20 sec. duration when administered with a 2-second stimulus train

than with a 1-second train. Their study demonstrates the dependence of threshold measures on the particular stimulus characteristics selected, and suggests that the threshold of 154 mC reported by Sackeim et al (1987a,b) might have been substantially smaller had a longer stimulus train or a lower stimulus frequency been used. The recent study of Devanand et al (1998) confirms this expectation: the mean seizure threshold obtained with shorter pulse train durations was below 100 mC. [*add Rosenquist et al citation here*]

However determined, the seizure threshold has never specifically been related to treatment efficacy, nor is there a quantitative model that predicts clinical efficacy from the seizure threshold—the efficacy of ECT given near threshold simply varies with treatment electrode placement. The mere occurrence of seizures exceeding a specified minimum motor or EEG duration does not of itself assure good efficacy, because right unilateral ECT given just above or even 2.5 times threshold yields very low remission rates despite inducing seizures of "adequate" length (Sackeim et al, 1993).

From a therapeutic perspective, the simple fact is that those studies using a fixed, high stimulus dose (Abrams et al, 1991; Pettinati, 1994; Lamy et al, 1994; McCall et al, 1995) have obtained substantially better clinical results in depression than those using the titration method (Sackeim et al, 1987a, 1993; Letemendia et al, 1993; McCall et al, 1995).

A seizure-related event that correlated with outcome would be a far better clinical guide to treatment than simple seizure occurrence or duration; several such events have been proposed (Nobler et al, 1993; Krystal et al, 1993, 1995, 1996; Krystal, 1998; Petrides et al, 2000) and are described in the section on *Seizure Quality Measures* below. For example, the important finding that ECT responders exhibit greater postictal suppression than non-responders, and that greater symptomatic improvement with ECT is associated with greater postictal suppression, strongly suggest that the stimulus charge necessary to induce a seizure with a high degree of postictal suppression (i.e., the "Postictal Suppression Threshold") should prove a more useful guide to stimulus selection than the charge required to produce a minimum duration seizure.

- ***The new Seizure Quality Measures of the Thymatron™ System IV for the first time empower the physician with the means to determine clinically relevant physiologic and therapeutic thresholds from actual practice (e.g., a Postictal Suppression Threshold), for rational stimulus selection without repeated subconvulsive stimulations.***

This being said, the Thymatron™ System IV nevertheless also provides the clinician with the *fastest and easiest stimulus titration method* of any brief pulse ECT instrument, as described below.

INDEPENDENT TESTING LABORATORY CERTIFICATION

With full patient isolation from the electrical mains current, Instant Impedance™ test meter, and treatment button protector, Thymatron™ ECT instruments have been certified by many independent safety testing laboratories, and meet the international standards set by ISO 9000 and IEC 601 for obtaining the CE mark. Additional protective features of the Thymatron™ System IV include a 1 sec stimulus delay with warning tone, characteristic buzzing sound and illumination of the oversized treatment button while the stimulus is on, patented *Audible EEG*™ monitor, *and Extended Seizure Alert.*

EASE OF USE

The rational stimulus dosing method of simply setting the stimulus dial according to the patient's age saves time while automatically providing a stimulus dose most likely to induce an effective seizure. The integral front-panel *FlexDial*™ for rapid selection of all stimulus parameters and special features, *Instant Impedance*™ testing without the need for bypass or override, the built-in elapsed time clock for timing seizure duration, the automatic, paperless *Audible EEG*™ monitor, the Thymapad™ disposable stimulus electrodes, Ventil-A™ disposable mouth protectors, and the automatic printout of EEG, EMG, and ECG seizure duration estimates, and the multiple *Seizure Quality Features*, all substantially facilitate efficient treatment and monitoring.

DESCRIPTION OF FEATURES

FOUR-CHANNEL MONITOR-RECORDER

The Thymatron™ System IV's 4-Channel monitor-recorder allows the treating physician to simultaneously monitor and record 2 channels of EEG and 1 channel each of ECG and EMG, with the *digital heart rate* and the time elapsed since stimulus delivery printed each second along the edge of the strip. At the end of the treatment, any or all of the clinical variables described in the following paragraphs are printed.

In comparison to transient oscilloscopic-type monitoring displays that require constant vigilance to observe and comprehend (during which time attention must be diverted from the patient), and that disappear from view in a few seconds, the permanent 4-channel treatment record produced by the Thymatron™ System IV's monitor allows the treating physician ample time to examine the quality of all aspects of the tracing, integrate this knowledge with that provided by the *Seizure Quality Measures*, and form a judgment on the next step to be taken. The 4-channel recording and integral end-of-treatment printed report are suitable for inclusion in the patient's permanent record.

FLEXDIAL™ SELECTOR/PROGRAMMER

This front-panel dial -and-button combination lets the treating physician rapidly set all of the variable features of the Thymatron™ System IV without having to scroll through multiple touch-screens of choices. (It can also be bypassed by simply accepting the preselected values for all variables, chosen to reflect standard clinical ECT practice). The *FlexDial*™ controls stimulus parameter selection, monitoring and recording parameters, and the selection of the special computer features of the Thymatron™ System IV, including preset and user-assignable programs, as follows.

***Stimulus frequency and pulsewidth*—individually, or combined according to preset or user-assignable stimulus programs. Includes a stimulus choice that reproduces the settings of the *Thymatron™ DGx*, two *Optimal Charge Rate* programs (using ¼ and ½ ms pulsewidths, respectively), an intermittent *Pulse Volley* stimulus, a *Double Dose* selection (where available), a program that automatically sets and stores any *User-entered Stimulus Combination*, and a program that reproduces all the standard settings of the *Thymatron DGx*.**

***Automated Seizure monitoring and endpoint* features—including the *Automatic EEG, EMG, and ECG* seizure duration estimates, the *Peak Heart Rate* report, and the *Extended Seizure Alert* signal.**

EEG Seizure Quality* and related measures—including the *Seizure Energy Index, Postictal Suppression Index, Seizure Generalization Index, Maximum

Sustained Power, Time to Peak Power, Maximum Sustained Coherence, Time to Peak Coherence, and Duke University **ictal amplitude measures.**

***User-Specified FlexDial Configurations*—allows the physician to set and store up to 8 different combinations of stimulus, recording, monitoring, and reporting features.**

***Printing Options*—for the *Power Spectral Analysis* table, *the End-of-Treatment* report, and each of the 4 monitoring-recording channels.**

Date & Time set for the printed report.

Channel 1-4 Position & Gain settings.

***Data In and Out options*—for data transfer to and from a PC via the Thymatron™ System IV's RS232 (serial) port. Allows user to *reprint the complete data*, including all tracings, from the treatment just given, and send *raw, digitized, or FFT EEG to a PC* for storage and analysis.**

AUTOMATIC EEG, EMG, and ECG analyzer (U.S. Patents 4873981, 4878498, 5269302, and 5871517).

This computer-automated analyzer automatically processes the EEG, EMG, and ECG during the ECT-induced seizure, estimates the seizure endpoint from each according to specific criteria, and prints the 3 corresponding seizure duration estimates in the end-of-treatment report.

Reliability and validity of Thymatron™ System IV computer-derived EEG, EMG, and seizure endpoint estimates.

The EEG seizure duration assessed from moving average EEG correlates highly with seizure duration assessed from unprocessed EEG (Couture et al, 1988a, b; Gilmore et al, 1991). Even higher validity has now been obtained with the Thymatron™ 's integral EEG and EMG computer analyzer according to comparisons with two expert clinicians' separate visual assessments of the same records. For EEG the agreement (by weighted kappa) between the Thymatron™ and the experts was 0.98; for EMG, the agreement was 0.92 (Swartz et al, 1994). Krystal and Weiner (1995) confirmed this high validity, reporting correlations between the Thymatron™ and their own blind analysis of the EEG and EMG tracings ranging from 0.83 to 0.90 ($p<.001$), and noting that the Thymatron™ failed to identify the seizure endpoint in only 1/40 instances, despite the fact that the majority of the seizures were rated as having a gradual endpoint.

The computer algorithm for estimating the seizure endpoint from ECG derives from the study of Larson, Swartz, and Abrams (1984), who found a close correspondence between the durations of the ECT-induced tachycardia and the concurrent paroxysmal EEG activity. The correlation between the point of maximal heart rate deceleration towards the end of the seizure and cessation of all paroxysmal EEG activity was 0.75 ($p<.0001$).

In addition to computer-automated monitoring and interpretation of the EEG, EMG, and ECG, the Thymatron™ System IV provides the treating physician with several other unique features described below.

SEIZURE QUALITY MEASURES

Traditionally, doctors have had to guess at the therapeutic quality of each ECT, with no physiological measures other than seizure duration to guide them; this is analogous to giving antidepressant drugs without the feedback from blood drug levels. Although measuring seizure duration is necessary to ensure that a minimum duration has been achieved and to confirm that paroxysmal cerebral activity has ended, given adequate seizure length, total seizure duration has invariably been found irrelevant to the therapeutic efficacy of ECT (Abrams et al, 1972; 1983; Sackeim et al, 1987a,b; Weiner et al, 1991; Nobler et al, 1993).

In a series of studies at Duke University attempting to identify specific markers of ECT seizure efficacy (Krystal and Weiner, 1992; Krystal et al, 1993, 1995,1996; Krystal, 1998) several proposed measures of ECT seizure "adequacy" were examined and found to predict the efficacy of ECT in depressed patients: greater EEG amplitude during the seizure, increased interhemispheric EEG coherence during the seizure, and reduced interhemispheric coherence (increased postictal suppression) immediately following the seizure.

Beginning almost a decade ago, Thymatron™ instruments were the first to include such physiological markers. Now, the Thymatron™ System IV offers the following expanded range of computer-automated measures intended to provide the clinician even more specific evidence of the physiologic quality of a given seizure than its duration alone.

POSTICTAL SUPPRESSION INDEX

A variety of evidence suggests that more intense and more generalized seizures are followed by greater immediate postictal EEG suppression (Enderle et al, 1986; Weiner et al, 1991; Krystal et al, 1992; Nobler et al, 1993; Krystal et al, 1998; Petrides et al, 2000).

Lidocaine-modified seizures lack therapeutic efficacy and show little postictal suppression (Ottosson, 1960); less postictal suppression also accompanies right unilateral than bitemporal ECT (Small et al., 1970; Abrams et al., 1973; Weiner, 1986; Nobler et al, 1993). Weiner et al (1991) asserted that "...the degree of postictal suppression [is] a measure believed to be more directly related to the intensity or generalization of the seizure rather than to its duration...". As noted above, Nobler et al (1993) provided the first direct demonstration under controlled conditions that greater postictal suppression corresponds to greater clinical improvement.

The *Postictal Suppression Index* reflects how quickly and completely the EEG amplitude falls ("flattens") just after the end of the seizure. It is computed as the 3-second mean amplitude beginning 0.5 sec. after seizure termination, divided by the mean 3-second peak amplitude obtained during the seizure, and expressed as the percent suppression (range 0% to 100%) in the printed report.

SEIZURE GENERALIZATION INDEX

This index—originally computed from EEG and EMG by the Thymatron™ DGx, and designated the *seizure concordance index*—now combines 3 separate seizure duration estimates obtained by the Thymatron™ System IV from EEG, EMG, and ECG, in a single measure that reflects the concordance among the 3 different endpoint estimates, which may vary considerably. EEG seizures are about 30% longer than motor seizures (Abrams et al, 1973; Larson et al, 1984; Liston et al, 1988; Couture et al, 1988b; Gilmore et al, 1991). Swartz and Larson (1986) found the correlation between EEG and motor seizure durations to be significantly larger for bitemporal than right unilateral ECT. Because EMG reflects cortical motor strip discharges, the prefrontal EEG reflects more anterior cortical activity, and the ECG reflects brainstem activity, the concordance among the three measures—the *Seizure Generalization Index*—provides a presumptive measure of intracerebral seizure generalization, a proposed major component of therapeutic efficacy.

EEG AMPLITUDE AND POWER MEASURES

Just as neurophysiologists routinely describe neural responses to stimuli in terms of magnitude (e.g., voltage) and duration, characterization of the ECT-induced seizure requires a measure of intensity as well as duration. Higher integrated EEG voltage, for example, occurs during seizures induced by bitemporal as compared with right unilateral ECT (d'Elia and Perris, 1970), and peak EEG slow wave amplitudes are greater with high-dose than low-dose bitemporal ECT and right unilateral ECT, regardless of dose.

The clinical implications of this are important. According to Weiner et al (1991), "...seizures elicited by stimuli close to threshold are often characterized by a lower amplitude and less regular ictal pattern", and "...increasing stimulus intensity at the same (or the next) ECT treatment was associated with a higher amplitude and/or greater regularity of the ictal EEG response." In subsequent studies of the Duke University group cited above, (Krystal and Weiner, 1992; Krystal et al, 1993, 1995,1996; Krystal, 1998), greater ictal EEG amplitudes were associated with better-generalized seizures and a better therapeutic response in depression; other investigators have reported similar results (Folkerts, 1996; Hrdlicka et al, 1996).

The Thymatron™ System IV provides 4 different measures of ictal EEG amplitude or power: *Seizure Energy Index, Maximum Sustained EEG Power, Time to Peak Powere,* and the Duke-University-proposed measures of *early-ictal, mid-ictal,* and *post-ictal EEG amplitude.*

***Seizure Energy Index*: This index integrates EEG power throughout the duration of the seizure and prints this total value in the end-of-treatment printed report. Calculation of the *Seizure Energy Index* necessarily includes the variable of seizure length; the remaining measures reflect only amplitude or power, without regard to seizure duration.**

***Time to Peak EEG Power:* This is a measure of the number of seconds elapsed before the point of maximum EEG power is reached.**

***Maximum Sustained EEG Power*: Rather than simply averaging EEG seizure amplitude across the entire seizure, this measure identifies the segment of the seizure with the *highest* average power, thus reflecting the maximum output capacity of the brain achieved during that particular seizure.**

***Early-ictal, Mid-ictal, and Post-ictal EEG Amplitudes*: These are calculated according to the published method of the Duke University group and allow the treating physician to separately assess the mean amplitudes of 3 different seizure phases that have correlated with seizure generalization and treatment response in depression (Krystal et al, 1992, 1995, 1996).**

COHERENCE MEASURES

EEG coherence is an inter-hemispheric cross-correlational measure of the extent to which the two sides of the brain are discharging in unison. When the ECT stimulus first reaches the cortex it initiates depolarization of cortical neurons, establishing localized areas of cortical discharge which then eventually spread to the brainstem (centrencephalon), thereby causing a generalized, grand-mal seizure (Abrams, 1997). The degree to which both hemispheres respond to the driving of this centrencephalic pacemaker reflects how well-generalized the seizure is throughout the brain.

Clinically, interhemispheric coherence measures have been shown to reflect seizure quality and therapeutic impact during ECT (Roemer et al, 1990-1991; Krystal and Weiner, 1994; Krystal et al, 1995; Krystal, 1998). The Thymatron™ System IV provides two separate measures of EEG coherence during the seizure: *Peak Coherence*, and *Maximum Sustained Coherence.*

***Peak Coherence*: This is a measure of the maximum coherence measured in any epoch during the seizure.**

***Maximum Sustained Coherence*: This is a measure of the highest coherence measured over any 3 sec seizure segment during the seizure.**

PEAK HEART RATE

The brainstem-driven tachycardia that occurs during the ECT-induced seizure correlates highly with the EEG and motor aspects of the seizure (Larson, Swartz, and Abrams, 1984), differentiates between unilaterally- and bilaterally-induced seizures (Lane et al, 1989), and provides evidence for broad intracerebral generalization of the seizure activity (Swartz 1993;1996).

The Thymatron™ System IV automatically determines the *Peak Heart Rate* and prints this figure in the end-of-treatment report.

POWER SPECTRAL ANALYSIS

Power spectral analysis is a powerful tool for breaking down the broad frequency range of the EEG signal into its component waveforms, frequency by frequency, computing the EEG power contained in each bandwidth, and displaying the results. All modern, computer-analytic EEG studies are based on power spectral analysis, but its usefulness is by no means limited to research—it can provide important clinical information as well.

For example, an early study (Fink & Kahn, 1957) showed a significant correlation between ECT-induced slowing in the delta EEG frequency band (the *delta index*) as recorded on days between treatments, and the ultimate therapeutic response to ECT. In an important recent confirmation of this work, Sackeim et al (1996) showed that increased interictal frontal delta EEG activity significantly predicted clinical improvement in depressed patients. The conclusion from these two studies performed more than 40 years apart is the same: the degree of frontal EEG slowing in the delta range recorded over a treatment course is an important correlate of treatment response that can serve as a guide to treatment.

The Thymatron™ System IV's powerful 32-bit internal computer digitizes, de-artifacts, analyzes (using the fast Fourier transform algorithm), stores, and prints up to 10 minutes of continuous EEG recording in the form of *a Power Spectral Analytic* array. *In fact, the Thymatron™ System IV has all the functions of a sophisticated digital 4-channel EEG machine.* These allow the clinician to measure, for example, the amount of cumulative frontal EEG delta activity *between* ECTs, as a guide to treatment efficacy (Fink and Kahn, 1957; Sackeim et al, 1996).

THE ICTAL LINE™ EEG SEIZURE INDICATOR

After the stimulus is delivered, a thin black line appears at the top of the paper recording strip as long as EEG seizure activity exceeds a specified amplitude *determined individually* for each patient by the Thymatron™ System IV.

EXTENDED SEIZURE ALERTING SIGNAL

Because ECT-induced EEG seizures rarely last longer than 90 seconds (Weiner, 1980), and longer durations have been associated with cognitive side-effects but not therapeutic quality (Miller et al, 1985), consideration should be given to termination of seizures that exceed 120 to 180 seconds EEG activity (APA, 1990; Abrams, 1990). To remind the clinician that this point is approaching, the EEG seizure monitor provides an intermittent click tone when a preset number (e.g., 120) of post-stimulus seconds have elapsed and the "START/STOP" or "IMPEDANCE TEST" buttons have not been pressed, or the "POWER" button turned off.

AUDIBLE EEG™ SEIZURE MONITOR (U.S. PATENT 4777952)

Every Thymatron™ System IV is equipped with a unique, patented Audible EEG™ seizure monitor that produces an auditory electronic signal from the cerebral EEG. Judgment of the seizure end-point using the *Audible EEG*™ monitor has been determined to be reliable and valid (Swartz and Abrams, 1986; Weiner et al, 1987), and it has successfully been used to detect prolonged seizures (Chen et al, 1990). The Audible EEG™ allows the treating physician to monitor the progress of the seizure from anywhere in the treatment room—or even outside the room—and without any danger of missing the seizure endpoint because of exhaustion of recording paper (Weiner, 1980).

INSTANT IMPEDANCE™ TEST

The static impedance is measured by passing a tiny high-frequency current across the treatment electrodes; the current is far too small to feel. This static impedance tends to be several times larger than the dynamic impedance to the treatment current of 0.9 A. The Thymatron™ System IV's Instant Impedance test stimulus uses an electrical frequency (1000 Hz) not necessarily near those of other impedance testing instruments, so the corresponding impedance results are generally not directly comparable with them.

ELAPSED TIME CLOCK

After the "TREAT" button is pressed and released, the L.E.D. shows seconds elapsed from the end of the treatment stimulus until the "Start/Stop", "IMPEDANCE TEST" or "POWER" button is pressed. This facilitates monitoring seizure duration.

EXTRA HAND™ REMOTE TREATMENT PEDAL BUTTON [_Not available in the EEC_]

The Extra Hand remote treatment pedal button can replace the "TREAT" button in function. It permits the physician use of both hands during stimulus administration. Its weighted metal base shields the unit from accidental triggering as has occurred with remote-treat buttons incorporated into treatment electrode handles.

PULSE VOLLEY STIMULUS MODE

The _Pulse Volley_ stimulus mode consists of a series of 1 ms pulses clustered in 100 ms volleys of 7 pulse-pairs each, with 100 ms pauses between volleys—similar to the S_iemens Konvulsator_. Each _Pulse Volley_ train is exactly twice as long as a regular Thymatron™ System IV stimulus of 1 ms, 70 Hz, but has the same charge. Thus, at 100% Energy the _Pulse Volley_ stimulus lasts 8 sec and has a 504 mC charge.

DOUBLE DOSE MODE (where available)

Doubles the stimulus charge at each % ENERGY setting so that the % Energy dial ranges from 10% to 200% in 10% increments, corresponding to 50.4 to 1008 mC in 50.4 mC increments). _Not available in the U.S._

OPTIMAL CHARGE RATE PROGRAM

As noted above, the Columbia University group (Devenand et al, 1998), reports that increasing the pulse train duration of the stimulus is the most efficient way to elicit a seizure, followed by increasing the frequency.

Swartz (1994, 1995) has approached this problem by focusing on the rate of administration of the stimulus charge in relation to efficiency of seizure induction, observing that lower charge rates were consistent with greater efficacy of seizure induction and better-quality seizures.

The Thymatron™ System IV features a user-selectable _Optimal Charge Rate_ program that employs both principles outlined above. This program first selects the lowest possible pulsewidth (_down to ¼ ms_) and then the lowest possible frequency (_down to 10 Hz_) to maximize stimulus duration (_up to 8 sec_), and minimize charge rate, for the particular stimulus charge set by the physician with the % Energy dial.

A _Low Charge Rate_ Program is also available, which always uses a ½ ms pulsewidth and systematically varies frequency (beginning at 30 Hz) to yield long-duration (_up to 8 sec_), low charge rate, stimuli.

SPECIAL SAFETY MONITORING CIRCUIT

To fulfill international safety standards and assure that patients will not receive a stimulus exceeding the dose setting even if any electronic component fails, TUV-approved Thymatron™ System IV models incorporate a special dose-measuring and -limiting circuit with alarm system that is independent of the regular circuitry. Required to meet the stringent safety standards of TUV-Bavaria, this circuit (unique to the Thymatron™ System IV) prevents the patient from receiving an electrical stimulus that varies more than +/- 5% from specifications.

"JUST SET TO PATIENT'S AGE AND TREAT"

Since 1985 this rational stimulus selection method has made treatment with the Thymatron™ easy and reliable. The scientific basis for this is the observation that seizure duration falls with age, first applied by Ottosson (1960)—who systematically increased stimulus dose for each decade of age—and subsequently confirmed by numerous other investigators who found seizure threshold to be strongly correlated with age (Abrams, 1997).

For just-above-threshold seizure induction, patients receiving brief pulse right unilateral ECT require a stimulus dose (when expressed in mC) that is about twice their age. Thus, a just-above-threshold dose for a 50 yr old patient would be about 100 mC (20% Energy on the Thymatron stimulus dial). However, right unilateral ECT stimuli are ineffectual when given at this minimum dosage (Abrams, 1997), and efficacy for right unilateral ECT comparable to bitemporal ECT may require a stimulus charge that is many multiples of the patient's age (e.g., 350 mC to 500 mC for a 50 yr old patient, which is equivalent to70% to 100% Energy on the Thymatron stimulus dial). Cognitive advantages of right unilateral ECT have been reported to be preserved at such stimulus doses, i.e., 336 mC (Squire and Zouzounis, 1986; Sackeim et al, 2000).

THYMAPAD™ ADHERENT STIMULUS ELECTRODES (U.S. pat. 477952)

Reusable electrodes have transmitted a variety of infectious pathogens between patients (Lockley et al, 1973; Murray et al, 1986a; Cefai et al, 1988; Elliot, 1989; Nolan et al, 1991). Incomplete decontamination and disinfection are the main causes, and these are bypassed by the use of disposable electrodes (Berlin et al, 1986; Young, 1987).

In addition to reducing cross-infections, the care of which is not often reimbursed, Thymapad™ adherent stimulus electrodes have the following advantages:

1. **Reduced risks to medical personnel of accidental and potentially dangerous electrical shocks; there are no exposed metal surfaces or connectors**
2. **The self-adherence and flexible conformity of Thymapads™ to skin surfaces reduces risks of skin burn and diminished efficacy from electrode slippage during the stimulus.**
3. **Thymapads™ avoid subjecting apprehensive, agitated or irritable patients to the unpleasant sensation and potentially frightening experience of cold metal electrodes wrapped tightly around the head with a rubber strap, and additional uncomfortable pressure when the electrode plug is inserted.**
4. **Thymapads™ facilitate treatment in restless or uncooperative patients by avoiding awkward wrapping of a headstrap around the back of the head and over the ears—especially problematic if the patient won't lift his head or has long hair. In fact, many physicians prefer simply to apply Thymapads™ after the patient is asleep.**
5. **Use of Thymapads™ frees the doctor to use his hands for other purposes (e.g., pressing the "TREAT" button).**

MICRO-STIM TEST FOR MUSCLE-RELAXATION

A battery-powered hand-held nerve stimulator [Somatics Micro-Stim, ENS1] provides a convenient measure of the degree of muscle-relaxation: repeated stimulations of the radial nerve over the ventral forearm (of the arm without the blood-pressure cuff) are started as soon as the succinylcholine is administered, producing clonic contractions of the hand muscles. Alternatively, the nerve stimulator electrodes can be placed one inch lateral to the tibia, half-way between ankle and knee, to produce dorsiflexion of the foot. When the muscle contraction response is abolished or markedly attenuated, the patient is ready to be treated. Succinylcholine dosage for subsequent treatments should be adjusted according to the patient's response.

SOMATICS' ORAL PROTECTORS

During ECT, an oral protector is inserted to protect the teeth, lips, and tongue from excessive stress. Direct electrical stimulation of the jaw muscles during ECT causes them to clamp the teeth shut, severely stressing the fragile incisors (Durrant, 1966) and risking tongue bite. An air channel is also required for ventilation before, during, and after the seizure.

The Thymatron™ System IV is shipped with 2 types of oral protectors for ECT, Somatics' traditional multiple-use, sterilizable rubber MouthGuard™, and the new, patented, single-use Ventil-A™ model, which is non-sterilizable.

***Somatics' multiple-use MouthGuard™* is constructed of synthetic rubber and guaranteed to withstand autoclaving and other standard sterilization methods. It**

has a tubular air-channel, and a protective rim that fits between the teeth and the lips. It comes in 2 sizes, to fit all patients.

Somatics' single-use Ventil-A™ oral protector **is constructed of closed-cell foam and is the only single-use oral protector to cushion all the teeth and to feature an integral air-channel that does not obstruct oxygen mask application. Its design was based on measurements of dozens of adult dental impression molds, and its one size is guaranteed to fit over 95% of patients.**

OPERATING INSTRUCTIONS

Front Panel Layout

The new Thymatron™ System IV features two front-panel controls for display and selection of all treatment choices: the PERCENT ENERGY dial, and the *FlexDial*™ selector.

In addition, you will see a POWER switch (power on/off), an IMPEDANCE TEST button, a START/STOP button (to manually control the 4-channel printer), a TREAT button (to deliver the treatment stimulus), two alphanumeric L.E.D.s (the left one with 8 characters, the right one with 4 characters), and 4 individual dot L.E.D.s (to indicate activation of the *FlexDial*™ selection mode, activation of the *Safety Monitor* alarm, and whether a *preset* or a *user*-set program is in effect).

POWER ON/OFF

Be sure the power cable is plugged into a grounded, 3-prong hospital-grade socket. Press the top half of the front-panel POWER switch (labeled "I") to turn the unit on; press the bottom half of the POWER switch (labeled "0") to turn the unit off.

SELF TEST

The Thymatron System IV incorporates an automatic self-test feature that tests the integrity of all circuits. When the unit is first powered on, the flashing message "SELFTEST" appears for a few seconds in the 8-character L.E.D., following which a self-test confirmation report is printed and the words "NO BASE" appear in the 8-character L.E.D., indicating that baseline EEG collection still has to be accomplished

PERCENT ENERGY DIAL

This dial-and-button combination has two functions.

1. **Rotation of the dial displays the % ENERGY settings for each stimulus dose, followed by a 1-second display of the corresponding stimulus charge in mC.**
2. **A press of the central button displays a reminder in the 4-character L.E.D. of the stimulus program currently in effect (the one most recently selected via the *FlexDial*™).**

To Set Stimulus Dose

Rotate the % ENERGY dial to display the available stimulus settings (range: 5% to 100% ENERGY in 5% increments). Stop rotating the dial at the desired % ENERGY setting. A 1-second display then appears of the charge in millicoulombs (mC) that corresponds to the % ENERGY setting, followed by a return to the % ENERGY display. *To display the corresponding charge again, briefly rotate the % energy dial in either direction and back to the desired setting.*
Press and hold the central button at any time to display an abbreviated 4-character L.E.D. identification of the *FlexDial*™ stimulus program currently in effect. Release the button to return to the % ENERGY display.

Because stimulus duration is limited to a maximum of 8 sec, the higher % Energy settings may not be available when using the lower range of pulsewidth and frequency values. Whenever the % Energy setting for a given pulsewidth and frequency would cause the stimulus duration to exceed 8 sec, the message > 8s will briefly appear in the display, followed by a display of the maximum % Energy available for the particular stimulus parameters or program chosen.

LIGHT-EMITTING FUNCTION DISPLAYS

The Thymatron™ System IV front panel has two alphanumeric L.E.D.s (the left one with 8 characters, the right one with 4 characters), and 4 individual dot L.E.D.s

8-character L.E.D.

Located directly above the IMPEDANCE TEST button, this L.E.D. has the following functions:

1. **It displays the message "SELFTEST" immediately the unit is powered on.**
2. **It displays the message "NO BASE" following completion of the self-test procedure and before baseline EEG collection has been accomplished.**
3. **It displays the message "READY" when baseline EEG collection has been accomplished.**
4. **It displays the *static impedance in ohms* when the "IMPEDANCE TEST" button is pressed, and continues to display this figure until the button is released.**
5. **After the "TREAT" button is pressed and released, it shows the *time elapsed in sec* since the end of the stimulus.**
6. **It displays the flashing message "REPORT" when the START/STOP button is pressed to terminate recording and the end-of-treatment report is being printed.**
7. **It displays the designations and values of all *FlexDial*™-selectable variables during their setup.**

4-character L.E.D.

Located directly above the PERCENT ENERGY dial this L.E.D. has the following functions:

1. **It displays the % Energy choices as the % Energy dial is rotated.**
2. **It briefly displays the millicoulombs of *charge* corresponding to each % Energy dial setting.**
3. **It displays a reminder of the *stimulus program in effect* when the central button of the % Energy dial is pressed.**

Dot L.E.D.s

1. **The one labeled "FLEXDIAL" flashes whenever the *FlexDial*™ is in use.**
2. **The one labeled "SAFETY MONITOR ACTIVATED" flashes when *the Safety Monitor* has been activated.**
3. **The one labeled "SETTING" lights when a *preset FlexDial*™ program is in effect.**
4. **The one labeled "USER SET" lights when a *user-set FlexDial*™ program is in effect.**

SAFETY MONITOR CIRCUIT ALARM TEST

The Thymatron™ System IV has a special *Safety Monitor Circuit* test button on the back panel labeled "ALARM TEST". The *Safety Monitor Circuit* can be tested as follows:

1. **Turn power to Thymatron™ System IV on; do not connect cables.**
2. **Set % Energy dial to any setting.**
3. **Connect ECT treatment cable clips to 200 ohm, 10 watt load.**
4. **Press and hold down rear panel "ALARM TEST" button while pressing the TREAT" button as if giving a real treatment.**
5. **Continue pressing "ALARM TEST" and "TREAT" buttons while the Thymatron™ System IV goes through the full cycle of warning signal and stimulus indicator tones.**

At the end of the stimulus indicator tone the "SAFETY MONITOR ACTIVATED" front panel indicator light will go on and a high-pitched, continuous signal tone will sound until the unit is powered off. If the indicator light and alarm signal tone do not occur, do not use the unit to treat patients until it has been examined and cleared by authorized biomedical personnel.

FRONT PANEL JACKS

ECT Stimulus jack

This 9-pin jack labeled "ECT" is located directly below and to the *left* of the IMPEDANCE TEST button. It accepts the plug from the *ECT Stimulus Cable.*

EEG/EMG/ECG Recording Jack

This 9-pin jack labeled "EEG/EMG/ECG" is located directly below and to the *right* of the IMPEDANCE TEST button. It accepts the plug from the *EEG/EMG/ECG recording cable.*

[NOTE: It is impossible to insert the plug from the stimulus cable into the recording jack, and vice versa]

FLEXDIAL™ OPERATION

The *FlexDial*™ ADJUSTS by *turning* the dial and SETs by *pressing* it. It enables the selection of multiple functions by the following general principles:

1. Rotating the *FlexDial*™ clockwise or counterclockwise provides a continuous-loop display of its functions. That is, from any function location you can reach any other function location by turning the dial in *either* direction.

2. Pressing the *FlexDial*™ selects the function displayed in the 8-character L.E.D. and advances to the next choice.

After power up, press the *FlexDial*™ to enter *FlexDial*™ selection mode. The *FlexDial*™ dot L.E.D. flashes and the most recently-set function (e.g., "SETTING") will appear in the 8-character alphanumeric L.E.D.. This indicates that you are now in the *FlexDial*™ "shell"—the initial, or primary, layer of the *FlexDial*™ locations of which "SETTING" is one.

These headings (e.g., "SETTING", "PROGRAMS", "PRINTOUT", "INDEXES", etc.) do not themselves change a particular setting, but are the *FlexDial*™ locations (the *FlexDial*™ shell entry-points) for a range of related specific selections. For example, pressing the "PROGRAMS" heading leads you to a related series of choices enabling you to enable/disable the traditional Thymatron™ stimulus settings (*Default*), the *Optimal Charge Rate* programs, the *Pulse Volley* stimulus mode, the *Double Dose* mode (where available), and a *User-Selectable* stimulus mode. *[NOTE:* Once a variable is set with the FlexDial™ *it remains in effect until changed, even when the unit is powered off.]*

The precise method for selecting each of the *FlexDial*™ variables is given below in the sections describing the individual features.

LOADING PRINTER PAPER

The Thymatron™ System IV printer paper holder is located just below the Somatics logo on the front panel. Press the arrow on the printer cover release bar just above the printer cover to open the paper holder and view the instructions for loading the fan-fold paper.

CONNECTING THE ECT STIMULUS CABLE

Connect the plug of the *black* ECT stimulus cable to the jack labeled "ECT", located on the front panel, just beneath the triangular symbol containing an exclamation point.

CONNECTING THE EEG/ECG/EMG RECORDING (PATIENT CONNECTION) CABLE

Connect the plug of the *gray* EEG/ECG/EMG recording (patient connection) cable to the jack labeled "EEG/ECG/EMG", located on the front panel, just to the right of symbol of the human figure inside a box.

[NOTE: For safety, it is impossible to insert the plug from one cable into the jack for the other, and vice versa.]

CONNECTING EEG/ECG/EMG RECORDING LEAD WIRES

[See figure below]

The Thymatron™ System IV is shipped with 9 standard-length lead wires: 4 red, 4 black, and 1 green; plus 2 extra-length brown lead wires for recording the channel 4 EMG from the leg, if desired.

Plug the 4 red lead wires into the 4 receptacles (for channels 1,2,3 & 4) indicated by red dots on the lead wire holder attached to the end of the gray cable, and plug the 4 black lead wires into the corresponding 4 receptacles (for channels 1,2,3 & 4) indicated by black dots. Plug the green lead wire into the green receptacle marked "*Iso Gnd*". If you are using the extra-length brown lead wires for recording EMG in the leg, insert them in the channel 4 receptacle (in any order) instead of the red and black lead wires.

RECORDING ELECTRODE APPLICATION

Somatics' stick-on recording electrodes [Cat. # EEDS] supplied with the Thymatron™ System IV are ideal for EEG, ECG, and EMG. They are easy and quick to use, and their small size and narrow rectangular shape facilitate bifrontal and fronto-mastoid application without interfering with stimulus electrode placement. Instantly and firmly adherent, they remain in place throughout the seizure.

<u>EEG</u>: You can choose to monitor up to 4 channels of EEG. Rub the skin over the monitoring sites with an alcohol swab and wipe dry.

For 1-channel EEG recording **from the traditional bifrontal position, place a stick-on electrode just above each eyebrow. For fronto-mastoid placement, place one recording electrode just above an eyebrow, and the other recording electrode over the ipsilateral mastoid bone (a single fronto-mastoid placement over the non-stimulated hemisphere when giving unilateral ECT helps confirm generalization of the seizure.) Apply a recording electrode to either shoulder as a patient ground.**

Connect the channel 1 lead wire clips to the EEG recording electrodes in any order of polarity (black or red); connect the green recording wire clip to the ground electrode.

2-channel EEG recording, as follows, provides the most specific evidence for interhemispheric seizure generalization.

For 2-channel EEG recording**, fronto-mastoid placements are recommended, on each side of the head. Place a recording electrode just above an eyebrow and another electrode over the ipsilateral mastoid bone. Repeat this for the other side of the head. Connect the channel 1 lead wire snaps to the first pair of EEG recording electrodes in any order (red or black), and then connect the channel 2 lead wire snaps to the second pair of EEG recording electrodes *in the same order* (e.g., if a red snap is connected to the channel 1 supra-orbital recording electrode, connect a red snap to the channel 2 supra-orbital recording electrode, and so forth). Apply a recording electrode to either shoulder as a patient ground and connect it to the green lead wire snap.**

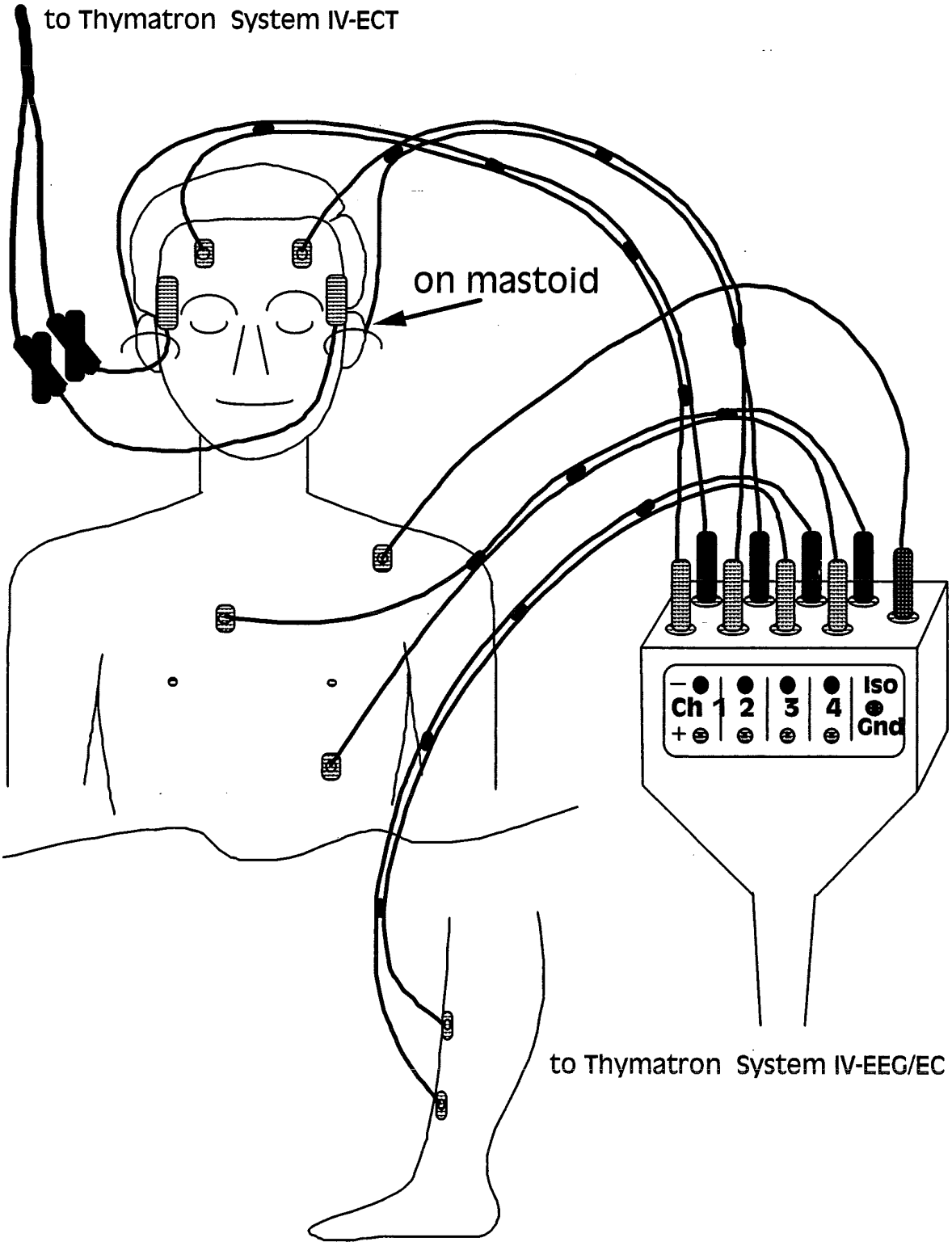
For 3- or 4-channel EEG recording**, use the electrode placements of your choice, remembering to keep the polarity (relationship of red and black lead wires) consistent for corresponding channels on each side of the head (e.g., if you connect the red and black lead wires to frontal and temporal recording electrodes, respectively, on the *left* side of the head, be sure to maintain the same polarity relationship when connecting the corresponding pair of frontal and temporal recording electrodes on the *right* side of the head).**

ECG: You can monitor ECG from channel 3. Apply two monitoring electrodes over the anterior chest above and below the heart, spaced about 8" apart. Connect the two channel 3 leads from the recording cable to the precordial electrodes in any order of polarity (red and black). The ground lead used for EEG as described above is also the ground for the ECG. (If only EEG is being monitored then a separate ground lead must still be connected to a shoulder electrode.)

EMG: You can monitor EMG from channel 4. Apply 2 monitoring electrodes spaced about 3" apart to a limb that has been cuffed to prevent the effects of the muscle-relaxant drug used (see next paragraph). Connect the channel 4 lead wires in any order of polarity (red and black). Use the pair of brown 60" leads for recording from the foot. If you are already recording from another channel, the

same ground lead will serve for EMG as well. If you are not recording other channels, then apply a separate green ground lead to a shoulder electrode.

The "cuffed limb" method relies on observing the motor manifestations of the cerebral seizure activity in a limb that has been blocked from the effects of the muscle-relaxant agent (e.g., succinylcholine) by inflation of a blood pressure cuff over the biceps or calf to just above systolic pressure immediately prior to succinylcholine administration. As soon as the seizure ends, the blood pressure cuff is deflated. With this method, the EMG electrodes are applied over the forearm or dorsum of the foot, as needed.



Electrode connections for channel 1-2 EEG, channel 3 EMG, channel 4 ECG re

SETTING CHANNEL 3 & 4 RECORDING OPTIONS

EEG is always recorded in channels 1 & 2; they are not user-selectable. *To record 2 additional channels of EEG in channels 3 & 4* (for 4-channel EEG recording), proceed as follows:

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "CH 3-4" is displayed.**
3. **Press the *FlexDial*™ to display the existing setting ("EEG-EEG", or "EMG-ECG").**
4. **If "EEG-EEG" is flashing, just press the START/STOP button to retain that setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "EMG-ECG" is flashing, rotate the *FlexDial*™ left or right until "EEG-EEG" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save setting and return to the *FlexDial*™ shell ("CH 3-4" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

***To record EMG and ECG in channels 3 & 4, follow steps 1-3 above, then proceed as follows*:**

4. **If "EMG-ECG" is flashing, just press the START/STOP button to retain that setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "EEG-EEG" is flashing, rotate the *FlexDial*™ left or right until "EMG-ECG" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save setting and return to the *FlexDial*™ shell ("CH 3-4" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

STIMULUS ELECTRODE APPLICATION

Apply the Thymapad™ adherent stimulus electrodes [Cat. #EPAD] supplied with the Thymatron™ System IV.

For conventional *bitemporal* stimulus electrode placement:

Clean the skin over the temples by rubbing vigorously with a *saline*-moistened swab (do not use solvents with Thymapad™ disposable stimulus electrodes), and pat dry. Remove a Thymapad™ from its wrapper, peel it from its plastic backing, and apply it firmly to the bare skin over one temple. Apply a second Thymapad™

to the other temple. Insert a "banana" plug from the ECT stimulus cable into the plastic electrode receptacle at the end of each Thymapad™'s wire until the entire conducting surface of each banana plug is covered and no metal shows. Press firmly once more on the Thymapads™ to ensure that they are properly applied, and test impedance as described below.

For *anterior frontal* stimulus electrode placement:

For Swartz' (1993b) asymmetrical anterior bilateral placement, the left-sided Thymapad™ is placed above the left eye, with its lateral edge bordering the bony ridge between the forehead and the temple. Before peeling the left Thymapad™ from its backing, bend it to match the forehead's curve. Place the right frontotemporal electrode exactly as described above for bitemporal ECT.

For the bifrontal placement of Lawson et al (1990), simply place the centers of each Thymapad™ 5 cm above the lateral angle of each orbit, about 14-15 cm apart. Before peeling the Thymapads™ from their backing, bend them to match the shape of the skull at the electrode site.

For *right unilateral* stimulus electrode placement:

The placement of d'Elia and Raotma (1975) is recommended. Clean and dry the skin over the patient's right temple as above. Remove a Thymapad™ from its wrapper, peel it from its plastic backing, and apply it firmly to the bare skin over the temple (this is the lower electrode site). Part the hair on the right side of the head near the vertex, moisten the scalp thoroughly with a saline-soaked gauze pad or saline solution spray (patients with dense, wiry hair may require full saline saturation of the hair and scalp area directly under the electrode), and apply a Thymapad™ to the site, holding it firmly in place with the special unilateral electrode handle supplied. If the patient is bald at the near-vertex site, or you have elected to clip any hair there, the Thymapad™ can be applied directly to the bare scalp after cleaning and drying it as described above. Insert a "banana" plug from the ECT stimulus cable into the plastic electrode receptacle at the end of each Thymapad™'s wire until the entire conducting surface of each banana plug is covered and no metal shows. Check to make sure Thymapads™ remain properly applied, and test impedance as described below.

STATIC IMPEDANCE TEST

Turn the front panel "POWER" button on. With both ECT treatment electrodes firmly applied (as for either bilateral or unilateral ECT), press the front panel "IMPEDANCE TEST" button and observe the impedance meter display.

CAUTION: <u>DO NOT PRESS THE "TREAT" BUTTON</u> WHEN TESTING THE IMPEDANCE

A number ranging from 0 to 3000, representing the static impedance in ohms, will appear in the 8-digit L.E.D. when the "IMPEDANCE TEST" button is pressed, and disappear when it is released. [*If the automatic EEG feature of the Thymatron™ System IV has been enabled the message "READY" may appear several seconds after the "IMPEDANCE TEST" button is released, indicating successful collection of the baseline EEG sample.*]

Checking the static impedance tests the quality of the skin-to-electrode contact. With the Thymatron™ System IV, the static impedance should be at least 100 ohms and less than 3000 ohms before the treatment stimulus is administered. An impedance of under 100 ohms suggests the possibility a short circuit, probably in the recording cable. An impedance of 3000 ohms should be reduced by the following steps:

a) **Try pressing firmly on the Thymapad™ again while testing the impedance; this is especially important for the vertex electrode with unilateral ECT, which should be pressed vigorously in place with the rubber cupped handle provided with Thymapads™. Also for unilateral ECT, make sure that the hair and scalp under the vertex electrode are thoroughly moistened with a saline-soaked pad.**
b) **If necessary, remove the Thymapad™, lightly moisten the entire solid gel surface of with the tip of a finger dipped in water, and reapply. Rarely, the impedance will remain over 3000 ohms despite these efforts—in such instances, try applying a small amount of fluid gel [e.g., Somatics' EGEL] just under the edge of the Thymapad™ perimeter while leaving the central portion attached to the skin.**
c) **Check to be sure the electrodes have not slipped or twisted.**
d) **Reposition electrodes to minimize the amount of hair underneath.**
e) **Increase pressure on the treatment electrodes by pressing harder with the unilateral electrode handle.**
f) **Gently rub the skin under the stimulus electrodes with a fine emery board or Skin Prep tape (3-M) just enough to remove the top layer of dead cells and sebum and reattach the stimulus electrodes exactly as before. (Alternatively, rub an abrasive gel [e.g. Omniprep] into the skin before reapplying the stimulus electrodes coated with conductive gel.)**

If the impedance reading remains at 3000 ohms after the above procedures have been carried out, try replacing the Thymapads™, electrode wires, or the ECT cable, in that order.

STIMULUS SELECTION

The Thymatron™ System IV is shipped with the ½ ms *Low Charge Rate* program already enabled. This is the recommended choice for the first treatment in all patients for whom there is no prior information concerning their response to ECT or their seizure threshold. (Where such prior information exists, the *FlexDial*™ can be used to select stimulus parameters specifically tailored to the patient's established requirements, or to select from among several preset stimulus programs. As a general rule, however, we prefer to use the ½ ms *Low Charge Rate* program wherever possible, because it provides a broadly effective stimulus well within in the physiological range for most patients.

***To set the stimulus frequency*, proceed as follows:**

1. **Press the *FlexDial*™: the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "FREQUENC" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing frequency setting.**
4. **If the frequency you want is flashing, just press the START/STOP button to retain that setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **To select a different frequency, rotate the *FlexDial*™ left or right until the desired number is flashing in the display.**
6. **Press the *FlexDial*™ to select and save setting and return to the *FlexDial*™ shell ("FREQUENC" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

***To set the stimulus pulsewidth*, proceed as follows:**

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "P-WIDTH" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing pulsewidth setting.**
4. **If the pulsewidth you want is flashing, just press the START/STOP button to retain that setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **To select a different pulsewidth, rotate the *FlexDial*™ left or right until the desired number is flashing in the display.**
6. **Press the *FlexDial*™ to select and save setting and return to the *FlexDial*™ shell ("P-WIDTH" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

To select a preset stimulus array, proceed as follows.

To reproduce the traditional *stimulus settings of the Thymatron DGx* (1 ms pulsewidth, automatically variable frequency range of 70 to 30 Hz, 4-sec maximum stimulus train duration):

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing program.**

4. **If "DGx" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "DGx" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

For the *Lowest Charge Rate* programm using a ¼ msec pulsewidth wherever possible:

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing program.**
4. **If "LOWEST" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "LOWEST" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

For the *Low Charge Rate* program using a constant ½ ms pulsewidth (this is the default program the System IV is shipped with):

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing program.**
4. **If "LOW 0.5" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "LOW 0.5" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

For the intermittent *Pulse Volley Stimulus*:

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ see a flashing display of the existing program.**
4. **If "INTERMIT" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "INTERMIT" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

For the *Double Dose* stimulus *[where available]*:

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ see a flashing display of the existing program.**
4. **If "2X DOSE" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "2X DOSE" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

To program into memory all of the *FlexDial*™ settings currently in effect (e.g., as *most recently selected and set by the user)*:

1. **Press the *FlexDial*™ : the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "PROGRAMS" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the existing program.**

4. **If "USER" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If a different program is flashing, rotate the *FlexDial*™ left or right until "USER" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

STIMULUS DOSE FOR *BILATERAL* ECT:

For the initial treatment the dial labeled "PERCENT ENERGY" should be set to approximate one-half the patient's age (e.g., 25% for a 50 year-old. If no seizure activity results the "PERCENT ENERGY" setting should be increased to 100% and the patient restimulated within 30-60 seconds to maximize the likelihood of obtaining a therapeutically satisfactory seizure during the first treatment session. If this does not work, consider giving an additional stimulus at 100% energy using the *FlexDial*™ to select a 40 Hz, 1 ms combination (for a 7 second pulse train) or a 70 Hz, 0.5 ms combination (for an 8 second pulse train).

Before the next treatment day, the patient's history and records should be reviewed to ensure that dehydration or ingestion of sedative-hypnotic or anticonvulsant medications have not contributed to the difficulty in obtaining seizures, and consideration should be given at the next scheduled treatment session to administering a stimulus at maximum charge and duration.

STIMULUS DOSE FOR *UNILATERAL* ECT:

Satisfactory therapeutic results can be obtained with right unilateral ECT by simply setting the "PERCENT ENERGY" dial to approximate the patient's age in years (e.g., 75% energy for a 72 year-old patient). If a satisfactory seizure is not obtained to the initial stimulus with right unilateral ECT, proceed as described in the paragraphs above for bilateral ECT.

Note: Once a patient obtains a satisfactory seizure with a given "PERCENT ENERGY" setting, we do *not* recommend administering subsequent treatments with progressively lower settings in an attempt to deliver the smallest stimulus that will still induce a seizure. This is because minimum stimulus dosing has been associated with inadequate therapeutic efficacy for both bilateral and right unilateral ECT (Sackeim et al, 1987a,b; 1992).

EASY STIMULUS TITRATION WITH THE THYMATRON™ SYSTEM IV

For those who prefer to set the initial stimulus dose relative to the seizure threshold, McCall et al (1993) report a simple and effective stimulus titration schedule. An

initial setting of 5% Energy is followed by restimulations at 5% Energy increments as needed, to a maximum of 4 stimulations in a treatment session (on average, fewer than three stimuli are required). The mean threshold of 73.5 mC they reported) e.g., about 15% energy) for right unilateral ECT was identical to that determined by Sackeim et al (1993) using a substantially more complex protocol.

Because seizure thresholds for bitemporal ECT are about double those for right unilateral ECT, the initial dose for stimulus titration with bitemporal ECT should be 10% Energy, with 5% energy increments as described above. Subsequent treatments should be administered at doses that approximate 2.5 times threshold (e.g., 50% Energy in a patient with a 20% Energy seizure threshold), with the understanding that even higher doses may be required later in the treatment course if seizures become shorter or the *Seizure Quality Measures* reflect a poor-quality seizure. (To express the seizure threshold in mC, consult Table 1 on the back of this treatment manual for the charge that corresponds to each % Energy setting.)

Note: The stimulus titration method uses units of % Energy (or charge) for expressing dosage. For those who originally learned about ECT dosage in terms of joules (J), the % Energy setting on the Thymatron™ System IV dial directly equals the energy in joules for an average patient of 220 Ohms impedance (i.e., 50% energy = 50 joules).

ADMINISTRATION OF THE TREATMENT STIMULUS

The clear plastic hinged cover over the "TREAT" button is flipped up and the button pressed and held down until the treatment light comes on and then goes off again. While the "TREAT" button (or remote pedal button) is being held down, the following events will occur in order:

a. A one-second continuous clear tone warning signal sounds, during which the current will not be on.
b. The "TREAT" button lights up and a buzz tone sounds while the current is on. Both remain on for the full duration of the treatment stimulus.
c. The "TREAT" button light and buzz tone turn off when the treatment stimulus ends.
d. When the "TREAT" button is released the *Audible EEG*™ seizure monitor is automatically activated and the 4-channel monitor-recorder automatically provides a continuous written display beginning at the end of the stimulus. If the 4-channel monitor-recorder is already printing physiological activity when the ECT stimulus is delivered, the stimulus will appear on the paper, followed immediately by resumption of the physiological record.
e. The 8-digit L.E.D. on the front of the Thymatron™ System IV automatically shows the number of seconds elapsed since the end of the stimulus.

[NOTE: It is important to continue pressing the "TREAT" button until the light and buzzer stop automatically, as earlier release of the button immediately terminates the stimulus and delivers a smaller charge than intended.]

Keeping pressure on the "TREAT" button after the stimulus ends will not deliver additional current because no further stimulation will occur without first releasing the button, then pressing it again, and holding it down for longer than one second.

SEIZURE MONITORING

The Thymatron™ System IV allows the physician to monitor any or all of the physiological variables of EEG, ECG, and EMG.

***EEG Monitoring*: As described above, the Thymatron™ System IV provides 4 methods to monitor the EEG seizure:**

1) **The *Audible EEG*™**
2) **The paper EEG**
3) **The Ictal Line™**
4) **The computer-automated EEG monitor-analyzer with printout of seizure duration estimate.**

1) Audible EEG Seizure Monitor

This feature is always enabled and operates automatically when the TREAT button is pressed and released. The knob marked "VOLUME" on the back panel of the Thymatron™ System IV controls the volume of the tone for the Audible EEG seizure monitor. The volume should be set near the minimum level that can be comfortably heard, and left at that setting for all patients.

The pitch of the *Audible EEG*™ signal varies with the amplitude of the EEG; it will waver and warble intensely and rapidly during the initial tonic phase. It becomes increasingly irregular, with superimposed staccato bursts, during the clonic phase, and tends to correspond to each muscular contraction. Seizure termination is marked by a change to a nearly steady tone with little modulation or variability

Each Thymatron™ System IV is supplied with a cassette tape guide to the interpretation of the *Audible EEG*™ monitor.

2) Paper EEG Tracing

This can be activated before or after stimulus administration, as follows.

a) *Paper EEG recording prior to the stimulus* (or without any intent to administer stimulation) can be initiated after the EEG recording electrodes are applied as described above by pressing the "START/STOP" button on the front panel. EEG recording continues throughout stimulus administration, ictal, and postictal periods, until terminated by pressing the "START/STOP" button again, generating the end-of-treatment report.
b) *Automatic paper EEG recording* begins when the "TREAT" button is pressed and then released and continues until the "START/STOP" button is pressed again, generating the end-of-treatment report.

[Note: The baseline paper EEG record should not be confused with *the computer-derived* baseline EEG sample described below, which must be collected to activate the automatic EEG seizure endpoint detection program]

3) The Ictal Line™ EEG Seizure Indicator

If the *computer-determined baseline EEG sample* has first been obtained as described below, a thin black line is printed along the top of the paper recording strip when the EEG amplitude exceeds a specified baseline value determined individually for the patient being treated. An unbroken, solid black line reflects continuous seizure activity; a broken or intermittent line reflects waxing and waning, or intermittent seizure activity; and complete cessation the black line reflects EEG seizure termination.

4) Computer-Automated Seizure Duration Monitoring

A unique feature of the Thymatron™ System IV (U.S. patents 4873981, 4878498, 5269302, and 5871517) allows the physician to automatically monitor and print up to 3 computer-determined estimates of the duration of the induced seizure, derived from EEG, EMG, and ECG.

Automatic printout of EEG seizure duration

The Thymatron™ System IV continuously monitors the EEG for the endpoint of seizure activity and prints the seizure duration, in seconds, in the end-of-treatment report.

The Thymatron™ System IV is shipped with the computer-automated EEG endpoint detection feature already enabled. If the feature has been disabled prior to the present treatment, it can be restored with the *FlexDial*™ as follows:

1. Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.
2. Rotate the dial left or right until "ENDPOINT" is displayed.
3. Press the *FlexDial*™ to see a flashing display of the status of the EEG endpoint detection program ("ON" or "OFF").

4. **If "EEG ON" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "EEG OFF" is flashing, rotate the *FlexDial*™ left or right until "EEG ON" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

The Automatic EEG endpoint detection feature requires the initial collection of a computer-analyzed EEG baseline, which is accomplished as follows (after EEG electrodes have been applied to the patient as described elsewhere in this manual, and the recording cable has been plugged into the EEG/ECG/EMG recording jack on the front panel of the Thymatron System IV).

1) **Upon powering on the unit, the 8-character L.E.D. displays the message "NO BASE", indicating that a baseline EEG has not yet been recorded.**
2) **Press the "IMPEDANCE TEST" button after the EEG recording electrodes have been applied as instructed, and the recording cable connected to the unit. The impedance (in ohms) will appear on the 8-character L.E.D. and remain until the button is released, at which time it will display the message "BASELINE" for several seconds to indicate that EEG baseline recording is in progress.**
3) **During this brief interval the Thymatron™ System IV will automatically examine and process baseline EEG—rejecting any segments with artefact—until a satisfactory baseline has been collected, generally after about 4 seconds.**
4) **The L.E.D. will then display the message "READY" to indicate that the baseline EEG has been successfully gathered. For further precision, additional baseline EEG continues to be collected, and the baseline EEG sample continues to be updated, until the stimulus is delivered.**

Please also note that checking the impedance ANY TIME after the ECT stimulus electrodes have been applied will initiate the sequence described above. If ECT stimulus electrodes have not been applied, the number "3000" will flash on the L.E.D. but baseline EEG will be gathered and processed as usual. Repeatedly checking impedance does not prevent ongoing monitoring or processing of baseline EEG, or in any way affect the quality of the data collected.

NOTE: If the ECT stimulus is administered to the patient after the message "READY" appears in the display, EEG analysis and reporting—including *Ictal Line*™ and seizure length determination—will proceed automatically. *If the ECT stimulus is administered before the message "READY" appears, however, automatic EEG analysis will not occur*, and the end-of-treatment report will carry the

message "EEG baseline not determined." During the several seconds until "READY" appears it is advisable to avoid touching or moving the patient's head, the recording electrodes, or the wire leads, to minimize EEG artifacts.

In about 10-20% of ECT treatments, the EEG endpoint is not readily determined from the paper strip (Abrams, 1997). This typically occurs when paroxysmal activity decreases too gradually to provide a clear visual endpoint, or when the immediate post-seizure EEG contains high amplitude resting activity. In such circumstances, inability to detect a precise endpoint is expected with any method of examination; the Ictal Line™ might show an "on-again-off-again" broken line pattern, and the end-of-treatment report might state "EEG endpoint not determined."

***Extended Seizure Alert* signal: To set the number of seconds elapsed before this signal is initiated (range, 0-600 sec in 10-sec increments), proceed as follows:**

1. **Press the *FlexDial*™ ; the heading "SETTING" will appear on the 8-character L.E.D.**
2. **Rotate the *FlexDial*™ until "ENDPOINT" is displayed.**
3. **Press the *FlexDial*™ repeatedly to display the status of *the Extended Seizure Alerting* signal ("ESA ON", or "ESA OFF").**
4. **If "ESA ON" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "ESA OFF" is flashing, rotate the *FlexDial*™ left or right until "ESA ON" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

Automatic printout of motor seizure duration estimate by EMG

The Thymatron™ System IV is shipped with the EMG monitor enabled in channel 3. If this setting has been changed, restore it as described above under *Setting Channel 3 & 4 recording options*. When EMG recording electrodes have been properly applied and connected as described above, the EMG tracing automatically appears on the paper record after the TREAT button is pressed and released.

The Thymatron™ System IV continuously monitors the EMG for the endpoint of motor seizure activity and prints the EMG seizure duration, in seconds, in the end-of-treatment report. Baseline EMG collection is not required—or possible—for this

measure, just a pair of EMG recording electrodes and a ground electrode, properly applied as described above, and correctly connected to the recording cable.

The Thymatron™ System IV is shipped with the computer-automated EMG endpoint detection feature already enabled. If the setting has been changed prior to the present treatment, it must first be restored with the *FlexDial*™ as follows:

1. **Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "ENDPOINT" is displayed.**
3. **Press the *FlexDial*™ to see a flashing display of the status of the EMG endpoint detection program ("ON" or "OFF").**
4. **If "EMG ON" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "EMG OFF" is flashing, rotate the *FlexDial*™ left or right until "EMG ON" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

Automatic printout of ECG seizure duration

The Thymatron™ System IV is shipped with the ECG monitor enabled in channel 4. If this setting has been changed, restore it as described above under *Setting Channel 3 & 4 recording options*. When ECG recording electrodes have been properly applied and connected as described above, the ECG tracing automatically appears on the paper record after the TREAT button is pressed and released.

The Thymatron™ System IV continuously monitors the ECG for the endpoint of motor seizure activity and prints the ECG-based seizure duration estimate, in seconds, in the end-of-treatment report. Baseline ECG collection is not required—or possible—for this measure, just a pair of ECG recording electrodes and a ground electrode, properly applied as described above, and correctly connected to the recording cable.

The Thymatron™ System IV is shipped with the computer-automated ECG endpoint detection feature already enabled. If the setting has been changed prior to the present treatment, it must first be restored with the *FlexDial*™ as follows:

1. **Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "ENDPOINT" is displayed.**

3. **Press the *FlexDial*™ to see a flashing display of the status of the ECG endpoint detection program ("HR ON" or "HR OFF").**
4. **If "HR ON" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "HR OFF" is flashing, rotate the *FlexDial*™ left or right until "HR ON" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

[CAUTION: The computer-derived seizure duration measures and estimates of the Thymatron™ System IV, including the Ictal Line™ indicator, are derived solely by calculation and are provided to aid, not replace, the physician's judgment. It is possible for seizure activity to continue in the brain after any or all of the computer report s indicate seizure termination. It is also possible for artifact to be interpreted by the computer programs as seizure activity]

To print the *Peak Heart Rate* in the end-of-treatment report, proceed as follows:

1. **Press the *FlexDial*™; the most recently-set *FlexDial*™ function (e.g., "SETTING") will appear on the 8-character L.E.D.**
2. **Rotate the dial left or right until "ENDPOINT" is displayed.**
3. **Press the *FlexDial*™ repeatedly until to see a flashing display of the status of the PHR detection program ("PHR ON" or "PHR OFF").**
4. **If "PHR ON" is flashing, just press the START/STOP button to retain the setting and exit *FlexDial*™ mode ("READY" will appear in the display if a baseline EEG has already been collected; otherwise, "NO BASE" will appear).**
5. **If "PHR OFF" is flashing, rotate the *FlexDial*™ left or right until "PHR ON" is flashing in the display.**
6. **Press the *FlexDial*™ to select and save the setting and return to the *FlexDial*™ shell ("PROGRAMS" will return to the display).**

Or,

7. **Press the START/STOP button on the front panel to select and save setting and exit *FlexDial*™ mode**

Setting Gain & Position for Channels 1-4, or to block printing of a channel

CHANNEL 1 EXAMPLE

The choices for *gain* are as follows:

G1-OFF **Turns off printing for channel 1**