No. 21-55517

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 2 OF 6

Bijan Esfandiari
Monique Alarcon
R. Brent Wisner
BAUM, HEDLUND, ARISTEI & GOLDMAN, PC
10940 Wilshire Blvd., Suite 1600
Los Angeles, CA 90024
(310) 207-3233
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
rbwisner@baumhedlundlaw.com

Counsel for Plaintiffs-Appellants

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	2:17-cv-06686-RGK-JC	Date	August 9, 2021
Title	*Jose Riera et al v. Mecta Corporation et al*		

Present: The Honorable	R. GARY KLAUSNER, UNITED STATES DISTRICT JUDGE	
Sharon L. Williams	Not Reported	N/A
Deputy Clerk	Court Reporter / Recorder	Tape No.
Attorneys Present for Plaintiff:	Attorneys Present for Defendants:	
Not Present	Not Present	

Proceedings: **(IN CHAMBERS) Order Re: Defendant's Motion for Expert Costs [DE 288]**

I. INTRODUCTION

On June 15, 2020, Michelle Himes ("Himes"), Marcia Benjamin ("M. Benjamin"), and Daniel Benjamin ("D. Benjamin") (collectively, "Plaintiffs") filed the operative Fifth Amended Complaint ("FAC") against Somatics, LLC ("Defendant"). Plaintiffs asserted claims arising from injuries that Himes and M. Benjamin allegedly sustained as a result of electroconvulsive therapy ("ECT") administered to them by doctors using devices designed and manufactured by Defendant. D. Benjamin asserted a related claim for the loss of consortium of his wife, M. Benjamin.

On May 14, 2021, the Court granted summary judgment for Defendant as to all of Plaintiffs' claims. Presently before the Court is Defendant's Motion for an Award of Expert Fees. ("Motion") (ECF No. 288). For the following reasons, the Court **DENIES** Defendant's Motion.

II. FACTUAL BACKGROUND

ECT is the practice of inducing a grand mal motor seizure by applying electricity to the brain. (Pls.' Additional Separate Statement of Uncontroverted Facts (("SUF") ¶ 1, ECF No. 239-1.) ECT is typically performed as a treatment for psychiatric disorders.

Defendant designed and manufactured an ECT machine called the Thymatron System IV. Himes and M. Benjamin both underwent ECT that was administered by doctors using Defendant's Thymatron System IV. Himes received ECT from Dr. Raymond Fidaleo, and M. Benjamin received ECT from Dr. Michael Frankel (Pls.' Statement of Genuine Disputes of Material Fact (("SGD") ¶¶ 8, 10–11, ECF No. 239-1).

UNITED STATES DISTRICT COURT
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Defendant has never conducted any clinical trials of its Thymatron System IV device to determine its safety and efficacy. (Pls.' SUF ¶ 12.) Plaintiffs assert that over the years, Defendant became aware, or should have become aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death associated with ECT. (Id. ¶ 24.) At no point did Defendant investigate these complaints, nor did it submit reports of the adverse events to the FDA or warn physicians and consumers of these risks. (Id. ¶ 25.)

On June 15, 2020, Plaintiffs filed their FAC seeking damages for brain injuries Plaintiffs sustained during ECT treatment. On April 6, 2021, after taking depositions and moving for summary judgment, Defendant extended statutory offers of judgment to Plaintiffs. Defendant offered Himes and M. Benjamin $20,000 each to settle their claims, and offered D. Benjamin $5,000. (Opp. Ex. A, Statutory Offers, 1, 6, 11, ECF No. 288.) Further, under the statutory settlement offers, Plaintiffs had to "file a request for dismissal, with prejudice, of [Plaintiffs'] entire action against [Defendant] and execute a release as to [Defendant], pursuant to the terms set forth in this offer." (Id. at 1.) The offer set forth two terms: the first provided that the dismissal would be with prejudice and did not contemplate an entry of judgment; the second described the methods for acceptance and a time frame of thirty days to respond. (Id. at 1.)

Plaintiffs never accepted the offers. On May 4, 2021, the Court granted summary judgment for Defendant on all of Plaintiffs' claims. On June 4, 2021, Defendant filed this Motion to recover certain expert costs incurred during this action.

III. JUDICIAL STANDARD

Under Federal Rule of Civil Procedure 54(d), district courts have discretion to fix costs. *Crawford Fitting Co. v. J. T. Gibbons, Inc.*, 482 U.S. 437, 441 (1987). Additionally, Local Rule 54-8 provides that "any motion for an award of costs not governed by [Federal Rule of Civil Procedure 54(d)] such as a motion for a discretionary award of costs. . . shall be served and filed within fourteen (14) days after the entry of judgment or other final order, unless otherwise ordered by the Court." C.D. Cal. R. 54-8.

IV. DISCUSSION

Defendant contends that under Local Rule 54-8 and California Code of Civil Procedure § 998, the Court should exercise its discretion to shift expert witness costs to Plaintiffs because Plaintiffs failed to accept Defendant's statutory offers.

Section 998 California Code of Civil Procedure provides:

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> If an offer made by a defendant is not accepted and the plaintiff fails to obtain a more favorable judgment or award, the plaintiff shall not recover his or her post offer costs and shall pay the defendant's costs from the time of the offer ... the court ..., in its discretion, may require the plaintiff to pay a reasonable sum to cover costs of the services of expert witnesses, who are not regular employees of any party, actually incurred and reasonably necessary in either, or both, preparation for trial . . . or the case by the defendant.

Cal. Code. Civ. P. § 998.

In opposition, Plaintiffs assert that Defendant's § 998 offers were (1) invalid and (2) unreasonable, and therefore argue that the Court should not shift costs. For the reasons below, the Court finds that Defendant's § 998 offers of $20,000 each to Himes and M. Benjamin, and $5,000 to D. Benjamin were unreasonable, and therefore declines to shift costs to Plaintiffs.

"A good faith requirement must be read into § 998." *Wear v. Calderon*, 121 Cal. App. 3d 818, 821 (1981). In other words, the offer "must be realistically reasonable under the circumstances of the particular case." *Id.* Whether a § 998 offer is reasonable and made in good faith is a matter left to the trial court's sound discretion. *Elrod v. Oregon Cummins Diesel, Inc.*, 195 Cal. App. 3d 692, 700 (1987). The reasonableness of a defendant's offer can be measured by determining "whether the offer represents a reasonable prediction of the amount of money, if any, defendant would have to pay plaintiff following a trial, discounted by an appropriate factor for receipt of money by plaintiff before trial, all premised upon information that was known or reasonably should have been known to the defendant." *Id.* at 699. If the offer is found reasonable under this first step, the Court must then consider "whether defendant's information was known or reasonably should have been known to plaintiff." *Id.*

Here, the Court need not reach the question of whether Defendant's information was known or reasonably should have been known to Plaintiffs. $20,000 each for Himes and M. Benjamin, and $5000 for D. Benjamin, were not reasonable settlement offers given Defendant's potential liability when the offers were made. First, it is undisputed that Defendant conducted no clinical trials of its Thymatron System IV device to determine its safety and efficacy. (Pls. 'SUF ¶ 12.) Second, Defendant does not dispute that it became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death associated with ECT. (Id. ¶ 24.) Third, Defendant never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks. (Id. ¶ 25.) Fourth, Defendant does not dispute that on March 19, 2021, Plaintiffs presented Defendant with a table of comparable California jury awards for traumatic brain injuries. (Opp. at 7.) These jury awards ranged from $11 million to $113 million. (Id.)

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Defendant also asserts that because Defendant had already taken depositions and filed for summary judgment at the time of the § 998 offers, "it was clear" that Plaintiffs would be unable to meet their burden on summary judgment, and the offers were therefore reasonable. The Court disagrees.

Defendant overstates the strength of its position on summary judgment. Plaintiffs presented colorable arguments, and both parties had case law to support their positions. Had Plaintiffs survived summary judgment and later prevailed at trial, Defendant faced potential liability well over $20,000 per Plaintiff. Thus, Defendant's offers were unreasonable under § 998.

Because Defendant's statutory offers were unreasonable, the Court declines to exercise its discretion to shift expert witness costs to Plaintiffs.

V. CONCLUSION

For the foregoing reasons, the Court **DENIES** Defendant's Motion.

IT IS SO ORDERED.

_____ : _____

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (CA SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (CA SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-JCx
Assigned to Hon. R. Gary Klausner

REPLY BY SOMATICS, LLC TO PLAINTIFFS' OPPOSITION TO SOMATICS, LLC'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

Date: May 3, 2021
Time: 9:00 a.m.
Ctrm.: 850

Trial Date: June 15, 2021

Defendant, SOMATICS, LLC ("Somatics"), offers the following in reply to Plaintiffs' Opposition to Somatics' Motion for Summary Judgment or, in the Alternative, Partial Summary Judgment (Docket No. 239) (the "Opposition").

I. PLAINTIFFS' CLAIMS ARE SUBJECT TO SUMMARY JUDGMENT

Somatics' Motion for Summary Judgment (the "Motion") (Docket No. 231) demonstrates that Plaintiffs' claims are barred by the statute of limitations and that Plaintiffs cannot establish a causal effect between their purported injuries and the

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

allegedly insufficient warnings provided by Somatics. Consequently, as the parties with the burden of proof, Plaintiffs cannot survive summary judgment unless they establish genuine issues of material fact by presenting sufficient evidence from which a jury could reasonably render a verdict in their favor. *See Coomes v. Edmonds Sch. Dist. No. 15*, 816 F.3d 1255, 1259 n.2 (9th Cir. 2016) [internal citation omitted].

As to the statute of limitations, Plaintiffs were obligated to establish that the delayed discovery rule tolled the limitations period such that they filed their respective claims within two years of the time they were deemed to be on inquiry notice. *Yamauchi v. Cotterman*, 84 F. Supp. 3d 993, 1011 (N.D. Cal. 2015) (quoting *Czajkowski v. Haskell & White, LLP*, 208 Cal. App. 4th 166, 174-75 (Ct. App. 2012)). As to causation, Plaintiffs were obligated to establish that additional warnings by Somatics of potential side effects would have changed their doctors' decision to recommend and treat using electroconvulsive therapy ("ECT"). *See Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 991 (C.D. Cal. 2001), *aff'd*, 358 F.3d 659 (9th Cir. 2004). Neither Plaintiffs' Opposition, nor the evidence offered in support, creates a genuine issue of material fact with respect to *either* of these grounds. Accordingly, Somatics is entitled to summary judgment in its favor.

II. PLAINTIFFS' CLAIMS ARE BARRED BY THE STATUTE OF LIMITATIONS

A. The Evidence Confirms that Plaintiffs' Alleged Injuries Occurred During the Course of ECT Treatment.

While resolution of the statute of limitations issue is normally a question of fact, where the uncontradicted facts established through discovery are susceptible of only one legitimate inference, summary judgment is proper. *Jolly v. Eli Lilly & Co.*, 44 Cal.3d 1103, 1112 (Cal. 1988).

It is undisputed that the injuries both Ms. Himes and Ms. Benjamin attribute to

ECT began during the course of their ECT treatment.[1] Specifically, Ms. Himes testified that she experienced a total black out period extending from the time she underwent ECT (April 13, 2011 to January 9, 2012) and lasting for six to eight months afterward, until the Autumn of 2012. Ex. D, Himes Depo, at 31:20-32:2, 36:14-20, 37:5-24, Docket No. 231-6. Ms. Benjamin testified that she was experiencing unendurable side effects from ECT, including body pain, memory loss and complete confusion, in March 2013, when she elected to terminate her treatment. Ex. G, M. Benjamin Depo at 58:18-59:8, Docket No. 231-9.

B. Plaintiffs' Claims Are Not Saved by the Delayed Discovery Rule.

Nevertheless, Plaintiffs' Opposition is premised on the contention that discovery of their claims was delayed until they were each expressly informed by doctors that they had suffered injuries related to ECT. Opposition, p. 13 lines 13-20 & p. 14 lines 12-17, Docket No. 239. This grossly misconstrues the discovery rule.

Under the rule, discovery occurs once the plaintiff has reason to suspect the factual basis for his or her claim even if the plaintiff does not know the specific facts necessary to establish the claim. *See Gutierrez v. Mofid*, 39 Cal. 3d 892, 896-897 (1985). "A patient is charged with 'presumptive' knowledge of his negligent injury, and the statute commences to run, once he has 'notice or information or circumstances to put a reasonable person on inquiry, or has the opportunity to obtain knowledge from sources open to his investigation." *Gutierrez*, 39 Cal.3d at 897. "Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file or sit on her rights. So long as a suspicion exists, it is clear that the plaintiff must go find the facts, she cannot wait for the facts to find her." *Jolly*, 44 Cal. 3d at 1111 (emphasis added). As soon as a plaintiff has some reason to suspect that her injuries may have a wrongful cause, she is deemed to have inquiry notice and

[1] This alone is significant because the Ninth Circuit reversed this Court's prior dismissal of Plaintiffs' claims only because it was unclear on the face of the complaint when Plaintiffs' injuries occurred. (*See* Ninth Circuit Memorandum Decision, at p.3, Docket No. 168.)

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

the limitations period commences, unless the plaintiff proves that a reasonable investigation at that time would not have revealed a factual basis for that cause of action. *Fox v. Ethicon Endo–Surgery, Inc.*, 35 Cal. 4th 797, 803 (Cal. 2005); *Hendrix v. Novartis Pharm. Corp.*, 975 F. Supp. 2d 1100, 1107 (C.D. Cal. 2013), *aff'd*, 647 F. App'x 749 (9th Cir. 2016). California law does not require a plaintiff to be certain of the cause of his injury before his cause of action accrues, it merely requires facts sufficient to put a reasonable plaintiff in suspicion that he has been wronged. *Hendrix*, 975 F. Supp. 2d at 1108-09; *Fox*, 35 Cal. 4th at 807.

Moreover, a triable issue of fact cannot be established by simply contending that none of their doctors expressly informed them that their alleged injuries were caused by ECT, nor can one be established by asserting that the Plaintiffs lacked *actual* knowledge of such a connection. *In re Trasylol Prod. Liab. Litig.*, 2010 WL 6098571, at *12 (S.D. Fla. Mar. 16, 2010) (decided under California law).

1. Ms. Benjamin Fails to Refute Her Own Admission that She Suspected She Had Been Injured by ECT in March 2013.

Ms. Benjamin's attempt to parse the delayed discovery rule to preserve her claim is unavailing and directly refuted by the actual evidence in this case. The simple, undisputed truth is this: Ms. Benjamin was convinced that she had been harmed by ECT—by "20 sessions of horrific invasive electric shocks"—and that she knew she had been the victim of iatrogenic medicine in **March 2013** when she begged Dr. Frankel (who she refers to as the "shock doctor") to stop ECT treatment. Ex. G, M. Benjamin Depo. at 98:13-99:8, Docket No. 231-9; Ex. I, Ex. 10 to M. Benjamin Depo., at p. 1, Docket No. 231-11. Ms. Benjamin offers no evidence to refute this *express admission*; nor is her admission even acknowledged in the Opposition.

That Ms. Benjamin not only suspected, but was convinced, that she suffered harm by ECT is further confirmed by her behavior over the ensuing two years. For example, on September 25, 2014, Ms. Benjamin exclaimed "Excellent work!" in a post on her Facebook page with a link to a short article, discussing, in part, alleged

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

brain dysfunction and damage from ECT.[2] Ex. G, M. Benjamin Depo., at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. J, Ex. 15 to M. Benjamin Depo., Docket No. 231-12; Benkner Decl., Ex. K, Ex. 14 to M. Benjamin Depo., Docket No. 231-13. As another example, Ms. Benjamin made an exhaustive demand for all of her ECT records on July 16, 2015 because she "wanted to understand what had been done to [her]." (Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:9-12, Docket No. 231-9).

Moreover, the Opposition makes the disingenuous assertion that Ms. Benjamin "was continuously assured by her medical providers that her neurocognitive issues would be temporary and would resolve" and that "her cognitive issues were expected, transitory and due to various underlying diseases." (Opp. at 13:18-20.) This unsupported assertion is completely silent with respect to the other side effects that Ms. Benjamin attributed to ECT, namely "pain in [her body, bleeding ... difficulty walking..." Ex. G (M. Benjamin Depo.), at 58:18-59:8, Docket No. 231-9. Regardless, **no evidence** is offered to identify what, if any, assurances her doctors made, or that she, in fact, relied on any such "continuous" assurances.

To the contrary, the only evidence of any assurances provided to Ms. Benjamin about the duration of ECT side effects are those attributed to Dr. Frankel. His initial

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[2] At deposition, Ms. Benjamin acknowledged that she had previously seen and shared to her Facebook page an article about the book *Toxic Psychiatry* and that she had posted the article with the comment, "Excellent work!". Nevertheless, Ms. Benjamin now offers a declaration to contradict her own testimony by claiming that she did not read the article but "simply shared" it because the "photo of many pills" on the book's cover spoke to her. (Benjamin Decl. ¶ 12.) Of course, the declaration fails to account for her testimony that she had previously seen the article or, more importantly, her emphatic endorsement of it as "Excellent work!".

To the extent Ms. Benjamin is attempting to create a genuine issue of fact by this declaration, it plainly constitutes a "sham affidavit." A party cannot create an issue of fact by a declaration contradicting his or her own deposition or other sworn testimony. 1 Robert E. Weil et al., Prac. Guide Fed. Civ. Pro. Before Trial ¶ 14.166 (The Rutter Group 2021). Without providing a valid excuse or explanation for the inconsistency, the contradictory declaration creates no genuine issue of fact on a summary judgment motion. *Id.*; *Van Asdale v. International Game Tech.*, 577 F.3d 989, 998 (9th Cir. 2009).)

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

representations, made prior to and during the course of treatment, were that the cognitive side effects would last between one and a half to two months. Ex. G, M. Benjamin Depo. at 59:9-14. When Ms. Benjamin's cognitive problems lasted beyond that initial timeframe, Dr. Frankel explained that the effects could take up to six months. Ex. G, M. Benjamin Depo., at 59:21-60:7; Opposition Ex. 4 at 33:4-19. However, Ms. Benjamin testified that as soon as Dr. Frankel told her that the side effects could last longer than initially advised, she no longer trusted him. Ex. G, M. Benjamin Depo. at 60:1-14. Thus, the assertion that Ms. Benjamin "had every right to rely upon the expert judgment, assurances, and advice of her medical treaters" (Opp. at 13:23-24, Docket No. 239) is utterly misleading, and the case law cited in support such proposition (*Id.* at 13:24-14:6) is inapplicable.

In summation: Ms. Benjamin first attributed her cognitive injuries to ECT in January 2013; she was convinced that ECT had injured her in March 2013; she posted on social media of the dangers of psychiatry, including allegations that ECT causes brain damage, in September 2014; she was advised by one of her physician to see a neuropsychologist in March 2015; and she requested her complete treatment records from Dr. Frankel, including information to identify the ECT device used, to determine "what had been done to her" in July 2015. Simply stated, Ms. Benjamin was on inquiry notice of her potential claim, and the limitations period commenced, prior to November 7, 2015, two years before she brought this action. And by Plaintiffs' own admission, information regarding the alleged connection between ECT and the injuries claimed was widely available to the public. Fifth Amended Complaint, ¶¶ 59-65; see e.g. ¶59 ["A vocal 'ECT survivor community' has been voicing their objection to the continued use of shock treatment for decades."]

2. Ms. Himes Failed to Investigate Her Alleged Injuries.

Similarly, none of the evidence submitted by Ms. Himes refutes the fact that a reasonable person would have been suspicious of an apparent injury after rousing from a multi-month blackout period that lasted long after she completed ECT

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

treatment. The evidence Ms. Himes offers to validate the contention that she did not suspect she had suffered an injury as a result if ECT is that "her psychiatrist and primary care physician, with whom she was receiving regular care, did not inform her" that she had suffered an injury. Himes Decl. ¶ 8. Ms. Himes contends that the limitations period did not commence until she started to research the effects of psychiatric medicine and ECT treatment in 2017. Himes Decl. ¶¶ 14-15. This evidence is irrelevant.

First, the rule does not delay discovery until a plaintiff begins to investigate a potential claim; it only delays discovery until the plaintiff has reasonable suspicion that such a claim exists. *See Gutierrez*, 39 Cal. 3d at 897. Whether a plaintiff had reason to suspect a factual basis for his or her cause of action is judged by a reasonable person standard. *See Jolly*, 44 Cal. 3d at 1110-11. Here, Ms. Himes was experiencing allegedly extreme cognitive side effects of ECT from the time the treatment commenced in April 2011. Given her allegation that she was not warned of the potential for long-term impairment of her ability to learn and retain new information (Ex. A Himes' Responses to Interrogatories Propounded by Somatics, Set One, at 26:3-13, 28:10-17), a reasonable person in Ms. Himes' position would necessarily have reason to suspect that she suffered an injury from ECT once the blackout period lifted and her other purported, severe symptoms persisted thereafter. At that point, she had an affirmative obligation to investigate the potential cause of those alleged injuries and is charged with knowledge of the results of such investigation. *See Jolly*, 44 Cal. 3d at 1111.

Second, the contention that Ms. Himes' doctors did not tell her that she had suffered an injury from ECT is grossly disingenuous because *she never discussed* her alleged cognitive injuries with any of her doctors. Ms. Himes testified that, for personal reasons, she *affirmatively avoided* discussing her purported injuries with her

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

doctors. Ex. D, Himes Depo., at 40:15-23, Docket No. 231-6.)[3] Thus, by Ms. Himes' own admission, she did not conduct a reasonable investigation into her purported injury or its source, as a reasonable investigation "surely includes ordinary discussions with one's treating physicians as to possible causes of one's injuries." *Hendrix*, 975 F. Supp. 2d at 1109. Her personal reasons for concealing purported injuries from her doctors do not relieve Ms. Himes of her legal obligation to investigate them and do not serve to toll the limitations period on her claims.

III. PLAINTIFFS CANNOT ESTABLISH CAUSATION

A. The Learned Intermediary Doctrine Applies to this Case

Relying on *Hill v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 943, 954 (E.D. Cal. 2014), Plaintiffs argue that the learned intermediary doctrine does not apply and that Somatics' duty to warn runs to patients because it did not provide *adequate* warnings to treating physicians—the learned intermediaries. (Opp. at 15:15-17:11.) Such proposition has been roundly rejected. "California courts … consistently apply the learned intermediary rule even when a plaintiff alleges and proves that warnings were inadequate." *Sanchez v. Bos. Sci. Corp.*, 38 F. Supp. 3d 727, 734 (S.D.W. Va. 2014) (applying California law) (citing *Stanley v. Novartis Pharm. Corp.,* 11 F. Supp. 3d 987, 1002-03, 2014 WL 1316217, at *11 (C.D. Cal. Apr. 2, 2014); *Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984, 991, 995–98 (C.D. Cal. 2001), *aff'd,* 358 F.3d 659 (9th Cir. 2004); *Conte v. Wyeth, Inc.,* 168 Cal. App. 4th 89 (Ct. App. 2008); *Valentine v. Baxter Healthcare Corp.,* 68 Cal. App. 4th 1467 (Ct. App. 1999); *Plenger v. Alza Corp.,* 11 Cal. App. 4th 349 (Ct. App. 1992)). "[T]his authority [*Hill*] is "incorrect to the to the extent that it 'suggest[s] that the learned intermediary doctrine has no effect where plaintiffs allege that warnings are inadequate[.]'" *Shahbaz v. Johnson & Johnson*,

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[3] This further demonstrates the erroneous nature of Plaintiffs' assertion that the limitations period was tolled until their medical providers expressly advised them of a claim, as such contention would effectively allow for a plaintiff to delay discovery of a purported claim for an indefinite period by simply refusing to investigate any purported injury with a medical professional.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

2020 WL 5894590, at *13 (C.D. Cal. July 31, 2020).

B. Plaintiffs Cannot Establish that Additional Warnings Would Have Changed their Prescribing ECT Doctors' Decision to Recommend ECT

A plaintiff in a failure to warn action must prove that inadequate warnings altered the *prescribing physician's decision* to prescribe. *Id.* at *14 (citing *Sanchez*, 38 F. Supp. 3d at 734). Plaintiffs' Opposition does not create a triable issue with respect to whether additional warnings would have changed their ECT doctors' decision to recommend ECT. *Motus*, 196 F. Supp. 2d at 991. This is the correct lens through which causation must be analyzed. The Opposition attempts to confuse this principle by hypothecating that additional warnings might have been given to Plaintiffs if Somatics had given additional warnings to Plaintiffs' ECT doctors. Setting aside the speculative nature of the position, it is irrelevant because it does not establish that either ECT *doctor* would have changed their mind about recommending ECT to either treating Plaintiff. This distinction is important and was expressly analyzed in *Motus*. In that case, the treating physician agreed that he would have passed along information related to an increased risk of suicide if he were provided such information from the manufacturer. *Motus*, 196 F. Supp. 2d at 997. However, the *Motus* court found that this did not create a triable issue because the Plaintiffs' attorney failed to ask the key question: whether the treating physician still would have prescribed the disputed treatment if he had been informed of the risk of increased suicide rate. *Id.*

Here, the record makes it clear that both treating ECT doctors would have still recommended treatment even if they were provided additional warnings from the manufacturer, and Plaintiffs fail to offer any affirmative evidence, as is their burden, to prove otherwise. "The burden [is] on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff." *Id.* at 995-96 (emphasis added). Plaintiffs offer no evidence to support the assertion that additional warnings

would have altered either doctor's decision to recommend and administer ECT.

As to Ms. Himes, Dr. Fidaleo discussed the dire status in which she presented to him, including numerous prior hospitalizations for a progressively worsening condition that made her an imminent threat to herself and a potential threat to her family. Ex. B, Fidaleo Depo., at p. 22:17-23:5; 24:2-25:12, 26:19-27:8. As Dr. Fidaleo confirmed, he was not concerned with "brain damage" being a risk of ECT because it is a treatment of last resort to help people who exhibit grave conditions. *Id.* at p. 34:19-35:5. He further confirmed that even if he were informed of a risk of permanent memory loss (one of the conditions alleged by Ms. Himes), he would not be deterred from recommending ECT. *Id.* at p. 64:19-65:8.

Similarly, Ms. Benjamin's doctor, Dr. Frankel, testified that he was not concerned about complaints of cognitive disturbances because he is careful to make sure that every other treatment option has been exhausted before using ECT. Ex. F, Frankel Depo., at p. 18:16-19:7. He further confirmed that he does not pay much attention to updated safety information provided to him by manufacturers of drugs or devices. Id. at p. 54:6-11. Perhaps most importantly, Dr. Frankel testified that he did not rely on any disclosures from Somatics to inform him of the risks of ECT. Id. at p. 14:4-15:7.

Accordingly, Plaintiffs cannot establish a causal connection between the purportedly inadequate warnings the purported injuries claimed by either of the Plaintiffs.

IV. CONCLUSION

Based on the foregoing, Somatics respectfully requests that the Court enter summary judgment in its favor.

DATED: April 19, 2021 **POOLE SHAFFERY & KOEGLE, LLP**

By: /s/ Jason A. Benkner
Jason A. Benkner
Attorneys for Defendant, SOMATICS, LLC

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **April 19, 2021**, I served the foregoing document described as: **REPLY BY SOMATICS, LLC TO PLAINTIFFS' OPPOSITION TO SOMATICS, LLC'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **April 19, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

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United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (SBN 94690)
Jason A. Benkner (SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

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-JCx

DEFENDANT'S RESPONSE TO PLAINTIFFS' ADDITIONAL SEPARATE STATEMENT OF UNCONTROVERTED FACTS IN OPPOSITION TO DEFENDANT'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

Complaint Filed: September 12, 2017
Trial Date: June 15, 2021

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

Plaintiffs' Uncontroverted Fact	Defendant's Evidentiary Objections and Response
1. Electroshock or electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain. **Plaintiffs' Evidentiary Support:** Ex. 10, Breggin Decl., ¶ 8.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
2. In the late 1930's, Ugo Cerletti, the chair of the Department of Neuropsychiatry at the University of Rome, after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, theorized that electricity could be used to treat psychosis. **Plaintiffs' Evidentiary Support:** Ex. 29, Wright, An Historical Review of Electroconvulsive Therapy, Jefferson Journal of Psychiatry, Vol. 8: Iss. 2, Article 10, p. 70 (1990).	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
3. Cerletti, who was assisted by Lucino Bini on the technical aspects of electrical convulsion, began to test the theory by applying electricity to dogs. Bini noted that there was a high	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

mortality rate in Cerletti's dogs following the experiments. **Plaintiffs' Evidentiary Support:** Id. at 70-71.	adequate. Solely for purposes of this motion, **undisputed**.
4. In April 1938, Cerletti and Bini applied ECT to the first human patient. A 40-year-old man who had been found wandering the train station in Rome and speaking gibberish was brought to the University of Rome and had 70 volts of electricity applied to his temple by Cerletti. **Plaintiffs' Evidentiary Support:** Id. at 71.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
5. It has been reported that, while the scientists were deliberating whether they should apply a second higher voltage, the patient pleaded "Non una seconda! Mortifera!" ("not again it will kill me!"). **Plaintiffs' Evidentiary Support:** Id.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
6. Seeing success that the man was speaking as opposed to his initial gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. The scientists reported that, after the	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

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application of the electricity, the patient was purportedly able to speak more coherently. The patient was administered approximately a dozen more sessions of ECT but was subsequently lost to follow-up. **Plaintiffs' Evidentiary Support:** Id. at 71-72.	adequate. Solely for purposes of this motion, **undisputed**.
7. In May 1938, Cerletti publicly presented his results on the use of ECT on this patient at the Medical Academy of Rome. Shortly thereafter and starting in the early 1940s ECT began to gain acceptance for the purported treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States. **Plaintiffs' Evidentiary Support:** Id.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
8. In the 1980s, Richard Abrams, M.D. and Conrad Swartz, M.D., formed Somatics, LLC ("Somatics") for the purpose of developing their own ECT machine for profit. **Plaintiffs' Evidentiary Support:**	**Disputed in part**: Somatics was not initially formed as an LLC. Except as expressly disputed, and solely for purposes of this motion, **undisputed**.

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Ex. 7, Abrams Dep. 50:15-25. *See also*, Ex. 8, Swartz Dep., 7:2-8:24; 11:2-16:25.	
9. Somatics has never obtained FDA approval to market its ECT machine. **Plaintiffs' Evidentiary Support:** Ex. 9, Mirkowitz Dep. 165:2-16.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
10. Somatics obtained clearance from the FDA to sell its "Thymatron" ECT device, after representing to the FDA that its device was equivalent to an already existing device. **Plaintiffs' Evidentiary Support:** Ex. 41, Sept. 27, 1984 510(k) notification; Ex. 30, 1984 clearance.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
11. Somatics has not conducted any clinical trials of its Thymatron ECT device to determine its safety and efficacy ("Somatics has never conducted any studies of any kind.") **Plaintiffs' Evidentiary Support:** Ex. 7, Abrams Dep. 154:11-14.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
12. Dr. Abrams, the founder, owner and member of SOMATICS, testified that	**Objection**: Not relevant to issues raised in underlying motion

SOMATICS has never performed any studies or tests to analyze the long-term side effects associated with ECT because "that's not our business." **Plaintiffs' Evidentiary Support:** Ex. 7, Abrams Dep. 81:15-20.	regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
13. Dr. Abrams testified that it is not SOMATICS' business to conduct such safety studies on its ECT device. **Plaintiffs' Evidentiary Support:** Id.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
14. An FDA approved device requires clinical trials to demonstrate the safety and efficacy of the device. **Plaintiffs' Evidentiary Support:** See Premarket Approval (PMA) requirements at https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
15. The FDA spends approximately 1,200 hours of review prior to approving a medical device while devices that obtain grandfathering clearance, are usually cleared within 20 hours.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

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Plaintiffs' Evidentiary Support: See Medtronic, Inc. v. Lohr, 518 U.S. 470, 478-79 (1996) ("The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours.") Fed. Register, Vol. 86, No. 10, 4088, 4089, Friday, January 15, 2021, Notices, available online at https://www.govinfo.gov/content/pkg/FR-2021 -01 -15/pdf/2021-00787.pdf .	adequate. Solely for purposes of this motion, **undisputed**.
16. In issuing its clearance to Somatics, the FDA on multiple occasions, informed Somatics that: 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.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

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Plaintiffs' Evidentiary Support: See Ex. 30, 1984 Clearance; see also Ex. 31, 1995 Clearance.	
17. Somatics has promoted its Thymatron ECT device as being FDA "approved." **Plaintiffs' Evidentiary Support:** See e.g., Ex. 24, Somatics' Website Stating "Approval"; Ex. 32, Somatics' Website Claiming Safety and Efficacy; Ex. 33, Somatics' Website Dropping Claims of Safety and Efficacy).	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
18. Somatics' promotion of its Thymatron ECT device as FDA "approved" is a violation of federal law and constitutes misbranding. **Plaintiffs' Evidentiary Support:** *See* 21 CFR §807.97; *see also* Ex. 30, 1984 Clearance; and Ex. 31, 1995 Clearance.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
19. During the relevant time period, Somatics promoted its ECT device as "The most advanced ECT device technically and operationally, with demonstrated superior safety and clinical effectiveness." **Plaintiffs' Evidentiary Support:** See Ex. 8, Swartz Dep. 158:1-162:25; Ex. 24, Somatics' Website Stating "Approval";	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

Ex. 32, Somatics' Website Claiming Safety and Efficacy.	
20. Somatics removed the claims of safety and efficacy from its Thymatron brochure and now states, as the FDA requires: "The long-term safety and effectiveness of ECT treatment has not been demonstrated." **Plaintiffs' Evidentiary Support:** Ex. 32, Somatics' Website Claiming Safety and Efficacy; Ex. 33, Somatics' Website Dropping Claims of Safety and Efficacy); 21 C.F.R. § 882.5940.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
21. The FDA requires that Somatics include a statement in its promotional and instructional literature that: "The long-term safety and effectiveness of ECT treatment has not been demonstrated." **Plaintiffs' Evidentiary Support:** *See* 21 C.F.R. § 882.5940.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. **Disputed**. This requirement was not imposed until after December 2018, when the regulation was amended.
22. During the relevant time period, Somatics did not have appropriate procedures in place to identify, evaluate and warn about adverse events in	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

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violation of applicable FDA regulations. **Plaintiffs' Evidentiary Support:** *See* Ex. 34, 2012 FDA Inspection Report; see also 21 C.F.R. §§ 803.17, 803.18, 803.50 & 820.198; 21 U.S.C. §§ 331 & 352(t).	adequate. Solely for purposes of this motion, **undisputed**.
23. Between 1984 and 2017, Somatics never submitted a single adverse event report to the FDA. **Plaintiffs' Evidentiary Support:** See Ex. 25, RFA No. 30; see also Pressly Decl. at TT 2-4.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
24. Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death. **Plaintiffs' Evidentiary Support:** See Ex. 36, 2011 FDA Executive Summary at SOM00262.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
25. Somatics never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks. **Plaintiffs' Evidentiary Support:**	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

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Telephone: (661) 290-2991 Facsimile: (661) 290-3338

See Ex. 36, 2011 FDA Executive Summary at SOM00262; Ex. 25, RFA Nos. 36, 40, 41 & 42; Pressly Decl. at ¶¶2-4.	adequate. Solely for purposes of this motion, **undisputed**.
26. Somatics' co-owner, Conrad Swartz, M.D. testified that the manuals Somatics prepared for its ECT device and distributed to the two hospitals where plaintiffs received their respective ECTs, did not contain any warnings. **Plaintiffs' Evidentiary Support:** See Ex. 8, Swartz Dep. 48:2-57:5; 66:20-24; 72:20-78:2; Ex. 22, Thymatron System IV Manual, Sixth Edition (2001) from Sharp; Ex. 23 Thymatron System IV Manual, Fifth Edition (2000) from Northridge.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. Disputed. Dr. Swartz testified that only one of the manuals sent to Sharp Mesa Vista Hospital did not contain warnings. At least one other manual sent to Sharp Mesa Vista Hospital contained warnings. Dr. Swartz further testified that the manual sent to Northridge Hospital contained warnings. Somatics' Exhibit N, Swartz Depo, pp. 45:17-46:23, 49:15-50:3, 72:20-73:2; Somatics' Exhibit O, Thymatron System IV Instruction Manual, 16th Edition produced by Sharp Mesa Vista Hospital (SHARP00034-00095).

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

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TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

27. Somatics did not provide any warnings to plaintiffs' physicians or to the plaintiffs concerning any risks, including permanent memory loss or brain damage associated with ECT. **Plaintiffs' Evidentiary Support:** *Id.*	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. Disputed. Dr. Swartz testified that only one of the manuals sent to Sharp Mesa Vista Hospital did not contain warnings. At least one other manual sent to Sharp Mesa Vista Hospital contained warnings. Dr. Swartz further testified that the manual sent to Northridge Hospital contained warnings. Somatics' Exhibit N, Swartz Depo, pp. 45:17-46:23, 49:15-50:3, 72:20-73:2; Somatics' Exhibit O, Thymatron System IV Instruction Manual, 16th Edition produced by Sharp Mesa Vista Hospital (SHARP00034-00095).
28. Prior to Plaintiffs' ECT treatments, Somatics was aware, or should have been aware, of numerous articles published in the peer reviewed medical literature and in numerous textbooks	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

concerning the risk of permanent memory loss, severe cognitive impairment and brain damage. **Plaintiffs' Evidentiary Support:** *See e.g.* Ex. 10, Breggin Decl. ¶ 18.	adequate. Solely for purposes of this motion, **undisputed**.
29. In his 2002 book, Electroconvulsive Therapy, Fourth Edition, Richard Abrams quoted an editorial published in The Journal of ECT in 2000 by Harold Sackeim, a researcher and advocate of ECT, who Abrams quotes as stating that "virtually all patients experience some degree of persistent and, likely permanent retrograde amnesia," that "in many patients the recovery from retrograde amnesia extending several years prior to ECT," and "increasing evidence has accumulated that some degree of persistent memory loss [with ECT] is common." **Plaintiffs' Evidentiary Support:** Ex. 28, "Electroconvulsive Therapy, Fourth Edition" by Richard Abrams, M.D. at p. 200.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
30. The article by Sackeim, referenced in Abrams' book, includes the statement:	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

"[V]irtually all patients experience some degree of persistent and, likely permanent retrograde amnesia. A series of recent studies demonstrates that retrograde amnesia is persistent, and that this long-term memory loss is substantially greater with bilateral than right unilateral ECT (Weiner et al., 1986b; McElhiney et al., 1995; Lisanby et al. [in press]; Sackeim et al. [in press]. It has also become clear that for rare patients the retrograde amnesia due to ECT can be profound, with the memory loss extending back years prior to receipt of the treatment." **Plaintiffs' Evidentiary Support:** Ex. 37, Sackeim, Memory and ECT: From Polarization to Reconciliation, The Journal of ECT, Vol. 16, No. 2 (2000).	causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
31. Sackeim also writes "The most prominent deficits [from ECT] are antegrade amnesia (rapid forgetting of newly learned information) and a temporally graded retrograde amnesia."	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

Plaintiffs' Evidentiary Support: *Id.*	adequate. Solely for purposes of this motion, **undisputed**.
32. Sackeim concludes that there is a need to "update what is communicated in the consent process and to monitor cognitive outcomes." **Plaintiffs' Evidentiary Support:** *Id.* p. 93.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
33. In response to Sackeim's statements regarding ECT and memoy loss, Abrams states in his book, "what supporting evidence is provided to back [Sackeim's claims] up? Unfortunately, none--- The reader is required to accept the statements on faith alone." **Plaintiffs' Evidentiary Support:** Ex. 28, Abrams p. 200.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
34. Abrams also referenced in his book a "memoir," published in the same 2000 edition of the Journal of ECT, titled Electroconvulsive Therapy and Memory Loss: A Personal Journey, wherein the ECT patient, Anne B. Donahue, recounts her experience with memory loss after ECT.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

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Plaintiffs' Evidentiary Support: Ex. 28, Abrams, p. 200 and Ex. 38, Donahue, Electroconvulsive Therapy and Memory Loss: A Personal Journey, The Journal of ECT, Vol. 16, No. 2 (2000).	
35.Ms. Donahue wrote that her "medical cost-benefit analysis in accepting ECT treatment was skewed from the start by the fact that the existing professional statements on potential risks did not match the actual risks presented by current mainstream practice." **Plaintiffs' Evidentiary Support:** *Id.* at 141.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
36.In her article, Ms. Donahue states: "in informing patients about ECT, it is important to relate that a few individuals report profound and long-lasting cognitive impairment that they attribute to this treatment modality." * **Plaintiffs' Evidentiary Support:** *Id.* **p.** 141.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
37.In his book, Abram's description of Donahue's article was: "The author of the memoir is no overt enemy of ECT ... she is highly educated, writes cogently	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were

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and well, has a thorough knowledge of the relevant literature, and engages in no polemics. Nevertheless, her conviction that she suffered `devastating and permanent memory loss with ECT' is just that: a personal conviction, and one that is, like many other personal convictions, unsupported by any objective evidence ... The sincerity of its author is not in question; the difficulty lies elsewhere, in the disjunction between objective science and subjective experience ..." **Plaintiffs' Evidentiary Support:** Ex. 28, Abrams p. 200.	adequate. Solely for purposes of this motion, **undisputed**.
38. In 2006, Richard Abrams and Conrad Swartz, aware of the alleged risk of permanent memory loss associated with ECT, contemplated warning of the risk. **Plaintiffs' Evidentiary Support:** Ex. 39, 2006 Email between Abrams and Swartz.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
39. In 2006, Abrams and Swartz discussed issuing a warning concerning the alleged risk of permanent memory loss	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or

associated with ECT for purposes of avoiding lawsuits, but they were also concerned they would "alienate psychiatrists" if they were to do so. **Plaintiffs' Evidentiary Support:** *Id.*	causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
40. Abrams and Swartz agreed upon issuing a disclaimer rather than a warning. **Plaintiffs' Evidentiary Support:** Ex. 39, 2006 Email between Abrams and Swartz.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
41. Conrad Swartz testified that the disclaimer "is not a warning." **Plaintiffs' Evidentiary Support:** *See* Ex. 8, Swartz Dep. 99:22-100:4; *see also* Exh. 39.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
42. This disclaimer was not distributed to the two hospitals where plaintiffs had their ECT procedures. **Plaintiffs' Evidentiary Support:** *See* Ex. 8, Swartz Dep. 91:1-93:8; *see also* Esfandiari Decl. IN (Plaintiffs issued subpoenas to Northridge and Sharp, but the	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

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only relevant instructions for use that were produced included the 2000 Fifth Edition Manual (Northridge), and 2001 Sixth Edition Manual (Sharp) (Esfandiari Decl. IN 2-3), and neither of these manuals contain the disclaimer that Somatics added to its post-2006 manuals.	
43. In 2009, the FDA announced it was opening a docket and inquiry to further look into the safety and efficacy of ECT given the devices had never received FDA approval. **Plaintiffs' Evidentiary Support:** *See* 74 Fed.Reg. 46607-01.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
44. By 2010, the FDA's public docket had received more than 3,000 notifications of alleged ECT injury and, according to the FDA: "The most common type of adverse event reported in the public docket was memory adverse event (529 reports). This was followed by other cognitive complaint (413 reports), brain damage (298 reports) and death (103 reports)." **Plaintiffs' Evidentiary Support:** *See* Ex. 36, FDA Executive Summary at SOM00262.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

45. As of 2010, Somatics was aware of these adverse events being reported, but took no steps to investigate any of these reports and likewise took no steps to issue any warnings concerning these risks to plaintiffs' medical providers. **Plaintiffs' Evidentiary Support:** *See* 21 C.F.R. §803.50(b)(3); *see also* Ex. 25, RFA Nos. 36, 40, 41 & 42.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
46. Somatics' Person Most Knowledgeable testified that one patient who had attempted to report memory loss to Somatics was "wacko." **Plaintiffs' Evidentiary Support:** *See* Ex. 9, Mirkovich Depo. at 62:21-63:5.	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.
47. Somatics manufactures an ECT machine that administers electric current to a patient's head that is approximately one hundred times what tasers use, approximately the same current used to stun pigs prior to slaughter, roughly one-fifth as much current as the electric chair, and applies voltage that is more than one hundred times what is required to damage brain cells, and yet Somatics chose not to	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

provide any warnings to plaintiffs' medical providers concerning any risks or adverse events associated with its ECT device. **Plaintiffs' Evidentiary Support:** *See* Ex. 12, Castleman Report at 10; *see* Ex. 8, Swartz Dep. 48:22-57:25; see Ex. 22, Somatics Manual Given to Sharp Hospital; Ex. 23, Somatics Manual Given to Northridge Hospital.	
48. In late 2018, after the FDA concluded that Somatics needed to provide instructions and warnings concerning permanent cognitive injuries (see 21 C.F.R. § 882.5940), Somatics began to implement warnings on its website and in its manuals including warning that "ECT may result in anterograde or retrograde amnesia" and that "in rare cases, patients may experience permanent memory loss or permanent brain damage." **Plaintiffs' Evidentiary Support:** *See* Ex. 26 (warnings on Somatics' website issued in late 2018); see also Ex 27 (updated warnings Somatics purportedly sent to all customers via mail sometime	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

after 2018); *see also* Ex. 8, Swartz Dep. 112:7-118:22; 121:23-124:24.	
49. A recently published meta- analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read and Laura McGrath of the University of East London, concluded: "Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risk can be weighed." **Plaintiffs' Evidentiary Support:** Ex. 40, John Read, Ph.D. et al, *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses,* 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).	**Objection**: Not relevant to issues raised in underlying motion regarding statute of limitations or causation. Somatics is not relying on a finding that its warnings were adequate. Solely for purposes of this motion, **undisputed**.

50. Plaintiff Marcia Benjamin was a successful architect who, after obtaining her Bachelor of Architecture degree and having 25 years of work experience, opened her own architectural firm in 2005. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 19:15-21:15.	**Objection**: Vague and ambiguous as to "successful architect." Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
51. Since approximately 2008, Ms. Benjamin has suffered from and has been treated for hypothyroidism. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 2.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
52. In March 2011, Ms. Benjamin's thyroid medication dosage was increased, and she was at home when she began experiencing dizziness, discomfort, and chest pain. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 2; Ex. 6, Frankel Dep. 20:13-23:8.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
53. Ms. Benjamin visited the emergency room where she was diagnosed with severe anxiety and prescribed Xanax. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 38:14-39:15; Benjamin Decl. ¶ 2.	**Objection**: Vague and ambiguous as to time when Ms. Benjamin visited the emergency room and when she was diagnosed with severe anxiety or prescribed Xanax. Otherwise, **undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

54. Shortly thereafter, she responsibly sought out treatment with a psychiatrist in her area, Dr. David Gudeman, so that her use of psychiatric medication would be properly monitored. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 38:14-39:15.	**Objection**: Vague and ambiguous as to time when Ms. Benjamin sought treatment from Dr. Gudeman. Otherwise, **undisputed**.
55. While Ms. Benjamin was under Dr. Gudeman's care, he increased her Xanax dose, and she developed an adverse reaction to the medication. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 4.	**Objection**: Vague and ambiguous as to "adverse reaction." Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
56. She complained that, while taking Xanax, she felt extremely weak, to the point that she could not sit upright in a chair. **Plaintiffs' Evidentiary Support:** *Id.* Ex. 6, Frankel Dep. 20:13-23:8.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
57. Without realizing it, Ms. Benjamin developed a tolerance to the medication, so, in late 2011, she sought treatment at a detox clinic in Sao Paulo, Brazil with psychiatrist Dr. Raymond Rosenberg. **Plaintiffs' Evidentiary Support:**	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.

Benjamin Decl. ¶ 4.	
58. She was at the clinic for about one month from late 2011 to early 2012, where she was able to titrate off Xanax by taking controlled doses of Valium and Tegretol. **Plaintiffs' Evidentiary Support:** *Id.;* Ex. 6, Frankel Dep. 20:13-23:8.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
59. In early 2012, Ms. Benjamin returned home and continued treatment with Dr. Gudeman, per Dr. Rosenberg's recommendation. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 4.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
60. Rather than keeping her on Valium and Tegretol, however, Dr. Gudeman switched her to Klonopin, which made her feel worse. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 40:25-41:8.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, undisputed.
61. The symptoms Ms. Benjamin was experiencing from Klonopin "were so severe that [she] was not able to walk." **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 42:22-43:5.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. Calls for expert opinion on the cause of her perceived limitation. Otherwise, purposes of this motion only, **undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

62. Dr. Gudeman told her ECT was a treatment that could help her overcome the symptoms she was experiencing from Klonopin and, because she had not responded well to previous medications, ECT was her next treatment option. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 43:6-12; Benjamin Decl. ¶ 5.	**Objection**: Not relevant to issues raised in motion regarding statute of limitations or causation. For purposes of this motion only, **undisputed**.
63. In September 2012, Dr. Gudeman referred Ms. Benjamin to Dr. Michael Frankel at Northridge Hospital Medical Center (Northridge) for an ECT consult. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 6.	**Undisputed**.
64. When Ms. Benjamin and her husband, Plaintiff Daniel Benjamin, met with Dr. Frankel to discuss ECT, Dr. Frankel told them that ECT was safe, that it was an easy, outpatient procedure that took only 20 minutes. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 51:22-53:17.	**Objection**: Vague and ambiguous as to time this conversation occurred. Otherwise, for purposes of this motion only, **undisputed**.
65. Dr. Frankel only informed the Benjamins that the side effects of ECT included some confusion right after	**Objection**: Vague and ambiguous as to time this conversation occurred. **Disputed** in part to the extent that

treatment and short-term memory loss that would be temporary. **Plaintiffs' Evidentiary Support:** *Id.;* Benjamin Decl. ¶ 6.	Ms. Benjamin attempts to contend that this is the only thing Dr. Frankel told her about the risks of ECT. Dr. Frankel testified that he also tells his patients that there is a risk of permanent memory loss. Somatics' Exhibit P, Frankel Depo. 16:10-22
66. Ms. Benjamin signed a consent form to undergo ECT treatment, which did not advise her of the risk of permanent memory loss, brain injury, or an inability to create new memories. **Plaintiffs' Evidentiary Support:** Ex. 15, Sept. 28, 2012 Consent Form.	**Objection**: Vague and ambiguous as to time when she signed the referenced informed consent form. Ms. Benjamin signed multiple informed consent forms during her ECT treatment.
67. Had Ms. Benjamin been adequately warned of the risk of permanent or long-term memory loss, she would not have consented to ECT treatment. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 52:5-11; Benjamin Decl. ¶ 18	**Objection**: Vague and ambiguous as to "adequately warned." Incomplete hypothetical and calls for speculation. **Disputed**. Ms. Benjamin was told there was a risk of long-term and potentially permanent memory loss by Dr. Frankel.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

	Somatics' Exhibit P, Frankel Depo. 16:10-22
68. From September 28, 2012 to March 4, 2013, Dr. Frankel administered 20 ECT treatments to Ms. Benjamin. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 7.	**Undisputed.**
69. During her ECT treatment, Ms. Benjamin complained of memory problems, but Dr. Frankel repeatedly assured her these were temporary side effects of ECT that were expected and in fact in response to her complaints, he prescribed further ECT sessions. **Plaintiffs' Evidentiary Support:** Ex. 6, Frankel Dep. 34:10-35:15; Ex. 14, Jan. 21, 2013 Progress Note.	**Undisputed.**
70. In early March 2013, Dr. Frankel recommended, for the second time, that Ms. Benjamin continue taking Lithium while she was on maintenance ECT. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 8.	**Undisputed.**
71. At this point, Mr. Benjamin suggested that she stop ECT treatment, because he felt that if ECT was not going to eliminate the need for her to take	**Undisputed** only as to what Mr. Benjamin may have suggested.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

psychiatric medications, it was time to stop ECT treatment. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 5; Ex. 4, D. Benjamin Dep. 33:24-34:12.	
72. Ms. Benjamin's last ECT treatment was on March 4, 2013. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 5.	**Undisputed.**
73. After her last ECT treatment with Dr. Frankel, Ms. Benjamin returned to the care of Dr. Gudeman in March 2013, and he performed "maintenance" Transcranial Magnetic Stimulation (TMS) treatment in lieu of additional "maintenance" ECT. **Plaintiffs' Evidentiary Support:** Ex. 2, Benjamin Dep. 64:3-12; Ex. 6, Frankel Dep. 41:23-42:14.	**Undisputed.**
74. She continued with her psychiatrist's recommended course of maintenance treatment and received TMS with Dr. Gudeman until October 2013. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 9.	**Undisputed.**
75. In October 2013, Ms. Benjamin learned that the Medical Board of California	**Undisputed.**

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

revoked Dr. Gudeman's medical license after two of his patients died from intoxication of medications prescribed by him, and five others lodged complaints with the Medical Board due to Dr. Gudeman overprescribing them. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 10.	
76. Ms. Benjamin was disappointed by this news, so she searched for another clinic to help her safely detox from the Klonopin that Dr. Gudeman had re-started her on before his license was revoked. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**
77. In late October 2013, Ms. Benjamin began treatment with Dr. Raymond Armstrong (internist and cardiologist) who helped her detox from the medication over a period of 18 months (October 2013 to March 2014). **Plaintiffs' Evidentiary Support:** *Id.* ¶ 11.	**Undisputed.**
78. In October 2014, Ms. Benjamin began seeing a new primary care physician,	**Undisputed.**

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Dr. Michael Hirt, who continued treating her thyroid disorder. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 13; Ex. 2, Benjamin Dep. 71:11-72:4.	
79. When Ms. Benjamin completed her detox program in March 2015, Dr. Hirt put her on a treatment plan consisting of IVs, vitamins, and supplements to help her with the effects she was still feeling from the medications. **Plaintiffs' Evidentiary Support:** *Id.*	**Objection**: Vague and ambiguous as to "the effects she was still feeling from the medication." Otherwise, for purposes of this motion, **undisputed** that Dr. Hirt put Ms. Benjamin on a treatment plan consisting of IVs, vitamins and supplements.
80. At the time, Ms. Benjamin still had difficulty walking, and she told Dr. Hirt that she was having difficulty with her memory and concentration. **Plaintiffs' Evidentiary Support:** *Id.*	**Objection**: vague and ambiguous as to time. Otherwise, for purposes of this motion, **undisputed**.
81. Dr. Hirt told her that once she was able to walk on her own again, he wanted her to see a neuropsychologist. **Plaintiffs' Evidentiary Support:** *Id.*	**Objection**: vague and ambiguous as to time. Otherwise, for purposes of this motion, **undisputed**.
82. In July 2015, Ms. Himes requested her medical records from Dr. Frankel's office, but he failed to immediately release them to her, even after she	**Undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

called his office twice to follow up on her request. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 14.	
83. In late 2015, Ms. Benjamin was slowly walking on her own again and only used her wheelchair when necessary, at which time she began searching for a neuropsychologist. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 15.	**Undisputed.**
84. She contacted K. Drorit Gaines, Ph.D., who scheduled Ms. Benjamin for a neuropsychological evaluation in March 2016. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**
85. During her examination, Ms. Benjamin stated she had difficulty with her memory, concentration, reading, and math. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**
86. In April 2016, Dr. Gaines called Ms. Benjamin to discuss her findings, and she stated that the results revealed "processing deficits" but diagnosed	**Undisputed.**

Ms. Benjamin with Post-Traumatic Stress Disorder (PTSD). **Plaintiffs' Evidentiary Support:** *Id.*	
87. In September 2016, Ms. Benjamin finally received a copy of her ECT treatment records that Dr. Frankel had delayed producing. **Plaintiffs' Evidentiary Support:** *Id.;* Ex. 2, Benjamin Dep. 96:9-97:24.	**Disputed** in part insofar as the reason for the production of her medical records in September 2016 has not been disclosed or indicated by Dr. Frankel or his office.
88. Thereafter, in October 2016, Ms. Benjamin received a copy of Dr. Gaines' written neuropsychological report. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 15.	**Undisputed.**
89. When reading it, Ms. Benjamin was displeased with various errors in the report and confused by Dr. Gaines' diagnosis of PTSD which, to Ms. Benjamin, seemed inconsistent with her symptoms, so she sought out a second opinion. **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 16.	**Undisputed.**
90. In January 2017, Ms. Benjamin underwent a neuropsychological	**Undisputed.**

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

examination with Dennis Robinson, Ph.D. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 17; Ex. 42, Dr. Robinson Report	
91. The neuropsychological testing took place over the course of four different sessions, from January to April 2017. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**
92. In July 2017, Dr. Robinson discussed his written report with Ms. Benjamin and informed her, for the first time, that she had verified learning difficulties, memory problems, and major neuro-cognitive disorder resulting from "Hypothyroidism and the resulting medically based treatments — Medications, Electroshock, and [TMS]." **Plaintiffs' Evidentiary Support:** Benjamin Decl. ¶ 17.	**Undisputed.**
93. Dr. Robinson was the first medical specialist to opine and inform Ms. Benjamin that her neurocognitive injuries and memory issues were due in part to her Electroshock treatment. **Plaintiffs' Evidentiary Support:**	**Undisputed.**

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

Id.	
94. Within four months of Dr. Robinson's July 31, 2017, neuropsychological evaluation report, Ms. Benjamin (and her husband) timely filed their lawsuit against Somatics on November 7, 2017. **Plaintiffs' Evidentiary Support:** *See* FAC Dkt. No. 22.	**Objection**. Whether the Benjamins timely filed this action is a matter of law, not a statement of fact. **Disputed**. Ms. Benjamin was convinced that she suffered an injury immediately after undergoing ECT when she begged Dr. Frankel to stop treatment in March 2013. Ms. Benjamin's behavior over the next two years confirms her suspicion that ECT caused her injuries. She requested her ECT medical records to find out what had been done to her and she posted a link to her Facebook page and commented "excellent work!" to an article discussing brain damage and brain dysfunction as a side effect of treatment. Plaintiff further admits that at least one of her treating physicians advised her to obtain neuropsychological testing starting in March 2015 (Plaintiff Facts #79-81).

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

	Somatics Exhibit G at 58:18-59:8, 59:9-14, 59:21-60:14, 60:16-20, 94:9-12; 94:18-95:8; 98:13-99:8; 106:5-107:17, 108:5-109:19; Somatics' Ex. G; Somatics' Ex. H; Somatics' Ex. I, p. 1; Somatics' Ex. J, Somatics' Ex. K,
95. Plaintiff Michelle Himes is a 35- year-old mother of five children who underwent ECT at Sharp Mesa Vista Medical Center (Sharp) in San Diego California from April 2011 to June 2012. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 11:12-15.	**Disputed**. Ms. Himes' underwent ECT treatment at Sharp Mesa Vista Hospital between April 13, 2011 and January 9, 2012. Michelle Himes' Responses to Interrogatories Propounded by Somatics, Dkt. No. 231-3.
96. Ms. Himes had a difficult upbringing while growing up in Las Vegas, Nevada and, as a result, she was hospitalized on various occasions for depression and suicidal ideation. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 3.	**Objection**: Vague and ambiguous as to timing of hospitalizations. Otherwise, **undisputed**.
97. Over the course of these hospitalizations, she was prescribed at least nine different antipsychotics and antidepressants to attempt to treat her	**Objection**: Vague and ambiguous as to timing of hospitalizations. Otherwise, for purposes of this motion, **undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

depression, but her symptoms continued. **Plaintiffs' Evidentiary Support:** *Id.*	
98. In April 2011, Ms. Himes enrolled in an inpatient program at Sharp and she began treatment with Dr. Raymond Fidaleo. **Plaintiffs' Evidentiary Support:** *Id.* ¶ **4;** Ex. 5, Fidaleo Dep. 27:18-21.	**Undisputed.**
99. When Ms. Himes first began her inpatient program at Sharp, her husband, Paul Himes, visited her and met with Dr. Fidaleo to discuss Ms. Himes' psychiatric care. **Plaintiffs' Evidentiary Support:** Ex. 3, P. Himes Dep. 26:11-23	**Undisputed.**
100. Dr. Fidaleo determined that ECT was appropriate for Ms. Himes, and he began discussing this treatment option with her. **Plaintiffs' Evidentiary Support:** Ex. 5, Fidaleo Dep. 28: 18-23.	**Undisputed.**
101. During the Himes' second meeting with Dr. Fidaleo, the Himes' both watched an informational video on ECT which explained "how great ECT	**Objection**. Lacks foundation and calls for speculation, as no copy of the purported video has been obtained or produced.

was" and they received informational pamphlets touting the benefits of ECT. **Plaintiffs' Evidentiary Support:** Ex. 3, P. Himes Dep. 28:3-18.	Solely for purposes of this motion, **undisputed.**
102. The *only* side effect the video informed them of was the risk of short-term memory loss. **Plaintiffs' Evidentiary Support:** Ex. 3, P. Himes Dep. 28:24-25:8.	**Objection**. Lacks foundation and calls for speculation, as no copy of the purported video has been obtained or produced. **Disputed**. A copy of the purported video has not been obtained in this action and it cannot be stated that the only side effects that Mr. Himes recalls seeing from the video were the only ones that were actually disclosed.
103. Dr. Fidaleo similarly told the Himes that short-term memory loss was a side effect of ECT, and that Ms. Himes may experience confusion due to the anesthesia. **Plaintiffs' Evidentiary Support:** Ex. 3, P. Himes Dep. 29:30-31:13.	**Objection**. Vague and ambiguous as to time of the conversation. **Disputed** in part to the extent that Plaintiffs' contend that these are the only risks warned by Dr. Fidaleo. Dr. Fidaleo also testified that warned Ms. Himes of a risk of permanent memory loss. He further testified that he warns his patients that their ability to remember and to work and to function would come back within

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

	two weeks to two months following treatment. Somatics Ex. B at 30:17-31:20; 64:19-23.
104. Dr. Fidaleo never advised Ms. Himes that brain damage or permanent memory loss was a risk of ECT. **Plaintiffs' Evidentiary Support:** Ex. 5, Fidaleo Dep. 34:15-17.	**Disputed**. Dr. Fidaleo testified he warned Ms. Himes of a risk of permanent memory loss. Somatics Ex. B at 30:17-31:20; 64:19-23.
105. On April 13, 2011, Ms. Himes signed a consent form to undergo ECT treatment which did not warn of the risk of permanent memory loss, brain injury, or an inability to create new memories. **Plaintiffs' Evidentiary Support:** Ex. 5, Fidaleo Dep. 91:13-92:20; Ex. 19, April 13, 2011 ECT Consent Form.	**Disputed** in part insofar as Ms. Himes claims that the April 13, 2011 informed consent form is the only form she signed during her treatment. She signed multiple forms, including one on January 9, 2012 which did warn of the risk of permanent memory loss. Somatics Ex Q, Fidaleo Depo. at 39:17-25; Somatics' Ex R, Informed Consent dated January 9, 2012
106. Had she been adequately informed of the risk of permanent memory loss, brain injury, or the inability to create	**Objection**: Vague and ambiguous as to "adequately informed." Incomplete hypothetical and calls for speculation.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

new memories, Ms. Himes would never have consented to ECT. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 6.	**Disputed**. Ms. Himes was warned of a risk of permanent memory loss by Dr. Fidaleo and the informed consent form that she signed. Somatics Ex. B at 30:17-31:20; 64:19-23; Somatics Ex Q, Fidaleo Depo. at 39:17-25; Somatics' Ex R, Informed Consent dated January 9, 2012
107. Dr. Fidaleo administered 26 ECT treatments to Ms. Himes, from April 13, 2011 to January 3, 2012. **Plaintiffs' Evidentiary Support:** *Id.* ¶ 7; Ex. 5, Fidaleo Dep. 35:14-36:22.	**Undisputed**.
108. Dr. Fidaleo never followed up with Ms. Himes after her ECT treatment ended. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 7.	**Undisputed.**
109. At the conclusion of her ECT treatment course, Ms. Himes, her husband, and their one-year-old daughter moved back to Las Vegas, Nevada, so that Ms. Himes could live with family while her husband, who	**Undisputed.**

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

works for the United States Navy, was stationed in Korea. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 10:5-19; Ex. 3, **P.** Himes Dep. 10:2-20.	
110. In April 2013, Ms. Himes was again hospitalized in Las Vegas when her depressive symptoms returned. **Plaintiffs' Evidentiary Support:** Ex. 20, April 2013 Discharge Note and MRI Report.	**Undisputed.**
111. During that hospital visit, she explained to her treating psychiatrist, Dr. Keith Breiland, that her primary care physician wanted her to undergo an MRI scan to rule out a pituitary tumor because she had elevated protactin levels. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**
112. Ms. Himes had an MRI scan of her pituitary gland completed on April 26, 2013 and the results were normal. **Plaintiffs' Evidentiary Support:** *Id.*	**Undisputed.**

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

113. Ms. Himes had no reason to suspect that she had suffered any injury as a result of ECT, as her psychiatrist and primary care physician, with whom she was receiving regular care, did not inform her otherwise. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 8.	**Disputed**. Ms. Himes testified that her black out period lifted in the autumn 2012. The black out extended over a period of multi-months. A reasonable person would have been alarmed at the inability to recall any or most events that occurred over such a long period of time. Ms. Himes testified that she was not warned that this could be a risk of treatment ahead of consenting to ECT. Ms. Himes further testified that she did not inform her doctors of this condition for fear that they would take her kids away. Somatics Ex. D at 26:3-13, 28:10-17, 31:20-32:2, 40:15-23.
114. When Mr. Himes returned from Korea in September 2013 he was restationed to California and the Himes' moved to Camarillo, California. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 9.	**Undisputed.**
115. At the time, Ms. Himes was still taking psychiatric medications that made her	**Undisputed.**

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25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

feel foggy, fatigued, and she was still exhibiting signs of depression. **Plaintiffs' Evidentiary Support:** *Id.*	
116. Ms. Himes stopped taking psychiatric medications in early 2014 when she became pregnant with her second child who was born in November 2014. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 32:25-33:2; Ex. 2, **P.** Himes Dep. 9:1-12.	**Undisputed.**
117. In approximately December 2015, Ms. Himes learned that she was pregnant with her third child. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 10.	**Undisputed.**
118. In her second trimester (approximately February 2016), women from her church asked her how her current pregnancy compared to her prior two, but Ms. Himes realized she had a faint to no recollection of her prior pregnancies. **Plaintiffs' Evidentiary Support:** *Id.* ¶ *11;* Ex. 1, Himes Dep. 38:11-25.	**Undisputed.**
119. This was the first time she was able to appreciate that she had had an	**Disputed**. Ms. Himes testified that her black out period lifted in the

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25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

extensive "black out period" of important events in her life that she could not remember. **Plaintiffs' Evidentiary Support:** *Id.*	autumn 2012. The black out extended over a period of multi-months. A reasonable person would have been alarmed at the inability to recall any or most events that occurred over such a long period of time. Ms. Himes testified that she was not warned that this could be a risk of treatment ahead of consenting to ECT. Ms. Himes further testified that she did not inform her doctors of this condition for fear that they would take her kids away. Somatics Ex. D at 26:3-13, 28:10-17, 31:20-32:2, 40:15-23.
120. Ms. Himes had been off medication for over a year by this time, and did not feel "so flat and emotionless," and she began reading about side effects of psychiatric medications in books such as "Mad in America." **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 47:20-49:25.	**Undisputed**.
121. Ms. Himes felt that the book validated her concerns that the	**Disputed**. Ms. Himes testified that her black out period lifted in the

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

psychiatric medications actually made her feel worse when she was taking them and she attributed her memory difficulties to the medications she had been taking. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 12.	autumn 2012. The black out extended over a period of multi-months. A reasonable person would have been alarmed at the inability to recall any or most events that occurred over such a long period of time. Ms. Himes testified that she was not warned that this could be a risk of treatment ahead of consenting to ECT. Ms. Himes further testified that she did not inform her doctors of this condition for fear that they would take her kids away. Somatics Ex. D at 26:3-13, 28:10-17, 31:20-32:2, 40:15-23.
122. Ms. Himes' third child was born in July 2016 and, in December 2016, she and her family moved to Oak Harbor, Washington because her husband was re-stationed at Whidbey Island Naval Base. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 49:12-50:4.	**Undisputed**.
123. After moving to Oak Harbor, Ms. Himes began noticing that, in addition to memory difficulties, she was having	Solely for purposes of this motion, **undisputed**.

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

difficulty with her words and trouble communicating. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 43:18-25.	
124. At this point (in 2017), she started researching psychiatric treatment again and this time, she began researching ECT specifically on a wide range of websites. **Plaintiffs' Evidentiary Support:** Ex. 1, Himes Dep. 50:6-19.	Solely for purposes of this motion, **undisputed**.
125. While reading about ECT side effects online, she learned for the first time that other people believed they had brain injury from ECT treatment. **Plaintiffs' Evidentiary Support:** Himes Decl. ¶ 15.	**Objection**. Calls for expert opinion regarding whether ECT causes brain injury. Otherwise, for purposes of this motion, **undisputed**.
126. Shortly thereafter, Ms. Himes sought the assistance of counsel, and she timely and diligently filed the instant action on September 11, 2017. **Plaintiffs' Evidentiary Support:** *See* Compl. Dkt. 4.	**Objection**. Whether Ms. Himes timely filed this action is a matter of law, not a statement of fact. **Disputed**. Ms. Himes testified that her black out period lifted in the autumn 2012. The black out extended over a period of multi-months. A reasonable person would have been alarmed at the inability to recall any or most events that occurred over

	such a long period of time. Ms. Himes testified that she was not warned that this could be a risk of treatment ahead of consenting to ECT. Ms. Himes further testified that she did not inform her doctors of this condition for fear that they would take her kids away. Somatics Ex. D at 26:3-13, 28:10-17, 31:20-32:2, 40:15-23.

DATED: April 19, 2021

POOLE SHAFFERY & KOEGLE, LLP

By: /S/ Jason Benkner
John H. Shaffery
Jason A. Benkner
Attorneys for Defendant,
SOMATICS, LLC

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

PROOF OF SERVICE

(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **April 19, 2021**, I served the foregoing document described as: **DEFENDANT'S RESPONSE TO PLAINTIFFS' ADDITIONAL SEPARATE STATEMENT OF UNCONTROVERTED FACTS IN OPPOSITION TO DEFENDANT'S STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

☐ I caused said document(s) to be transmitted by email to each addressee set forth below on this date. The transmission of this document was complete and without error.

☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **April 19, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250, Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY & KOEGLE, LLP
David S. Poole (CA SBN 94690)
dpoole@pooleshaffery.com
Jason A. Benkner (CA SBN 286790)
jbenkner@pooleshaffery.com
25350 Magic Mountain Parkway, Suite 250
Santa Clarita, CA 91355
(661) 290-2991 Tel.
(661) 290-3338 Fax

Attorneys for Defendant
SOMATICS, LLC

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN,

Plaintiffs,

vs.

SOMATICS, LLC;

Defendant.

Case No.: 2:17-CV-06686-RGK-JCx
Assigned to Hon. R. Gary Klausner

DECLARATION OF JASON A. BENKNER IN SUPPORT OF DEFENDANT'S RESPONSE AND OBJECTION TO PLAINTIFFS' SEPARATE STATEMENT OF UNCONTROVERTED FACTS

Date: May 3, 2021
Time: 9:00 a.m.
Ctrm.: 850

Trial Date: June 15, 2021

COMES NOW, Defendant, SOMATICS, LLC ("Somatics"), and submits this declaration from Jason A. Benkner in support of its Response and Objection to the Separate Statement of Uncontroverted Facts submitted by Plaintiffs, MICHELLE HIMES; MARCIA BENJAMIN; and DANIEL BENJAMIN ("Plaintiffs") in opposition to Somatics' Motion for Summary Judgment, as follows:

///

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250, SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

DECLARATION OF JASON A. BENKNER

I, Jason A. Benkner, declare:

1. I am an attorney employed by Poole, Shaffery & Koegle, LLP, counsel of record for Defendant, SOMATICS, LLC ("Somatics"). I am not a party to this action.

2. Attached hereto as **Exhibit N** (Docket No. 242-3) is a true and correct copy of pertinent pages from the transcript from the deposition of Conrad Swartz, Ph.D., M.D., taken in this action on April 1, 2021.

3. Attached hereto as **Exhibit O** (Docket No. 242-4) is a true and correct copy of the Thymatron System IV Instruction Manual, 16th Ed., that was produced by Plaintiffs' counsel, Bijan Esfandiari, who has declared in this action that he received said document from Sharp Mesa Vista Hospital in response to a Subpoena Duces Tecum. Esfandiari Decl. ¶ 2, Docket No. 239-2.

4. Attached hereto as **Exhibit P** (Docket No. 242-5) is a true and correct copy of pertinent pages from the transcript from the deposition of Michael Frankel, M.D. taken in this action on February 19, 2021.

5. Attached hereto as **Exhibit Q** (Docket No. 242-6) is a true and correct copy of pertinent pages from the transcript from the deposition of Raymond Fidaleo, M.D. taken in this action on February 12, 2021.

6. Attached hereto as **Exhibit R** (Docket No. 242-7) is a true and correct copy of an ECT Informed Consent Form signed by Ms. Himes on or about January 9, 2012 that was identified as Exhibit "3" at Dr. Fidaleo's deposition taken in this action on February 12, 2021.

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The foregoing is asserted within my personal knowledge, and if called as a witness, I could and would competently testify thereto. I declare under penalty of perjury that the foregoing is true and correct. This declaration is executed on the 16th day of April, 2021 at Huntington Beach, California.

/s/ Jason A. Benkner
Jason A. Benkner, declarant

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

POOLE SHAFFERY
25350 MAGIC MOUNTAIN PARKWAY, SUITE 250; SANTA CLARITA, CA 91355
TELEPHONE: (661) 290-2991 FACSIMILE: (661) 290-3338

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(F.R.Civ.P. Rule 5(b); U.S.D.C., C.D. Cal., L.R. 5-3; C.C.P. §§ 1013a, 2015.5)

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

I am employed in the County of Los Angeles, State of California; I am over the age of 18 years and not a party to the within action; my business address is 25350 Magic Mountain Pkwy, Suite 250, Santa Clarita, CA 91355.

On **April 19, 2021**, I served the foregoing document described as: **DECLARATION OF JASON A. BENKNER IN SUPPORT OF DEFEDANT'S RESPONSE AND OBJECTION TO PLAINTIFFS' SEPARATE STATEMENT OF UNCONTROVERTED FACTS** on the interested parties in said action as follows:

SEE ATTACHED SERVICE LIST

☐ By Mail [Federal] I placed such envelope with postage thereon fully prepaid in the United States mail at Santa Clarita, California.

☒ (BY COURT'S CM/ECF SYSTEM) Pursuant to Local Rule, I electronically filed the documents with the Clerk of the Court using the CM/ECF system, which sent notification of that filing to the persons listed below

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☐ I caused such envelope to delivered via overnight delivery to the party(ies) listed on the attached mailing list.

Executed on **April 19, 2021**, at Santa Clarita, California.

☐ [State] I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

☒ [Federal] I declare that I am employed in the office of a member of the bar of this Court at whose direction this service was made.

Nicole Lyons, Declarant

SERVICE LIST

Michelle Himes, et al. v. Somatics, LLC
United States District Court Case No. 2:17-CV-06686-RGK-JCx

Bijan Esfandiari, Esq.
Monique Alarcon, Esq.
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
10940 Wilshire Boulevard, 17th Floor
Los Angeles, CA 90024
T: 310-207-3233
F: 310-820-7444
For e-service:
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
CHall@BaumHedlundLaw.com
vadlivankina@baumhedlundlaw.com
jjoseph@baumhedlundlaw.com

Attorneys for Plaintiffs, Michelle Himes; Diane Scurrah; Marcia Benjamin; and Daniel Benjamin

POOLE SHAFFERY
25350 Magic Mountain Parkway, Suite 250; Santa Clarita, CA 91355
Telephone: (661) 290-2991 Facsimile: (661) 290-3338

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.

not have those lists anymore.

Q Okay. And how would you target the doctors? Were you just sending them to all psychiatrists?

A No, we sent them to all psych -- all hospitals with psychiatric beds. We sent them to all members of the Association for Convulsive Therapy. We sent them to all psychiatry residency training programs in the U.S. This is just in the U.S. we sent these, although we may have sent some to Canada.

Q Does -- to your knowledge, does Sharp have a residency program for ECT?

A I do not know.

Q Okay. All right.

A I suppose if they have psychiatry residents, the residents would be affiliated with a university. But, again, I don't know.

Q Okay. All right. Let me stop sharing and look at another document here, Doctor. Bear with me. Doctor, this would normally be a lot smoother in person, so please bear with me. We're all learning the new technology.

(Pause in proceedings)

Q All right. And so, Doctor, just so I'm clear then, so the manual that accompanies the ECT devices that either Sharp or Northridge would have received, that was, you said, primarily authored by Dr. Abrams from Somatics, correct?

A That's right.
Q Okay.
A But I do -- I believe the 2001 manual did include several passages from the DGx manual, this -- the ECT instruction manual (indicating).
Q And who wrote the DGx manual, Doctor?
A I primarily wrote that, but Richard Abrams collaborated.
Q So the source of the manual that hospitals and doctors would receive from Somatics is Somatics? Somatics is the author of those manuals?
A Yes.
Q Okay. And what is the purpose of the manuals, Doctor?
A There was two different purposes, actually. The -- this manual was to provide a broad understanding of electroconvulsive therapy, what it is and how it's given, not to provide sufficient information in detail to enable a physician to then go and give ECT. That requires a lot of training and supervision and experience before an ECT practitioner may himself give ECT. But it was to give a broad understanding to all psychiatry residents and all psychiatrists about ECT.
Q And that's the DGx manual you're talking about?
A That's the DGx manual, yes. But most of the

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 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

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.)

FIRSTLEGAL RECORDS
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Los Angeles CA, 90026
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ORDER VERIFICATION LIST

Order#: 123726-03

Enclosed documents have been reviewed for the following:

_____ Date of Birth ()

_____ Social Security Number (xxx-xx-)

✓ Subject (SOMATICS, LLC., ET AL.)

_____ Date of Treatment and/or Accident ()

_____ File/Claim Number ()

_____ Other: _____

Please note, the original documents that were provided by the location were of:

_____ Good Quality

✓ Satisfactory Quality

_____ Poor Quality

Type of Records:

_____ Medical	_____ X-Rays	_____ Employment	_____ School
_____ Billing	_____ Pathology	_____ Insurance	_____ Legal
_____ Dental	_____ Ambulance	_____ Prescription	_____ Psych
_____ Sign-In	_____ Path Matl	_____ Payroll	

✓ Other

Date Limitations (if any): _____

Additional Information:

_____

_____

_____

_____

Assembled By: Joey Tan **Verified By:** Joey Tan

Paginated By: _____ **Charted By:** _____

THYMATRON® SYSTEM IV INSTRUCTION MANUAL

Richard Abrams, M.D.

Conrad M. Swartz, Ph.D., M.D.

CE 0344

ECT is a complex medical procedure. Its proper and safe conduct requires a staff of professionals who are experienced with the procedures and familiar with the medical literature concerning the risks, benefits, complications, and methods of ECT. This literature includes the major textbooks of ECT and of psychiatry, the Journal of ECT, and publications about ECT that have appeared in the major journals of psychiatry. As with other aspects of medical practice, knowledge about ECT continues to change and clinicians are responsible for maintaining awareness of these changes from these publications and other sources.

Reports in the medical literature describe the incidence of death associated with ECT as about 1 in 40,000. Other serious adverse events have occurred, including cardiac arrhythmia, myocardial infarction, acute hypertension, aspiration, pneumonia, hypoxia, respiratory obstruction such as laryngospasm, pulmonary embolism, prolonged apnea, tardive seizure, non-convulsive status epilepticus, partial relief of depressive anergia enabling suicidal behavior, and falls. Concurrent administration of antipsychotic (neuroleptic) medication may increase the risks of adverse cardiac, pulmonary, and neurological events, and falls. Concurrent administration of stimulants may increase the risks of cardiac and neurological complications, such as prolonged seizure.

Sixteenth Edition, Revised February, 2013

Technical Support
USA and Canada
(800) 642 – 6761
Fax: (847) 234 – 6763
E-mail: sales@thymatron.com

UM-TS4, Rev. 16

TABLE OF CONTENTS

SAFETY INFORMATION

Please read the following important safety requirements before using the Thymatron® System IV ECT Instrument.

⚠ **CAUTION: Do not subject the Thymatron® System IV to extreme moisture or use it after it has been partially or totally immersed in liquid or when a significant amount of liquid has been spilled on it. Power the unit off and have it checked by a qualified technician before powering it on or using it again.**

WARNING: Do not remove the top or bottom covers of the Thymatron® System IV. There are no user serviceable parts inside. Any servicing must be performed by qualified service personnel.

CAUTION: Only use with the Somatics' Treatment or Monitoring Cables.

CAUTION: The Treatment and Monitoring Cables are not interchangeable, and can not be inserted into the wrong front panel connector. Attempting to insert the Treatment Cable into the connector intended for the Monitoring Cable (and vice versa) will damage both the connector and the cable.

WARNING: Do not use any cables or lead wires that appear to be damaged.

WARNING: The Thymatron® System IV is defibrillator protected. 
Nevertheless, for safety reasons, all cable connections between the Thymatron® System IV ECT Instrument and the patient must be disconnected prior to initiation of the defibrillation stimulus.

CAUTION: Do not dispose of your Thymatron® System IV in the general waste. As per Directive 2002/96/EC for the disposal of electrical and electronic equipment please contact the manufacturer for instructions.

WARNING: Avoid the risk of accidental shock to medical personnel. Do not contact the patient, or any conductive surface touching the patient, unless wearing electrically insulated gloves. If holding the patient's jaw or touching the patient's head during the electrical stimulus, make sure to use electrically insulating gloves.

CAUTION: Prior to initiating ECT on a patient with a cochlear implant, healthcare professionals should discuss the issue with an otolaryngologist or audiologist and review the cochlear implant Instructions for Use.

WARNING: Administering ECT to a patient with an implanted DBS device can damage the DBS device or cause it to malfunction and cause injury to the patient.

The Thymatron® System IV Treatment Cable, Monitoring Cable and lead wires can be cleaned by wiping them off with a Germicidal Disposable Cloth. Steel stimulus electrodes may be cleaned with soapy water or alcohol. Thymapad® electrodes are single use only and must be discarded after the treatment.

The Thymatron® has no special requirements for restricted environment during transport or storage, beyond Standard Sub-clause 10.1 criteria.

DISCLAIMER

Please note that nothing in this manual constitutes, or should be construed as, a claim by Somatics LLC that confusion, cognitive impairment, or memory loss (short-term, long-term, recent, remote, transient, or persistent) can not occur as the result of ECT. Many patients experience temporary loss of recent or remote memories with ECT, particularly with traditional bilateral ECT. A few patients have reported experiencing persisting loss of memories or memory functions after ECT. These are subjective symptoms that have not been related to observable structural brain changes. Mental and physical illnesses, anesthesia, medications, and postponement of treatment each have their own adverse effects, which can be substantial.

The 0.3 ms pulsewidth is available as an option at no charge. If the Thymatron® System IV has 0.3 pulsewidth enabled, please change all 0.25 in the manual listing to be 0.3.

SPECIFICATIONS

The Thymatron® System IV is *Class 1, Type BF* 

STIMULUS OUTPUT
Current: 0.9 amps constant current, limited to 450 volts, isolated from line current

Frequency: 10 to 70 Hz, in 10 Hz increments (to 140 Hz in *LOW 0.25/0.3 Programs*)

Pulsewidth: 0.25 to 1.5 ms, in 0.25 ms increments (0.3 ms is available)

Duration: 0.14 to 7.99 s in increments of equal charge

Maximum output: Standard maximum output across 220 ohms impedance, 504 mC (99.8 joules). Output for double dose modes (where available) across 220 ohms impedance: 1008 mC (199.6 joules). Actual (delivered) treatment output shown on printed report in mC

RECORDING
4 recording channels: channels 1 & 2, EEG; channel 3, EMG; channel 4, ECG.
8 user selectable gain positions for EEG channels (10, 20, 50, 100, 200, 500, 1,000 and 2000 µV/cm) and EMG or ECG channels (50, 100, 200, 500, 1000, 2000, 5000 and 10,000 µV/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 800 Hz (L.E.D. and printed report)
Dynamic Impedance Measure: 0 - 500 ohms (printed report)

SEIZURE MONITORING

Channel specifications:
Maximum gain: EEG, 10 µV/cm; EMG 50 µV/cm; ECG 50 µV/cm
Common mode rejection: 80 dB
Isolation: full, opto-electronic
Printer paper speed: user selectable: 5 - 50 mm/s

Seizure Quality Measures:

Postictal Suppression Index (EEG): range, 0-100%
Average Seizure Energy Index (EEG)
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, (FFT)
Peak Heart Rate: beats/min
Computer Seizure Endpoint Estimates by EEG and EMG

EEG FREQUENCY MEASURES

95% Spectral Edge Frequency
Median Frequency
Relative Delta Power

DIMENSIONS

Weight:	**22 lb**
Height:	**5.5"**
Width:	**17.5"**
Depth:	**13.0"**

INDICATIONS FOR USE

We recommend that doctors planning to use the Thymatron® System IV read and follow the recommendations of the Task Force Report of the American Psychiatric Association as set forth in "The Practice of Electroconvulsive Therapy" (American Psychiatric Association, 2001). To briefly summarize these recommendations here, the Thymatron® System IV is intended to be used to administer electroconvulsive therapy (ECT) to patients suffering from mental disorders in which a rapid, definitive response is desired. ECT is most often indicated in patients who have not responded to adequate courses of appropriate pharmacotherapies, but is also indicated as the primary treatment for patients in whom a rapid or high probability of response is desired (as when they are severely medically ill or in danger of harming themselves) or who are known by their treatment history to respond only to ECT, or who have expressed a valid preference for ECT over alternate therapies.

PATIENT SELECTION CRITERIA

The principal diagnostic indications for ECT as outlined in the Task Force Report of the American Psychiatric Association (APA, 2001) are Major Depression (all types), Mania, and Schizophrenia (characterized by abrupt or recent onset, catatonic features, psychotic symptoms, or a history of ECT response).

CONTRAINDICATIONS AND WARNINGS

The Task Force Report of the American Psychiatric Association (APA, 2001) recognizes no absolute medical contraindication to ECT. It does warn about specific conditions that may be associated with substantially increased risk, including unstable or severe cardiovascular conditions (recent myocardial infarction, unstable angina, poorly-compensated congestive heart failure, severe

valvular cardiac disease), vascular aneurysms susceptible to rupture with increased blood pressure, increased intracranial pressure, recent cerebral infarction, severe chronic obstructive pulmonary disease, asthma, pneumonia and anesthesia risk level ASA 4 or 5.

INSTALLATION

Unpack the instrument, open the black case, and place the instrument on a firm, flat surface such as a hospital cart. Check the instrument for any damage, and make sure the rear panel voltage designation matches that of the electrical outlet to be used. Determine that all manuals and items are present. If required, have the Safety Check performed as described in the Service Manual, Section 2.

Connect the power cable to the rear of the unit. Power the unit on and observe that the POWER switch light comes on, the self test runs successfully and "BASELINE" is displayed. Load a pad of thermal paper as per the instructions inside the paper door (see page 12). Turn the power switch off and on again to verify that the recorder prints the date and software version. This completes the installation.

OPERATING INSTRUCTIONS

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™ function and 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 5 individual dot L.E.D.s (to indicate activation of the *FlexDial*™ selection mode, activation of the *Safety Monitor* alarm, activation of monitoring ECG in channel 4, and whether the *preset* program or a *user set selection* 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 automatically tests the integrity of all circuits. When the unit is powered on, a flashing nonsense symbol appears for several seconds in the 8-character L.E.D., followed by the flashing message "SELFTEST" for a few seconds, then a self-test confirmation report is printed and the words "NO BASE" appear, indicating that baseline EEG collection still has yet to be accomplished. (See IMPEDANCE TEST procedure section for baseline EEG collection.)

The printed SELF TEST confirmation report will appear on the paper strip as:

Thymatron® System IV S/N [*serial number here*]

Date - Time S-IV version [*software version*] / [*the number 60 or 50 Hz*]

The Thymatron® S/N line can be replaced with the hospital's name (see page 30).

PERCENT ENERGY DIAL

The PERCENT ENERGY dial is used to select the treatment stimulus dose. This dial has three functions that are displayed in the 4 character L.E.D. above the dial.

1. ***Rotating*** **the dial displays the PERCENT ENERGY settings for each stimulus dose, followed by a brief display of the corresponding stimulus charge in mC.**
2. ***Pressing*** **the dial displays the stimulus program currently in effect.**
3. ***Pressing, holding in*** **and then *rotating* the dial enables the operator to rapidly change stimulus programs without using the *FlexDial*™.**

To display the corresponding charge in mC again, **rotate *the PERCENT ENERGY dial in either direction and then back again to the desired setting.***

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 5 individual dot L.E.D.s

8-character L.E.D. **Located above the IMPEDANCE TEST button**

1. **It displays the message "SELFTEST" immediately after 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 second 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" from the time the IMPEDANCE TEST button is released until baseline EEG is obtained, about 6-10 seconds.**
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 seconds* since the end of the treatment stimulus.**
8. **It displays the flashing message "REPORT" when the START/STOP button is pressed to generate and print the end-of-treatment report.**
9. **It displays the designations and values of all *FlexDial*™ functions and options during their selection.**

4-character L.E.D. **Located above the PERCENT ENERGY dial**

1. **It displays the different PERCENT ENERGY values as the dial is *rotated.***
2. **It then briefly displays the mC of *charge* corresponding to each PERCENT ENERGY dial setting.**
3. **It displays the *stimulus program in effect* when the dial is *pressed.***
4. **It displays the options for the stimulus programs when the dial is *pressed, held in and rotated.* Releasing the dial, selects that program.**

Dot L.E.D.s **Located on the front panel**

1. **The L.E.D. labeled "FLEXDIAL" flashes when the *FlexDial*™ is activated.**
2. **The L.E.D. labeled "SAFETY MONITOR ACTIVATED" flashes when the *Safety Monitor* has been activated.**
3. **The L.E.D. labeled "PRESET" lights when the *LOW 0.5 program* is in effect.**
4. **The L.E.D. labeled "USER SET" lights when a *user set selection* is in effect.**
5. **The L.E.D. directly above the "EEG/ECG/EMG" monitoring jack stays lit unless channel 4 is being used to monitor the patient's ECG. When channel 4 is connected, the light goes off.**

SAFETY MONITOR CIRCUIT ALARM TEST

The Thymatron® System IV has a *Safety Monitor Circuit* test button on the back panel labeled "ALARM TEST". This test can be performed annually or as hospital regulations require. The *Safety Monitor Circuit* test is performed as follows:

1. **Power on the Thymatron® System IV and connect the ECT stimulus cable.**
2. ***Rotate* the PERCENT ENERGY dial to any setting.**
3. **Connect the ECT stimulus cable banana plugs to a 200 ohm, 10 watt load resistor (or insert these banana plugs into the designated jacks of the ECTOBRAIN™ II testing device).**
4. **First *press and hold down* the rear panel "ALARM TEST" button. Next, *press and hold* the "TREAT" button, and then *release* the "ALARM TEST" button.**
5. **Continue *pressing* the "TREAT" button while the Thymatron® System IV goes through the full cycle of stimulus warning signal and stimulus indicator tones, then *release* the "TREAT" button.**

At the end of the stimulus indicator tones the "SAFETY MONITOR ACTIVATED" dot L.E.D. 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 2-pin jack labeled "ECT" is located below and to the *left* of the IMPEDANCE TEST button. It accepts the plug from the *ECT stimulus cable.*

EEG/ECG/EMG Monitoring Jack
This 9-pin jack labeled "EEG/ECG/EMG" is located below and to the *right* of the IMPEDANCE TEST button. It accepts the plug from the *EEG/ECG/EMG monitoring cable.*

⚠CAUTION: It is impossible to insert the plug from the stimulus cable into the monitoring jack and vice versa. Forcing the wrong cable in will break the connector.

FLEXDIAL™ OPERATION

The *FlexDial*™ has 18 different user-selectable functions, plus the ability to change EEG gain *while the printer is running.* All functions and options can be displayed, then selected with alternating *rotations* and *presses* of the *FlexDial*™, according to the following general principles:

1. ***Rotating the FlexDial*™ in either direction provides a sequential display of all functions or options in that particular level. You can reach any other function or option in the same level by *rotating* the dial.**
2. ***Pressing the FlexDial*™ selects the function or option displayed in the 8-character L.E.D. and advances to the next choice.**
3. ***Pressing, holding in,* and *rotating* the *FlexDial*™ *while the printer is running* allows the operator to rapidly change the gain in all EEG channels.**

TO ENTER FLEXDIAL™ MODE:

With power on, *press* the *FlexDial*™. The most recently selected *function* in the "SETTING" level will appear in the 8-character L.E.D. The *FlexDial*™ dot L.E.D. will flash to indicate that you are now in the *FlexDial*™ mode.

These function headings (e.g., "SETTING", "PROGRAMS", "INDEXES", etc.) do not change a particular setting, but are the *FlexDial*™ locations from which to select a range of related options. For example, selecting the "PROGRAMS" function, leads you to the options of: the traditional *DGx program*, three *Low Charge Rate programs*, the *Intermittent* (Pulse Volley) stimulus mode, the *double dose program* (where available) and the *USER* mode.

NOTE: Pressing the FlexDial*™ *will select the above program being displayed. Once a function or option is selected 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 or *pressing* the IMPEDANCE TEST button. The *FlexDial*™ dot L.E.D. will stop flashing upon exit.

1. ***Pressing* the START/STOP button locks in the selection, generates a printed report of the 13 *FlexDial*™ selections in effect and exits the *FlexDial*™ mode.**

2. ***Pressing* the IMPEDANCE TEST button locks in the selections and exits the *FlexDial*™ mode *without* generating a printed report.**

FLEXDIAL™ MODEL PROCEDURE

For the remainder of this manual, selection of *FlexDial*™ functions and options will be shown by the following shorthand notation with the explanation listed below:

FLEXDIAL™ → [*function*] → [*options*]

1. ***Press* the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.**
2. ***Rotate* the *FlexDial*™ in either direction to display the desired function.**
3. ***Press* the *FlexDial*™ to flash-display the option in effect for that function.**
4. ***Rotate* the *FlexDial*™ to flash-display the other options.**
5. ***Press* the *FlexDial*™ to select the desired option and advance to the next option (if there is one) or to return to *FlexDial*™ function level.**
6. ***Press* the IMPEDANCE TEST or START/STOP button to lock in the option and to exit the *FlexDial*™ mode.**

***Example*:**

FLEXDIAL™ → CH 3-4 → EMG-ECG, EEG-EEG means

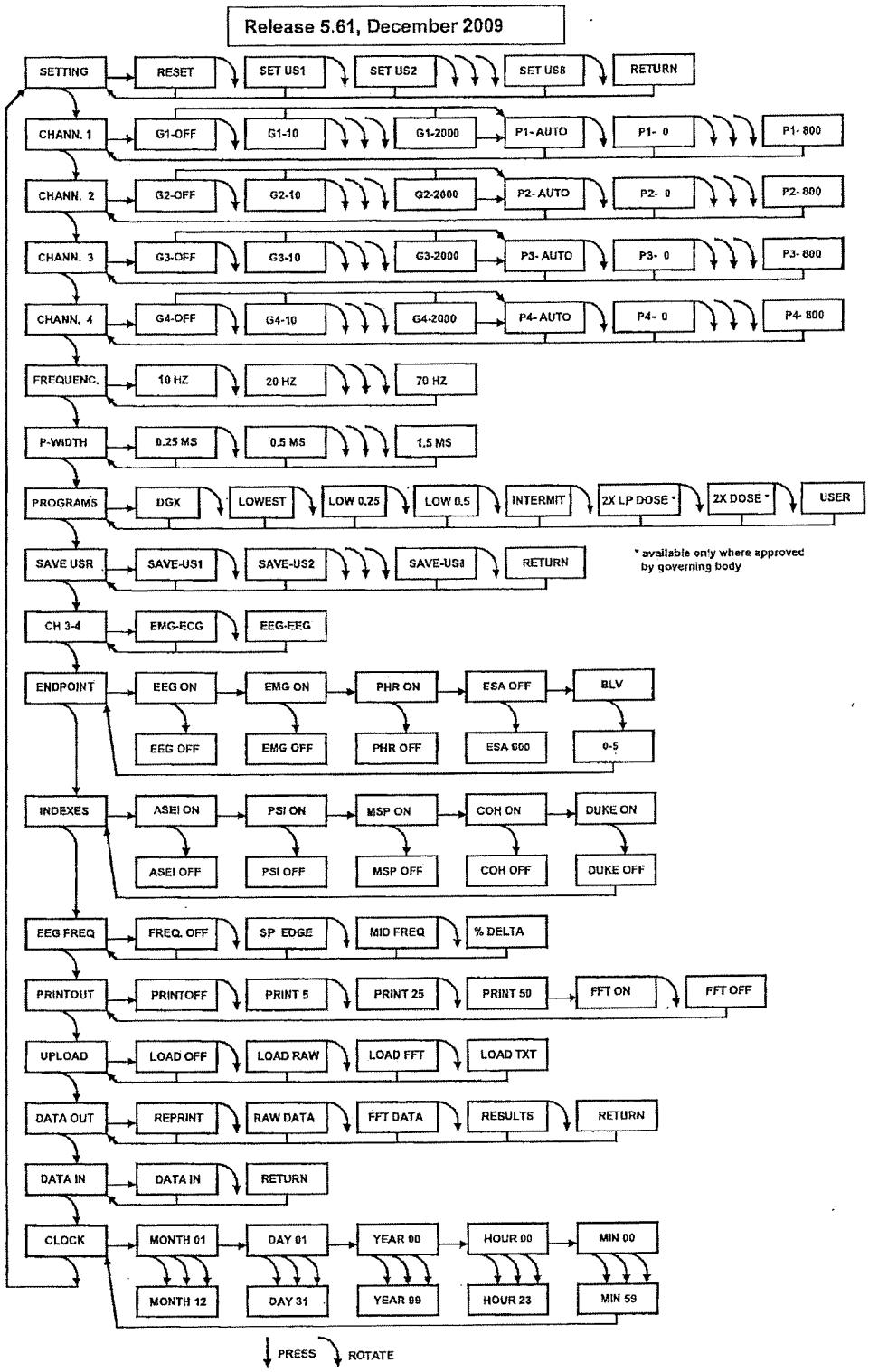
1. ***Press* the *FlexDial*™ to display the most recently-adjusted *FlexDial*™ function.**
2. ***Rotate* the *FlexDial*™ in either direction to display the "CH 3-4" function.**
3. ***Press* the *FlexDial*™ to flash-display the option in effect.**
4. ***Rotate* the *FlexDial*™ to flash-display the options, EMG-ECG or EEG-EEG.**
5. ***Press* the *FlexDial*™ to select the desired option and return to *FlexDial*™ function level, "CH 3-4".**
6. ***Press* the IMPEDANCE TEST or START/STOP button to lock in the option and to exit the *FlexDial*™ mode.**

FLEXDIAL™ FUNCTIONS AND WHAT THEY CONTROL

FLEXDIAL™ FUNCTION	SELECTS THESE OPTIONS
SETTING	Resets to factory specifications, loads up to 8 user set selections
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 6 steps) (0.3 ms available)
PROGRAMS	Selects from 7 factory pre-programmed or user stimulus programs
SAVE USR	Stores up to 8 user set selections
CH 3-4	Enables channels 3-4 to monitor either EMG-ECG or EEG-EEG
ENDPOINT	Enables endpoint detection of EEG, EMG, HR measures, prolonged seizure alert signal and Baseline Retention, BLV
INDEXES	Enables seizure quality measures
EEG FREQ	Selects one of three EEG measures
PRINTOUT	Enables printer and FFT printout, sets paper speed
UPLOAD	Enables sending treatment data to a PC automatically
DATA OUT	Reprints treatment just given; sends treatment data to PC
DATA IN	Accepts hospital's name from PC for the printed report; Accepts treatment data for re-printing treatment record
CLOCK	Sets month, day, year, hour, and minute on printed report

Additionally, *pressing, holding in, and rotating* the *FlexDial™* *while the thermal printer is running* will change the gain in all EEG monitoring channels.

If the 0.3 ms pulsewidth is enabled, there are no 0.25 ms pulsewidth settings. All other pulsewidths are available.



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PAPER LOADING INSTRUCTIONS

The Thymatron® System IV printer paper holder is located just below Somatics' logo on the right side of the front panel. Press the arrow on the top cover release bar to open the printer cover door. Remove the cardboard sheets and place the fan folded paper pad inside. Make sure the black squares are on the right side and the warning strips on the bottom of the pad. Fold over the top sheet and feed these double sheets into the printer, just below the roller. The printer will automatically advance the paper to the correct point and stop. *Press* and *release* the START/STOP button to feed a sheet of paper.

STIMULUS CABLE CONNECTION

Connect the plug of the *black* ECT stimulus cable into the jack labeled "ECT", located on the lower left front panel.

MONITORING CABLE CONNECTION

Connect the plug of the *gray* EEG/ECG/EMG monitoring cable into the jack labeled "EEG/ECG/EMG", located on the lower left front panel, just to the right of symbol of the human figure inside a box.

CAUTION: The Treatment and Monitoring Cables are not interchangeable. They can not be inserted into the wrong connector. However, forcing them into the wrong place will damage the connectors or the cables.

LEAD-WIRE CONNECTIONS

The Thymatron® System IV is shipped with 9 standard length (24 inch) lead-wires: 4 red, 4 black, and 1 green. Also included are 2 extra length (60 inch) brown lead-wires for recording EMG from the leg, if desired. Any combination of channels (from 1 to 4) can be used to monitor the patient. *Not all channels need to be used.* However, channel 1 *must* be used to obtain baseline EEG and seizure endpoints.

Plug the red lead-wires into the receptacles for channels 1, 2, 3 & 4 indicated by red dots at the flared end of the *gray* monitoring cable, and plug the black lead-wires into the *corresponding* receptacles for channels 1, 2, 3 & 4 indicated by black dots. Plug the green lead-wire into the green receptacle marked "*Iso Gnd*". If monitoring EMG from the leg, insert the brown lead-wires into the channel 3 receptacles (in any order) instead of the red and black lead-wires. The ordinary lifespan of a lead-wire is one year. With infrequent use some will last longer. Replacement lead-wires are available separately from the entire monitoring cable.

SEIZURE MONITORING CONSIDERATIONS

Somatics' stick-on, snap monitoring electrodes, [Cat. # EEDS] are ideal for EEG, ECG and EMG monitoring. Their size and rectangular shape facilitate fronto-mastoid and bifrontal application without interfering with the stimulus electrodes. Prepare the skin sites by vigorously rubbing with an alcohol swab and wiping dry.

Polarity of recording electrodes can be important for EEG recording, so carefully follow the instructions below. Each recording channel takes one negative and one positive lead-wire, designated as black and red, respectively. On the monitoring cable, the holes facing the label are designated red (positive), and those on the side opposite from the label are designated black (negative). The 2 long lead-wires for recording EMG from the foot are color-coded brown for quick recognition since polarity is not an issue with either EMG recording.

The green ground lead-wire always plugs into the green-coded socket labeled ISO-GRND; only one ground is required no matter how many channels you monitor.

Monitoring Electrode Placement:

We recommend two-channel EEG monitoring because it takes full advantage of all the special and unique monitoring features of the Thymatron® System IV, and with the splitter included, requires only one more lead-wire than single-channel EEG monitoring. If you do choose single-channel EEG monitoring we recommend a left fronto-mastoid placement because it can demonstrate seizure generalization to the left hemisphere when giving right unilateral ECT.

Regardless of how many channels you choose to monitor, Channel 1 must always be used for EEG in order to obtain a baseline EEG sample for the determination of the EEG endpoint and the EEG indexes, channel 3 must always be used to monitor EMG, channel 4 must always be used to monitor ECG, and the green ISO-GRND channel must always be used for the ground.

The preferred 4-channel monitoring configuration using the splitter (EEG in channels 1 & 2, EMG in channel 3, and ECG in channel 4)

EEG: fronto-mastoid EEG electrode placements are recommended. Place a monitoring electrode in the center of the forehead, another electrode over the left mastoid bone, and a third electrode over the right mastoid bone. Plug the two narrow ends of the splitter into the black positions for channel 1 and 2. Then connect a black lead-wire to the channel 1 position on the splitter, leaving the channel 2 position on the splitter empty. Connect this black lead-wire to the top front forehead monitoring electrode. Connect two red lead-wires to channel 1 & 2 red positions and clip the ends to the corresponding mastoid electrodes. Apply a monitoring electrode to either shoulder as a ground and connect it to the green lead-wire.

ECG: The great advantage of monitoring ECG with the Thymatron® System IV rather than (or in addition to) equipment provided by the anesthetist is that you get a permanent record of the heart rate printed every three seconds on the recording strip, plus an end-of-treatment printout of the baseline and peak heart rates, to help you assess the efficacy of the seizure just given.

Apply two monitoring electrodes over the anterior chest above and below the heart, spaced about 8" apart. Connect the channel 4 red and black lead-wires to the precordial electrodes in any order of polarity, and insert in the channel 4 holes.

EMG: The purpose of monitoring EMG is to provide an automated and highly accurate estimate of the motor seizure duration. Apply two monitoring electrodes spaced about 3" apart to a limb that has been cuffed to prevent the effects of the muscle-relaxant drug. Connect the channel 3 red and black lead-wires in any order of polarity to monitor from the patient's arm and plug into the channel 3 holes. (Use the brown 60 inch lead-wires to monitor from the patient's foot, as illustrated.)

A 3-channel monitoring setup (EEG in channel 1, EMG in channel 3, and ECG in channel 4)

For the preferred left fronto-mastoid EEG configuration, place one monitoring electrode above the left eyebrow and the other electrode over the left mastoid bone. Connect the channel 1 lead-wires to the monitoring electrodes in any order of polarity (no splitter is used), and connect the ECG and EMG electrodes, ground electrode, and lead-wires as described above.

For 3 or 4-channel EEG monitoring **(primarily used for research) 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. If you connect the red and black lead-wires to frontal and temporal monitoring 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 electrodes on the *right* side of the head. Apply a monitoring electrode to either shoulder as a ground and connect it to the green lead-wire clip.**

CHANNELS 3 & 4 SELECTION

EEG is always monitored from channels 1 & 2 and they are not user selectable. Channels 3 & 4 can monitor either EMG and ECG or two more channels of EEG. To select the monitoring options for channels 3 & 4, follow the procedure below:

***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, according to the directions, "Use of Thymapad™ Disposable ECT Stimulus Electrodes". Clean the patient's skin sites by rubbing vigorously with a *saline* moistened swab and pat dry. *Do not use solvents (e.g., alcohol) with Thymapad™ stimulus electrodes.* Spread 1-2 drops of Pre-Tac solution over the site and rub into the skin with a fingertip *until dry.* Remove a Thymapad™ from its wrapper, peel it from the plastic backing, and apply it firmly to the bare skin.

Insert the banana plug from the ECT stimulus cable into the plastic receptacle at the end of each Thymapad™ wire, until the entire conducting surface of each banana plug is covered and no metal shows. *Press* firmly once more on each Thymapad™ to ensure that it is properly applied and then test impedance.

For conventional *bitemporal* stimulus electrode placement, clean the skin sites over the temples as above. Remove a Thymapad™ from its wrapper and apply it firmly to the bare skin of the temple. Apply a second Thymapad™ to the other temple.

For *bifrontal* placement, place the center of each Thymapad™ 5 cm above the lateral angle of each orbit, about 14-15 cm apart. Before peeling the Thymapad™ from the backing, bend it to match the shape of the skull at each electrode site.

For Swartz' *left-anterior right-temporal* (LART) placement, place the left-sided Thymapad™ 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 at the right temple. Part the hair on the right side of the head near the vertex and 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. Apply a Thymapad™ to the site, holding it firmly in place with the special foam handle applicator supplied. (If the patient is bald at the near-vertex site, the upper Thymapad™ can be applied directly to the bare scalp after cleaning and drying as described above.)

IMPEDANCE TEST (FOR *STATIC* IMPEDANCE)

Be sure the front panel POWER button is on, the ECT stimulus cable connected to the front panel and both stimulus electrodes are firmly applied. *Press* the front panel IMPEDANCE TEST button and observe the static impedance displayed in ohms, in the 8-digit L.E.D. Repeatedly checking impedance does not prevent ongoing monitoring or affect baseline EEG collection.

CAUTION: DO NOT PRESS THE "TREAT" BUTTON WHEN TESTING THE IMPEDANCE

The static impedance test checks the quality of the skin-to-electrode contact. With the Thymatron® System IV, the static impedance should be greater than 100 ohms and less than 3000 ohms before the treatment stimulus dose is administered. A static impedance reading of less than 100 ohms suggests a short circuit, probably in the stimulus cable. An impedance reading of 3000 ohms or more appears as the flashing number 3000; if this occurs the impedance should be reduced by the following steps:

a) **Try pressing firmly on each 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 foam handle applicator provided. Also for unilateral ECT, make sure that the hair and scalp under the vertex stimulus electrode are thoroughly moistened with a saline-soaked pad.**
b) **If necessary, remove the Thymapad™, pass it under running water, shake off the excess water, wait a few minutes and then reapply the Thymapad™ by pressing it firmly into place.**
c) **Check to make sure the electrodes have not slipped or twisted.**
d) **Reposition the stimulus electrodes to minimize the amount of hair underneath.**
e) **Increase pressure on the stimulus electrode by pressing harder with the foam handle applicator.**
f) **Gently rub the skin under the stimulus electrodes with a fine emery board or Skin Prep tape (3-M) to remove the top layer of dead cells and sebum. Reapply the stimulus electrodes exactly as before.**

A common reason for high impedance is that one or more steps were omitted from skin site preparation. Please be sure to follow each instruction step when using Thymapad™ stimulus electrodes.

During cold weather skin thickens and hardens, causing the static impedance to rise. Also, some patients have high readings despite all procedures. Try applying skin lotion to the electrode sites between treatments and shortly after waking on ECT days.

If the static impedance reading remains >3000 ohms after trying the above procedures, try replacing each Thymapad™, the lead-wires or the stimulus cable, in that order.

BASELINE EEG COLLECTION

Prior to collecting a baseline EEG, be sure the automatic EEG endpoint detection feature of the Thymatron® System IV is enabled; the EEG monitoring electrodes are properly applied to the patient; the monitoring cable with attached lead-wires is connected to the front panel; and the lead-wires are clipped to the monitoring electrodes.

When the IMPEDANCE TEST button is pressed and held, the word "TESTING", will briefly appear in the 8-digit L.E.D. Then a number ranging from 0 to >3000 ohm, representing the static impedance, will appear. When the IMPEDANCE TEST button is released, the number is replaced by the message "BASELINE". The "BASELINE" message indicates that baseline EEG collection *is in progress.* When baseline EEG collection has been accomplished, the word "READY" will appear in the L.E.D. It normally takes about 6-10 seconds for "READY" to appear.

However, moving the patient's head, touching or moving the monitoring electrodes, lead-wires, or monitoring cable during baseline EEG collection will prolong the process by introducing EEG artifact. The less the patient and monitoring connections are moved or touched during baseline EEG collection, the sooner the "READY" message will appear and the patient will be ready to treat. If necessary, stop ventilating the patient for the few seconds it takes for the "READY" message to appear. Place the lead-wires so that they will not be disturbed by the anesthetist. Each pair of wires can be taped together about every 6 inches to minimize movement and artifact.

NOTE: If the "READY" message does not appear before the treatment stimulus dose is administered, there will be neither an Ictal Line™ nor EEG endpoint determinations or seizure quality measurements because an adequate baseline was not obtained. However, the treatment itself will not be affected.

It is *not* necessary for the Thymapad™ stimulus electrodes to be applied in order to obtain a baseline EEG collection. Do not be concerned with an impedance reading >3000 ohms when no stimulus electrodes have been applied; baseline EEG collection will proceed anyway. Static impedance will be tested *after* the stimulus electrodes have been applied. Repeated pressing of the IMPEDANCE TEST button does not interfere with baseline EEG collection.

TIP: It is strongly recommended to initiate baseline EEG collection by pressing the IMPEDANCE TEST button on the Thymatron® System IV's front panel as soon as the monitoring electrodes and a ground electrode have been applied., even before applying the Thymapad™ stimulus electrodes (e.g., while the patient is fully awake and before anesthesia has been administered). This will provide the longest possible period of baseline EEG collection, maximizing the likelihood that a good baseline will be collected by the time the treatment stimulus is administered.

STIMULUS DOSE SELECTION

The Thymatron® System IV is shipped with the *LOW 0.5* program enabled. This is the recommended choice for the first treatment in all patients for whom there is no prior information concerning ECT response or seizure threshold. When desired, the *FlexDial*™ can be used to select stimulus parameters specifically tailored to the patient's established requirements, or to select from among other factory- or user-set stimulus programs. However, we recommend use of the LOW 0.5 program wherever possible, because it provides a broadly effective stimulus that is in the physiological range for most patients.

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 (mC) that corresponds to the PERCENT ENERGY setting, followed by a return to the PERCENT ENERGY number.

NOTE: The stimulus dose in mC that corresponds to any PERCENT ENERGY figure shown in the L.E.D. can be viewed again for 1 second by *rotating* the PERCENT ENERGY dial to either side and then back again.

Because stimulus duration is limited to a maximum of 8 seconds, the higher PERCENT ENERGY settings may not be available when the user selects pulsewidth or frequency values at the lower end of their ranges. Whenever the PERCENT ENERGY setting for a given pulsewidth and frequency would deliver a stimulus exceeding 8 seconds, the message ">8 S" will appear.

However, all the factory-programmed preset programs shown in the next paragraph will work at all PERCENT ENERGY settings.

Table 1 shows all the standard dosages and stimulus parameters for each PERCENT ENERGY setting.

STIMULUS PROGRAMS: FACTORY PROGRAMMED

There are 7 factory set stimulus programs. The "LOW" programs automatically adjust the frequency to provide the longest stimulus duration available for a given PERCENT ENERGY setting; providing the optimum stimulus for each dose. The LOW 0.5 program is the *only* preset program that will show as "PRESET" on the front panel L.E.D. *(Both Double Dose Programs are not available in USA or Canada)*

DGX	Reproduces the standard stimulus of the Thymatron® DGx
LOWEST	Automatically adjusts parameters to provide the lowest charge rate
LOW 0.25	Fixed 0.25 ms pulsewidth varies frequency to maximize duration
LOW 0.5	Fixed 0.5 ms pulsewidth, varies frequency to maximize duration
INTERMIT	Intermittent pulse-volley stimulus mimics the Siemens *Konvulsator*
2X LP	Double dose stimulus program using the lowest pulsewidth available*
2X DOSE	Double dose stimulus program* (**not available in USA or Canada*)

STIMULUS PROGRAM SELECTION

Any standard (factory-programmed) setting can be selected using the procedure listed below. Or, to quickly change programs without the *FlexDial™*, *press, hold in* and *rotate* the PERCENT ENERGY dial. *Releasing* it selects the program displayed.

FLEXDIAL™ → PROGRAMS → DGX, LOWEST, LOW 0.25, LOW 0.5, INTERMIT, 2X LP, 2X DOSE, USER

Press and *hold in* the PERCENT ENERGY dial at any time to display the stimulus program in effect. *Release* the dial to return to the PERCENT ENERGY display.

FREQUENCY SELECTION

When a factory-programmed preset stimulus is in effect, frequency is *automatically adjusted* for any given PERCENT ENERGY setting. Selecting a specific frequency takes the Thymatron® System IV out of any preset program. To select a specific stimulus frequency:

FLEXDIAL™ → FREQUENC → 10, 20, 30, 40, 50, 60, 70 Hz

PULSEWIDTH SELECTION

When a factory-programmed preset stimulus is in effect, the pulsewidth is *automatically adjusted* for any given PERCENT ENERGY setting. Selecting a specific pulsewidth takes the Thymatron® System IV out of any preset program. To select a specific stimulus pulsewidth:

FLEXDIAL™ → P-WIDTH → 0.25, 0.5, 0.75, 1.0, 1.25, 1.5 ms

Because stimulus duration is limited to a maximum of 8 seconds, the higher PERCENT ENERGY settings will not be available when *manually* setting the 0.25 ms pulsewidth, which will provide stimuli only up to the 50% ENERGY. However, when the LOW 0.25 program is in effect, stimuli of up to 100% ENERGY can be delivered because, for this program only, the frequency can go as high as 140 Hz.

STIMULUS DOSE FOR *BILATERAL,* BITEMPORAL, BIFRONTAL, LART ECT

For the initial treatment, select the LOW 0.5 program. The PERCENT ENERGY dial should be set to approximately 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 re-stimulated within 30-60 seconds to maximize the likelihood of obtaining a therapeutically satisfactory seizure at the first treatment session.

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 a good seizure. Consideration should be given at the next treatment session to administering a stimulus dose at the patient's age or at maximum charge.

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 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. This is because minimum stimulus dosing has been associated with inadequate therapeutic efficacy for right unilateral ECT.

STIMULUS TITRATION PROCEDURE

For those who prefer to set the initial stimulus dose relative to the seizure threshold, a simple and practical stimulus titration schedule for unilateral ECT starts with an initial setting of 5% ENERGY, followed by re-stimulations at 5% ENERGY increments until a seizure occurs, to a maximum of 4 stimulations in a treatment session (on average, fewer than three stimuli are required). 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 (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. The subsequent treatments should be administered at doses approximately 2 times this threshold (e.g., 40% ENERGY for a patient with 20% ENERGY seizure threshold).

"BENCHMARK" METHOD FOR SETTING AND ADJUSTING 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 Suppression Index (PSI), Maximum Sustained Power (MSP), or peak heart rate (PEAK HR).

Unlike stimulus threshold titration, the benchmark method does not require administering consecutively increasing sub-threshold stimulus doses until a seizure is obtained. Rather, at the first ECT treatment a high enough stimulus dose is given to induce an expected vigorous and effective seizure in virtually all patients. The value for the benchmark measurement reported in the end-of-treatment report for this first ECT treatment is then used as a target for all subsequent treatments.

Selection of the initial stimulus dose for the benchmark method 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 most patients, regardless of treatment electrode placement. Alternatively, the PERCENT ENERGY dial can be set to the patient's age for unilateral ECT, or to 50-75% ENERGY 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 established target, keeping in mind the often dramatic rise in seizure threshold across a course of treatment. Lower target values suggest 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 rate 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 Available in USA or Canada*)

The double dose programs *automatically* vary the pulsewidth and frequency to obtain the longest duration possible for any given PERCENT ENERGY dial setting, up to 200% ENERGY or 1008 mC. The PERCENT ENERGY settings are in increments of 5% up to 100% ENERGY and then in increments of 10% up to 200% ENERGY. The double dose programs are selected as follows:

FLEXDIAL™ → PROGRAMS → 2X DOSE
FLEXDIAL™ → PROGRAMS → 2X LP

Table 2 of this manual shows the doses, pulsewidths, and frequencies that correspond to the PERCENT ENERGY dial settings for the double dose programs. The pulsewidth varies between 0.5 ms and 1.0 ms, while the frequency varies between 10 and 140 Hz.

TREATMENT STIMULUS ADMINISTRATION

Flip up the clear plastic hinged cover over the "TREAT" button. *Press* and *hold* the button down until the treatment light comes on and then goes off again. While the "TREAT" button is held down, the following events will occur:

a. **A one second continuous tone warning signal comes on, during which no current is delivered. If the impedance is >3000, the warning tone is extended to 3 seconds. If the "TREAT" button is still pressed, the treatment will be delivered.**
b. **The "TREAT" button lights up *and* an intermittent buzzing tone sounds while the current is being delivered.**
c. **The "TREAT" button light and buzzing tone both turn off when the treatment stimulus ends. The "TREAT" button can then be released.**
d. **The *Audible EEG*™ seizure monitor is activated (unless the volume is turned off) and the 4-channel printer automatically starts to provide a paper recording. If the printer is already running when the treatment stimulus is delivered, the printer will stop and automatically resume when the stimulus current ends.**
e. **The 8-digit L.E.D. on the front panel automatically displays 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 buzzing tone stop. Releasing the button early terminates the stimulus and delivers a smaller charge than intended. However, keeping pressure on the "TREAT" button after the stimulus ends, will not deliver additional stimulation. When holding the patient's jaw or touching the patient, make sure electrically insulated gloves are used.

SEIZURE MONITORING

The Thymatron® System IV allows the physician to monitor the physiological variables of EEG, ECG, and EMG. The paper tracing provides the wave forms and beats per minute for the ECG. The EEG and EMG also appear on the tracings, with additional information provided.

EEG SEIZURE MONITORING

1) **The *Audible EEG*™ seizure monitor**
2) **The EEG paper recording**
3) **The Ictal Line™ seizure indicator**
4) **The EEG endpoint and indexes determined values**

Audible EEG™ Seizure Monitor

This feature operates automatically when the "TREAT" button is pressed and released. The knob marked "VOLUME" on the back panel controls the volume of the tone. To inactivate this feature, turn the volume control knob all the way counterclockwise.

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 for the interpretation of the *Audible EEG™* seizure monitor.

EEG paper recording

a) *Paper EEG recording prior to the treatment stimulus* can be initiated (after the EEG electrodes have been properly applied) by pressing the "START/STOP" button on the front panel. This will provide a paper record of the patient's baseline recording. The printer stops during treatment stimulus administration.
b) *Automatic paper EEG recording* begins or resumes when the treatment stimulus ends. The EEG recording continues through ictal and postictal periods, until the "START/STOP" button is pressed, which generates the end-of-treatment report.

NOTE: Obtaining a paper baseline EEG record does not replace *the baseline EEG collection* procedures described above.

Ictal Line™ Seizure Indicator

After baseline EEG collection is completed by the Thymatron® System IV and the "READY" message light appears, a thin black line is printed along the top of the paper recording strip when the EEG amplitude exceeds a specified baseline value. An unbroken, solid black line reflects continuous seizure activity. A broken or intermittent line reflects waxing and waning, or intermittent seizure activity. Complete cessation of the black line reflects EEG seizure termination, as determined by the Thymatron® System IV. *Wait several seconds before pressing the "START/STOP" button to terminate recording because the computer takes that long to process and report the seizure endpoints and indices.*

Endpoints and Indices

A unique feature of the Thymatron® System IV, (U.S. patents: 4873981, 4878498, 5269302 and 5871517), provides two computer-determined estimates of the duration of the induced seizure, derived from the EEG and EMG data.

Automatic EEG Seizure Endpoint Determination

The Thymatron® System IV continuously monitors the EEG for the endpoint of seizure activity and prints the EEG seizure duration, in seconds, on the end-of-treatment report, *provided the baseline EEG collection procedures have been properly followed and the "READY" message has appeared. (If the treatment stimulus is administered before the "READY" message appears, automatic EEG analysis will not occur and the end-of-treatment report will state the message* "Baseline not available.")

In about 10-20% of ECT treatments, the EEG endpoint is not readily determined (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 activity. In these circumstances, inability to detect a precise EEG 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 is not detected".

Automatic EMG (Motor) Seizure Endpoint Determination

The Thymatron® System IV is shipped with the EMG monitor enabled in channel 3. When EMG monitoring electrodes have been properly applied, the lead-wires and monitoring cable connected, then EMG tracing automatically appears on the paper record after the treatment stimulus ends.

The Thymatron® System IV continuously monitors the EMG for motor seizure activity and prints the EMG endpoint seizure duration in seconds, on the end-of-treatment report. Baseline EMG collection is neither required, nor possible, in obtaining this measure.

CAUTION: The computer-derived endpoint seizure duration measures, including the Ictal Line™ seizure 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 reports indicate seizure termination. It is also possible for artifact to be interpreted by the computer programs as seizure activity.

GAIN AND POSITION SETTINGS

The factory preset "GAIN" and "POSITION" settings should produce the best results. For those who prefer individualized settings, please note that "POSITION" is always set *after* "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".

FLEXDIAL™ → CHANN. [n] → G[n]-10 to G[n]-2000 → P[n]-AUTO, P[n]-0 to P[n]-800

G[*n*]-OFF	**Turns off printing in channel [*n*]**
G[*n*]-10 to G[*n*]-2000	**Adjusts channel [*n*] gain (in microvolts)**
P[*n*]-AUTO	**Selects *automatic* positioning for printing channel [*n*]**
P[*n*]-0 to P[*n*]-800	**Adjusts position on strip from 0 (bottom) to 800 (top)**

NOTE: The amplitudes of the tracings decrease as the gain numbers increase.

TURN OFF PRINTING IN A CHANNEL

To turn off printing in a given channel, set the gain for that channel to "OFF". If a given channel has been turned off, the other channels should be set to the "AUTO" position in order to evenly space the remaining tracings on the paper.

FLEXDIAL™ → CHANN. [n] → G[n]-OFF

CHANGING EEG GAIN RAPIDLY

TIP: To rapidly change the gain in all EEG channels, while the printer is running, press, hold in and then rotate the FlexDial™ to print successive new gain values on the paper chart; release the FlexDial™ to lock in the desired value when it appears.

SEIZURE QUALITY MEASURES

The Thymatron® System IV provides 7 Seizure Quality Measures under the "INDEXES" function level that can be individually enabled/disabled. EEG monitoring must be enabled to obtain these measures. Their names and FlexDial™ designations are as follows:

Average Seizure Energy Index	ASEI ON/OFF
Postictal Suppression Index	PSI 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 AVERAGE SEIZURE ENERGY INDEX (ASEI) integrates the total ictal EEG power across the entire seizure and divides the result by the total seizure duration.

The POSTICTAL SUPPRESSION INDEX (PSI) measures the percentage decrease in ictal EEG amplitude immediately following seizure termination.

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 (COH) 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.

DUKE UNIVERSITY AMPLITUDE MEASURES display the amplitudes of the 3 seizure segments (early ictal, mid-ictal, and post-ictal) reported by Duke University investigators to correlate with ECT treatment response.

BASELINE RETENTION

Baseline Retention, BLV, found under ENDPOINTS, is the length of time the EEG baseline will be kept in memory after the treatment. It can be set from 0 - 5 minutes. After this time a new EEG baseline must be acquired. This feature is useful for re-stimulation without acquiring a new EEG baseline.

TO ENABLE/DISABLE SEIZURE QUALITY MEASURES

FLEXDIAL™ → INDEXES → AESI ON/OFF, PSI ON/OFF, MSP ON/OFF, COH ON/OFF, DUKE ON/OFF

In the "INDEXES" function level, repeatedly *pressing* the *FlexDial*™ will show a sequential flashing status display (ON/OFF) for ASEI, PSI, MSP, COH, and DUKE measures, in that order. *Rotating* the *FlexDial*™ will flash-display the enable/disable (ON/OFF) options, for each index. *Press* the *FlexDial*™ to select "ON" or "OFF" for each index and advance to the next. When the last index (DUKE) is enabled/disabled the display returns to INDEXES function level.

EEG FREQUENCY MEASURES

The Thymatron® System IV provides a continuously updated display of the user's choice of one of 3 additional EEG measures: the *95% Spectral Edge Frequency* (the EEG frequency below which 95% of the total EEG power is found), the *Median Frequency* (the EEG frequency above and below which 50% of power is found) and the *Relative Delta Power* (the % EEG power found in the delta bandwidth: 1.5–3.5 Hz).

FLEXDIAL™ → EEG FREQ → SP. EDGE, MID FREQ, % DELTA

SP. EDGE	**95% Spectral Edge Frequency**
MID FREQ	**Median EEG frequency**
% DELTA	**Relative EEG power in the delta bandwidth**

When EEG FREQ is enabled with one of these options, baseline EEG collection has been obtained and the "READY" message appears, the values are continuously displayed in the 8-character L.E.D. After several seconds, the "READY" is replaced with the letter "R" to the right of the EEG values being displayed.

PRINTER PAPER SPEED SELECTION

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 turned off entirely,* as follows.

FLEXDIAL™ → PRINTOUT → PRINT 5, PRINT 25, PRINT 50
TURN OFF PRINTING ENTIRELY

FLEXDIAL™ → PRINTOUT → PRINTOFF

POWER SPECTRAL ANALYSIS (FFT) SELECTION

After the paper speed has been selected by *rotating* and then *pressing* the *FlexDial™*, the FFT option ("ON" or "OFF") flash-displays. FFT ("Fast Fourier Transform") is an algorithm for extracting frequency information from the EEG signal to perform a *Power Spectral Analysis* that displays the EEG frequencies in various bandwidths for advanced clinical or research purposes. The Thymatron® System IV is shipped with the FFT printout disabled; to enable this feature:

FLEXDIAL™ → PRINTOUT → FFT ON, FFT OFF

USER SPECIFIED FLEXDIAL™ SELECTIONS

This feature allows the user to save and then recall up to 8 user-specified *FlexDial™* selections in the Thymatron® System IV memory. Individual doctors' preferred range of *FlexDial™* settings can be saved as "USER" selections, or specific *FlexDial™* settings within a factory program can be saved, (e.g., turn channel 4 "OFF" and "UPLOAD" automatically.) Once the different user-specified selections have been made and locked in by *pressing* the IMPEDANCE TEST button or the START/STOP button, they may be saved as a USER selection as follows:

FLEXDIAL™ → SAVE USR → SAVE US1-SAVE US8

After they have been saved, these user-specified selections can be recalled using the "SETTING" function of the *FlexDial™* shell by selecting from the options "SET US1" through "SET US8". *Be sure to remember or write down which number this specific configuration was saved as, so it can easily be recalled.*

FLEXDIAL™ → SETTING → SET US1 – SET US8

When a user-specified *FlexDial™* selection is in force, the "USER SET" dot L.E.D. on the front panel will light.

RESET FLEXDIAL™ SETTINGS TO FACTORY VALUES

The factory-programmed values listed below for the 13 *FlexDial*™-selectable settings can be *reset* as a group as follows:

FLEXDIAL™ → SETTING → RESET

Chann. 1.....G1--200 µV; P1--AUTO
Chann. 2.....G2--200 µV; P2--AUTO
Chann. 3.....G3--1000 µV; P3--AUTO
Chann. 4.....G4--1000 µV; P4--AUTO
FREQUENC.....Variable with LOW 0.5 program
P-WIDTH.....0.5mS
PROGRAMS....LOW 0.5 program
CH. 3-4.....EMG-ECG
ENDPOINT.....EEG-ON; EMG-ON; HR-ON; PHR-ON; ESA-OFF; BLV-2
INDEXES.....ASEI-ON; PSI-ON; MSP-ON; COH-ON; DUKE-OFF
EEG FREQ.....FREQ. OFF
PRINTOUT.....PRINT-25; FFT-OFF
UPLOAD.....LOAD - OFF

***TIP*: To quickly reset all values to factory settings right after the "SELFTEST" has been performed at power-on, *press* the *FlexDial*™ three times in a row, then *press* the IMPEDANCE TEST button.**

To print a report showing all the *FlexDial*™ settings in effect at any given time, simply *press* the *FlexDial*™ to enter any function level and then *press* the START/STOP button.

TRANSFERRING DATA BETWEEN A PC AND THYMATRON® SYSTEM IV

The Thymatron® System IV allows the operator either to send data (upload) or to receive data (input or download) from a personal computer. The data transfers all require using GENIE™ IV software, which is included with the Thymatron® System IV. The data can be *alphanumeric*, such as the name of the hospital or patient information, or it can be *digitized* EEG, ECG, or EMG.

With the exception of the hospital's name, all data to be downloaded must have been first uploaded to a PC using the GENIE™ IV software. One reason for downloading this data to the Thymatron® System IV would be to print a paper copy of an earlier treatment.

NOTE: All procedures listed below require the GENIE ™ IV software to be installed on a PC connected to the Thymatron® System IV through the rear panel RS 232 serial port and the GENIE™ IV software program opened to the proper section. Please consult the GENIE™ IV manual for further details.

INPUT HOSPITAL NAME FOR THE PRINTED REPORT

This name will replace the Thymatron® System IV, S/N line on the start-up report.

FLEXDIAL™ → DATA IN → DATA IN

1. ***Press*** **the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.**
2. ***Rotate*** **the *FlexDial*™ until "DATA IN" is displayed.**
3. ***Press*** **the *FlexDial*™ once; "DATA IN" will flash-display.**
4. ***Press*** **the *FlexDial*™ again; "IN ← ← ←" will flash-display.**
5. **On the PC, from the GENIE™ IV software main menu, click on CONNECT → SEND NAME.**
6. ***Type in*** **hospital name in the "Name to Send" box and click "Send".**
7. ***Press*** **the "IMPEDANCE TEST" or "START/STOP" button to exit the *FlexDial*™ mode.**

DOWNLOAD PRE-RECORDED TREATMENT DATA FROM PC FOR REPRINTING BY THYMATRON® SYSTEM IV

FLEXDIAL™ → DATA IN → DATA IN

This feature allows for previously recorded treatment data to be sent back to the Thymatron® System IV. Once the data has been received back in the Thymatron® System IV, it can then be reprinted using the "REPRINT" option in the "DATA OUT" function level.

1. ***Press*** **the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.**
2. ***Rotate*** **the *FlexDial*™ until "DATA IN" is displayed.**
3. ***Press*** **the *FlexDial*™ once; "DATA IN" will flash-display.**
4. ***Press*** **the *FlexDial*™ again; "IN← ← ←" will flash-display.**
5. **On the PC, from the GENIE™ IV software main menu, click on FILE → OPEN. Highlight the file to be sent and click OPEN. From the main menu, click on CONNECT → SEND DATA.**
6. **Transfer is complete when the display stops flashing and returns to "DATA IN".**
7. ***Press*** **the "IMPEDANCE TEST" or "START/STOP" button to exit the *FlexDial*™ mode.**

This treatment data will now replace that of the last treatment given and will stay in the Thymatron® System IV memory until the unit is turned off or another treatment is given. To reprint this treatment on a paper record, see the DATA OUT section below.

UPLOAD TREATMENT DATA AUTOMATICALLY TO A PC

This feature allows for the automatic transfer of the treatment data to a PC after the printed end-of-treatment report. The PC must be connected to the Thymatron®

System IV and the Genie™ IV software opened to the correct function; please review the GENIE™ IV manual for further details. The options are as follows:

LOAD OFF	Disables UPLOAD function and no data will be transferred.
LOAD RAW	Sends all EEG data, including the FFT points and end-of-treatment report.
LOAD FFT	Sends all FFT points and end-of-treatment report.
LOAD TXT	Sends ASCII file of the end-of-treatment report.

FLEXDIAL™ → UPLOAD → LOAD OFF, LOAD RAW, LOAD FFT, LOAD TXT

1. *Press* the *FlexDial*™ to display the most recently adjusted *FlexDial*™ function.
2. *Rotate* the *FlexDial*™ until "UPLOAD" is displayed.
3. *Press and rotate* the *FlexDial*™ to flash-display the above options.
4. *Press* the *FlexDial*™ to select the desired option, usually "LOAD RAW".
5. *Press* the "IMPEDANCE TEST" or "START/STOP" button to exit the *FlexDial*™ mode.

After the patient is treated and the end-of-treatment report is printed, the Thymatron® System IV is ready to send the data to the PC. Make sure all the connections are correct and the GENIE™ IV software is opened. From the GENIE™ IV main menu click on CONNECT → AUTO UPLOAD. A small screen will pop up showing the progress of the transfer. When the transfer is complete a new REPORT screen pops up with the treatment date and time.

Note: The transferred file will be automatically saved as the "date and time" of the treatment. This file can then be renamed and saved under the proper patient's file by selecting from the GENIE™ IV main menu FILE → SAVE AS.

MONITOR EEG/EMG/ECG ON THE PC SCREEN

This feature allows for real-time monitoring of all enabled EEG/EMG/ECG channels via the PC screen, providing a constantly updated display of the actual EEG/EMG/ECG tracings before and after the treatment stimulus has been administered. *This monitoring will not affect the printed paper recording.*

Before starting to monitor, make sure all the connections are correct and the GENIE™ IV software is opened. From the GENIE™ IV main menu, click on WINDOW → GRAPH. From the main menu, click on TOOLS → PLAY CONTROL and then TOOLS → CHANNEL SETTING. Adjust the size of the graph screen to allow for these two pop up screens. To start the monitoring, follow the procedure below:

1. *Press* the IMPEDANCE TEST button to begin sending data.
2. *Click* on MONITOR in the PLAY CONTROL section.

The monitoring will stop while the treatment stimulus is given with the "TREAT" button and it will automatically re-start after the stimulus is completed. The monitoring function will not interfere with the paper recording function as both will proceed at the same time. When the "START/STOP" button is pressed, the monitoring will also stop.

NOTE: To combine the monitoring and automatic upload features, go to the GENIE™ IV main menu, click on CONNECT → AUTO UPLOAD. A small screen will pop up with the date & time for the name. Re-name the file using the patient's information, if desired and click UPLOAD. From the GENIE™ IV main menu, click on WINDOWS → GRAPH and then TOOLS → PLAY CONTROL and TOOLS → CHANNEL SETTING as above.

OUTPUT TREATMENT DATA MANUALLY

This feature allows for manual transfer of the treatment data after the end of a given treatment. The Thymatron® System IV *stores only the last treatment* in memory. *If the unit is turned off or another treatment is given before data transfer, this data will be lost.* This feature can be used when an occasional treatment is to be stored on the PC. Make sure all the connections are correct and the GENIE™ IV procedures are followed. Please review the GENIE™ IV manual. The options for "DATA OUT" are:

REPRINT	Reprints a complete record of the treatment just given, or can be used to reprint the treatment data just received from the PC.
RAW DATA	Sends all data including the FFT points and end-of-treatment report.
FFT DATA	Sends the FFT points and end-of-treatment report.
RESULTS	Sends ASCII files of end-of-treatment report.
RETURN	Returns to the DATA OUT function level of the *FlexDial™*.

FLEXDIAL™ → DATA OUT → REPRINT, RAW DATA, FFT DATA, RESULTS, RETURN

1. *Press* the *FlexDial™* to display the most recently adjusted *FlexDial™* function.
2. *Rotate* the *FlexDial™* until "DATA OUT" is displayed.
3. *Press and rotate* the *FlexDial™* to flash-display the options listed above.
4. *Press* the *FlexDial™* to select the desired option, usually "RAW DATA".
5. The message "OUT→ → →" appears as the data is transferred to the computer.
6. *If no treatment data is stored in memory the message "EMPTY" will flash and no data transfer will occur.*
7. From the GENIE™ IV main menu, click on CONNECT → RECEIVE DATA. The small pop up screen will display the transfer progress. When finished, a new pop up screen, REPORT will contain the data. This file may be saved using the main menu FILE → SAVE AS feature.
8. When the transfer is complete, the *FlexDial™* display returns to "DATA OUT".
9. *Press* the "IMPEDANCE TEST" or "START/STOP" button to exit the *FlexDial™* mode.

REPRINT THE LAST TREATMENT

The Thymatron® System IV automatically stores the last treatment in memory. If the recording paper runs out or is damaged, the last treatment can be reprinted using this feature. This "REPRINT" feature also allows for the reprinting of the treatment data *just* transferred to the Thymatron® System IV from the PC. In either case, the only treatment reprinted will be the last one in the memory. *If the unit is turned off, another treatment is transferred from the computer or another treatment is given, the earlier treatment data will be lost.* The procedure for reprinting the treatment data is:

FLEXDIAL™ → DATA OUT → REPRINT

While the treatment data is being reprinted, the "REPRINT" message will flash until all the data has been reprinted, after which the printer will automatically stop, providing the original data contained an end-of-treatment report.

SET DATE & TIME IN PRINTED REPORT

To change/reset the time or date, use the following procedure. Enter the *FlexDial*™ mode, *rotate* to the "CLOCK" function level and then alternate *pressing* and *rotating* the *FlexDial*™ to make the following selections:

FLEXDIAL™→ CLOCK →MONTH→DAY→YEAR→HOUR→MIN

MONTH	01 - 12
DAY	01 - 31
YEAR	00 - 99
HOUR	00 - 24
MIN	00 – 60

TABLE 1: STANDARD DOSE STIMULUS PARAMETERS: STIMULUS DURATION (in seconds), CHARGE (in 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
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 = 60 PW= .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 = 70 PW= .5

DIAL	DURATION	mC	JOULES
5 %	0.40	25.2	5.0
10 %	0.80	50.4	10.0
15 %	1.20	75.6	15.0
20 %	1.60	100.8	20.0
25 %	2.00	126	24.9
30 %	2.40	151.2	29.9
35 %	2.80	176.4	34.9
40 %	3.20	201.6	39.9
45 %	3.60	226.8	44.9
50 %	4.00	252	49.9
55 %	4.40	277.2	54.9
60 %	4.80	302.4	59.9
65 %	5.20	327.6	64.9
70 %	5.60	352.8	69.9
75 %	6.00	378	74.8
80 %	6.40	403.2	79.8
85 %	6.80	428.4	84.8
90 %	7.20	453.6	89.8
95 %	7.60	478.8	94.8
100 %	8.00	504	99.8

FREQ = 10 PW= .75

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 = 20 PW= .75

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 = 30 PW= .75

DIAL	DURATION	mC	JOULES
5 %	0.62	25.2	5.0
10 %	1.24	50.4	10.0
15 %	1.87	75.6	15.0
20 %	2.49	100.8	20.0
25 %	3.11	126	24.9
30 %	3.73	151.2	29.9
35 %	4.36	176.4	34.9
40 %	4.98	201.6	39.9
45 %	5.60	226.8	44.9
50 %	6.22	252	49.9
55 %	6.84	277.2	54.9
60 %	7.47	302.4	59.9

FREQ = 40 PW= .75

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 = 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
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45 %	1.68	226.8	44.9
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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
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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 PARAMETERS: Frequency (in Hertz), Pulsewidth (in milliseconds) and Stimulus Duration (in seconds), for each Energy Dial Setting above 100%. ***(Not available in USA or Canada)***

The 2X Dose and 2X LP programs provide the only method for exceeding the 100% Energy maximum of the Thymatron® System IV. When selected, either program automatically chooses the requisite frequency and pulsewidth, which are then NOT user-selectable. It is not possible to further set either frequency or pulsewidth because the Thymatron® System IV will not go past 100% Energy with manual (FlexDial) selection of these variables.

	2X Dose			2X Dose Lowest Pulsewidth		
% Energy	Freq. Hz	Pulse Width	Duration Sec.	Freq. Hz	Pulse width	Duration Sec.
5	10 Hz	0.5 ms	2.75 sec	10 Hz	0.25 ms	5.55 sec
10	10	0.5	5.55	20	0.25	5.58
15	20	0.5	4.18	30	0.25	5.58
20	20	0.5	5.58	30	0.25	7.45
25	30	0.5	4.65	40	0.25	6.99
30	30	0.5	5.58	50	0.25	6.71
35	30	0.5	6.52	50	0.25	7.83
40	30	0.5	7.45	60	0.25	7.46
45	40	0.5	6.29	70	0.25	7.19
50	40	0.5	6.99	70	0.25	7.99
55	50	0.5	6.15	80	0.25	7.69
60	50	0.5	6.71	90	0.25	7.46
65	50	0.5	7.27	100	0.25	7.28
70	50	0.5	7.83	100	0.25	7.84
75	60	0.5	6.99	110	0.25	7.63
80	60	0.5	7.46	120	0.25	7.46
85	70	0.5	6.79	120	0.25	7.93
90	70	0.5	7.19	130	0.25	7.75
95	70	0.5	7.59	140	0.25	7.60
100	70	0.5	7.99	140	0.25	8.00
110	60	0.75	6.83	100	0.4	7.70
120	60	0.75	7.46	110	0.4	7.63
130	70	0.75	6.83	120	0.4	7.58
140	70	0.75	7.46	100	0.5	7.84
150	70	0.75	7.99	110	0.5	7.63
160	60	1.0	7.46	120	0.5	7.46
170	60	1.0	7.93	120	0.5	7.93
180	70	1.0	7.19	110	0.6	7.63
190	70	1.0	7.59	120	0.6	7.38
200	70	1.0	7.99	100	0.7	8.00

EMC SUPPLEMENT

1. An externally generated artifact is indicated if all the channels exhibit the same pattern superimposed on or interfering with the signal. Try repositioning the electrode leads to eliminate this pattern.

2. A power mains artifact is indicated if all channels exhibit a thick solid line. Try repositioning the electrode leads to eliminate this.

3. A large static discharge may cause the system to reset. The system would go through the "SELFTEST" again and be ready to treat in about five seconds. To minimize static electricity make sure to maintain sufficient humidity in the treatment room and have a good grounding system on your mains.

4. A large high frequency pulse (e.g., as from electromagnetic imaging equipment) may cause the system to reset. The system would go through the "SELFTEST" again and be ready to treat in about five seconds. If this occurs make sure to identify the device(s) producing these pulses and maintain sufficient distance between the Thymatron® System IV and the device(s) to prevent reoccurrence; if this is not possible, shielding may be required.

EMC DECLARATION

Guidance and manufacturer's declaration – electromagnetic emissions		
Thymatron® ECT Systems are intended for use in the electromagnetic environment specified below. The customer or the user of a Thymatron® System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	Thymatron® Systems use RF energy only for internal functions. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Thymatron® Systems are suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

EC DECLARATION OF CONFORMITY
To the Medical Device Directive 93/42/EEC

SOMATICS, LLC.
910 Sherwood Drive
Lake Bluff IL 60044, USA

Represented in EEC by Fred Berninger Importe OHG, Bergstrasse 12, 82024 Taufkirchen, Germany

Declares that the distributed CE marked products conform to the types covered by the

EC Certificate Number 86253CE01
issued by DEKRA, in accordance with Annex II of the Medical Directive 93/42/EEC

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the production quality assurance set out in Annex II.

This declaration is supported by the Quality System certification based on the harmonized standards ISO 13485:2003

Quality System Certificate No. *160440.01*

This Declaration of Conformity covers Thymatron Electroconvulsive Therapy Devices and is valid for all products distributed by Somatics, LLC. bearing the CE mark, including the Thymatron® System IV, starting with serial No. *40020 and* Thymatron System® II, starting with serial No. *40236* and ending with serial No. *41950*

INDEX PAGE

ADDENDUM I

SOFTWARE UPGRADES TO THYMATRON® SYSTEM IV

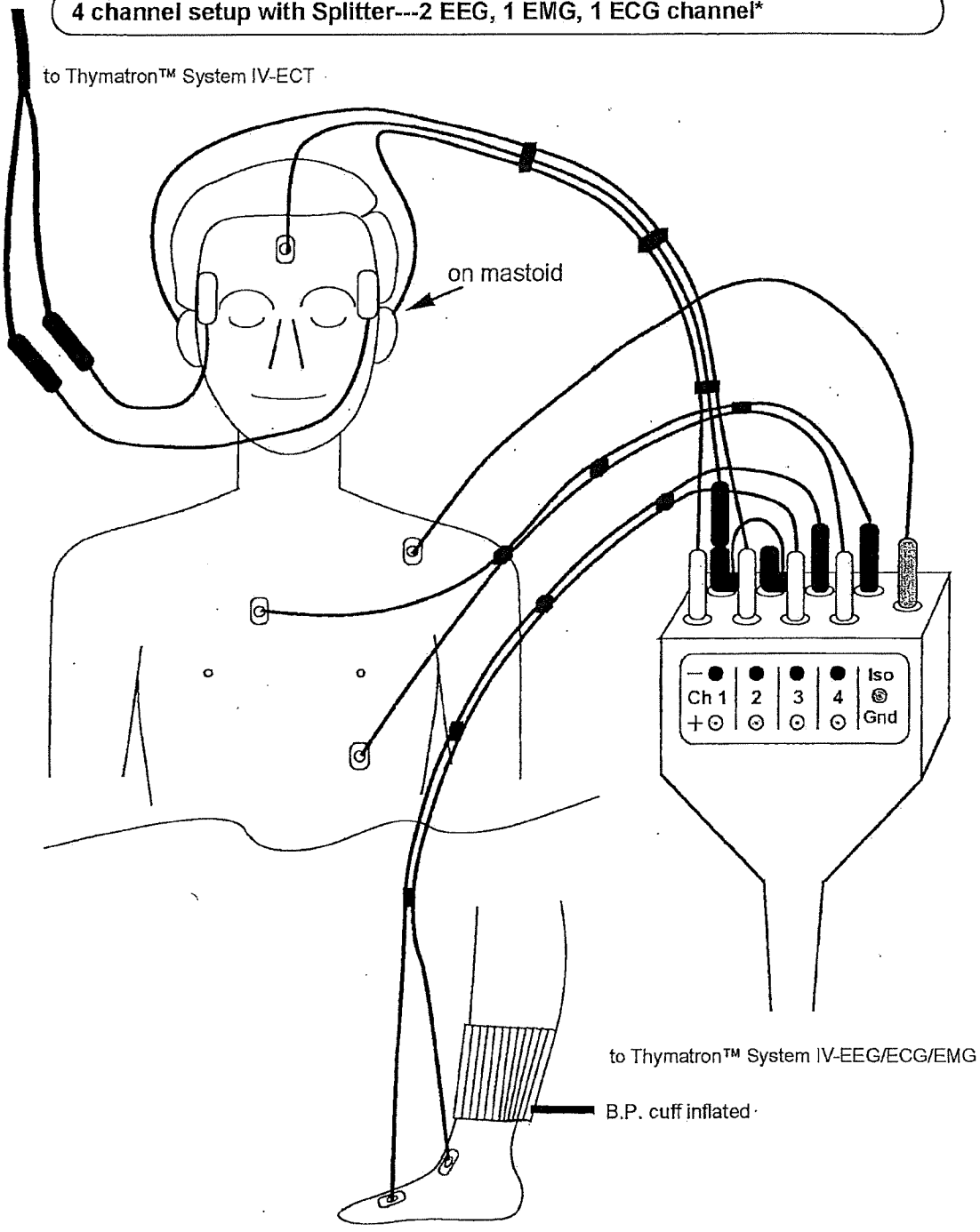
NB: *The software version of your Thymatron® System IV is automatically printed at power-up.*

Each of the following Thymatron® System IV and GENIE™ IV software upgrades includes all previous upgrades.

SOFTWARE VERSION	DATE	DESCRIPTION	REQUIRES GENIE VERSION
4.31	6/1/99	The initial software	4.5
4.32	6/15/99	DOS-compatible	4.5
5.00	9/1/00	Real time PC monitoring Palm® connection.	5.0
5.10	5/1/01	Diagnostic messages for EEG endpoint.	5.0
5.20	8/1/01	LOW 0.25 program	5.0
5.30	5/1/02	Automatic upload to PC SEI upgraded to ASEI, SGI retired Impedance test increased to 800 Hz.	6.3
5.40	11/15/02	EEG Frequency Measures	6.3
5.41	2/1/03	Eliminates recalibration after chip upgrade.	6.3
5.50	7/1/04	Improved algorithm for PSI Change program via Percent Energy Dial Change EEG gain *while* recording 2X Dose, (where available) changes by 5% increments, up to 100%, then by 10% to 200%	6.3
5.60	6/15/09	Adjust baseline retention (BLV), 0-5 minutes Reset EEG Baseline when pushing Impedance Test & Energy Buttons simultaneously Allows for 0.25 or 0.3 & 2X-LP Program	6.3
5.61	12/1/09	USER programs display up to 70 Hz	6.3
5.62	09/07/10	Reset "USER" mode to last frequency	6.3
5.63	11/03/10	Changes Baseline Validity settings	6.3

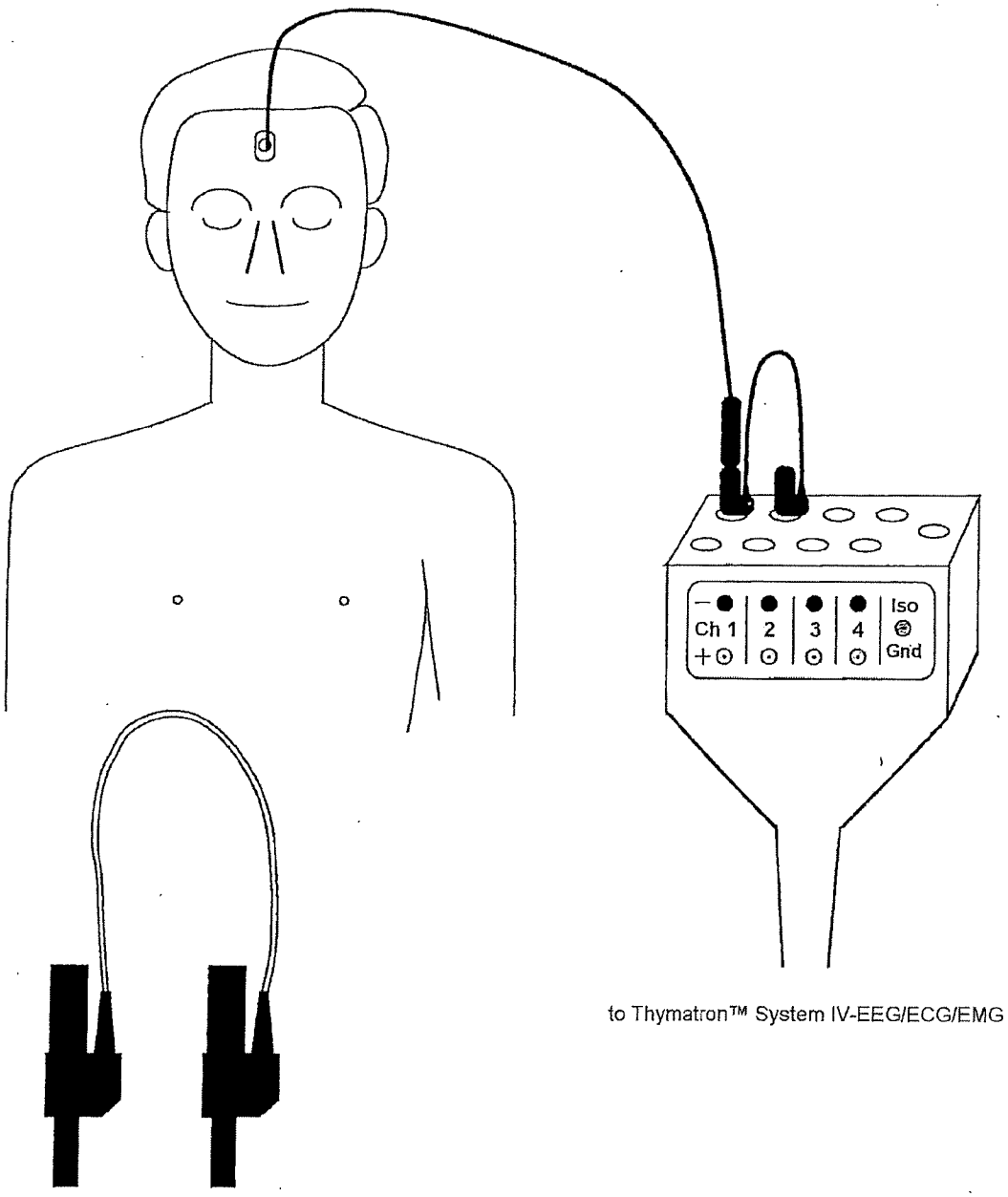
ADDENDUM II
ELECTRODE PLACEMENTS

4 channel setup with Splitter---2 EEG, 1 EMG, 1 ECG channel*



*Electrode connections for channel 1, 2 EEG, channel 3 EMG, channel 4 ECG recording

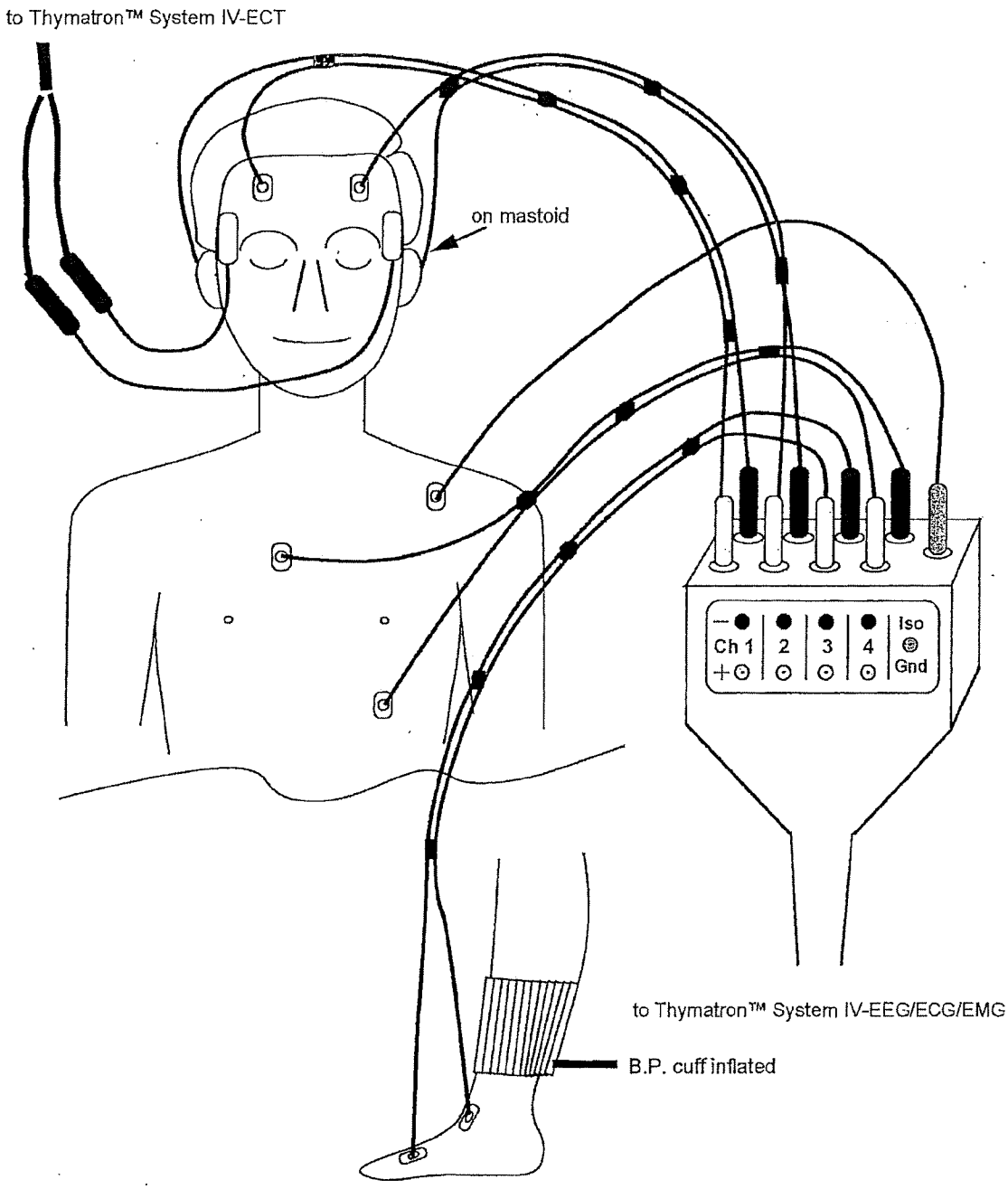
Electrode Splitter



to Thymatron™ System IV-EEG/ECG/EMG

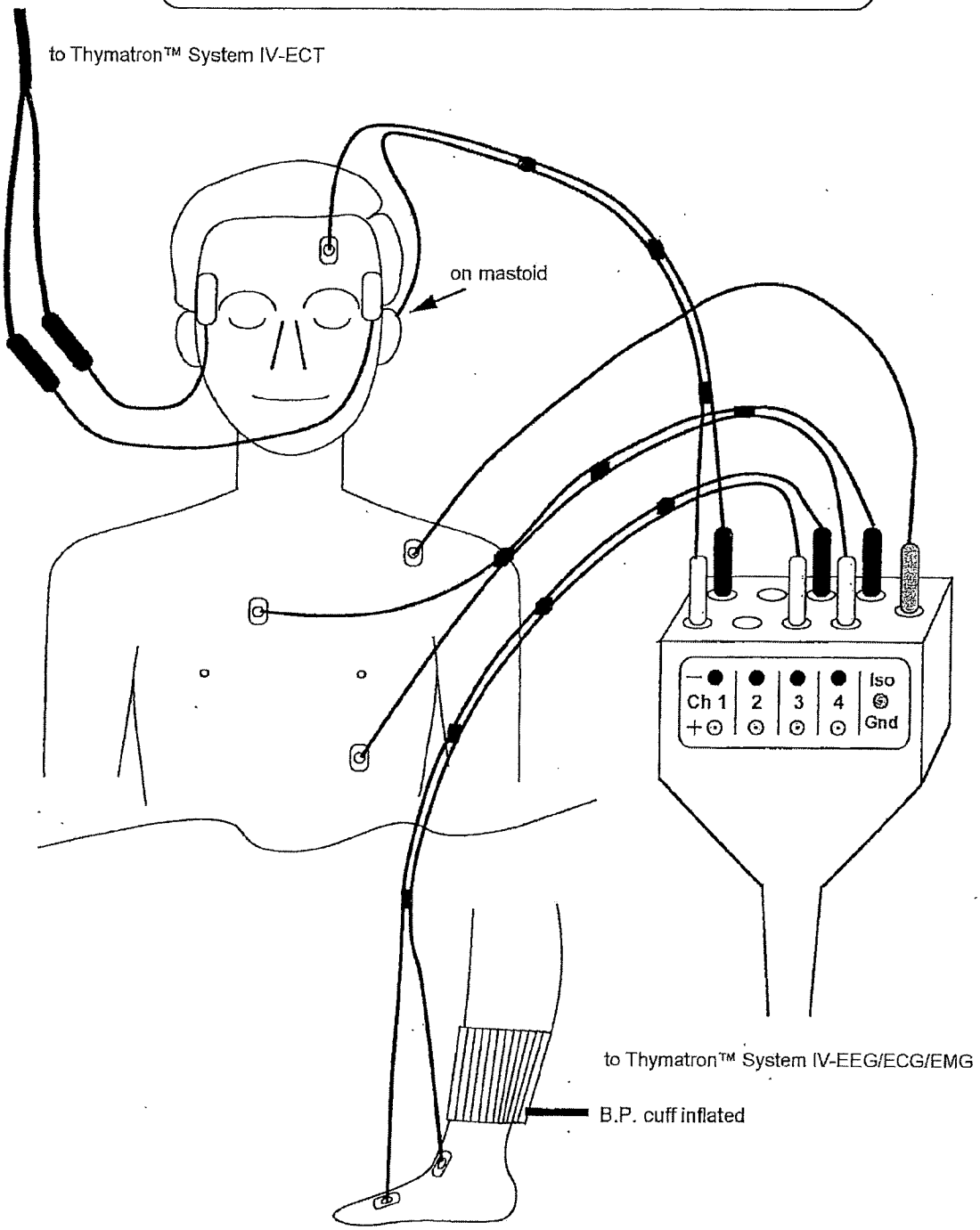
Somatics, LLC 9/23/05

4 channel setup---2 EEG, 1 EMG, 1 ECG channel *

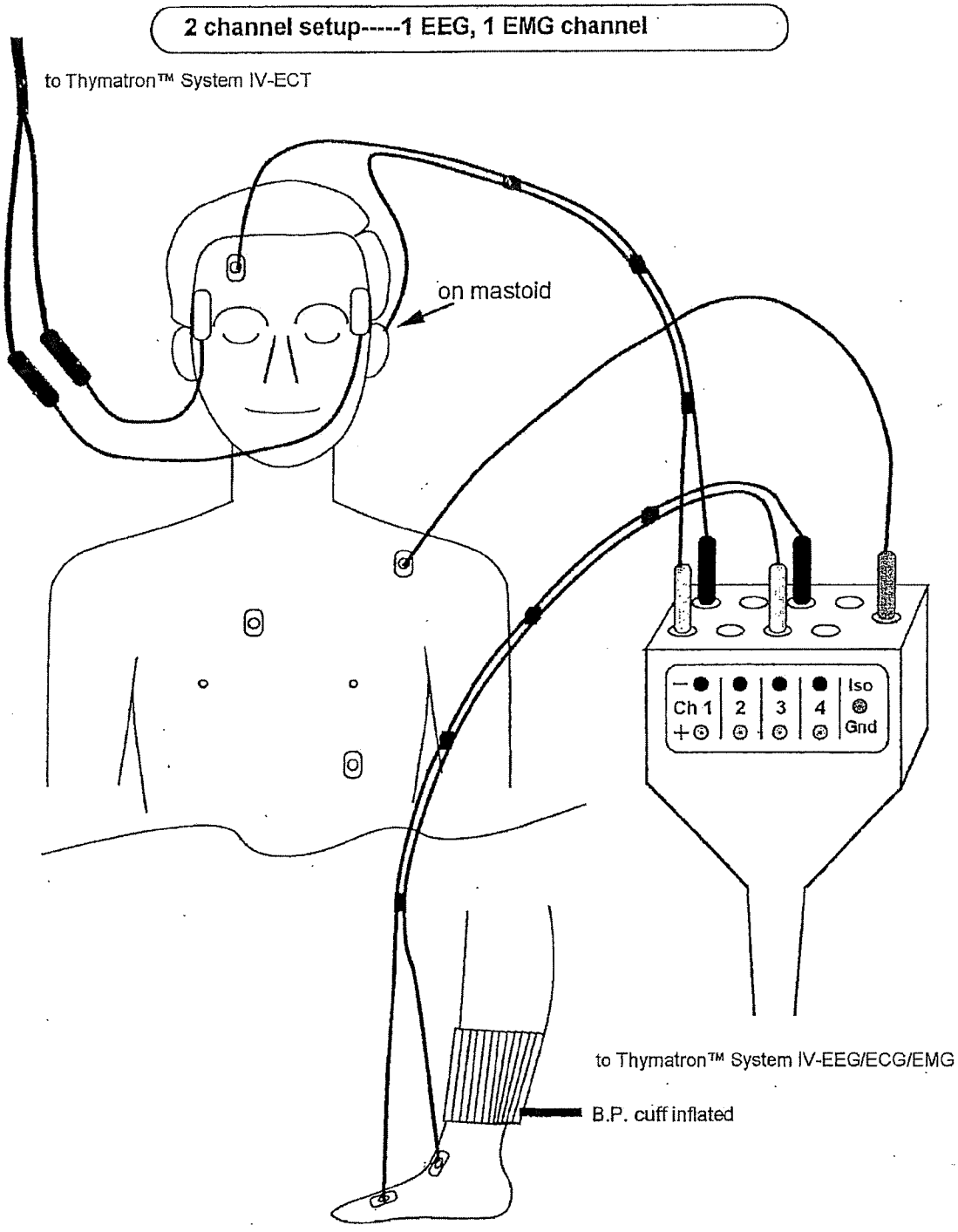


*Electrode connections for channel 1, 2 EEG, channel 3 EMG, channel 4 ECG recording

3 channel setup-----1 EEG, 1 EMG, 1 ECG channel

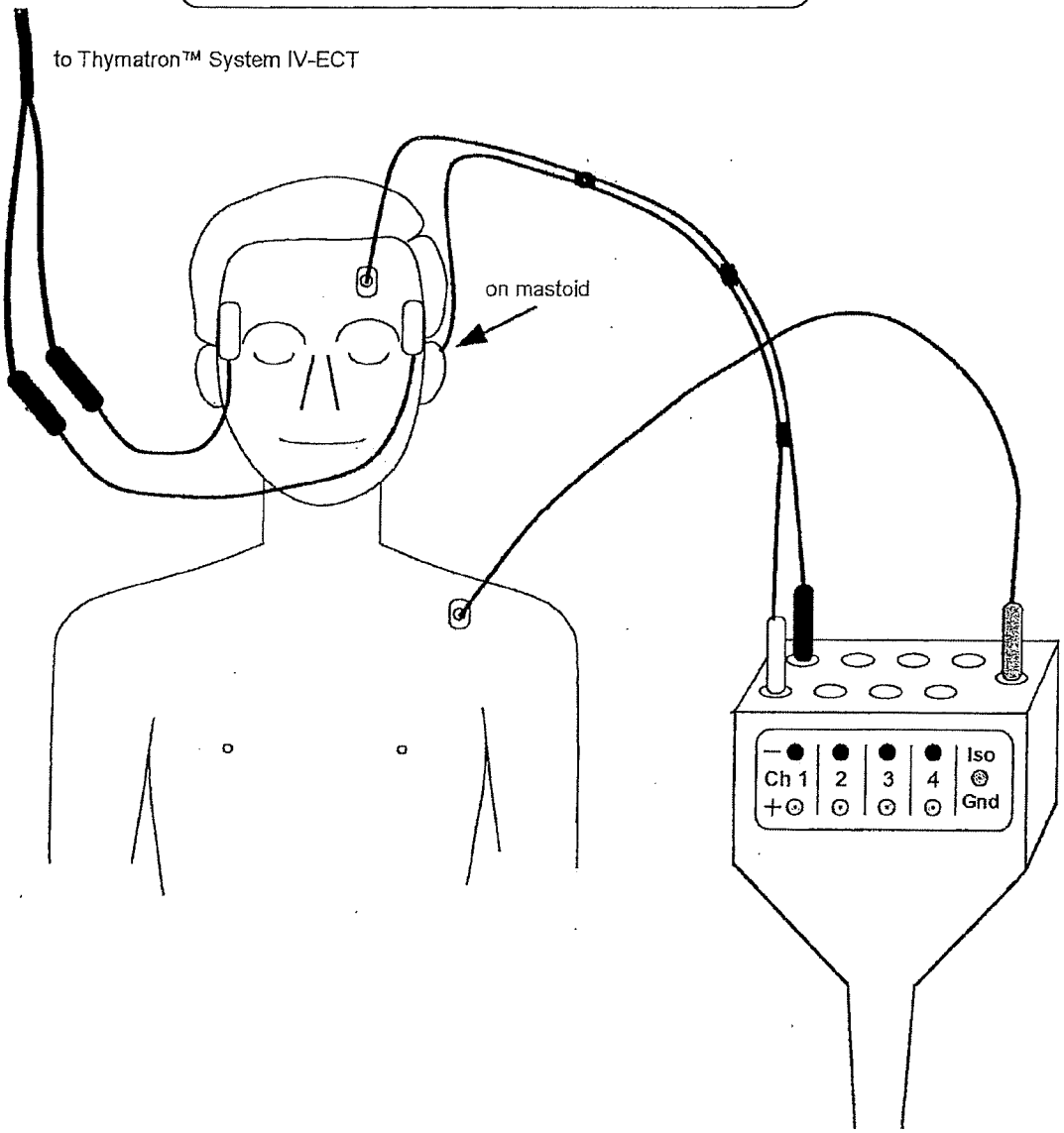


Electrode connections for channel 1 EEG, channel 3 EMG, channel 4 ECG recording



Electrode connections for channel 1 EEG, channel 3 EMG recording

1 channel setup-----1 EEG channel



Electrode connections for channel 1 EEG recording

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

THE WITNESS: Both, I'd say both.

I depend more on my clinical observations since I've been doing this for so many decades, that I do spend time with the patients before proceeding with treatments, before each treatment, and I assess the patient from a clinical perspective at that time. So I'm very much aware, and in follow-up with these patients clinically, I'm very much aware of the side effects that they encounter.

Q. (BY MR. BENKNER) Thank you for that.

And can you tell me what your understanding of the risks of ECT treatment is?

A. Mostly memory disturbance. The patients experience almost exclusively recent memory problems that are temporary, that will go away with time virtually in every case. I have had a number of patients who've had lost of pieces of remote memory permanently, and that's what I basically inform the patients of when I do give them informed consent. But almost everyone does have some temporary memory disturbance, more specifically recent memory disturbance.

Q. Have you ever heard that ECT causes short-term, any short-term deficits in the ability to process or retain information?

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;

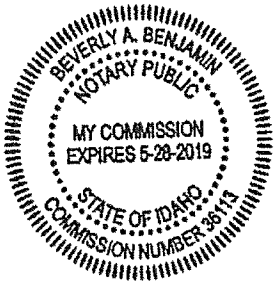
That the foregoing is a true and correct record of all testimony given, to the best of my ability;

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



CONFIDENTIAL

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

problems, you know.

And they -- they felt no, and she was comfortable with receiving more treatment. The treatment helped her. She was back to normal again and able to function again. She wasn't functioning before, so what we call a good response to treatment. Okay. But the doctors, you know, they mention in their progress note or their consultation note that cognitively she was doing well.

I didn't see anything that said she was doing badly with memory. She wasn't complaining about any memory problems. Okay. When you do once a month, you know, you're not going to get any memory problems from that kind of treatment, you know. You just have trouble that day and then the next day, and then it's over after that.

Q I'm going to show you a new document, mark this as Exhibit No. 3. Do you see that?

A Right. This is the consent form. Right.

Q Okay. So I think you said that this document was mandated by the State of California?

A Yeah, it's the State of California, right.

Q And did you go over this document with Ms. Himes before she signed it?

A Yes. She signed this each time a month is up.

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

State of California - Health and Human Services Agency — Department of Mental Health

ELECTROCONVULSIVE TREATMENT (ECT), INFORMED CONSENT FORM
MH 300 (11/90)

DO NOT SIGN THIS FORM UNTIL YOU HAVE ALL THE INFORMATION YOU DESIRE CONCERNING ELECTROCONVULSIVE TREATMENT (ECT).

The nature and seriousness of my mental Condition, for which ECT is being recommended, is bipolar disorder

RECOMMENDATION: I understand that ECT involves passage of an electrical stimulus across my brain for a few seconds, sufficient to induce a seizure. In my case the treatments will probably be given 3 times per week for 4 1/2 weeks, not to exceed a total of 15 treatments and not to exceed 30 days from the first treatment. Additional treatments cannot be given without my written consent.

Reasonable alternative treatments (such as psychotherapy and/or medication) have been considered and are not presently recommended by my doctor because they have not been effective

IMPROVEMENT: I understand that ECT may end or reduce depression, agitation and disturbing thoughts. In my case there may be permanent improvement, no improvement, or the improvement may last only a few months. Without this treatment my condition may improve, worsen or continue with little or no change.

SIDE EFFECTS AND RISKS: I understand there is a division of opinion as to the effectiveness of this treatment as well as uncertainty as to how this procedure works.

I also understand this treatment may have brief side effects: headaches, muscle soreness and confusion.

There may be some memory loss which could last less than an hour or there may be a permanent spotty memory loss. Memory loss and confusion may be lessened by the use of unilateral (one-sided) electrical brain stimulation rather than bilateral (two-sided) stimulation.

Anesthesia and muscle relaxants will be used during these treatments to prevent accidental injury. Oxygen will be administered to minimize the small risk of heart, lung, brain malfunction or death as a result of the anesthesia or treatment procedures.

My physician states I have the following medical condition(s) which increase the risk in my case, as follows:

I HAVE THE RIGHT TO ACCEPT OR REFUSE THIS TREATMENT. IF I CONSENT, I HAVE THE RIGHT TO REVOKE MY CONSENT FOR ANY REASON AT ANY TIME PRIOR TO OR BETWEEN TREATMENTS.

Dr. Fidaleo has explained the above information to my satisfaction. At least 24 hours have elapsed since the above information was explained to me. I have carefully read this form or had it read to me and understand it and the information given to me.

I HEREBY CONSENT TO ECT /s/ Michelle Himes (Signature) 1/9/12 10:00 (Date and Time)

(Witness Signature) RN 1-9-12 1010

(42329656) 05/13/2011
HIMES,MICHELLE [redacted]
01-67-88-45 OPY AGE: 25 F

EXHIBIT 3

Bijan Esfandiari, Esq., State Bar No. 223216
Monique Alarcon, Esq., State Bar No. 311650
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC;

Defendants.

Case No.: 2:17-CV-06686-RGK- JCx

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

CORRECTED PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

[Filed concurrently with Plaintiffs' Separate Statement of Uncontroverted Facts; Declarations of Bijan Esfandiari, Marcia Benjamin and Michelle Himes]

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

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STATEMENT OF FACTS

Plaintiffs Marcia Benjamin and Michelle Himes sustained neurocognitive decline, permanent memory loss and brain injury as a result of undergoing multiple rounds of electroshock treatment ("ECT"). Defendant Somatics, LLC ("Somatics") has moved for summary judgment on two limited issues: *first* arguing plaintiffs' claims are time barred and *second* arguing plaintiff's claims are barred by the learned intermediary defense. Somatics is mistaken on both fronts.[1]

A. Brief History of the Discovery of ECT

Electroshock or electroconvulsive therapy ("ECT") is the practice of inducing grand mal seizure through application of electricity to the brain. In the late 1930's, after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, Ugo Cerletti and Lucino Bini, two scientists at the University of Rome, thought electricity could be used to treat schizophrenia. Ex. 29, Bruce A. Wright, *An Historical Review of Electroconvulsive Therapy*, 8 JEFFERSON JOURNAL OF PSYCHIATRY 70 (1990). In 1938, they applied ECT to the first human patient, a 40-year-old man wandering the train station and speaking gibberish. They applied 70 volts of electricity to his temple and, while deliberating whether they should apply a second higher voltage, the patient pleaded "*Non una seconda! Mortifera*!" ("not again it will kill me!"). *Id.* Considering this a success as the man was no longer speaking gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. *Id.* Cerletti presented his experiment at a conference and, shortly thereafter, ECT began to gain acceptance for the treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States. *Id.*

B. Somatics Failed to Comply with FDA Regulations, Failed to Issue *Any* Timely Warnings to Plaintiffs' Medical Providers and Has Now Admitted (via Tardily Issued Warnings in 2018) That ECT Can Cause Brain Injury and Permanent Memory Loss

[1] Somatics has also moved to dismiss the First and Fourth Causes of Action for Misbranding and Adulteration. Given this Honorable Court previously dismissed similar claims in this action with respect to the prior plaintiffs, *see Riera v. Somatics, LLC*, 2018 WL 6242154 at *8 & 10 (C.D. Cal. Sept. 14, 2018), in the interest of judicial economy and to streamline the case for trial, plaintiffs agree to dismiss the First and Fourth Claims.

In the 1980s, Richard Abrams and Conrad Swartz, formed defendant, Somatics, LLC ("Somatics") for the purpose of selling their own ECT machine for profit. Ex. 7, Abrams dep. 50:15-25. Normally, medical devices require advance FDA approval, however, Somatics ***never*** obtained FDA approval to market its ECT machine. Rather, relying upon a loophole that allows a new manufacturer to simply claim its device is equivalent to a prior marketed device, Somatics in 1984 obtained *clearance* from the FDA to sell its "Thymatron" ECT device. Ex. 9, Mirkowitz Dep at 165. The distinction between approval and clearance is critical—an FDA *approved* device would require clinical trials to demonstrate safety and efficacy and the FDA usually spends 1,200 hours prior to approving a medical device. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). On the other hand, devices that obtain *clearance*, are usually cleared within a mere 20 hours. *Id.* The FDA has never approved *any* ECT device and no manufacturer has ever conducted any clinical trials to prove they are safe and effective.

In addition to never having performed any safety and efficacy studies on its ECT devices, discovery as well as a January 2012 FDA inspection reveal that, during the relevant time period, Somatics did not have appropriate procedures in place to identify, evaluate and warn about adverse events in violation of applicable FDA regulations. Ex. 34, 2012 FDA Inspection Report at (Observations 3 & 4); *see also* 21 C.F.R. §§ 803.17, 803.18, 803.50 & 820.198; 21 U.S.C. §§ 331 & 352(t). Indeed, between 1984 and 2017, Somatics has admitted it never submitted a single adverse event report to the FDA. Ex. 25, RFA No. 30. Moreover, even though Somatics became aware, or should have been aware, of *hundreds* of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death, Somatics during the relevant time period never took any meaningful measures to investigate these complaints, submit adverse event reports to the FDA or warn physicians and consumers of these risks. *Id.*; *see also* Ex. 36, Executive Summary at SOM00262; Ex. 35, Pressly Decl. at ¶¶2-4.

Tellingly, the manuals Somatics prepared for its ECT device and distributed to the two hospitals where plaintiffs received their respective ECTs, ***did not contain any***

warnings – as even Somatics' co-owner, Conrad Swartz, M.D. admitted. Ex. 22 (manual given to Sharp Hospital - no warnings), Ex. 23 (manual given to Northridge Hospital - no warnings); and Ex. 8, Swartz Dep. at 48-57. Notably, in its summary judgment motion, Somatics has not presented ***any*** evidence that it provided ***any*** warnings to plaintiffs' physicians concerning any risks associated with ECT – and certainly has not presented any evidence that it provided any warnings during the relevant time period concerning permanent memory loss or brain damage.

Sadly, discovery has revealed that, in 2006, the two Somatics owners were aware of the risk of permanent memory loss associated with ECT and contemplating warning of the risk. It appears the owners were concerned about the potential of lawsuits, but also that a warning would cause them to lose customers (i.e., "alienate psychiatrists"). Ex. 39 (2006 email). They ultimately agreed only upon a disclaimer, which even one of the owner's admitted "is not a warning." *Id.* Even this disclaimer (which was not a warning), was never timely given to the hospitals where plaintiffs received their ECT.

In 2009, the FDA announced it was opening a docket and inquiry to further look into the safety and efficacy of ECT given the devices had never received FDA approval. *See* 74 Fed.Reg. 46607-01. By 2010, the FDA's public docket had received more than 3,000 notifications of ECT induced injury and, according to the FDA: "The most common type of adverse event reported in the public docket was ***memory adverse event*** (529 reports). This was followed by other ***cognitive complaint*** (413 reports), ***brain damage*** (298 reports) and ***death*** (103 reports)." Ex. 36, FDA Executive Summary at SOM00262. While Somatics has admitted that, as of 2010, it was aware of these adverse events, Somatics, in violation of 21 C.F.R. §803.50(b)(3), took no steps to investigate the reports and likewise took no steps to issue warnings concerning these risks to plaintiffs' medical providers. Exh. 25, RFA Nos. 36, 40, 41 & 42.

It is apparent that Somatics, during the relevant time period, never took its obligations to investigate adverse events or issue warnings seriously. Illustrative of this point is when Somatics' PMK testified that a patient who had attempted to report

memory loss to Somatics was "*wacko*." Ex. 9, Mirkovich Depo. at 62-63. However, the myriad of patients who have been seriously and debilitatingly injured by ECT are not *wackos* – they are human beings whose memories have been robbed and who have suffered neurocognitive decline and brain injury as a result of ECT. What is "*wacko*" is that Somatics manufactures an ECT machine that administers electric current to a patient's head that is approximately one *hundred* times what tasers use, approximately the same current used to stun pigs prior to slaughter, roughly *one-fifth* as much current as the electric chair, and applies voltage that is more than one *hundred* times what is required to damage brain cells, and yet Somatics chose not to provide *any* warnings to plaintiffs' medical providers concerning *any* risks or adverse events associated with its ECT device. *See* Ex. 12, Castleman Report at 10; Ex. 8, Swartz Dep. at 48-57.

It was not until sometime in late 2018 – *after* the filing of this lawsuit and after the FDA concluded that Somatics needed to provide instructions and warnings concerning permanent cognitive injuries (*see* 21 C.F.R. § 882.5940), that Somatics began to implement warnings on its website and in its manuals including finally warning that "ECT may result in anterograde or retrograde amnesia" and that "in rare cases, patients may experience permanent memory loss or permanent brain damage." Ex. 26 (Somatics' website, late 2018); Ex. 27 (updated warnings Somatics purportedly sent to all customers via mail sometime *after* 2018); see also Exh. 8, Swartz Dep. 112-118 &121-124. Unfortunately, these warnings, which could and should have been issued decades earlier, came too late for plaintiffs Himes and Benjamin, who are but two of the many victims of Somatics' negligence and failure warn.

C. Marcia Benjamin Timely Filed Her Action Within Four Months of Being Informed Her Neurocognitive Injuries Were Caused By ECT

Benjamin was a successful architect who, after obtaining her Bachelor of Architecture degree and having 25 years of work experience, opened her own architectural firm in 2005. Ex. 2, Benjamin Dep. 19-21. Since approximately 2008, Benjamin has been treated for hypothyroidism. Benjamin Decl. ¶ 2. In March 2011, Benjamin's thyroid medication dosage was increased, and she was at home when she

began experiencing dizziness, discomfort, and chest pain. Ex. 6, Frankel Dep. 20-23. Benjamin visited the emergency room where she was diagnosed with severe anxiety and prescribed Xanax. Ex. 2, Benjamin Dep. 38-39. Shortly thereafter, she responsibly sought out treatment with a psychiatrist in her area, Dr. David Gudeman, so that her use of psychiatric medication would be properly monitored. *Id.*

While Benjamin was under Dr. Gudeman's care, he increased her Xanax dose, and she developed an adverse reaction to the medication. Benjamin Decl. ¶ 4. She complained that, while taking Xanax, she felt extremely weak, to the point she could not sit upright in a chair. Benjamin Decl. ¶ 4; Ex. 6, Frankel Dep. 20-23. Without realizing it, Benjamin developed a tolerance to the medication, so, in late 2011, she sought treatment at a detox clinic in Sao Paulo, Brazil with psychiatrist Dr. Raymond Rosenberg. She was at the clinic for about one month until early 2012, where she was able to titrate off Xanax by taking controlled doses of Valium and Tegretol. *Id.*

In early 2012, Benjamin returned home and continued treatment with Dr. Gudeman. Benjamin Decl. ¶ 4. Rather than keeping her on Valium and Tegretol, however, Dr. Gudeman switched her to Klonopin, which made her feel worse. Ex.2 Benjamin Dep. 40-41. The symptoms Benjamin was experiencing from Klonopin "were so severe that [she] was not able to walk." Id. at 42-43. Dr. Gudeman told her ECT was a treatment that could help her overcome the symptoms she was experiencing from Klonopin and, because she had not responded well to previous medications, ECT was her next treatment option. *Id.* at 43; and Benjamin Decl. ¶ 5. In September 2012, Dr. Gudeman referred Benjamin to Dr. Michael Frankel at Northridge Hospital for an ECT consult. Benjamin Decl. ¶ 6. When Benjamin and her husband, Daniel Benjamin, met with Dr. Frankel to discuss ECT, Dr. Frankel told them ECT was safe, it was an easy, outpatient procedure that took only 20 minutes. Ex. 2, Benjamin Dep. at 51-53. Dr. Frankel only informed the Benjamins that the side effects of ECT included some confusion right after treatment and short-term memory loss. *Id.*

Benjamin signed a consent form to undergo ECT treatment, which did not advise

her of the risk of permanent memory loss, brain injury, or an inability to create new memories. Ex. 15, Consent Form. Had Ms. Benjamin been adequately warned of the risk of permanent or brain damage, she would not have consented to ECT treatment. Ex. 2, Benjamin Dep. at 52; Benjamin Decl. ¶ 18.

From September 28, 2012 to March 4, 2013, Dr. Frankel administered 20 ECT treatments to Benjamin. Benjamin Decl. ¶ 7. During her ECT treatment, Benjamin complained of memory problems, but Dr. Frankel repeatedly assured her these were temporary side effects of ECT that were expected and in fact in response to her complaints, he prescribed further ECT sessions. Ex. 14, January 2013 Progress by Dr. Frankel; Ex. 6, Frankel Dep. 34-35. In early March 2013, Dr. Frankel recommended, for the second time, that Benjamin continue taking Lithium while she was on maintenance ECT. At this point, Mr. Benjamin suggested that she stop ECT treatment, because he felt that if ECT was not going to eliminate the need for her to take psychiatric medications, it was time to stop ECT treatment. Ex. 4, D. Benjamin Dep. 33-34; Benjamin Decl. ¶ 5. Benjamin's last ECT treatment was on March 4, 2013. *Id.*

After her last ECT treatment with Dr. Frankel, Benjamin returned to the care of Dr. Gudeman in March 2013, and he performed "maintenance" Transcranial Magnetic Stimulation (TMS) treatment in lieu of additional "maintenance" ECT. Ex. 2, Benjamin Dep. at 64; Ex. 6, Frankel Dep. at 41-42. She continued with her psychiatrist's recommended course of maintenance treatment and received TMS with Dr. Gudeman until October 2013. Benjamin Decl. ¶ 9. In October 2013, Benjamin learned that the Medical Board of California revoked Dr. Gudeman's medical license after two of his patients died from intoxication of medications prescribed by him. *Id.* ¶ 10. Benjamin was disappointed by this news, so she searched for another clinic to help her safely detox from the Klonopin that Dr. Gudeman had re-started her on before his license was revoked. *Id.* In late October 2013, Benjamin began treatment with Dr. Raymond Armstrong (internist and cardiologist) who helped her detox from the medication over a period of 18 months (October 2013 to March 2014). *Id.* ¶ 11.

In October 2014, Benjamin began seeing a new primary care physician, Dr. Michael Hirt, who continued treating her thyroid disorder. Benjamin Decl. ¶ 13. When Benjamin completed her detox program in March 2015, Dr. Hirt put her on a treatment plan consisting of IVs, vitamins, and supplements to help her with the effects she was still feeling from the medications. *Id.* At the time, Benjamin still had difficulty walking, and she told Dr. Hirt that she was having difficulty with her memory and concentration. *Id.* Dr. Hirt told her that once she was able to walk on her own again, he wanted her to see a neuropsychologist. *Id.* In July 2015, she requested her medical records from Dr. Frankel's office, but he failed to immediately release them to her, even after she called his office twice to follow up on her request. Benjamin Decl. ¶ 14.

In late 2015, Benjamin was slowly walking on her own again and only used her wheelchair when necessary, at which time she began searching for a neuropsychologist. Benjamin Decl. ¶ 15. She contacted K. Drorit Gaines, Ph.D, who scheduled a neuropsychological evaluation in March 2016. *Id.* In **April 2016**, Dr. Gaines called Benjamin to discuss her findings, and stated that the results revealed "processing deficits" but diagnosed Benjamin with Post-Traumatic Stress Disorder (PTSD). *Id.* In September 2016, Benjamin finally received a copy of her ECT treatment records that Dr. Frankel had delayed producing. *Id.*; Benjamin Dep. 96-97. Thereafter, in October 2016, Benjamin received a copy of Dr. Gaines' written report. Benjamin Decl. ¶ 15. When reading it, Benjamin was displeased with various errors in the report and confused by Dr. Gaines' diagnosis of PTSD which, to Benjamin, seemed inconsistent with her symptoms, so she sought out a second opinion. Benjamin Decl. ¶ 16.

In January 2017, Benjamin underwent a neuropsychological examination with Dennis Robinson, Ph.D. Ex. 42, Robinson Report; Benjamin Decl. ¶ 17. The neuropsychological testing took place over the course of four different sessions, from January to April 2017. *Id.* On **July 31, 2017**, Dr. Robinson discussed his written report with Benjamin and informed her, for the first time, that she had verified learning difficulties, memory problems, and major neuro-cognitive disorder resulting from

"Hypothyroidism and the resulting medically based treatments – Medications, Electroshock, and [TMS]." Ex. 42. Dr. Robinson was the first medical specialist to opine and inform Benjamin that her neurocognitive injuries and memory issues were due in part to her Electroshock treatment. Within four months of Dr. Robinson's July 31, 2017, neuropsychological evaluation report, Benjamin (and her husband) timely filed their lawsuit against Somatics on November 7, 2017. *See* FAC Dkt No. 22.

D. Michelle Himes Timely Filed Her Action Within a Year of Suspecting and Discovering She Had Neurocognitive Injuries Caused By ECT

Himes is a 35-year-old mother of five children who underwent ECT at Sharp Mesa Vista Medical Center (Sharp) in San Diego California from April 2011 to June 2012. Ex. 1, Himes Dep. at 11. Himes had a difficult upbringing while growing up in Las Vegas, Nevada and, as a result, she was hospitalized on various occasions for depression and suicidal ideation. Himes Decl. ¶ 3. Over the course of these hospitalizations, she was prescribed at least nine different antipsychotics and antidepressants to attempt to treat her depression, but her symptoms continued. *Id.* In April 2011, Himes enrolled in an inpatient program at Sharp and she began treatment with Dr. Raymond Fidaleo. Ex. 5, Fidaleo Dep. at 27; Himes Decl. ¶ 4. Dr. Fidaleo determined that ECT was appropriate for Himes. Fidaleo Dep. at 28. During the second meeting with Dr. Fidaleo, Himes and her husband watched an informational video on ECT which explained "how great ECT was" and they received informational pamphlets touting the benefits of ECT. Ex. 3, P. Himes Dep. at 28. The *only* side effect the video informed them of was the risk of short-term memory loss. *Id.* Dr. Fidaleo similarly told the Himes that short-term memory loss was a side effect of ECT, and that Himes may experience confusion due to the anesthesia. Ex. 3, P. Himes Dep. at 29-31. Dr. Fidaleo never advised Himes that brain damage or permanent memory loss was a risk of ECT. Ex. 5, Fidaleo Dep. 34:15-17.

On April 13, 2011, Himes signed a consent form to undergo ECT treatment which did not warn of the risk of permanent memory loss, brain injury, or an inability to create new memories. Ex. 5, Fidaleo Dep. 91:13-92:20; Ex. 19, Consent Form. Had

she been adequately informed of the risk of permanent memory loss, brain injury, or the inability to create new memories, Himes would never have consented to ECT. Himes Decl. ¶ 6. Dr. Fidaleo administered 26 ECT treatments to Himes, from April 13, 2011 to January 3, 2012. Ex. 5, Fidaleo Dep. 35-36; Himes Decl. ¶ 7. Dr. Fidaleo never followed up with Ms. Himes after her ECT treatment ended. *Id.*

In April 2013, Himes was again hospitalized when her depressive symptoms returned. Ex. 20. During that hospital visit, she explained to her treating psychiatrist, Dr. Keith Breiland, that her primary care physician wanted her to undergo an MRI scan to rule out a pituitary tumor because she had elevated protactin levels. *Id.* Himes had an MRI scan of her pituitary gland completed on April 26, 2013 and the results were normal. *Id.* Himes had no reason to suspect that she had suffered any injury as a result of ECT, as her psychiatrist and primary care physician, with whom she was receiving regular care, did not inform her otherwise. Himes Decl. ¶ 8. After her 2013 hospitalization, Himes continued to be prescribed psychiatric medications that made her feel foggy, fatigued, and was still exhibiting signs of depression. Himes Decl. ¶9.

Himes stopped taking psychiatric medications in early 2014 when she became pregnant with her second child who was born in November 2014. Ex. 1, Himes Dep. 32-33; Ex. 3, P. Himes Dep. at 9. In approximately December 2015, Himes learned that she was pregnant with her third child. Himes Decl. ¶ 10. In her second trimester (approximately **February 2016**), women from her church asked her how her current pregnancy compared to her prior two, but Himes realized she had a faint to no recollection of her prior pregnancies. *Id.* at ¶ 11; Ex. 1, Himes Dep. at 38. This was the first time she was able to appreciate she had had an extensive "black out period" of important events in her life that she could not remember. *Id.* Himes had been off medication and did not feel "so flat and emotionless," and she began reading about side effects of psychiatric medications in books such as "Mad in America." Ex. 1, Himes Dep. 47-49. Himes felt that the book validated her concerns that the psychiatric medications actually made her feel worse when she was taking them and she attributed

her memory difficulties to the medications she had been taking. Himes Decl. ¶ 12.

Himes' third child was born in July 2016 and, in December 2016, she and her family moved to Oak Harbor, Washington because her husband was re-stationed at Whidbey Island Naval Base. Ex. 1, Himes Dep. 49-50. After moving to Oak Harbor, Himes began noticing that, in addition to memory difficulties, she was having difficulty with her words and trouble communicating. Ex. 1, Himes Dep. at 43. At this point (in 2017), she started researching psychiatric treatment again and this time, she began researching ECT specifically on a wide range of websites. Ex. 1, Himes Dep. at 50. While reading about ECT side effects online, she learned for the first time that other people believed they had brain injury from ECT treatment. Himes Decl. ¶ 15. Shortly thereafter, Ms. Himes sought the assistance of counsel, and she timely and diligently filed the instant action on September 11, 2017. *See* Compl. Dkt. 4.

ARGUMENT

A. At this Procedural Posture The Court Must Construe all Evidence and Draw All Reasonable Inferences In Favor of the Plaintiffs

The rules for granting summary judgment are well settled. "[S]ummary judgment will not lie ... if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In applying this standard, the Court should not weigh the evidence. *Id.* at 249. Rather, the Court is obligated to view the record in a light most favorable to the party opposing summary judgment and must construe all evidence and reasonable inferences in favor of the non-moving party. *Id.* at 255; *see also Tolan v. Cotton*, 572 U.S. 650, 656–57 (2014). The Ninth Circuit has emphasized that "[i]t is also clear that the court must not make any credibility determinations." *Zetwick v. Cty. of Yolo*, 850 F.3d 436, 440 (9th Cir. 2017). And, "the district court must recognize that, where evidence is genuinely disputed on a particular issue—such as by conflicting testimony—that 'issue *is inappropriate* for resolution on summary judgment.'" *Zetwick*, 850 F.3d at 440.

Under established California case law, issues of statute of limitations and causation ordinarily present *a factual question for the jury* and are thus not the proper

fodder of summary judgment. *Ward v. Westinghouse Canada, Inc.*, 32 F.3d 1405, 1407 (9th Cir. 1994) ("Under California law, the question of when [plaintiff] was on inquiry notice of potential wrongdoing is a factual question."); *Bibeau v. Pac. Nw. Research Found. Inc.*, 188 F.3d 1105, 1108 & 1110 (9th Cir. 1999) ("'what a plaintiff knew and when he knew it are questions of fact.'"); *Clark v. Baxter Healthcare Corp.*, 83 Cal. App. 4th 1048, 1054-55 (2000) (summary judgment reversed where although plaintiff was aware of her allergic reaction, there was question of fact regarding knowledge that wrongdoing had occurred causing the injury); *see also Vickers v. United States*, 228 F.3d 944, 953 (9th Cir. 2000) ("under California law, the basic causation-related issues involve questions of fact, unless 'reasonable persons will not dispute the absence of causality.'"); *Vasquez v. Residential Invs., Inc.*, 118 Cal. App. 4th 269, 288 (2004) ("causation in fact generally is a question of fact for the jury.")

B. Plaintiffs Timely Filed Their Action Well Within Two Years of the Discovery of Their Respective Injuries and Its Negligent Cause

California proscribes a two-year statute of limitations for personal injury claims including medical-device products liability cases. CAL.CIV.PROC. §§ 335.1 & 340.8; *Bekins v. AstraZeneca Pharm. LP*, 739 F. App'x 884, 885, & n.1 (9th Cir. 2018); *Eidson v. Medtronic, Inc.*, 40 F. Supp. 3d 1202, 1217 (N.D. Cal. 2014).

Under California law, the statute of limitations generally begins to run upon the occurrence of the last element essential to the cause of action. *Gutierrez v. Mofid*, 39 Cal.3d 892, 899 (1985); *see also Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal.4th 797, 806 (2005) ("a cause of action accrues at the time when the cause of action is complete with all of its elements."). For personal injury claims, the date of accrual of the cause of action is generally the date of physical injury. *Jolly v. Eli Lilly & Co.*, 44 Cal. 3d 1103, 1109 (1988). Although the general rule provides that the statute of limitations begins to run "when the cause of action is complete with all of its elements," *Norgart v. Upjohn Co.*, 21 Cal.4th 383, 389 (1999), ***the discovery rule*** delays the commencement of the running of the statute until the plaintiff "is aware of her injury *and its negligent cause*." *Jolly*, 44 Cal.3d at 1109 (emphasis added). More specifically, under the discovery rule,

the statute of limitations begins to run *not* when the plaintiff sustains her injury, but rather "when the plaintiff suspects or should suspect that her injury was caused by wrongdoing, that someone has done something wrong to her." *Jolly*, 44 Cal.3d at 1110. As outlined by the California Supreme Court, "the term 'injury,' as used in determining the date of accrual of a cause of action, means both a person's physical condition *and its negligent cause*...Thus, physical injury alone is often insufficient to trigger the statute of limitations." *Fox*, 35 Cal. 4th at 808, n.2 (cleaned up and emphasis added). The Court of Appeal has clarified that suspicion *cannot* be imputed upon the plaintiff:

> Our Supreme Court has never held that under the discovery rule, the suspicion necessary to trigger the statute may be imputed to a plaintiff, and we do not believe that to be the law. When the cases are read in whole, rather than in isolated quotes, it is clear that a plaintiff's duty to investigate does not begin until the plaintiff actually has a reason to investigate. 'A plaintiff has reason to discover a cause of action when he or she has *reason* at least to suspect a factual basis for its elements... We look to whether the plaintiffs have reason to at least suspect that a type of wrongdoing has injured them.'

See Nelson v. Indevus Pharms., Inc., 142 Cal. App. 4th 1202, 1206 (2006) (*quoting Fox*, 35 Cal.4th at 807); see also *Ward*, 32 F.3d at 1407 ("Under California law, *knowledge of an injury and its cause does not necessarily imply that any wrongdoing has occurred or that anyone is to blame*.") (emphasis added). This principle is encapsulated by the following quote from the California Supreme Court:

> 'It is no sufficient answer to say, as have counsel in their brief, that plaintiff must have known that he was blown up, and realized that he was injured. This he undoubtedly knew; but it was the fact that defendant by its negligence was the cause of the injury that gave rise to the cause of action against it, not the mere fact of injury.'

Pashley v. Pac. Elec. Co., 25 Cal. 2d 226, 231 (1944) (*quoting Waugh v. Guthrie Gas*, 37 Okla. 239 (1913)). The facts presented herein and outlined in detail in the Statement

of Facts *supra* confirm that, while **Marcia Benjamin** received her last ECT treatment in March 4, 2013, she continued to receive treatment with *multiple* doctors thereafter and was subjected to multiple different medications and medical procedures, including but not limited to Transcranial Magnetic Stimulation. It was not until *after* **April 2016** when she was examined by a neuropsychologist, Dr. Gaines, and was informed that her neurocognitive testing revealed she had "processing deficits," that she suspected that she had permanent brain injury – however, Dr. Gaines attributed her injury to Post-Traumatic Stress Disorder (PTSD). Unsatisfied with the PTSD diagnosis, Benjamin sought a second opinion and underwent additional neuropsychological examinations by Dr. Robinson beginning in January 2017 and, in a July 31, 2017 report, Dr. Robinson concluded that she had verified learning difficulties, memory problems, and major neuro-cognitive disorder resulting in part from ECT. Within four months of receiving Dr. Robinson's report, Benjamin initiated her lawsuit against Somatics. Dr. Robinson was the first medical specialist to opine and inform Benjamin that her neurocognitive injuries and memory issues were due in part to her Electroshock treatment. While prior to this time, Benjamin had seen multiple medical providers, none of them had told her that she had sustained permanent neurocognitive injuries, rather she was continuously assured by her medical providers that her neurocognitive issues would be temporary and would resolve. Moreover, prior to Dr. Robinson's July 31, 2017 report, no medical provider had informed her that she had sustained injuries as a result of ECT or the wrongdoing of a third party, rather she was informed that her cognitive issues were expected, transitory and due to various underlying diseases. Benjamin had every right to rely upon the expert judgment, assurances, and advice of her medical treaters. *See Kitzig v. Nordquist*, 81 Cal. App. 4th 1384, 1393 (2000) (a patient who relies upon the advice of her health care providers cannot be charged with knowledge or suspicion that someone had done something wrong with respect to her care and treatment); *Brown v. Bleiberg*, 32 Cal. 3d 426, 435 (1982) (Supreme Court held that granting of summary judgment on statute of limitations grounds was inappropriate because "[t]hough the

pain in her feet persisted for a long time [12 years after the procedure], she could reasonably expect that after serious surgery. Dr. Bleiberg told her that her condition would improve, but did not say when. Neither her friends' ridicule, nor her niece's urgings to see a doctor to have her feet checked, nor her nursing training amount to conclusive evidence that plaintiff was on notice of defendants' wrongdoing."). In summary, the first time Benjamin had any suspicion or any reason to suspect that she had sustained permanent injury caused by a third-party's wrongdoing was after April 2016, and her suspicion was confirmed by Dr. Robinson in July 2017. Accordingly, Benjamin timely filed her action on November 7, 2017, well within two years of her April 2016 suspicion (and within four months of Dr. Robinson's July 2017 report).

As to **Michelle Himes**, the facts outlined in the Statement of Fact *supra* confirm that, while Himes received her last ECT treatment in June 2012, she continued to see medical providers and continued to be prescribed multiple medications and even had an MRI of her brain. Himes had no reason to suspect that she had suffered any injury as a result of ECT, as her psychiatrist and primary care physician, with whom she was receiving regular care, did not inform her otherwise. Himes Decl. ¶ 8. It was not until being pregnant with her third child (in approximately **February 2016**) and when she had weaned off of all the psychiatric medications she had been prescribed that she realized she had no recollection of her prior pregnancies and could not recall key events in her life that she suspected that the many "*pills*" she had been taking may have caused her continuing and permanent memory loss and she began to research the issue. After the birth of her third child, and when she saw that her memory issues persisted, she again in **2017**, began researching the link between her psychiatric treatment and memory loss and learned for the first time that other people believed they had brain injury from ECT treatment. Himes Decl. ¶ 15. Shortly thereafter, Himes sought the assistance of counsel, and she timely and diligently filed the instant action on September 11, 2017 – well within two years of her February 2016 suspicion that she had been permanently injured by the wrongdoing of a third party (i.e., the psychiatric

pills). Prior to this time, while she had seen multiple medical providers, no provider had ever informed her that she had permanent memory loss, brain injury, or that she had been injured by the wrongful conduct of a third party – thus she had no reason to suspect any wrongdoing earlier. *Brown*, 32 Cal. 3d at 435; *Nelson*, 142 Cal.App.4th at 1206 ("it is clear that a plaintiff's duty to investigate does not begin until the plaintiff actually has a reason to investigate."); *Fox*, 35 Cal.4th at 807 ("a potential plaintiff *who suspects that an injury has been wrongfully caused* must conduct a reasonable investigation of all potential causes of that injury."); *Bibeau v. Pac. Nw. Research Found. Inc.*, 188 F.3d 1105, 1110 (9th Cir. 1999) (reversing summary judgment and holding a triable issue of fact remained as to statute of limitations even though injured plaintiff had not consulted with doctors and the wrongdoing at issue had been reported in the press, was discussed in medical literature and there were other lawsuits).

C. Somatics May Not Rely Upon the Learned Intermediary Defense Because It Failed to Provide Any Warnings to Plaintiffs' Medical Providers

Under established California law, manufacturers have a duty to warn consumers about the hazards inherent in their products. *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal. 3d 987, 1003 (1991). The purpose of warnings is to inform consumers about a product's hazards and faults, so they can refrain from using the product altogether or evade the danger by careful use. *Id.* In California, manufacturers are strictly liable for injuries caused by their failure to warn of dangers that were known or reasonably knowable at the time they manufactured and distributed their product. *Id.*; *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1108. The Supreme Court has made it clear that "[w]hatever may be reasonable from the point of view of the manufacturer, the user of the product must be given the option either to refrain from using the product at all or to use it in such a way as to minimize the degree of danger." *Anderson*, 53 Cal.3d at 1003. In *Anderson*, the Supreme Court relied in part upon the Ninth Circuit's decision in *Davis v. Wyeth Laboratories, Inc.* 399 F.2d 121, 129-130 (9th Cir.1968), which described the manufacturer's duty to warn in order to provide "*true choice*" to

consumers and patients. *Anderson*, 53 Cal. 3d at 1003 (*quoting Davis*, 399 F.2d at 129).

In the context of medical products that require a prescription, the California Supreme Court has held that ***if*** a manufacturer provides adequate warnings to a patient's doctor, then there is no need to warn the patient directly. *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65 (1973); *Carlin*, 13 Cal. 4th at 1116. *Stevens* held:

> In the case of medical prescriptions, '***if*** adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.'

Stevens, 9 Cal. 3d at 65 (*quoting Love v. Wolf*, 226 Cal.App.2d 378, 395 (1964))(emphasis added). Thus, by using the word "***if***" the Supreme Court has made it clear that in order to take refuge behind the learned intermediary defense (i.e., to avoid a duty to warn patients directly), the manufacturer must demonstrate it provided "adequate warnings" to patients' doctor. *Stevens*, 9 Cal. 3d at 65. In this case, it is undisputed that Somatics did not provide ***any*** warnings to plaintiffs' ECT doctors, much less any adequate warnings concerning brain injury or permanent memory loss. Notably, the manual that accompanied its ECT machines and which was given to the hospitals did not discuss *any* adverse events and did not provide any warnings. Ex. 22, Manual to Sharp (no warnings); Ex. 23, Manual to Northridge (no warnings); *see also* Ex. 8, Swartz Depo at 48-57. Rather, evidence has revealed that the first time Somatics provided any warnings of risks associated with its ECT device was in late 2018 – many years after plaintiffs' ECT procedures, and indeed after plaintiffs' lawsuit. Ex. 27, 2018 Warnings. In sum, because Somatics has failed to meet its burden of demonstrating it provided adequate warnings about brain injury and permanent memory loss, it cannot invoke the learned intermediary defense and its summary judgment must be denied. *Stevens*, 9 Cal. 3d at 65. The inapplicability of the learned intermediary doctrine under such circumstances wherein the manufacturer has failed to provide adequate warnings to physicians was recently confirmed by the District Court in *Hill v. Novartis Pharms.*

Corp., 944 F. Supp. 2d 943, 953-54 (E.D. Cal. 2013), wherein the Court held:

> the doctrine, 'where it applies at all, applies only if a manufacturer provided adequate warnings to the intermediary.' Consequently, where a manufacturer provides inadequate warnings, or no warning at all, it 'cannot rely upon the intermediary, even if learned, to pass on or give warnings.'.

Hill, 944 F. Supp. 2d at 953–54 (internal citations and brackets omitted). Consistent with Supreme Court precedent as espoused in *Stevens* and the district court decision in *Hill*, this Honorable Court should likewise conclude that, because Somatics has not provided any warnings (much less adequate warnings) to plaintiffs' ECT treaters, it cannot seek shelter behind the learned intermediary defense.

D. Even if the Learned Intermediary Defense Were Applicable, Plaintiffs Have Established That Somatics' Failure to Warn Was a Cause of Their Injuries

As an offshoot of its inapplicable learned intermediary argument, Somatics argues that, because Himes' ECT treater, Dr. Fidaleo, purportedly testified he *does not recall* reading Somatics' manual, that Somatics is immune from all liability under the learned intermediary doctrine.[2] Somatics is mistaken. *First*, as discussed *supra*, under California law, because Somatics *never* provided any warnings to Dr. Fidaleo (i.e., manual it sent to Sharp Hospital did not contain any warnings), Somatics cannot invoke the learned intermediary defense and had a duty to directly warn patients. Ex. 8, Swartz Depo at 48-57; *Stevens*, 9 Cal. 3d at 65; see also *Hill*, 944 F. Supp. 2d at 953.

Second, Dr. Fidaleo did not testify that he did not read the manual, rather he merely testified that he *did not recall* reading the manual and noted that the manual was made available to him by the hospital. Exh. 5, Fidaleo Dep at 14. At this procedural juncture where all inferences must be drawn in favor of the non-moving party, there is a triable issue of fact as to whether Dr. Fidaleo consulted the manual. *Mason v. SmithKline Beecham*, 2010 WL 2697173, *9 (C.D.Ill. July 7, 2010) (denying learned intermediary MSJ in a Paxil-suicide case and holding: "Nurse Schertz did not testify

[2] Somatics does not make a similar argument concerning Benjamin's treater, Dr. Frankel, as he testified that he read and relied upon the Somatics manual. Exh. 6, Frankel Depo. at 12-13 & 46-47.

that she had never read the label; rather she '*did not recall*' whether she read it or not. At summary judgment stage all reasonable inferences are drawn in favor of non-moving party. Certainly it is reasonable to assume that Nurse Schertz did read the PDR and package insert at some point prior to prescribing it...") (emphasis added).

Third, Dr. Fidaleo testified the hospital technician who conducts the ECT read and knows the Somatics manual, that the technician was trained by Somatics personnel on how to use the ECT machine and the technician then trained Dr. Fidaleo on its use. Thus, even if one were to assume that Dr. Fidaleo did not himself read the manual (which we cannot do at this procedural posture), the evidence is clear that the hospital technician who administered the ECT and who trained Dr. Fidaleo did in fact read the manual, and because the manual had no discussions of risks and did not provide any warnings, no warnings were provided to the hospital or to Dr. Fidaleo. Ex 5, Fidaleo Dep. at 14-15, 49, 52-53.[3]

Fourth, contrary to Somatics' argument, the California Supreme Court has held that the manual or label is not the sole, nor even the most effective, means that medical device companies have to communicate with physicians. *Stevens*, 9 Cal. 3d at 67 ("Many prescribing physicians would not come into contact with package inserts or warning labels attached to the drug when the pharmacist filed the prescription... It was within reason for the jury to find such warnings inadequate and to hold Parke, Davis liable for failing to reasonably warn of the drug's danger."). Moreover, device companies communicate with surgeons through a myriad of ways, including, promotional literature, sales representatives, "Dear Doctor" letters, seminars, and medical journal articles. *Stevens*, 9 Cal.3d at 67-69 (sales representatives are "a highly effective means of promoting the use" and "to disseminate information as to the drug's

[3] Somatics argues it had a "Patient Information Pamphlet" which Dr. Fidaleo never read. However, Somatics has not established it ever provided the Pamphlet to Dr. Fidaleo or to Sharp Hospital, nor has it even attached the Pamphlet to its MSJ. When plaintiffs subpoenaed Sharp Hospital for all documents it had received from Somatics, Sharp never identified or produced the Pamphlet. Esfandiari Dec;. at ¶ 2. Moreover, at one point in his deposition, Somatics's PMK testified that Somatics did not send the Pamphlet to Sharp. Ex. 8, Swartz Dep at 42-43. Dr. Fidaleo cannot be expected to read something Somatics never provided to him or to his hospital.

hazard"). Thus, whether or not a doctor read a package insert does not serve as a litmus test for causation, rather, the key question is whether the doctor relied upon the device manufacturer's representations, irrespective of the venue in which those representations occurred. *Stevens*, 9 Cal.3d at 67. Indeed Dr. Fidaleo testified that he receives "dear doctor" letters from device manufacturers updating and warning him of risks associated with their devices and he relies upon these warning updates. Ex 5, Fidaleo Dep. at 59. However, Somatics never timely issued any such safety updates and as Somatics has testified, the first time it issued an amended and updated warning to its customers concerning risks of brain injury and permanent memory loss was in late 2018 (a year after the filing of this lawsuit). Ex. 8, Swartz Dep at 112-118 & 121-124.

Somatics' final argument is that causation is lacking because, Drs. Fidaleo (Himes' treater) and Frankel (Benjamin's treater) would purportedly have recommended ECT even if they had been informed of the risks of brain damage and permanent memory loss. Somatics, however, misconstrues the facts and the law. *First*, both Drs. Fidaleo and Frankel testified that, had Somatics issued timely warnings of the risks of brain damage and permanent memory loss, they would have changed their conduct and would have relayed such warnings and risks to their respective patients, including to Ms. Himes and Ms. Benjamin. *See* Ex. 5, Fidaleo Dep. at 65-71, 92-94; Ex. 6, Frankel Dep at 73. *Second*, both Ms. Himes and Ms. Benjamin have testified that, had they received warnings concerning brain damage or permanent memory loss from their doctor concerning ECT, they would *not* have consented to its administration. Himes Decl. at ¶ 6; Benjamin Decl. at ¶ 18; see also Ex. 2, Benjamin Dep. at 52. Under California law, this is sufficient to establish causation. *Georges v. Novartis Pharms. Corp.*, 988 F. Supp. 2d 1152, 1158 (C.D. Cal. 2013). In *Georges*, this Court affirmed a jury verdict and held a plaintiff in a prescription drug products liability case had met her burden of causation since she testified that, even if the doctor would have prescribed the medications, if she would have received the enhanced warnings (which the manufacturer had failed to provide), her use of the drug would have differed with

adequate warnings, and this Court held that "[t]his alone is sufficient for a jury to find that Plaintiff's use of the Treatment Drugs would have changed with adequate warning." *Georges*., 988 F. Supp. 2d at 1158.[4] Indeed, this Honorable Court previously rejected Somatics' arguments on *identical* grounds and should do so again here. *Riera v. Somatics, LLC*, 2018 WL 6242154, at *11 (C.D. Cal. Sept. 14, 2018) ("Moreover, Plaintiffs present evidence that had doctors known of the risk of permanent memory loss or brain damage, they would have told their patients. Therefore, there is a genuine dispute of fact on this issue, and summary judgment is not appropriate.")

CONCLUSION

For all of the foregoing reasons, there are multiple triable issues of facts that are not ripe for summary adjudication, but which require adjudication by the trier of fact. Plaintiffs respectfully request that Somatics' motion for summary judgment be denied and that Plaintiffs be permitted to proceed to a trial on the merits.

Dated: April 13, 2021

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: */s/ Bijan Esfandiari*

Bijan Esfandiari, Esq. (SBN: 223216)
Monique Alarcon, Esq. (SBN: 311650)
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
10940 Wilshire Blvd., 17th Floor

[4] Somatics' heavy reliance upon *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 997 (C.D. Cal. 2001) and its progeny is misguided. *First*, *Motus* actually confirms that failure to read the label is not a litmus test since doctors are exposed to warnings through different means. Specifically, in *Motus*, although the physician unequivocally testified he had not read the label, the Court noted that this would not have been fatal to plaintiff's case as long as the plaintiff asked the doctor: " Dr. Trostler, *if even without reading the package insert* you had become aware that Pfizer itself had disclosed that [what is the precise warning regarding suicide that plaintiff considers necessary], would you have prescribed Zoloft..." and the doctor had responded that his treatment option would have changed. *Motus*, 196 F.Supp.2d at 997 (emphasis added). By couching the key question in such terms, the Court implicitly held that the package insert is not a litmus test. *Second*, *Motus* (as well as *Latiolais v. Merck & Co.*, 302 F. App'x 756, 757 (9th Cir. 2008)) were suicide cases and thus the injured patients were dead and could not testify as to what they would have done had they been properly warned by their doctor or the manufacturer, thus the prescribing decision of the doctor was the sole means of how the plaintiffs could show causation. In our case, however, both doctors testified they would have relayed warnings issued by Somatics to their patients and Himes and Benjamin (who are both alive, unlike the *Motus* victim) have testified had they been properly warned by their doctors, they would not have consented to ECT and thus would not have been injured by ECT, thus establishing that Somatics' lack of warning was a substantial factor in their ECT induced injuries. *Georges*, 988 F. Supp. 2d at 1157–58 (causation is met by testimony of patient as to how she would have acted in response to enhanced warnings).

Los Angeles, CA 90024
Telephone: (310) 207-3233
Facsimile: (310) 820-7444

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Bijan Esfandiari, hereby certify that, on April 13, 2021, I electronically filed the foregoing with the Clerk for the United States District Court for the Central District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Bijan Esfandiari
Bijan Esfandiari

Bijan Esfandiari, Esq., State Bar No. 223216
Monique Alarcon, Esq., State Bar No. 311650
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC;

Defendants.

Case No.: 2:17-CV-06686-RGK- JCx

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

PLAINTIFFS' STATEMENT OF GENUINE DISPUTES OF MATERIAL FACTS AND PLAINTIFFS' ADDITIONAL SEPARATE STATEMENT OF UNCONTROVERTED FACTS IN OPPOSITION TO DEFENDANT SOMATICS' STATEMENT OF UNCONTROVERTED FACTS AND CONCLUSIONS OF LAW

[Filed concurrently with Memorandum in Opposition to Defendant's Motion for Summary Judgment; Declarations of Bijan Esfandiari, Marcia Benjamin, and Michelle Himes]

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

Pursuant to Federal Rule of Civil Procedure 56 and Central District of California Local Rule 56-1, Plaintiffs, MICHELLE HIMES, MARCIA BENJAMIN, AND DANIEL BENJAMIN (collectively "Plaintiffs") hereby submit their Statement of Genuine Disputes of Material Fact and Plaintiffs' Additional Separate Statement of Uncontroverted Facts in Opposition to Defendant SOMATICS, LLC's ("Somatics" or "Defendant") Statement of Uncontroverted Facts and Conclusions of Law.

Plaintiffs refer to Defendant's Exhibits "A" through "M" as the exhibits attached to the Declaration of Jason Benkner (Dkt. 231-2) in support of Defendant Somatics' Motion for Summary Judgment. Unless otherwise indicated, all references to Exhibits "1" through "42" refer to the exhibits attached to the Declaration of Bijan Esfandiari, filed concurrently with Plaintiffs' Opposition to Defendant's Motion for Summary Judgment.

Defendant's Uncontroverted Fact	**Plaintiffs' Evidentiary Objections and Response**
1. On September 11, 2017, Plaintiff MICHELLE HIMES ("Ms. Himes") filed a complaint against SOMATICS, LLC ("Somatics") in this action. **Defendant's Evidentiary Support:** Complaint, Docket No. 4.	**Undisputed.**
2. On November 7, 2017, Plaintiffs MARCIA BENJAMIN ("Ms. Benjamin") and Plaintiff DANIEL BENJAMIN ("Mr. Benjamin") were added as parties to this action with the filing of the First Amended	**Undisputed.**

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
Complaint. **Defendant's Evidentiary Support:** First Amended Complaint, Docket No. 22.	
3. On June 19, 2018, Ms. Himes, Ms. Benjamin, and Mr. Benjamin (collectively, "Plaintiffs") were dismissed from this action pursuant to a Motion to Dismiss. **Defendant's Evidentiary Support:** Minute Order dated June 19, 2018, Docket No. 70.	**Undisputed.**
4. On October 30, 2018, Plaintiffs filed a notice of appeal from the order dismissing them from this action. **Defendant's Evidentiary Support:** Notice of Appeal to Ninth Circuit Court of Appeals, Docket No. 161.	**Undisputed.**
5. On April 7, 2020, the United States Court of Appeals for the Ninth Circuit reversed and remanded this Court's order dismissing Plaintiffs. **Defendant's Evidentiary Support:**	**Undisputed.**

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
Ninth Circuit Memorandum Decision, Docket No. 168.	
6. The Ninth Circuit reasoned that this Court erred in dismissing Plaintiffs' claims as being time barred because the operative complaint did not identify the dates that Plaintiffs were injured. **Defendant's Evidentiary Support:** Ninth Circuit Memorandum Decision, p.3, Docket No. 168.	**Undisputed.**
7. On June 15, 2020, Plaintiffs filed the Fifth Amended Complaint ("5AC"), which is the operative complaint. **Defendant's Evidentiary Support:** Fifth Amended Complaint ("5AC"), Docket No. 178	**Undisputed.**
8. Ms. Himes underwent electroconvulsive therapy ("ECT") at Sharp Mesa Vista Hospital from Dr. Raymond Fidaleo between April 13, 2011 to January 9, 2012. **Defendant's Evidentiary Support:** Declaration of Jason A. Benkner	**Undisputed.**

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
("Benkner Decl."), Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:1-9, Docket No. 231-3.	
9. Ms. Himes contends that ECT cause [sic] her to experience cognitive impairment resulting in permanent loss of past memories, chronic and lasting short term memory difficulties, and the ability to recall or retain information. **Defendant's Evidentiary Support:** Benkner Decl., Ex. C (Michelle Himes' Responses to Interrogatories Propounded by Mecta, Set One), at 3:13-20, Docket No. 231-5.	**Objection:** Incomplete. **Disputed in part.** In addition to the stated injuries, Ms. Himes has also suffered a brain injury resulting from ECT, as well as pain, suffering, inconvenience, and severe psychological and emotional distress. Ms. Himes has suffered a loss of knowledge and skills, and has lost cherished memories of her children, family, friends, and events. Ms. Himes was an avid reader, but now reading is difficult for her and she cannot recall the meaning of words previously known. Ms. Himes' sense of smell has been compromised and certain smells now trigger severe anxiety. (Benker Decl. Ex. C (Michelle Himes' Responses to Interrogatories Propounded by Mecta, Set One), at 3:13-21-27). Ms. Himes used to write fictional stories for pleasure, and now

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
	Ms. Himes is unable to do so. (Ex. 1, Himes Dep. 36:14-25).
10. Ms. Benjamin underwent ECT at Northridge Hospital from September 28, 2012 to March 4, 2013. **Defendant's Evidentiary Support:** Benkner Decl., Ex. E (Marcia Benjamin's Responses to Interrogatories, Set One), at 26:10-19, 28:6-13, Docket No. 231-7.	**Undisputed.**
11. Dr. Michael Frankel, M.D. recommended and administered ECT to Ms. Benjamin. **Defendant's Evidentiary Support:** Benkner Decl., Ex. F (Transcript of Deposition of Michael Frankel, M.D. ("Frankel Depo.")), at 20:2-20, 36:6-17, Docket No. 231-8.	**Objection:** Incomplete. **Disputed in part.** Dr. David Gudeman was the first psychiatrist to recommend ECT to Ms. Benjamin. Dr. Gudeman referred Ms. Benjamin to Dr. Michael Frankel at Northridge Hospital Medical Center ("Northridge") for an ECT consult. Dr. Frankel then prescribed and administered ECT to Ms. Benjamin. (Ex. 2, Benjamin Dep. 42:18-21; 44:4-9; Benjamin Decl. ¶¶ 5-7).
12. Ms. Benjamin stated when she stopped ECT treatment on March 4, 2013 she was experiencing unendurable side effects, including	**Objection:** Relevance; Vague and Ambiguous; Incomplete. **Disputed in part.** Ms. Benjamin

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
"[m]emory loss, pain in [her] body, bleeding, … difficulty walking, [and] complete confusion…." **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (Transcript of Deposition of Marcia Benjamin ("M. Benjamin Depo.")), at 58:18-59:8, Docket No. 231-9.	testified that she could not remember why she stopped ECT, but she believes she stopped treatment because ECT was not working. (Ex. 2, Benjamin Dep. 58:18-23). In fact, the purpose of Ms. Benjamin undergoing ECT was so she could discontinue medication, which she did not tolerate well. (Benjamin Decl. ¶¶ 5, 8). Specifically, when Ms. Benjamin was prescribed and taking Xanax prior to ECT, she felt extremely weak to the point that she could not sit in a chair. (Ex. 6, Frankel Dep. 20:13-23:8). When Dr. Gudeman switched Ms. Benjamin from Xanax to Klonopin, she experienced adverse reactions to Klonopin that "were so severe that [she] was not able to walk." (Ex. 2, Benjamin Dep. 42:22-43:5; 72:5-10). Dr. Gudeman told Ms. Benjamin that ECT was a treatment that could help her overcome the symptoms she was experiencing from Klonopin, and various failed medications, and that ECT would "bring [her] back to [her] old self." (Ex. 2, Benjamin Dep. 43:6-12). Further, during her ECT treatment,

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
	Ms. Benjamin was experiencing memory problems and naming difficulties, which Dr. Frankel repeatedly assured her were temporary side effects of ECT that were expected, and suggested new medication in addition to ECT. (Ex. 2, Benjamin Dep. 58:18-59-14; Ex. 6, Frankel Dep. 34:10-35:15; Ex. 14, Jan. 21, 2013 Progress Note). ("We discussed medications notriptyline 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 ECT … I suggest monthly maintenance ECT with medication."). Ms. Benjamin's husband, Daniel Benjamin testified that he ultimately stopped Ms. Benjamin's ECT treatment when Dr. Frankel suggested, for a second time, that Ms. Benjamin begin taking Lithium while undergoing ECT. (Ex. 4, D. Benjamin Dep. 33:24-34:12; Benjamin Decl. ¶ 8).
13.Ms. Benjamin stated that Dr. Frankel	**Objection:** Vague and Ambiguous as

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
advised her that the side effects she was experiencing during her ECT treatment would last about a month and a half to two months. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 59:9-14, Docket No. 231-9.	to time; Incomplete. **Disputed.** While Dr. Frankel initially told the Benjamins that ECT may result in short-term memory loss, for approximately a month and a half to two months, he later told the Benjamins that ECT could last for three months, and further assured them that sometimes it takes six months to a year. Ex. 4, D. Benjamin Dep. 26:24-27:12; 33:8-19.
14. Ms. Benjamin stated that when she advised Dr. Frankel that the side effects of her ECT treatment were persisting longer than two months after treatment ended, he told her that they could persist for six months. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 59:21-60:7, Docket No. 231-9.	**Objection:** Vague and Ambiguous as to time. **Undisputed. Objection:** Vague and Ambiguous as to time; Incomplete. **Disputed.** While Dr. Frankel initially told the Benjamins that ECT may result in short-term memory loss, for approximately a month and a half to two months, he later told the Benjamins that ECT could last for three months, and further assured them that sometimes it takes six months to a year. Ex. 4, D. Benjamin Dep. 26:24-27:12; 33:8-19.
15. When Dr. Frankel revised his opinion regarding the duration of ECT side effects to six months, Ms. Benjamin stated that she no longer	**Objection:** Irrelevant; Vague and Ambiguous as to time; Incomplete. **Disputed**. To the extent this statement is proffered to suggest that Ms.

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
believed him to be honest. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 60:1-14, Docket No. 231-9.	Benjamin was distrusting of Dr. Frankel in the month and a half following her ECT treatment, this inference is incorrect, speculative, and unsupported by the record. Dr. Frankel testified that at the end of her treatment, Ms. Benjamin thanked him for giving her life back to her. (Ex. 6, Frankel Dep. 36:24-37-7). After ECT, Ms. Benjamin returned to the care of Dr. Gudeman, who performed "maintenance" Transcranial Magnetic Stimulation (TMS) treatment in lieu of maintenance ECT. (Benjamin Decl. ¶ 9). When Dr. Frankel called Ms. Benjamin in July 2013 to see how she was progressing, Ms. Benjamin took his call and reported she was feeling better with "maintenance" TMS. (Ex. 6, Frankel Dep. 41:23-42:14).
16. Ms. Benjamin testified that she returned to see Dr. Gudeman, the doctor who had originally referred her to Dr. Frankel, after her ECT treatments and she remembers Dr. Gudeman being shocked that Dr. Frankel had given her 20 ECT	**Objection:** Irrelevant; Vague and Ambiguous as to time; Calls for Expert Opinion; Lacks Foundation; Assumes Facts not in Evidence. **Disputed**. To the extent this statement is proffered to suggest that Ms.

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
treatments when Dr. Gudeman had only asked for 6. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 60:16-20, Docket No. 231-9.	Benjamin was distrusting of Dr. Frankel when she completed her ECT treatment, and returned to Dr. Gudeman for TMS treatment, such an inference is incorrect, speculative, and unsupported. A complete course of ECT treatment is ordinarily 12 sessions of ECT. Ms. Benjamin's initial ECT consent form confirms she consented to 12 ECT treatments (three ECT sessions per week for four weeks). (Ex. 6, Frankel Dep. 78:21-79:15; Ex. 15, Sept. 28, 2012 Consent Form).
17. Ms. Benjamin reported to Dr. Hirt that she knew she had been the victim of iatrogenic medicine in March 2013 after begging Dr. Frankel to stop her ECT treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 98:13-99:8, Docket No. 2319; Benkner Decl., Ex. I (Ex. 10 to M. Benjamin Depo.), at p. 1, Docket No. 231-11	**Objection:** Vague and Ambiguous as to time; Incomplete. **Disputed**. To the extent Somatics relies on Ms. Benjamin's letter to Dr. Hirt (which she wrote on September 22, 2016) to suggest that, prior to September 2016, she suspected she had suffered permanent injuries as a result of ECT, the proffered evidence does not support this contention. After her last ECT treatment with Dr. Frankel in March 2013, Ms. Benjamin

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	returned to Dr. Gudeman who performed "maintenance" TMS in lieu of "maintenance" ECT, as Dr. Frankel informed her that she needed some form of maintenance treatment. (Benjamin Decl. ¶¶ 7-8; Ex. 6, Frankel Dep. 41:23-42:14). Dr. Frankel testified that, at the end of her treatment, Ms. Benjamin thanked him for giving her life back to her. (Ex. 6, Frankel Dep. 36:24-37-7). Indeed, Ms. Benjamin's September 22, 2016 letter to Dr. Hirt recounts that, after ECT treatment with Dr. Frankel, she and her husband were "still inoculated into believing" that Dr. Gudeman (who recommended ECT treatment to her) "actually knew what he was doing. Therefore, in addition to shocks, I underwent [TMS]…." (Benkner Decl., Ex. I (Ltr to Dr. Hirt at p.1) Dkt. 231-11). Further, on June 19, 2013, Ms. Benjamin underwent a brain MRI, ordered by Dr. Gudeman, due to her complaints of headaches. (Ex. 16, June 16, 2013 MRI Report). The MRI results returned normal, and only noted a small pineal cyst was present, which

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	was also there before Ms. Benjamin's ECT treatment. (*Id.*). Ms. Benjamin continued treatment with Dr. Gudeman until October 2013, when she learned that Dr. Gudeman's medical license was revoked after two of his patients died from intoxication of medications prescribed by Dr. Gudeman. (Benkner Decl., Ex. I (Ltr to Dr. Hirt at p.1) Dkt. 231-11; Benjamin Decl. ¶¶ 9-10). Thereafter, Ms. Benjamin searched for a way to detox from the medication Dr. Gudeman had prescribed her and from October 2013 to March 2015, Ms. Benjamin detoxed under the care of Dr. Armstrong (internist and cardiologist). (Benjamin Decl. ¶ 11). Ms. Benjamin needed a primary care physician to oversee her care and manage her hyperthyroidism before her detox program ended, so in October 2014, she began seeing Dr. Michael Hirt. (Benjamin Decl. ¶ 14). Dr. Hirt put her on a treatment plan consisting of IVs, vitamins, and supplements to help her with the effects she was still feeling from the psychiatric medications. (*Id*).

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	Even after detoxing from the medication, Ms. Benjamin still had difficulty walking, and she told Dr. Hirt that she was having difficulty with her memory and concentration. (*Id*). Dr. Hirt told her that, once she was able to walk on her own again, he wanted her to see a neuropsychologist. (*Id*). In late 2015, Ms. Benjamin was slowly walking on her own again and only used her wheelchair when necessary, at which time she began searching for a neuropsychologist. (Benjamin Decl. ¶ 15). She contacted K. Drorit Gaines, Ph.D, who scheduled Ms. Benjamin for a neuropsychological evaluation in March 2016. (*Id*). Plaintiffs incorporate by reference Plaintiffs' Additional Separate Statement of Uncontroverted Fact #85-94.
18. On September 26, 2014, Ms. Benjamin commented "Excellent work!" and posted a link on her Facebook page to an article entitled, "A Prescription for Love: An	**Objection:** Irrelevant. **Undisputed.**

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Introduction to Toxic Psychiatry" **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. J (Ex. 15 to M. Benjamin Depo.), Docket No. 231-12; Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), Docket No. 231-13.	
19. The article to which Ms. Benjamin's September 26, 2014 Facebook post linked contains claims that individuals ended up with permanent brain dysfunction and damage from shock treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), at p. 3, Docket No. 231-13.	**Objection:** Irrelevant; Lacks Foundation; Lacks Authentication; Assumes Facts not in Evidence. **Disputed**. The proffered evidence fails to establish that Ms. Benjamin actually read the article that she posted to her Facebook, or that she read any information concerning permanent brain injury in September 2014. In September 2014, Ms. Benjamin was disappointed in psychiatry because she felt she was improperly prescribed treatment by Dr. Gudeman who had his license revoked due to over-prescription. (Benjamin Decl. ¶ 12).

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	Ms. Benjamin was in the process of detoxing from psychiatric medications and she became interested in reading about psychiatry. (*Id.*). On September 26, 2014, a friend shared an article about psychiatry that caught Ms. Benjamin's attention because it displayed a book titled "Toxic Psychiatry" and the book's cover had a photo of many pills. (*Id.*). This book cover spoke to Ms. Benjamin because she felt like it depicted exactly what she went through due to Dr. Gudeman's over-prescription. (*Id.*). **Ms. Benjamin *did not* read the article further than the headline**, and she simply shared the article to her Facebook page. *Id.* Having now seen the article, Ms. Benjamin knows she did not scroll through the entire article, because it contains a Nazi flag with a swastika symbol. (*Id.*). As a woman of Jewish faith, Ms. Benjamin would not intentionally post something that contains this hateful symbol. (*Id.*). Had Ms. Benjamin read the article and seen the Nazi flag in the article, she would

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	not have posted it. (*Id.*).
20. Ms. Benjamin stated that she had seen and recognizes the article to which her September 26, 2014 Facebook post linked and that she has read materials and viewed videos published by Dr. Peter Breggin, the author of the book *Toxic Psychiatry*, which is the subject of the posted article. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 106:5-107:17, 108:5-109:19, Docket No. 231-9; Benkner Decl., Ex. K (Ex. 14 to M. Benjamin Depo.), Docket No. 231-13.	**Objection:** Irrelevant; Vague and Ambiguous; Lacks foundation; Assumes Facts not in Evidence. **Disputed**. The proffered evidence fails to establish what videos of Dr. Breggin Ms. Benjamin saw, or what materials she read. This implies Ms. Benjamin read the article she posted, or read the book written by Dr. Breggin. **Ms. Benjamin has never read the book** titled "Toxic Psychiatry." (Benjamin Decl. ¶ 12). **Nor has Ms. Benjamin never read the article** entitled, "A Prescription for Love: An Introduction to Toxic Psychiatry" further than the headline. (*Id.*). In fact, when asked whether this was the article she linked to her Facebook page, Ms. Benjamin testified "I'm not sure because [Dr. Breggin] has so many articles." (Ex. 2, Benjamin Dep. 107:10-12). Importantly, this article was not written by Dr. Breggin, but written by an independent blog. (*See* Benkner Decl., Ex. K (Ex. 14 to Benjamin Dep.)). Had

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	Ms. Benjamin scrolled through and read the article, she would have seen the image of the Nazi flag and would not have shared the article to her Facebook page. (Benjamin Decl. ¶ 12).
21. On July 16, 2015, Ms. Benjamin requested her ECT records from Dr. Frankel, including identification of the machine model used in her treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:18-95:8, Docket No. 2319; Benkner Decl., Ex. H (Ex. 8 to M. Benjamin Depo.) at p. 1, Docket No. 231-10.	**Objection:** Irrelevant; Calls for Speculation. **Disputed in part.** To the extent Somatics infers that Ms. Benjamin's request for her medical records means she knew she had been injured by ECT, such inference is incorrect, speculative, and unsupported. Notwithstanding, Dr. Frankel refused to release Ms. Benjamin's medical records to her, even after Ms. Benjamin followed up twice by phone, and on September 23, 2016, she sent a second letter, warning Dr. Frankel that she would report him to the medical board if he did not release her medical records to her. (Ex. 14, Sept. 23, 2016 Ltr to Dr. Frankel (Ex. 7 to M. Benjamin Dep.)). Dr. Gaines, Ms. Benjamin's neuropsychologist at the time, also requested Dr. Frankel's medical records in approximately July

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	2016, but Dr. Frankel did not send the records to Dr. Gaines. (*Id.*). Ms. Benjamin ultimately received a copy of her medical records in September 2016, after writing her second letter to Dr. Frankel. (Ex. 2, Benjamin Dep. 97:1-24).
22. Ms. Benjamin stated that she sought her ECT records from Dr. Frankel because she "wanted to understand what had been done to her." **Defendant's Evidentiary Support:** Benkner Decl., Ex. G (M. Benjamin Depo.), at 94:9-12, Docket No. 231-9.	**Objection:** Relevance, Incomplete; Vague and Ambiguous as to time. **Disputed in part.** To the extent Somatics relies on this statement to infer Ms. Benjamin had knowledge or suspicion of permanent injuries from ECT, the proffered evidence is incorrect, speculative, and unsupported by the record. Although Ms. Benjamin requested her records from Dr. Frankel, she did so for her own "personal information" (Ex. 18, July 16, 2021 Ltr to Frankel (Ex. 8 to Benjamin Dep.)), and Dr. Frankel withheld her records for over one year. (Ex. 14, Sept. 23, 2016 Ltr to Dr. Frankel (Ex. 7 to M. Benjamin Dep.)). After Ms. Benjamin learned that Dr. Gudeman's medical license was revoked, she spent 18

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	months carefully tapering from the medication he had prescribed her, and towards the end of her detox, she began seeing a new primary care physician, Dr. Hirt, who began monitoring her thyroid disorder and put her on various treatments to help her further recover from her detox. (Benjamin Decl. ¶¶ 11, 13). While she was under Dr. Hirt's care, she complained of problems with memory and concentration, and Dr. Hirt instructed her to see a neuropsychologist once she was walking on her own again. (Benjamin Decl. ¶ 13). Dr. Gaines, Ms. Benjamin's neuropsychologist at the time, also requested Dr. Frankel's medical records in approximately July 2016, but Dr. Frankel did not send the records to Dr. Gaines. (Ex. 14, Sept. 23, 2016 Ltr to Dr. Frankel (Ex. 7 to M. Benjamin Dep.)). Ms. Benjamin ultimately received a copy of her medical records in September 2016, after writing her second letter to Dr. Frankel. (Ex. 2, Benjamin Dep. 97:1-24).

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23. Mr. Benjamin testified that his sexual relationship with Ms. Benjamin was adversely affected when Ms. Benjamin underwent ECT treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex. L (Transcript of Deposition of Daniel Benjamin) at 44:15-45:15, Docket No. 231-14.	**Objection**. Relevance; Vague and Ambiguous. **Disputed**. Mr. Benjamin testified that, while Ms. Benjamin was receiving treatment with Dr. Gudeman prior to ECT, Ms. Benjamin "had ups and downs" so their sexual relations were "quasi normal." Mr. Benjamin further testified that, during ECT, there was not much intimacy, but the goal was not to re-establish intimacy, rather, the goal was for Ms. Benjamin to get better. (Ex. 4, D. Benjamin Dep. 44:22-45:24).
24. Ms. Himes stated that she experienced a blackout period that she attributed to ECT where her ability to remember events was totally impaired, extending from a period when she underwent ECT until Autumn 2012. **Defendant's Evidentiary Support:** Benkner Decl., Ex. D (Transcript of Deposition of Michelle Himes ("Himes Depo.")), at 31:20-32:2, 36:14-20, 37:5-24, Docket No. 231-6.	**Objection:** Vague and ambiguous as to time. **Undisputed**.

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25. According to Ms. Himes, Dr. Fidaleo did not warn her that she could experience long-term impairment to her ability to learn or retain new information. **Defendant's Evidentiary Support:** Benkner Decl., Ex. A (Michelle Himes' Responses to Interrogatories Propounded by Somatics, Set One), at 26:3-13, 28:10-17, Docket No. 231-3.	**Undisputed.**
26. Dr. Fidaleo stated that Ms. Himes presented to him in dire status, including numerous prior hospitalizations for a progressively worsening condition that made her an imminent threat to herself and a potential threat to her family, having failed to respond to other forms of less-intrusive treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex. B (Transcript of Deposition of Raymond Fidaleo, M.D. ("Fidaleo Depo.")), at 22:17-23:5, 24:2-25:12, 26:19-27:8,	**Objection:** Relevance. **Undisputed.**

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Docket No. 231-4.	
27. Dr. Fidaleo testified that he warns his patients that their ability to remember and to work and to function would come back within two weeks to two months following treatment. **Defendant's Evidentiary Support:** Benkner Decl	**Undisputed.**
28. Ms. Himes indicated that, for personal reasons, she did not inform her doctors of the ongoing problems she was experiencing after ECT. **Defendant's Evidentiary Support:** Benkner Decl., Ex. D (Himes Depo.), at 40:15-23, Docket No. 231-6.	**Objection**: Relevance. Vague and Ambiguous as to time, Incomplete. **Disputed.** To the extent this statement is used to support an inference that, prior to 2016, Ms. Himes had a suspicion that she had suffered a permanent loss of memory, the proffered evidence does not support this conclusion. When asked whether she had told any of her doctors that she was having trouble forming long term memories (without any clarification as to a point in time) Ms. Himes testified: "I don't recall. I don't think so." In fact, Ms. Himes was routinely seeing medical

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	providers in the time following ECT. (*See* Himes Decl. ¶ 11). In April 2013, Ms. Himes was hospitalized again when her depressive symptoms returned. (Ex. 20, April 2013 MRI and June 2013 Dr. Breiland Note). While she was receiving psychiatric care, Ms. Himes told her treating psychiatrist, Dr. Breiland that her primary care doctor had requested an MRI of her pituitary gland, to rule out any possible pituitary tumor, given her high protactin levels. (*Id.*). In April 2013, Ms. Himes' MRI of her pituitary gland came back normal. (*Id.*). She had no reason to suspect that she had suffered any injury as a result of ECT, as her treating physicians did not inform her otherwise. (Himes Decl. ¶ 8). In 2017, after Ms. Himes began to suspect that ECT may have caused her memory difficulties and trouble communicating, she sought the assistance of counsel and timely and diligently filed the instant action. (Himes Decl. ¶ 15; Compl. Dkt. 4). Further, since filing this action, Ms. Himes has attended talk therapy to

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	process her feelings related to her ECT-induced brain injury. (Ex. 21, Aug. 14, 2018 Psychotherapy Note).
29. Up through the dates that Ms. Himes and Ms. Benjamin underwent ECT treatment, Somatics' warnings regarding the risks of ECT treatment were published in two sources: (1) in the operator's manual provided with the device and (2) in a patient information pamphlet. **Defendant's Evidentiary Support:** Declaration of Conrad Swartz, M.D., Ph.D. ("Swartz Decl."), ¶ 6, Docket No. 231-15	**Objection:** Vague and Ambiguous, Lacks Foundation; Assumes Facts not in Evidence. **Disputed.** There were no warnings. Dr. Conrad Swartz, co-owner of Somatics, testified that, when Sharp Hospital purchased the Thymatron System IV device in 2002, the manual that accompanied that device **did not** contain *any* warnings about the risks associated with the device. (Ex. 8, Swartz Dep. 48:2-57:5; Ex. 22, Thymatron System IV Manual, Sixth Edition (2001) from Sharp). When Northridge Hospital purchased the Thymatron System IV device in 2000, the hospital received the Fifth Edition of the instruction manual, which **did not** contain any warnings of permanent memory loss, brain damage, and permanent retrograde or anterograde amnesia. (Ex. 8, Swartz Dep. 66:20-24; 72:20-78:2; Ex. 23, Thymatron System IV Manual, Fifth Edition (2000) from

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	Northridge). Dr. Swartz further testified that only new customers who purchased a Thymatron device from approximately 2007 to 2009 received a copy of the Patient Information Pamphlet, as did a few existing customers who called and asked for copies of the pamphlet. (Ex. 8, Swartz Dep. 42:6-43:12). But Northridge and Sharp purchased the subject devices in 2000 and 2001, and Somatics has no way of verifying whether such Patient Information Pamphlets were actually sent to hospitals. (Ex. 8, Swartz Dep. 78:21-79:13). Through discovery in this action, Plaintiffs issued subpoenas to Northridge and Sharp, which sought "[a]ny and all brochures or informational material concerning ECT or the THYMATRON device YOU received from Somatics, LLC" and "[a]ny and all DOCUMENTS YOU received from Somatics, LLC" but neither hospital produced a copy of the Patient Information Pamphlet in

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	response to these subpoenas. (Esfandiari Decl. ¶¶ 2-3).
30. Dr. Fidaleo stated that he did not recall reading the operator's manual for Somatics [sic] ECT device. **Defendant's Evidentiary Support:** Benkner Decl., Ex. B (Fidaleo Depo.), at 14:7-9, Docket No. 231-4	**Objection:** Vague and Ambiguous; Incomplete; Assumes Facts not in Evidence. **Disputed in part**. To the extent this suggests that Dr. Fidaleo did not *rely* on Somatics' ECT device operator's manual during the course of his treatment, such an inference is unsupported by the evidence. *First*, Dr. Fidaleo stated that he did not recall reading the operator's manual, but he did not testify that he never read the manual. (Ex. 5, Fidaleo Dep. 14:7-9). *Second*, Dr. Fidaleo further stated that Somatics' ECT device operator's manual was available at the hospital, and that a nurse technician, David Munden, refers to the material provided by Somatics and calls Somatics if there are any issues. (Ex. 5, Fidaleo Dep. 14:10-15:2). Nurse Munden was directly trained on how to use the Thymatron System IV device by a Somatics' employee, and Nurse

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	Munden, in turn, trained Dr. Fidaleo and other medical staff at Sharp on how to use the Thymatron device. (Ex. 5, Fidaleo Dep. 49:16-23; 52:9-53:13). *Third*, Dr. Fidaleo stated that, if a manufacturer informed him that its product carries a risk of permanent memory loss, he would relay that information to his patients. (Ex. 5, Fidaleo Dep. 65:9-16). Dr. Fidaleo further testified that, if Somatics had informed him that its ECT device carries a risk of causing a patient to lose the ability to formulate new memories, he would relay that information to his patients. (Ex. 5, Fidaleo Dep. 67:9-17). *Fourth*, Dr. Fidaleo testified that "had Somatics provided [him] warnings concerning either permanent memory loss, brain injury, or inability to formulate new memories" he would have relayed those warnings to his patients and such warnings "would be in the informed consent" form. (Ex. 5, Fidaleo Dep. 93:5-17). Finally, the operator's manual is not the exclusive means by which Somatics can distribute

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	warnings and safety information to practitioners and hospitals. As Dr. Fidaleo testified, in the scope of his practice, he has received "dear doctor" letters or other notices from manufacturers of new safety risks associated with their products, and he pays attention to those notices when he receives them. (Ex. 5, Fidaleo Dep. 59:15-21).
31. Dr. Fidaleo stated that he had not seen Somatics' patient information pamphlet. **Defendant's Evidentiary Support:** Benkner Decl., Ex. B (Fidaleo Depo.), at 94:10-95:9, Docket No. 231-4.	**Objection:** Relevance. **Disputed in part**. To the extent this suggests Somatics sent Dr. Fidaleo the Patient Information Pamphlet, this is unsupported by the record. The evidence indicates that Somatics did not send the pamphlet to Dr. Fidaleo or Sharp Hospital. Dr. Swartz testified that only new customers (hospitals) who purchased a Thymatron device from approximately 2007 to 2009 received a copy of the Patient Information Pamphlet, as did a few existing customers who called and asked for copies of the pamphlet. (Ex. 8, Swartz Dep. 42:6-43:12). Somatics has no way

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	of verifying whether such Patient Information Pamphlets were actually sent to hospitals. (Ex. 8, Swartz Dep. 78:21-79:13). And neither Northridge nor Sharp produced a copy of the Patient Information Pamphlet in response to subpoenas Plaintiffs issued to the hospitals, which sought "[a]ny and all brochures or informational material concerning ECT or the THYMATRON device YOU received from Somatics, LLC" and "[a]ny and all DOCUMENTS YOU received from Somatics, LLC." (Esfandiari Decl. ¶¶ 2-3).
32.Dr. Fidaleo stated that he was not concerned that brain damage was a risk of treatment because ECT is a treatment of last resort to help people who exhibit suicidality. **Defendant's Evidentiary Support:** Benkner Decl., Ex. B (Fidaleo Depo.), at 34:19-35:5, Docket No. 231-4.	**Objection:** Vague and Ambiguous; Incomplete. **Disputed**. Dr. Fidaleo stated that the risk of brain injury is a serious risk and if he knew that a drug or device has the potential to cause brain injury, he "would be reluctant to use it" if he knew of it. (Ex. 5, Fidaleo Dep. 63:9-12). Dr. Fidaleo testified that "had Somatics provided [him] warnings concerning either permanent memory

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	loss, brain injury, or inability to formulate new memories" he would have relayed those warnings to his patients and such warnings "would be in the informed consent" form. (Ex. 5, Fidaleo Dep. 93:5-17).
33. Dr. Fidaleo stated that if he were informed by the manufacturer that ECT carried a risk of permanent memory loss, it would not prevent him from recommending ECT treatment. **Defendant's Evidentiary Support:** Benkner Decl., Ex B (Fidaleo Depo.), at 64:19-65:8, Docket No. 231-4.	**Objection:** Relevance; Vague and Ambiguous; Incomplete. **Disputed**. Dr. Fidaleo stated if a manufacturer informed him that its product carries a risk of permanent memory loss, he would relay that information to his patients. (Ex. 5, Fidaleo Dep. 65:9-16). Dr. Fidaleo further testified that, if Somatics had informed him that the use of its ECT device carries a risk of causing a patient to lose the ability to formulate new memories, he would relay that information to his patients. (Ex. 5, Fidaleo Dep. 67:9-17).
34. Dr. Fidaleo stated that even if a manufacturer told him there was a risk of losing the ability to form new memories, he would need to see evidence of it himself in his clinical practice.	**Objection:** Relevance; Vague and Ambiguous; Incomplete, Misstates the Testimony. **Disputed.** The proffered evidence omits relevant testimony from Dr. Fidaleo, in which he stated that if a

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Defendant's Evidentiary Support: Benkner Decl., Ex B (Fidaleo Depo.), at 67:9-68:25, Docket No. 231-4.	medication or a procedure had a risk of the patient losing the ability to form new memories "that would be a real problem" and "means the person is functioning in a demented way. So that would not be a safe procedure." (Ex. 5, Fidaleo Dep. 65:22-66:4). Further, when asked: "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 information you have presented or at least informed your patients about?" Dr. Fidaleo responded: "Yes, we would inform them." (Ex. 5, Fidaleo Dep. 67:9-67:17). Dr. Fidaleo reiterated this point by stating: "If they told me the machine causes people to no longer be able to remember new information, that would be a serious concern, yea, I would tell them." (Ex. 5, Fidaleo Dep. 68:17-19).
35. Dr. Fidaleo has never spoken with anyone from Somatics, LLC. **Defendant's Evidentiary Support:** Benkner Decl., Ex B (Fidaleo	**Objection:** Relevance. **Undisputed.**

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Depo.), at 7:8-16, Docket No. 231-4.	
36. Dr. Frankel stated that he did not rely on any disclosures from Somatics to inform him of the risks of ECT. **Defendant's Evidentiary Support:** Benkner Decl., Ex. F (Frankel Depo.), at 14:4-15:7, Docket No. 231-4.	**Objection.** Vague and Ambiguous; Incomplete; Misstates the testimony. **Disputed.** Dr. Frankel testified that when Northridge Hospital purchased the Thymatron System IV device, he was provided the instruction manual, and he relied on the instruction manual for training on how to operate the ECT device. (Ex. 6, Frankel Dep. 12:13-13:15; 46:3-20).
37. Dr. Frankel testified that he does not pay much attention to updated safety information provided by manufacturers of drugs or devices. **Defendant's Evidentiary Support:** Benkner Decl., Ex. F (Frankel Depo.), at 54:6-11, Docket No. 231-4.	**Objection:** Vague and Ambiguous; Incomplete; Misleading. **Disputed.** Dr. Frankel testified that if he is alerted to new risks concerning a drug or device that he prescribes or utilizes, he pays attention to such information. He further testified that if a manufacturer warned him of new risks, he would relay that risk information to his patients. (Ex. 6, Frankel Dep. 55:9-17).
38. Dr. Frankel testified that he was not concerned about complaints of cognitive disturbances in patients because he is careful to make sure that every other treatment option has	**Objection:** Vague and Ambiguous; Incomplete; Misstates the Testimony. **Disputed.** Dr. Frankel testified that if Somatics had informed him that ECT could be linked to permanent brain

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been exhausted before using ECT and that patients will almost exclusively choose ECT despite the possibility of side effects. **Defendant's Evidentiary Support:** Benkner Decl., Ex. F (Frankel Depo.), at 18:16-19:7, Docket No. 231-4.	damage, that is information he would "definitely advise patients" of during the informed consent process. (Ex. 6, Frankel Dep. 73:18-23). Dr. Frankel further testified that brain injury from use of a prescription drug or device is a "serious" risk. (Ex. 6, Frankel Dep. 55:18-21).
39. Dr. Frankel does not recall having any conversations with anyone from Somatics, LLC. **Defendant's Evidentiary Support:** Benkner Decl., Ex. F (Frankel Depo.), at 7:4-18, Docket No. 231-4	**Undisputed**.
40. At all times during its existence, Somatics has operated with permission to sell its ECT devices from the Food and Drug Administration ("FDA") though Section 510(k) clearance. **Defendant's Evidentiary Support:** Swartz Decl. ¶ 3, Docket No. 231-15.	**Objection:** Relevance. **Disputed**. Although Somatics' Thymatron System IV device is a 510(k) cleared device, the Thymatron device has not been legally marketed under FDA's regulations. Dr. Swartz testified that, although Somatics has been instructed by the FDA that it cannot, in any way, represent or create an impression of official approval of its device, because doing so would be

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	misleading and constitute misbranding, Somatics has posted on its website (and elsewhere) that the Thymatron device is FDA approved. (Ex. 8, Swartz Dep. 152:2-157:7; Ex. 24, Somatics' Website Stating "Approval"; Ex. 32, Somatics' Website Claiming Safety and Efficacy; Ex. 33, Somatics' Website Dropping Claims of Safety and Efficacy).
41. Between 2009 and 2011, the FDA was directly advised of thousands of purported adverse event complaints resulting from ECT treatment. **Defendant's Evidentiary Support:** 5AC, ¶ 59., 18:20-23, Docket No. 178; 80 F.R. 81226	**Objection:** Relevance, Incomplete. **Disputed in part**. Plaintiffs do not dispute that thousands of adverse event complaints resulting from ECT were submitted to the FDA during this time. However, Somatics took no effort to investigate these reports, submit formal adverse event reports. (Ex. 25, Somatics' Responses to Plaintiffs' Requests for Admission, Set One, Nos. 36, 40, 41, 42). Nor did Somatics warn about these adverse events until late 2018 when it stated, for the first time, that serious adverse events with ECT treatment "have occurred, including … "cognitition and memory impairment" and "brain damage." (Ex. 26, 2018 Regulatory Update Posted on Somatics'

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	Website). Because Somatics did not bother to investigate these reports or submit formal adverse event reports, the FDA was deprived of complete adverse event reports corresponding to the allegations of, *inter alia*, death, brain damage, and permanent memory loss between 2009 and 2011. (*See* Ex. 25, Somatics' Responses to Plaintiffs' Requests for Admission, Set One, Nos. 36, 40, 41, 42). It is a device manufacturer's duty to investigate potential risks, to submit formal adverse event reports and to ensure that its labeling is current at all times.
42. The FDA has expressly acknowledged the significant risks associated with ECT but continues to believe that "the probable benefit to health from use of the [ECT] device outweighs the probable injury or illness from such use." **Defendant's Evidentiary Support:** 80 F.R. 81227.	**Objection**: Irrelevant; Incomplete; Misleading. **Disputed in part.** To the extent this suggests the benefits of ECT outweigh the probable injury or illness associated with ECT in all cases and without limitation, such an inference is not supported by the proffered evidence. The FDA has also expressly acknowledged that "controlled clinical trials are lacking regarding the effectiveness of ECT beyond the acute

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
	phase [less than 3 months after treatment], in part, due to the fact that many patients have an initial improvement in the depressive symptoms following an acute course of ECT and are able to return to alternative treatments for managing depression such as medications and psychotherapy." 80 F.R. 81227. In fact, according to a recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read of the University of East London, there is no scientifically reliable evidence that ECT works as a treatment for depression, and the negative impact on patients, including permanent memory loss, set against any potential benefits is so appalling that ECT cannot be scientifically or ethically justified, and "should be immediately suspended." (Ex. 40, "Electroconvulsive Therapy for Depression: A review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses.").

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
	The FDA has accordingly acknowledged that health risks can be mitigated by "providing information to both the user and patient on the potential adverse effects of the device, alternative treatments, and a prominent warning that ECT device use may be associated with: Disorientation, confusion, and memory problems" and that its effectiveness is limited to three months. 80 F.R. 81228. Somatics was thus required to provide an Addendum for the Thymatron System IV Manual, which warns: "A small minority of patients treated with ECT later report devastating cognitive consequences. Patients may indicate that they have dense amnesia extending far back into the past for events of personal significance or that broad aspects of cognitive function are so impaired that the patients are no longer able to engage in former occupations...in some patient self-reports of profound ECT-induced deficits may reflect objective loss of

Defendant's Uncontroverted Fact	Plaintiffs' Evidentiary Objections and Response
	function...In rare cases, ECT may result in a dense and persistent retrograde amnesia extending to years..." (Ex. 27, 2018 Addendum).

PLAINTIFFS' ADDITIONAL SEPARATE STATEMENT OF UNCONTROVERTED FACTS

Uncontroverted Fact	Supporting Evidence
1. Electroshock or electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain.	Ex. 10, Breggin Decl., ¶ 8.
2. In the late 1930's, Ugo Cerletti, the chair of the Department of Neuropsychiatry at the University of Rome, after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, theorized that electricity could be used to treat psychosis.	Ex. 29, Wright, An Historical Review of Electroconvulsive Therapy, Jefferson Journal of Psychiatry, Vol. 8: Iss. 2, Article 10, p. 70 (1990).
3. Cerletti, who was assisted by Lucino Bini on the technical aspects of electrical convulsion,	*Id.* at 70-71.

Uncontroverted Fact	Supporting Evidence
began to test the theory by applying electricity to dogs. Bini noted that there was a high mortality rate in Cerletti's dogs following the experiments.	
4. In April 1938, Cerletti and Bini applied ECT to the first human patient. A 40-year-old man who had been found wandering the train station in Rome and speaking gibberish was brought to the University of Rome and had 70 volts of electricity applied to his temple by Cerletti.	*Id.* at 71.
5. It has been reported that, while the scientists were deliberating whether they should apply a second higher voltage, the patient pleaded "Non una seconda! Mortifera!" ("not again it will kill me!").	*Id.*
6. Seeing success that the man was speaking as opposed to his initial gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. The scientists reported that, after the application	*Id.* at 71-72.

Uncontroverted Fact	Supporting Evidence
of the electricity, the patient was purportedly able to speak more coherently. The patient was administered approximately a dozen more sessions of ECT but was subsequently lost to follow-up.	
7. In May 1938, Cerletti publicly presented his results on the use of ECT on this patient at the Medical Academy of Rome. Shortly thereafter and starting in the early 1940s ECT began to gain acceptance for the purported treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States.	*Id.*
8. In the 1980s, Richard Abrams, M.D. and Conrad Swartz, M.D., formed Somatics, LLC ("Somatics") for the purpose of developing their own ECT machine for profit.	Ex. 7, Abrams Dep. 50:15-25. *See also*, Ex. 8, Swartz Dep., 7:2-8:24; 11:2-16:25.
9. Somatics has never obtained FDA approval to market its ECT machine.	Ex. 9, Mirkowitz Dep. 165:2-16.

Uncontroverted Fact	Supporting Evidence
10. Somatics obtained clearance from the FDA to sell its "Thymatron" ECT device, after representing to the FDA that its device was equivalent to an already existing device.	Ex. 41, Sept. 27, 1984 510(k) notification; Ex. 30, 1984 clearance.
11. Somatics has not conducted any clinical trials of its Thymatron ECT device to determine its safety and efficacy ("Somatics has never conducted any studies of any kind.")	Ex. 7, Abrams Dep. 154:11-14.
12. Dr. Abrams, the founder, owner and member of SOMATICS, testified that SOMATICS has never performed any studies or tests to analyze the long-term side effects associated with ECT because "that's not our business."	Ex. 7, Abrams Dep. 81:15-20.
13. Dr. Abrams testified that it is not SOMATICS' business to conduct such safety studies on its ECT device.	*Id.*
14. An FDA approved device requires clinical trials to demonstrate the safety and efficacy of the device.	*See* Premarket Approval (PMA) requirements at https://www.fda.gov/medical-

Uncontroverted Fact	Supporting Evidence
	devices/premarket-submissions/premarket-approval-pma
15. The FDA spends approximately 1,200 hours of review prior to approving a medical device while devices that obtain grandfathering clearance, are usually cleared within 20 hours.	*See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–79 (1996) ("The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours.") Fed. Register, Vol. 86, No. 10, 4088, 4089, Friday, January 15, 2021, Notices, available online at https://www.govinfo.gov/content/pkg/FR-2021-01-15/pdf/2021-00787.pdf .
16. In issuing its clearance to Somatics, the FDA on multiple occasions, informed Somatics that: 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	*See* Ex. 30, 1984 Clearance; *see also* Ex. 31, 1995 Clearance.

Uncontroverted Fact	Supporting Evidence
regulations is misleading and constitutes misbranding.	
17. Somatics has promoted its Thymatron ECT device as being FDA "approved."	*See e.g.*, Ex. 24, Somatics' Website Stating "Approval"; Ex. 32, Somatics' Website Claiming Safety and Efficacy; Ex. 33, Somatics' Website Dropping Claims of Safety and Efficacy).
18. Somatics' promotion of its Thymatron ECT device as FDA "approved" is a violation of federal law and constitutes misbranding.	*See* 21 CFR §807.97; *see also* Ex. 30, 1984 Clearance; and Ex. 31, 1995 Clearance.
19. During the relevant time period, Somatics promoted its ECT device as "The most advanced ECT device technically and operationally, with demonstrated superior safety and clinical effectiveness."	*See* Ex. 8, Swartz Dep. 158:1-162:25; Ex. 24, Somatics' Website Stating "Approval"; Ex. 32, Somatics' Website Claiming Safety and Efficacy.
20. Somatics removed the claims of safety and efficacy from its Thymatron brochure and now states, as the FDA requires: "The long-term safety and effectiveness of ECT treatment has not been demonstrated."	Ex. 32, Somatics' Website Claiming Safety and Efficacy; Ex. 33, Somatics' Website Dropping Claims of Safety and Efficacy); 21 C.F.R. § 882.5940.
21. The FDA requires that Somatics	*See* 21 C.F.R. § 882.5940.

Uncontroverted Fact	Supporting Evidence
include a statement in its promotional and instructional literature that: "The long-term safety and effectiveness of ECT treatment has not been demonstrated."	
22. During the relevant time period, Somatics did not have appropriate procedures in place to identify, evaluate and warn about adverse events in violation of applicable FDA regulations.	*See* Ex. 34, 2012 FDA Inspection Report; see also 21 C.F.R. §§ 803.17, 803.18, 803.50 & 820.198; 21 U.S.C. §§ 331 & 352(t).
23. Between 1984 and 2017, Somatics never submitted a single adverse event report to the FDA.	*See* Ex. 25, RFA No. 30; *see also* Pressly Decl. at ¶¶ 2-4.
24. Somatics became aware, or should have been aware, of hundreds of complaints and reports of brain injury, permanent retrograde amnesia, cognitive impairment, and death.	*See* Ex. 36, 2011 FDA Executive Summary at SOM00262.
25. Somatics never investigated these complaints, nor did it submit adverse events to the FDA or warn physicians and consumers of these risks.	*See* Ex. 36, 2011 FDA Executive Summary at SOM00262; Ex. 25, RFA Nos. 36, 40, 41 & 42; Pressly Decl. at ¶¶2-4.
26. Somatics' co-owner, Conrad	*See* Ex. 8, Swartz Dep. 48:2-57:5; 66:20-

Uncontroverted Fact	Supporting Evidence
Swartz, M.D. testified that the manuals Somatics prepared for its ECT device and distributed to the two hospitals where plaintiffs received their respective ECTs, did not contain any warnings.	24; 72:20-78:2; Ex. 22, Thymatron System IV Manual, Sixth Edition (2001) from Sharp; Ex. 23 Thymatron System IV Manual, Fifth Edition (2000) from Northridge.
27. Somatics did not provide any warnings to plaintiffs' physicians or to the plaintiffs concerning any risks, including permanent memory loss or brain damage associated with ECT.	*Id.*
28. Prior to Plaintiffs' ECT treatments, Somatics was aware, or should have been aware, of numerous articles published in the peer reviewed medical literature and in numerous textbooks concerning the risk of permanent memory loss, severe cognitive impairment and brain damage.	*See e.g.* Ex. 10, Breggin Decl. ¶ 18.
29. In his 2002 book, Electroconvulsive Therapy, Fourth Edition, Richard Abrams quoted an editorial published in The Journal of ECT in 2000 by Harold Sackeim, a researcher and	Ex. 28, "Electroconvulsive Therapy, Fourth Edition" by Richard Abrams, M.D. at p. 200.

Uncontroverted Fact	Supporting Evidence
advocate of ECT, who Abrams quotes as stating that "virtually all patients experience some degree of persistent and, likely permanent retrograde amnesia," that "in many patients the recovery from retrograde amnesia extending several years prior to ECT," and "increasing evidence has accumulated that some degree of persistent memory loss [with ECT] is common."	
30. The article by Sackeim, referenced in Abrams' book, includes the statement: "[V]irtually all patients experience some degree of persistent and, likely permanent retrograde amnesia. A series of recent studies demonstrates that retrograde amnesia is persistent, and that this long-term memory loss is substantially greater with bilateral than right unilateral ECT (Weiner et al., 1986b; McElhiney et al., 1995; Lisanby et al. [in press]; Sackeim et al. [in press]. It	Ex. 37, Sackeim, Memory and ECT: From Polarization to Reconciliation, The Journal of ECT, Vol. 16, No. 2 (2000).

Uncontroverted Fact	Supporting Evidence
has also become clear that for rare patients the retrograde amnesia due to ECT can be profound, with the memory loss extending back years prior to receipt of the treatment."	
31. Sackeim also writes "The most prominent deficits [from ECT] are antegrade amnesia (rapid forgetting of newly learned information) and a temporally graded retrograde amnesia."	*Id.*
32. Sackeim concludes that there is a need to "update what is communicated in the consent process and to monitor cognitive outcomes."	*Id.* p. 93.
33. In response to Sackeim's statements regarding ECT and memoy loss, Abrams states in his book, "what supporting evidence is provided to back [Sackeim's claims] up? Unfortunately, none— The reader is required to accept the statements on faith alone."	Ex. 28, Abrams p. 200.
34. Abrams also referenced in his book a "memoir," published in the same	Ex. 28, Abrams, p. 200 and Ex. 38, Donahue, Electroconvulsive Therapy and

Uncontroverted Fact	Supporting Evidence
2000 edition of the Journal of ECT, titled Electroconvulsive Therapy and Memory Loss: A Personal Journey, wherein the ECT patient, Anne B. Donahue, recounts her experience with memory loss after ECT.	Memory Loss: A Personal Journey, The Journal of ECT, Vol. 16, No. 2 (2000).
35. Ms. Donahue wrote that her "medical cost-benefit analysis in accepting ECT treatment was skewed from the start by the fact that the existing professional statements on potential risks did not match the actual risks presented by current mainstream practice."	*Id.* at 141.
36. In her article, Ms. Donahue states: "in informing patients about ECT, it is important to relate that a few individuals report profound and long-lasting cognitive impairment that they attribute to this treatment modality." *	*Id.* p. 141.
37. In his book, Abram's description of Donahue's article was: "The author of the memoir is no overt enemy of ECT … she is	Ex. 28, Abrams p. 200.

Uncontroverted Fact	Supporting Evidence
highly educated, writes cogently and well, has a thorough knowledge of the relevant literature, and engages in no polemics. Nevertheless, her conviction that she suffered 'devastating and permanent memory loss with ECT' is just that: a personal conviction, and one that is, like many other personal convictions, unsupported by any objective evidence … The sincerity of its author is not in question; the difficulty lies elsewhere, in the disjunction between objective science and subjective experience …"	
38. In 2006, Richard Abrams and Conrad Swartz, aware of the alleged risk of permanent memory loss associated with ECT, contemplated warning of the risk.	Ex. 39, 2006 Email between Abrams and Swartz.
39. In 2006, Abrams and Swartz discussed issuing a warning concerning the alleged risk of permanent memory loss associated with ECT for purposes of avoiding	*Id.*

Uncontroverted Fact	Supporting Evidence
lawsuits, but they were also concerned they would "alienate psychiatrists" if they were to do so.	
40. Abrams and Swartz agreed upon issuing a disclaimer rather than a warning.	Ex. 39, 2006 Email between Abrams and Swartz.
41. Conrad Swartz testified that the disclaimer "is not a warning."	*See* Ex. 8, Swartz Dep. 99:22-100:4; *see also* Exh. 39.
42. This disclaimer was not distributed to the two hospitals where plaintiffs had their ECT procedures.	*See* Ex. 8, Swartz Dep. 91:1-93:8; *see also* Esfandiari Decl. ¶¶ (Plaintiffs issued subpoenas to Northridge and Sharp, but the only relevant instructions for use that were produced included the 2000 Fifth Edition Manual (Northridge), and 2001 Sixth Edition Manual (Sharp) (Esfandiari Decl. ¶¶ 2-3), and neither of these manuals contain the disclaimer that Somatics added to its post-2006 manuals.
43. In 2009, the FDA announced it was opening a docket and inquiry to further look into the safety and efficacy of ECT given the devices had never received FDA approval.	*See* 74 Fed.Reg. 46607-01.
44. By 2010, the FDA's public docket had received more than 3,000	*See* Ex. 36, FDA Executive Summary at SOM00262.

Uncontroverted Fact	Supporting Evidence
notifications of alleged ECT injury and, according to the FDA: "The most common type of adverse event reported in the public docket was memory adverse event (529 reports). This was followed by other cognitive complaint (413 reports), brain damage (298 reports) and death (103 reports)."	
45. As of 2010, Somatics was aware of these adverse events being reported, but took no steps to investigate any of these reports and likewise took no steps to issue any warnings concerning these risks to plaintiffs' medical providers.	*See* 21 C.F.R. §803.50(b)(3); *see also* Ex. 25, RFA Nos. 36, 40, 41 & 42.
46. Somatics' Person Most Knowledgeable testified that one patient who had attempted to report memory loss to Somatics was "wacko."	*See* Ex. 9, Mirkovich Depo. at 62:21-63:5.
47. Somatics manufactures an ECT machine that administers electric current to a patient's head that is approximately one hundred times	*See* Ex. 12, Castleman Report at 10; *see* Ex. 8, Swartz Dep. 48:22-57:25; see Ex. 22, Somatics Manual Given to Sharp Hospital; Ex. 23, Somatics Manual Given

Uncontroverted Fact	Supporting Evidence
what tasers use, approximately the same current used to stun pigs prior to slaughter, roughly one-fifth as much current as the electric chair, and applies voltage that is more than one hundred times what is required to damage brain cells, and yet Somatics chose not to provide any warnings to plaintiffs' medical providers concerning any risks or adverse events associated with its ECT device.	to Northridge Hospital.
48. In late 2018, after the FDA concluded that Somatics needed to provide instructions and warnings concerning permanent cognitive injuries (see 21 C.F.R. § 882.5940), Somatics began to implement warnings on its website and in its manuals including warning that "ECT may result in anterograde or retrograde amnesia" and that "in rare cases, patients may experience permanent memory loss or permanent brain damage."	*See* Ex. 26 (warnings on Somatics' website issued in late 2018); see also Ex 27 (updated warnings Somatics purportedly sent to all customers via mail sometime after 2018); *see also* Ex. 8, Swartz Dep. 112:7-118:22; 121:23-124:24.

Uncontroverted Fact	Supporting Evidence
49. A recently published meta-analysis of pre-existing ECT studies, conducted by Irving Kirsch of Harvard University and John Read and Laura McGrath of the University of East London, concluded: "Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo-controlled studies have investigated whether there really are any significant benefits against which the proven significant risk can be weighed."	Ex. 40, John Read, Ph.D. et al, *Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and Meta-Analyses*, 21 ETHICAL HUMAN PSYCHOLOGY AND PSYCHIATRY 64 (2019).
50. Plaintiff Marcia Benjamin was a successful architect who, after obtaining her Bachelor of Architecture degree and having 25 years of work experience, opened her own architectural firm in 2005.	Ex. 2, Benjamin Dep. 19:15-21:15.
51. Since approximately 2008, Ms.	Benjamin Decl. ¶ 2.

Uncontroverted Fact	Supporting Evidence
Benjamin has suffered from and has been treated for hypothyroidism.	
52. In March 2011, Ms. Benjamin's thyroid medication dosage was increased, and she was at home when she began experiencing dizziness, discomfort, and chest pain.	Benjamin Decl. ¶ 2; Ex. 6, Frankel Dep. 20:13-23:8.
53. Ms. Benjamin visited the emergency room where she was diagnosed with severe anxiety and prescribed Xanax.	Ex. 2, Benjamin Dep. 38:14-39:15; Benjamin Decl. ¶ 2.
54. Shortly thereafter, she responsibly sought out treatment with a psychiatrist in her area, Dr. David Gudeman, so that her use of psychiatric medication would be properly monitored.	Ex. 2, Benjamin Dep. 38:14-39:15.
55. While Ms. Benjamin was under Dr. Gudeman's care, he increased her Xanax dose, and she developed an adverse reaction to the medication.	Benjamin Decl. ¶ 4.
56. She complained that, while taking Xanax, she felt extremely weak, to the point that she could not sit	*Id.* Ex. 6, Frankel Dep. 20:13-23:8.

Uncontroverted Fact	Supporting Evidence
upright in a chair.	
57. Without realizing it, Ms. Benjamin developed a tolerance to the medication, so, in late 2011, she sought treatment at a detox clinic in Sao Paulo, Brazil with psychiatrist Dr. Raymond Rosenberg.	Benjamin Decl. ¶ 4.
58. She was at the clinic for about one month from late 2011 to early 2012, where she was able to titrate off Xanax by taking controlled doses of Valium and Tegretol.	*Id.*; Ex. 6, Frankel Dep. 20:13-23:8.
59. In early 2012, Ms. Benjamin returned home and continued treatment with Dr. Gudeman, per Dr. Rosenberg's recommendation.	Benjamin Decl. ¶ 4.
60. Rather than keeping her on Valium and Tegretol, however, Dr. Gudeman switched her to Klonopin, which made her feel worse.	Ex. 2, Benjamin Dep. 40:25-41:8.
61. The symptoms Ms. Benjamin was experiencing from Klonopin "were so severe that [she] was not able to walk."	Ex. 2, Benjamin Dep. 42:22-43:5.
62. Dr. Gudeman told her ECT was a	Ex. 2, Benjamin Dep. 43:6-12; Benjamin

Uncontroverted Fact	Supporting Evidence
treatment that could help her overcome the symptoms she was experiencing from Klonopin and, because she had not responded well to previous medications, ECT was her next treatment option.	Decl. ¶ 5.
63. In September 2012, Dr. Gudeman referred Ms. Benjamin to Dr. Michael Frankel at Northridge Hospital Medical Center (Northridge) for an ECT consult.	Benjamin Decl. ¶ 6.
64. When Ms. Benjamin and her husband, Plaintiff Daniel Benjamin, met with Dr. Frankel to discuss ECT, Dr. Frankel told them that ECT was safe, that it was an easy, outpatient procedure that took only 20 minutes.	Ex. 2, Benjamin Dep. 51:22-53:17.
65. Dr. Frankel only informed the Benjamins that the side effects of ECT included some confusion right after treatment and short-term memory loss that would be temporary.	*Id.*; Benjamin Decl. ¶ 6.
66. Ms. Benjamin signed a consent form to undergo ECT treatment, which did not advise her of the	Ex. 15, Sept. 28, 2012 Consent Form.

Uncontroverted Fact	Supporting Evidence
risk of permanent memory loss, brain injury, or an inability to create new memories.	
67. Had Ms. Benjamin been adequately warned of the risk of permanent or long-term memory loss, she would not have consented to ECT treatment.	Ex. 2, Benjamin Dep. 52:5-11; Benjamin Decl. ¶ 18
68. From September 28, 2012 to March 4, 2013, Dr. Frankel administered 20 ECT treatments to Ms. Benjamin.	Benjamin Decl. ¶ 7.
69. During her ECT treatment, Ms. Benjamin complained of memory problems, but Dr. Frankel repeatedly assured her these were temporary side effects of ECT that were expected and in fact in response to her complaints, he prescribed further ECT sessions.	Ex. 6, Frankel Dep. 34:10-35:15; Ex. 14, Jan. 21, 2013 Progress Note.
70. In early March 2013, Dr. Frankel recommended, for the second time, that Ms. Benjamin continue taking Lithium while she was on maintenance ECT.	Benjamin Decl. ¶ 8.
71. At this point, Mr. Benjamin suggested that she stop ECT	*Id.* ¶ 5; Ex. 4, D. Benjamin Dep. 33:24-34:12.

Uncontroverted Fact	Supporting Evidence
treatment, because he felt that if ECT was not going to eliminate the need for her to take psychiatric medications, it was time to stop ECT treatment.	
72. Ms. Benjamin's last ECT treatment was on March 4, 2013.	Benjamin Decl. ¶ 5.
73. After her last ECT treatment with Dr. Frankel, Ms. Benjamin returned to the care of Dr. Gudeman in March 2013, and he performed "maintenance" Transcranial Magnetic Stimulation (TMS) treatment in lieu of additional "maintenance" ECT.	Ex. 2, Benjamin Dep. 64:3-12; Ex. 6, Frankel Dep. 41:23-42:14.
74. She continued with her psychiatrist's recommended course of maintenance treatment and received TMS with Dr. Gudeman until October 2013.	Benjamin Decl. ¶ 9.
75. In October 2013, Ms. Benjamin learned that the Medical Board of California revoked Dr. Gudeman's medical license after two of his patients died from intoxication of medications prescribed by him, and five others lodged complaints	Benjamin Decl. ¶ 10.

Uncontroverted Fact	Supporting Evidence
with the Medical Board due to Dr. Gudeman overprescribing them.	
76. Ms. Benjamin was disappointed by this news, so she searched for another clinic to help her safely detox from the Klonopin that Dr. Gudeman had re-started her on before his license was revoked.	*Id.*
77. In late October 2013, Ms. Benjamin began treatment with Dr. Raymond Armstrong (internist and cardiologist) who helped her detox from the medication over a period of 18 months (October 2013 to March 2014).	*Id.* ¶ 11.
78. In October 2014, Ms. Benjamin began seeing a new primary care physician, Dr. Michael Hirt, who continued treating her thyroid disorder.	*Id.* ¶ 13; Ex. 2, Benjamin Dep. 71:11-72:4.
79. When Ms. Benjamin completed her detox program in March 2015, Dr. Hirt put her on a treatment plan consisting of IVs, vitamins, and supplements to help her with the effects she was still feeling from the medications.	*Id.*

Uncontroverted Fact	Supporting Evidence
80. At the time, Ms. Benjamin still had difficulty walking, and she told Dr. Hirt that she was having difficulty with her memory and concentration.	*Id.*
81. Dr. Hirt told her that once she was able to walk on her own again, he wanted her to see a neuropsychologist.	*Id.*
82. In July 2015, Ms. Himes requested her medical records from Dr. Frankel's office, but he failed to immediately release them to her, even after she called his office twice to follow up on her request.	*Id.* ¶ 14.
83. In late 2015, Ms. Benjamin was slowly walking on her own again and only used her wheelchair when necessary, at which time she began searching for a neuropsychologist.	*Id.* ¶ 15.
84. She contacted K. Drorit Gaines, Ph.D, who scheduled Ms. Benjamin for a neuropsychological evaluation in March 2016.	*Id.*

Uncontroverted Fact	Supporting Evidence
85. During her examination, Ms. Benjamin stated she had difficulty with her memory, concentration, reading, and math.	*Id.*
86. In April 2016, Dr. Gaines called Ms. Benjamin to discuss her findings, and she stated that the results revealed "processing deficits" but diagnosed Ms. Benjamin with Post-Traumatic Stress Disorder (PTSD).	*Id.*
87. In September 2016, Ms. Benjamin finally received a copy of her ECT treatment records that Dr. Frankel had delayed producing.	*Id.*; Ex. 2, Benjamin Dep. 96:9-97:24.
88. Thereafter, in October 2016, Ms. Benjamin received a copy of Dr. Gaines' written neuropsychological report.	Benjamin Decl. ¶ 15.
89. When reading it, Ms. Benjamin was displeased with various errors in the report and confused by Dr. Gaines' diagnosis of PTSD which, to Ms. Benjamin, seemed inconsistent with her symptoms, so she sought out a second	Benjamin Decl. ¶ 16.

Uncontroverted Fact	Supporting Evidence
opinion.	
90. In January 2017, Ms. Benjamin underwent a neuropsychological examination with Dennis Robinson, Ph.D.	*Id.* ¶ 17; Ex. 42, Dr. Robinson Report
91. The neuropsychological testing took place over the course of four different sessions, from January to April 2017.	*Id.*
92. In July 2017, Dr. Robinson discussed his written report with Ms. Benjamin and informed her, for the first time, that she had verified learning difficulties, memory problems, and major neuro-cognitive disorder resulting from "Hypothyroidism and the resulting medically based treatments – Medications, Electroshock, and [TMS]."	Benjamin Decl. ¶ 17.
93. Dr. Robinson was the first medical specialist to opine and inform Ms. Benjamin that her neurocognitive injuries and memory issues were due in part to her Electroshock treatment.	*Id.*
94. Within four months of Dr.	*See* FAC Dkt. No. 22.

Uncontroverted Fact	Supporting Evidence
Robinson's July 31, 2017, neuropsychological evaluation report, Ms. Benjamin (and her husband) timely filed their lawsuit against Somatics on November 7, 2017.	
95. Plaintiff Michelle Himes is a 35-year-old mother of five children who underwent ECT at Sharp Mesa Vista Medical Center (Sharp) in San Diego California from April 2011 to June 2012.	Ex. 1, Himes Dep. 11:12-15.
96. Ms. Himes had a difficult upbringing while growing up in Las Vegas, Nevada and, as a result, she was hospitalized on various occasions for depression and suicidal ideation.	Himes Decl. ¶ 3.
97. Over the course of these hospitalizations, she was prescribed at least nine different antipsychotics and antidepressants to attempt to treat her depression, but her symptoms continued.	*Id.*
98. In April 2011, Ms. Himes enrolled in an inpatient program at Sharp and she began treatment	*Id.* ¶ 4; Ex. 5, Fidaleo Dep. 27:18-21.

Uncontroverted Fact	Supporting Evidence
with Dr. Raymond Fidaleo.	
99. When Ms. Himes first began her inpatient program at Sharp, her husband, Paul Himes, visited her and met with Dr. Fidaleo to discuss Ms. Himes' psychiatric care.	Ex. 3, P. Himes Dep. 26:11-23
100. Dr. Fidaleo determined that ECT was appropriate for Ms. Himes, and he began discussing this treatment option with her.	Ex. 5, Fidaleo Dep. 28: 18-23.
101. During the Himes' second meeting with Dr. Fidaleo, the Himes' both watched an informational video on ECT which explained "how great ECT was" and they received informational pamphlets touting the benefits of ECT.	Ex. 3, P. Himes Dep. 28:3-18.
102. The *only* side effect the video informed them of was the risk of short-term memory loss.	Ex. 3, P. Himes Dep. 28:24-25:8.
103. Dr. Fidaleo similarly told the Himes that short-term memory loss was a side effect of ECT, and that Ms. Himes may experience confusion due to the anesthesia.	Ex. 3, P. Himes Dep. 29:30-31:13.

Uncontroverted Fact	Supporting Evidence
104. Dr. Fidaleo never advised Ms. Himes that brain damage or permanent memory loss was a risk of ECT.	Ex. 5, Fidaleo Dep. 34:15-17.
105. On April 13, 2011, Ms. Himes signed a consent form to undergo ECT treatment which did not warn of the risk of permanent memory loss, brain injury, or an inability to create new memories.	Ex. 5, Fidaleo Dep. 91:13-92:20; Ex. 19, April 13, 2011 ECT Consent Form.
106. Had she been adequately informed of the risk of permanent memory loss, brain injury, or the inability to create new memories, Ms. Himes would never have consented to ECT.	Himes Decl. ¶ 6.
107. Dr. Fidaleo administered 26 ECT treatments to Ms. Himes, from April 13, 2011 to January 3, 2012.	*Id.* ¶ 7; Ex. 5, Fidaleo Dep. 35:14-36:22.
108. Dr. Fidaleo never followed up with Ms. Himes after her ECT treatment ended.	Himes Decl. ¶ 7.
109. At the conclusion of her ECT treatment course, Ms. Himes, her husband, and their one-year-old daughter moved back to Las	Ex. 1, Himes Dep. 10:5-19; Ex. 3, P. Himes Dep. 10:2-20.

Uncontroverted Fact	Supporting Evidence
Vegas, Nevada, so that Ms. Himes could live with family while her husband, who works for the United States Navy, was stationed in Korea.	
110. In April 2013, Ms. Himes was again hospitalized in Las Vegas when her depressive symptoms returned.	Ex. 20, April 2013 Discharge Note and MRI Report.
111. During that hospital visit, she explained to her treating psychiatrist, Dr. Keith Breiland, that her primary care physician wanted her to undergo an MRI scan to rule out a pituitary tumor because she had elevated protactin levels.	*Id.*
112. Ms. Himes had an MRI scan of her pituitary gland completed on April 26, 2013 and the results were normal.	*Id.*
113. Ms. Himes had no reason to suspect that she had suffered any injury as a result of ECT, as her psychiatrist and primary care physician, with whom she was receiving regular care, did not	Himes Decl. ¶ 8.

Uncontroverted Fact	Supporting Evidence
inform her otherwise.	
114. When Mr. Himes returned from Korea in September 2013 he was restationed to California and the Himes' moved to Camarillo, California.	Himes Decl. ¶ 9.
115. At the time, Ms. Himes was still taking psychiatric medications that made her feel foggy, fatigued, and she was still exhibiting signs of depression.	*Id.*
116. Ms. Himes stopped taking psychiatric medications in early 2014 when she became pregnant with her second child who was born in November 2014.	Ex. 1, Himes Dep. 32:25-33:2; Ex. 2, P. Himes Dep. 9:1-12.
117. In approximately December 2015, Ms. Himes learned that she was pregnant with her third child.	Himes Decl. ¶ 10.
118. In her second trimester (approximately February 2016), women from her church asked her how her current pregnancy compared to her prior two, but Ms. Himes realized she had a faint to no recollection of her prior pregnancies.	*Id.* ¶ 11; Ex. 1, Himes Dep. 38:11-25.

Uncontroverted Fact	Supporting Evidence
119. This was the first time she was able to appreciate that she had had an extensive "black out period" of important events in her life that she could not remember.	*Id.*
120. Ms. Himes had been off medication for over a year by this time, and did not feel "so flat and emotionless," and she began reading about side effects of psychiatric medications in books such as "Mad in America."	Ex. 1, Himes Dep. 47:20-49:25.
121. Ms. Himes felt that the book validated her concerns that the psychiatric medications actually made her feel worse when she was taking them and she attributed her memory difficulties to the medications she had been taking.	Himes Decl. ¶ 12.
122. Ms. Himes' third child was born in July 2016 and, in December 2016, she and her family moved to Oak Harbor, Washington because her husband was re-stationed at Whidbey Island Naval Base.	Ex. 1, Himes Dep. 49:12-50:4.
123. After moving to Oak Harbor, Ms. Himes began noticing that, in	Ex. 1, Himes Dep. 43:18-25.

Uncontroverted Fact	Supporting Evidence
addition to memory difficulties, she was having difficulty with her words and trouble communicating.	
124. At this point (in 2017), she started researching psychiatric treatment again and this time, she began researching ECT specifically on a wide range of websites.	Ex. 1, Himes Dep. 50:6-19.
125. While reading about ECT side effects online, she learned for the first time that other people believed they had brain injury from ECT treatment.	Himes Decl. ¶ 15.
126. Shortly thereafter, Ms. Himes sought the assistance of counsel, and she timely and diligently filed the instant action on September 11, 2017.	*See* Compl. Dkt. 4.

Dated: April 12, 2021

BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

By: */s/ Bijan Esfandiari*

Bijan Esfandiari, Esq. (SBN: 223216)
Monique Alarcon, Esq. (SBN: 311650)
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
Telephone: (310) 207-3233
Facsimile: (310) 820-7444

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I, Bijan Esfandiari, hereby certify that, on April 12, 2021, I electronically filed the foregoing with the Clerk for the United States District Court for the Central District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Bijan Esfandiari
Bijan Esfandiari

Bijan Esfandiari, Esq., State Bar No. 223216
Monique Alarcon, Esq., State Bar No. 311650
besfandiari@baumhedlundlaw.com
malarcon@baumhedlundlaw.com
BAUM HEDLUND ARISTEI & GOLDMAN P.C.
10940 Wilshire Blvd., 17th Floor
Los Angeles, CA 90024
(310) 207-3233 Tel
(310) 820-7444 Fax

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MICHELLE HIMES; MARCIA BENJAMIN; AND DANIEL BENJAMIN,

Plaintiffs,

v.

SOMATICS, LLC;

Defendants.

Case No.: 2:17-CV-06686-RGK- JCx

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

DECLARATION ON BIJAN ESFANDIARI IN SUPPORT OF PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT OR, IN THE ALTERNATIVE, PARTIAL SUMMARY JUDGMENT

Date: May 3, 2021
Time: 9:00 AM
Courtroom: 850

DECLARATION OF BIJAN ESFANDIARI

I, BIJAN ESFANDIARI, declare and state as follows:

1. I am an attorney and Partner at Baum, Hedlund, Aristei, & Goldman, PC. I am duly admitted to practice before this Honorable Court and am one of the attorneys of record for Plaintiffs Michelle Himes, Marcia Benjamin, and Daniel Benjamin. I have personal knowledge of the facts stated below and if called to testify as a witness, I could and would so competently. I make this declaration in support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment.

2. On February 26, 2021, my office issued a Subpoena Duces Tecum to Sharp Mesa Vista Hospital (Sharp), requesting, *inter alia*, "[a]ny and all brochures or informational material concerning ECT or the THYMATRON device YOU received from Somatics, LLC" and "[a]ny and all DOCUMENTS YOU received from Somatics, LLC." In response to the subpoena, Sharp produced the Sixth Edition (2001) and Seventh Edition (2013) of the Thymatron System IV manual. Sharp did not produce Somatics' Patient Information Pamphlet.

3. On February 26, 2021, my office issued a Subpoena Duces Tecum to Northridge Hospital Medical Center (Northridge), requesting, *inter alia*, "[a]ny and all brochures or informational material concerning ECT or the THYMATRON device YOU received from Somatics, LLC" and "[a]ny and all DOCUMENTS YOU received from Somatics, LLC." In response to the subpoena, Northridge produced the Fifth Edition (2000) of the Thymatron System IV manual. Northridge did not produce Somatics' Patient Information Pamphlet.

4. Attached hereto as **Exhibit 1** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Michelle Himes, taken in this action on February 25, 2021, which has been redacted as necessary to protect Ms. Himes' and her children's privacy rights.

5. Attached hereto as **Exhibit 2** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Marcia Benjamin, taken in this

action on February 17, 2021.

6. Attached hereto as **Exhibit 3** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Paul Himes, taken in this action on March 22, 2021, which has been redacted as necessary to protect Mr. Himes' and his children's privacy rights.

7. Attached hereto as **Exhibit 4** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Daniel Benjamin, taken in this action on March 4, 2021.

8. Attached hereto as **Exhibit 5** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Raymond Fidaleo, taken in this action on February 12, 2021, which has been redacted as necessary to protect Ms. Himes' privacy rights.

9. Attached hereto as **Exhibit 6** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Michael Frankel, M.D., taken in this action on February 19, 2021.

10. Attached hereto as **Exhibit 7** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Richard Abrams, M.D., taken in this action on August 2, 2018.

11. Attached hereto as **Exhibit 8** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Conrad Swartz, M.D., taken in this action on April 1, 2021.

12. Attached hereto as **Exhibit 9** is a true and correct copy of the relevant portions of the official transcript of the Deposition of Somatics' Person Most Knowledgeable, David L. Mirkovich, taken in this action on July 12, 2018.

13. Attached hereto as **Exhibit 10** is a true and correct copy of the Declaration of Peter Breggin, M.D., previously submitted in this action in support of Plaintiffs' Motion for Class Certification (Dkt. 26).

//

14. Attached hereto as **Exhibit 11** is a true and correct copy of the Declaration of Kenneth Castleman, Ph.D., previously submitted in this action in support of Plaintiffs Jose Riera and Deborah Chase's Opposition to Defendant Somatics' Motion for Summary Judgment (Dkt. 84-12).

15. Attached hereto as **Exhibit 12** is a true and correct copy of Kenneth Castleman, Ph.D.'s expert report.

16. Attached hereto as **Exhibit 13** is a true and correct copy of the Declaration of Janet Arrowsmith, M.D., previously submitted in this action in support of Plaintiffs Jose Riera and Deborah Chase's Opposition to Defendant Somatics' Motion for Summary Judgment (Dkt. 84-7).

17. Attached hereto as **Exhibit 14** is a true and correct copy of Exhibit 4 to the Deposition of Michael Frankel M.D. (Jan. 21, 2013 Progress note), taken in this action on February 19, 2021.

18. Attached hereto as **Exhibit 15** is a true and correct copy of Exhibit 3 to the Deposition of Marcia Benjamin (September 28, 2012 ECT Consent Form), taken in this action on February 17, 2021.

19. Attached hereto as **Exhibit 16** is a true and correct copy of Marcia Benjamin's June 19, 2013 MRI Report.

20. Attached hereto as **Exhibit 17** is a true and correct copy of Exhibit 7 to the Deposition of Marcia Benjamin (Sept. 23, 2016 Letter to Dr. Frankel), taken in this action on February 17, 2021.

21. Attached hereto as **Exhibit 18** is a true and correct copy of Exhibit 8 to the Deposition of Marcia Benjamin (July 16, 2015 Letter to Dr. Frankel), taken in this action on February 17, 2021.

22. Attached hereto as **Exhibit 19** is a true and correct copy of Michelle Himes' April 13, 2011 ECT Consent Form.

23. Attached hereto as **Exhibit 20** is a true and correct copy of Michelle Himes' April 6, 2013 Discharge Summary by Dr. Keith A. Breiland and April 26,

2013 MRI Report.

24. Attached hereto as **Exhibit 21** is a true and correct copy of Michelle Himes' August 15, 2018 Psychotherapy Note by Charlotte Myers, LICSW.

25. Attached hereto as **Exhibit 22** is a true and correct copy of the October 8, 2001 (Sixth Edition) Thymatron™ System IV Instruction Manual.

26. Attached hereto as **Exhibit 23** is a true and correct copy of the September 20, 2000 (Fifth Edition) Thymatron™ System IV Instruction Manual.

27. Attached hereto as **Exhibit 24** is a true and correct copy of Exhibit 17 to the Deposition of Swartz (Somatics, LLC's Website Stating FDA "Approval")., taken in this action on April 1, 2021.

28. Attached hereto as **Exhibit 25** is a true and correct copy of Somatics, LLC's June 15, 2018 and July 2, 2018 responses to Plaintiffs' First Set of Request for Admissions, numbers 30, 36, 40, 41 and 42.

29. Attached hereto as **Exhibit 26** is a true and correct copy of Exhibit 7 to the Deposition of Conrad Swartz, M.D. (Regulatory update to Thymatron® System IV instruction manual), taken in this action on April 1, 2021.

30. Attached hereto as **Exhibit 27** is a true and correct copy of the Addendum for Thymatron System IV Manual, created by Somatics, LLC.

31. Attached hereto as **Exhibit 28** is a true and correct copy of excerpts from Richard Abrams, M.D.'s Electroconvulsive Therapy, Fourth Edition.

32. Attached hereto as **Exhibit 29** is a true and correct copy of Bruce A. Wright, M.D.'s June 1990 Article "*An Historical Review of Electroconvulsive Therapy.*"

33. Attached hereto as **Exhibit 30** is a true and correct copy of Exhibit 15 to the Deposition of Conrad Swartz, M.D. (1984 Clearance), taken in this action on April 1, 2021.

34. Attached hereto as **Exhibit 31** is a true and correct copy of Exhibit 16 to the Deposition of Conrad Swartz, M.D. (1985 Clearance), taken in this action on April

1, 2021.

35. Attached hereto as **Exhibit 32** is a true and correct copy of Exhibit 19 to the Deposition of Conrad Swartz, M.D. (promotional statement claiming safety and efficacy), taken in this action on April 1, 2021.

36. Attached hereto as **Exhibit 33** is a true and correct copy of Exhibit 20 to the Deposition of Conrad Swartz, M.D. (promotional statement removing claims of safety and efficacy, taken in this action on April 1, 2021.

37. Attached hereto as **Exhibit 34** is a true and correct copy of Exhibit 9 to the Deposition of Conrad Swartz, M.D. (FDA inspection report), taken in this action on April 1, 2021.

38. Attached hereto as **Exhibit 35** is a true and correct copy of Declaration of Nancy A. Pressly, previously submitted in this action in support of Plaintiffs' Motion for Partial Summary Judgment (Dkt. 79-2).

39. Attached hereto as **Exhibit 36** is a true and correct copy of the FDA Executive Summary prepared for the January 27-28, 2011 meeting of the Neurological Devices Panel.

40. Attached hereto as **Exhibit 37** is a true and correct copy of Harold A. Sackeim, Ph.D.'s 2000 Article "*Memory and ECT: From Polarization to Reconciliation.*"

41. Attached hereto as **Exhibit 38** is a true and correct copy of Anne B. Donahue's 2000 Article "*Electroconvulsive Therapy and Memory Loss: A Personal Journey.*"

42. Attached hereto as **Exhibit 39** is a true and correct copy of Exhibit 6 to the Deposition of Conrad Swartz, M.D. (2006 Email re warning statement revisited), taken in this action on April 1, 2021.

43. Attached hereto as **Exhibit 40** is a true and correct copy of John Read, PhD, Irving Kirsch, PhD, and Laura McGrath's 2019 Article "Electroconvulsive Therapy for Depression: A Review of the Quality of ECT versus Sham ECT Trials and

Meta-Analyses."

44. Attached hereto as **Exhibit 41** is a true and correct copy of FDA Document Control # K843923 (Thymatron Predicate Device (Medcraft)).

45. Attached hereto as **Exhibit 42** is a true and correct copy of Dennis Robinson, Ph.D.'s July 31, 2017 neuropsychological examination report of Marcia Benjamin.

I declare under penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct.

Executed on this 12th day of April 2021 at Los Angeles, California.

/s/ Bijan Esfandiari
BIJAN ESFANDIARI

CERTIFICATE OF SERVICE

I, Bijan Esfandiari, hereby certify that, on April 12, 2021, I electronically filed the foregoing with the Clerk for the United States District Court for the Central District of California using the CM/ECF system, which shall send electronic notification to counsel of record.

/s/ Bijan Esfandiari
Bijan Esfandiari

EXHIBIT 1

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 VIDEOCONFERENCE DEPOSITION OF MICHELLE HIMES
TAKEN REMOTELY ON BEHALF OF THE DEFENDANT
IN OKLAHOMA CITY, OKLAHOMA
ON FEBRUARY 25, 2021

REPORTED BY: DAVID BUCK, CSR

Job No. CS4464908

please?

A. January 16th, 1986.

Q. And where were you born?

A. Las Vegas, Nevada.

Q. And at some point did you live down in San Diego, California?

A. Yes.

Q. What time period did you live in San Diego?

A. From 2009 until 2012.

Q. And when you left San Diego where did you go from there?

A. Las Vegas.

Q. And how long were you back in Las Vegas after 2012?

A. It was a little over a year.

Q. And where did you go after leaving Las Vegas?

A. Camarillo, California.

Q. Would that have been in 2013, approximately?

A. Yes.

Q. And how long were you in Camarillo?

A. Until December of 2016.

Q. At that point where did you leave -- or where did you go to?

A. Oak Harbor, Washington.

Q. Is that where you currently reside?

A. Yes.
Q. And are you married?
A. Yes.
Q. What's your spouse's name?
A. Paul.
Q. When did you get married to Paul?
A. June 21st, 2008.
Q. Does Paul have a job?
A. Yes.
Q. What does he do for a living?
A. He is in the United States Navy.
Q. Do you have any children?
A. Yes.
Q. How many?
A. Five.
Q. What are their names?
A. Illora, Victoria, Olivia, Sophia and Scott.
Q. And what are their ages?
A. Illora turns 10 tomorrow, Victoria is six, Olivia is four and Sophia and Scott are 13 months.
Q. Are they twins?
A. Yes.
Q. Perfect.
And I take it they all live with you?
A. Yes.

about autumn 2012?

A. Yes.

Q. Okay. And what's the first thing you recall from autumn 2012?

A. Cleaning my house in Las Vegas.

Q. And so at that point, at that point did you observe or believe that you had suffered any kind of injury from ECT treatment?

A. No.

Q. As you sit here today do you think that you suffered an injury from ECT treatment?

A. Yes.

Q. And when did you first think that you suffered an injury?

A. It had to have been after we moved here.

Q. When you say here you're talking about Washington?

A. Yes.

Q. And why do you think that?

A. When we were driving up here my husband and I were taking separate vehicles and I remember thinking that I was very grateful that I was not taking psychiatric meds anymore and because I thought that would have made it harder.

Q. When did you stop taking psychiatric meds?

A. When I was pregnant with my second born. That was in 2014.

Q. And has any of your doctors told you that they think you might have suffered an injury from ECT?

A. Not that I recall, no.

Q. Back in 2014 when you stopped meds, do you recall what medication you were on at that time?

A. Zoloft. I believe there were two others but I can't recall the names.

Q. Do you know if those medications were intended to treat depression?

A. One of them was a mood stabilizer and another one was -- I'm sorry, I don't know the other one.

Q. That's okay. I'm going to show you a new document on your screen identified as Exhibit Number 7.

(Defendant's Exhibit Number 7 marked for identification purposes and made part of the record.)

Q. (By Mr. Benkner) Do you see that?

A. Yes.

Q. Okay. I'll represent to you this is an initial patient packet we received from Dr. Lorna Barte or Barte, B-a-r-t-e. And I think you indicated you don't recall meeting or treating with this doctor.

a little bit here, do you recall meeting with any kind of doctor or therapist that was located at 1601 Carmen Drive in Camarillo?

A. No. I know where Carmen Drive is but I don't, I don't remember seeing her.

Q. Okay.

MR. BENKNER: Why don't we take another five minute break.

THE WITNESS: Okay.

THE VIDEOGRAPHER: Off the record at 11:17 a.m.

(A recess was here had 11:17 to 11:25.)

THE VIDEOGRAPHER: Back on the record, beginning media unit three at 11:25 a.m.

Q. (By Mr. Benkner) Okay. Ms. Himes, thinking about any symptoms or side effects that you experienced after ECT, can you explain if you've in your observations experienced anything that you think was related to ECT?

A. Yes. I have a long period of time that is completely blacked out. I have trouble making long term memories. I -- I used to write. I don't write anymore. I struggle with it. I have trouble with reading. I have to read the same thing more than once. I didn't used to. I have trouble with my words. I've forgotten people that are --

And then when you first started recalling things in autumn of 2012, is that also when you realized that you couldn't remember that period of time before autumn 2012?

A. I don't know. The -- the memories I do have starting then I -- I don't remember even thinking about it.

Q. Okay. Did you tell any of your doctors that you have this blackout period?

A. I don't know.

Q. In your mind when is the first time you can remember thinking and being concerned about having that blackout period?

A. The earliest I can remember?

Q. Yes.

A. When I was pregnant with my third, Olivia.

Q. Do you recall approximately when that was?

A. She was born July 28th, 2016.

Q. And what was it about that period of time that made you concerned about the blackout period?

A. There were ladies in my church who would ask me to compare that pregnancy with previous ones, my -- my first two, and I realized I couldn't remember my first really at all and my second I could not remember much. So I didn't have much to compare it to.

A. It was a few years ago when I saw that journal. I didn't even know I had it. I have since not seen it again. I don't know what happened to it.

Q. Have you looked for it?

A. I have. My husband has tried looking for it.

Q. And have you told any of your doctors that you were having trouble with your writing?

A. I don't know. I do know I told them that I used to write.

Q. And in those conversations you had with your doctors did they ever ask you why you weren't writing currently?

A. I don't know.

Q. All right. So the next thing you indicated was that you have trouble with your words and with communication. Is that right?

A. Yes.

Q. Okay. And when did you first start noticing that you had trouble with your words or with communication?

A. The earliest I can remember is talking about it with my husband here in this living room actually.

Q. Do you have any recollection of having problems communicating when you were living in San Diego?

A. Yes. Sorry.

Q. Sorry, I just couldn't hear you.

And that response was provided to -- in response to a question I asked is when did you first believe that you had suffered an injury from ECT. Is -- what was it about that event that made you believe that you suffered an injury from ECT?

A. Nothing.

MS. ALARCON: And I'm just going to make a belated objection to the form of the question to the extent it recaps a question and answer. I'm not entirely sure without reading back the record that that's exactly how it went, so I'm going to put that objection on the record.

MR. BENKNER: Yeah, that's fine.

Q. (By Mr. Benkner) And that's why I -- I told you the whole scenario because that's how I interpreted it in my mind. So let me just ask it brand new.

At what point did you believe that you suffered an injury from ECT?

A. Can I ask a question --

Q. Sure.

A. -- about -- are you asking at what point -- at what point did I believe my injury or difficulties

were from ECT or --

Q. Yes.

A. Okay. I do know it was after I moved here in the process of researching side effects of psychiatric medication.

Q. And what steps did you take to do that research?

A. Read some books. I had gone on the Internet.

Q. Do you recall what books you read?

A. One of them was Mad in America.

Q. Who is the author of that?

A. Sorry, I don't remember.

Q. Do you still have the book?

A. I believe I borrowed it.

Q. Who did you borrow it from?

A. I -- no, wait, I bought it off Kindle.

Q. That's okay.

Can you recall any other books that you read on this topic?

A. I do not. I know I have read other ones but I do not remember the titles.

Q. And you first started reading those books when you moved up to Washington?

A. I believe it was before.

Q. How -- how soon before did you first start

reading those books?

A. In the -- since I was pregnant with my third.

Q. And your pregnancy with your third child, was that down in Camarillo?

A. Yes.

Q. Do you recall what prompted you to start to look into reading these books or researching this further?

A. I believe it was that I had been off of meds for over a year at that point and I didn't feel so flat and emotionless and I wanted to look into that.

Q. And I know, I know I asked your children's ages, but your third child, was that Olivia?

A. Yes.

Q. What's her date of birth?

A. July [redacted] 2016.

Q. I might have the timeline a little confused. Let me just make sure that I have it correct here. So, you have a recollection of your pregnancy with your third child being down in Camarillo. Is that right? Was she born --

A. It was in a hospital in Thousand Oaks.

Q. So she was born down in -- in California. Right?

A. Yes, Ventura County.

Q. How soon after she was born did you move up to Washington?

A. That was in December. She was only five months old.

Q. Got you. Okay.

Can you recall any of the websites you looked at when you were researching the side effects of ECT or of the drugs that you were on?

A. Oh goodness, I -- I know I looked at a wide variety from mainstream pro ECT ones all the way to the other extreme.

Q. But you can't remember any of the sites that you might have visited?

A. I have been to the -- the Mad in America site. The more mainstream sites I don't remember specifically but I know they were of the type, you know, like --

Q. WebMD, Mayo Clinic?

A. Those types, yes, yes. Sorry.

Q. That's okay.

And so any of the -- any of those difficulties that you're experiencing now that you attribute to ECT, you don't have a recollection of having any of those problems prior to living in Washington. Is that right?

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C E R T I F I C A T E

STATE OF OKLAHOMA)
) SS:
COUNTY OF OKLAHOMA)

I, David Buck, Certified Shorthand Reporter within and for the State of Oklahoma, do hereby certify that MICHELLE HIMES was by me first duly sworn to testify the truth, the whole truth and nothing but the truth, in the case aforesaid; that the above and foregoing remote deposition was taken in shorthand and thereafter transcribed; that the same was taken on February 25th, 2021, in Oklahoma City, Oklahoma; that I am not an attorney for nor a relative of any said parties, or otherwise interested in said action.

IN WITNESS WHEREOF, I have hereunto set my hand and official seal this 2nd day of March, 2021.

David Buck, CSR #1585

EXHIBIT 2

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

CONFIDENTIAL

VIDEOTAPED DEPOSITION OF MARCIA BENJAMIN

TAKEN FEBRUARY 17, 2021

Job No. CS4463472

REPORTED REMOTELY BY:

BEVERLY A. BENJAMIN, CSR No. 710

Notary Public

Q. And how often do those courses meet?

A. Daily; they're online.

Q. And each session that you have online, how long does that usually last?

A. It can last -- it's self-paced; so it can last up to 2 or 3 hours.

Q. Is that per course?

A. Yes.

Q. I take it there is homework assignments for you to do outside of the portal instruction; is that right?

A. Absolutely. Homework assignments and exams.

Q. So when was the last time that you were employed?

A. The last time I was employed I believe was just before I closed my firm, 2000 -- I would say 2018, around that time.

Q. When you say your "firm," what was the name of your company?

A. AIE Design Studio, Incorporated.

Q. What did AIE do?

A. We did ADA compliance and small projects, like small space planning.

Q. So ADA compliance in terms of architectural structures of office buildings, things like that?

A. Yes; upgrading spaces for ADA compliance.

Q. And how many employees did AEI [sic] have just prior to closing?

A. Two.

Q. Who were they?

A. Myself and I hired a graphic designer to support me.

Q. And who would actually perform the architectural renovations for your clients?

A. An architect by the name of John Siebel.

Q. Can you spell his last name?

A. S-i-e-b-e-l.

Q. And this architect, he worked with you but he had a separate company; is that right?

A. Correct.

Q. Did you ever work with any other architects other than him?

A. At my company?

Q. Yes.

A. No. Outside my company for other firms, yes. I worked with HMC Architects and AWA Architects.

Q. And do you know if Mr. Siebel is still in practice as well?

A. I don't believe so.

Q. Do you know when he retired?

A. I don't.

Q. Did he retire before or after you closed AIE?

A. I retired just as I closed.

Q. My question was a little different. And you may not know. If you don't, it's okay to just tell me you don't know. But do you know if John Siebel retired before or after you closed your business?

A. No, I don't. He's older than I am.

Q. Did his decision to retire affect your ability to close AIE?

A. No.

MS. ALARCON: Objection; lacks foundation, calls for speculation.

Q. (BY MR. BENKNER) When did you first open AIE?

A. 2005.

Q. Did you operate AIE continuously from 2005 through 2018?

A. Yes. With the exception of when I was imposed with what I was imposed on.

Q. Do you remember what that time period was?

A. That was 2013 -- I would say 2013 until 2016, '17. No later.

Q. So your best estimate it was approximately a 2- to 3-year period that you weren't operating the business?

A. I don't think there was a physician that identified that; I did.

Q. How did you determine that you were misdiagnosed?

A. Because Dr. Gudeman lost his licenses, and it brought a red flag to me that perhaps that was not the correct treatment that he was giving to me.

Q. Are you receiving treatment for your thyroid condition currently?

A. Yes, I am.

Q. Which doctor is providing that treatment to you?

A. Dr. Michael Hirt.

Q. Now, going back to when Dr. Gudeman diagnosed you around March 2011, do you remember why you first started seeing him, the purpose for you going to see him?

A. Yes. I looked for a psychiatrist because I was given a medication that was from a psychiatric -- like, it was a psychiatric medication, and I wanted it to be properly monitored since I would have to take something like that.

Q. Do you remember which one of your physicians prescribed the psychiatric medication to you?

A. Sorry?

Q. Yeah. Do you remember which of your physicians prescribed you, first prescribed you that medication?

A. I believe it was the emergency room because I had a -- my heart was going too fast. I was diagnosed with anxiety and they gave me, I believe it was a medication by the name of Xanax.

Q. Do you remember why you visited the emergency room?

A. Because my heart was going too fast.

Q. And which emergency room did you go to?

A. Los Robles. It's located in Thousand Oaks.

Q. Was that around the same time, March 2011, that you went to the ER?

A. I don't remember. I'd probably have to check.

Q. But it's your recollection that they prescribed Xanax to you?

A. Yes.

Q. And then you went to Dr. Gudeman to have that monitored by a psychiatrist -- or psychologist I should say; is that right?

A. Actually, yes, I wanted to have somebody from -- since Xanax is a psychiatric medication, I felt it would be responsible of me to have a psychiatrist monitor it.

Q. Do you know how soon after you started taking the Xanax that you went to go see Dr. Gudeman?

A. No, I don't.

Q. Was it a matter of weeks, a couple months?

A. My apologies that I don't remember.

Q. That's okay.

Before you went to see Dr. Gudeman but after you started taking the Xanax, did you notice any symptoms while you were on the medication?

A. Yes. This medication did affect me quite a bit. I was not feeling well at all with it.

Q. Can you explain what you mean by that?

A. I just did not feel myself with this medication. I felt exhausted and just like not being able to be myself.

Q. Did you have trouble with your energy levels?

A. Um-hmm, I did.

Q. Did you have trouble with your concentration?

A. I don't remember.

Q. Did you have any problems with your memory while you were on the medication?

A. I don't remember that either. I don't think so. It was just making me feel very tired and not myself.

Q. Now, when you went to see Dr. Gudeman, did he

recommend that you continue Xanax?

A. Actually, he changed to another medication that made me feel even worse.

Q. Do you remember what that medication was?

A. The name I believe was Klonopin. Later on I understood that it was in the same family, that medication, but it was stronger and it was quite impactful on my body.

Q. Did he explain to you what the side effects were of Klonopin?

A. It was just an exa- -- how do you say? It was like Xanax on a higher level. I felt extremely exhausted, lost, like I wasn't -- my -- how do you say? I was having difficulty just focusing and doing things like my normal self.

Q. Did you have any problems with your memory while you were on Klonopin?

A. I don't remember.

Q. Do you know if Dr. Gudeman told you that memory problems was a risk of taking Klonopin?

A. No.

Q. Do you remember what he told you the risks were for taking that medication?

A. They didn't tell me.

MS. ALARCON: Lacks foundation.

Q. (BY MR. BENKNER) He didn't tell you any risks? Is that a no?

A. He didn't tell me of any risks.

Q. Do you remember how long you took Klonopin?

A. No, I don't.

Q. Did he prescribe any other medications to you while you were under his care?

A. I believe he did but I don't remember what they were. I'm sorry that I don't remember.

Q. Do you remember how those other medications made you feel?

A. I don't think they were medications; I think it was basically Klonopin. I don't think so. I tried different one but no, I don't think so.

Q. So fair to say that you didn't think the medication he prescribed you was helping you in any way?

A. It wasn't helping me in any way, hmm-um.

Q. Now, at some point was it Dr. Gudeman who recommended that you undergo electroconvulsive therapy, also known as ECT?

A. Correct.

Q. Do you know why he recommended ECT?

A. He said the only way that I could come out of those symptoms of Klonopin would be going through that.

Q. So you told him that you were --

A. Klonopin -- my apologies.

Q. That's okay. I didn't want to interrupt you either. Go ahead.

A. The symptoms of Klonopin at that time were so severe that I was not able to walk.

Q. Did he tell you anything about ECT in terms of what it was or any of the risks associated with ECT?

A. No. He said that it was a new thing that was being used often that could help me get out of the symptoms that I was experiencing from that medication. It would be, what he said was to bring me back to my old self.

Q. Do you have any of your medical records from the time that you treated with Dr. Gudeman?

A. Right now?

Q. Yeah, in your possession.

A. Absolutely no, I don't have anything with me.

Q. Not in the room with you, just in the general sense in your possession, do you have --

A. No, I don't.

Q. Okay.

A. Because to my surprise he lost, he had his medical licenses revoked. And my husband and I could not locate anything.

Q. Do you remember who Dr. Gudeman referred you

to for ECT?

A. My apologies, I didn't hear that.

Q. Sure. I'll repeat it.

Do you remember who Dr. Gudeman referred you to for ECT?

A. He referred to a doctor here in the Valley area by the name of Michael Frankel.

Q. That was at Northridge Hospital; right?

A. Correct.

Q. I'm going to share a document with your screen for you to look at, just let me know -- the host has disabled screen sharing.

Do you see a document in front of you, Mrs. Benjamin?

A. Yes, I do.

Q. Looks like it worked.

MR. BENKNER: For identification purposes, I'm going to mark this as Exhibit No. 1.

(Exhibit 1 marked.)

Q. (BY MR. BENKNER) Have you ever seen this document before, Mrs. Benjamin?

A. I don't remember.

Q. I'll represent to you that this is a consultation report that we received from Northridge Hospital pursuant to a subpoena. I just have a couple

A. No. I believe what we did, Danny and I, was look up Dr. -- what's his name? -- Dr. Frankel's reviews.

Q. But you didn't go online to take a look at ECT as a procedure?

A. I don't remember doing that. I was not in a position of doing anything at that time.

Q. Why do you say that?

A. I was suffering the side effects of coming off medication and all that.

Q. Do you recall how long you had been off the Klonopin before you met with Dr. Frankel for ECT?

A. No, I don't. The Klonopin, you don't stop. You have -- Klonopin is a benzodiazapine. You cannot get off a benzodiazapine stopping like that. You have to -- if you're going to be weaned off, you have to have another benzodiazapine. You cannot just stop it. It's extremely dangerous.

Q. When you transitioned over to Valium, did you notice that any of your symptoms were improving?

A. I don't remember.

Q. Now, when you met with Dr. Frankel in his office prior to undergoing ECT, did he explain what the risks of treatment were?

A. No.

Q. Is it no, he didn't tell you; or no, you don't remember if he told you?

A. To be honest with you, I don't remember the details of what we discussed.

Q. Would you know if he told you there was a risk of -- I'm sorry, go ahead.

A. He said it was safe. Otherwise I would have not done it.

Q. Did he tell you there was a risk of permanent or long-term memory loss?

A. No, he did not. I would never have done that.

Q. Did he tell you there was any risks to your ability to function at all?

A. He said there were -- it was a temporary loss of memory, up to 3 months, something like that.

Q. Anything other than loss of memory for up to 3 months that you can recall?

A. Confusion, something like that for -- right after. I don't remember the specifics, to be honest with you.

Q. That's okay. I'm going to ask and, again, if you don't know, it's perfectly fine to say you don't know or you don't recall. But to just make sure that I understand completely, I'm going to go through the questions here.

When you said "confusion," did he tell you how long the confusion was expected to last after treatment?

A. It was supposed to last that day, right after, which is right after the ECT, as the anesthesia was wearing off, something like that.

Q. So just to make sure, we talked about memory loss and confusion. Is there any other side effects that he brought to your attention before you underwent ECT?

A. No. He made it sound like it was an easy procedure, like outpatient, in and out, 20 minutes. It's being used more and more. I was -- actually, I had no idea that ECT was even used. I thought it had been eradicated at some point.

No, he just said that they gave -- how do you call it -- muscle-paralyzing agents and anesthesia, that it was a quick procedure, yeah, something like that.

Q. Okay. After you finished meeting with Dr. Frankel in his office, did you talk to anybody else about the risks of treatment of ECT before you had your first session?

A. No, absolutely not.

Q. How soon after your meeting in Dr. Frankel's office did you have your first session of ECT?

A. I don't remember.

any risks to your health?

A. No, there was no -- the operation itself was a risk because once you are weaning off, you have to go very slowly.

Q. So kind of going back to this Exhibit No. 2 here, March 4, 2013, as the last date of treatment. Do you recall why you stopped receiving ECT?

A. Why I stopped using ECT?

Q. Yeah. Do you know why?

A. Because there was no need for it.

Q. Why do you say that?

A. There was no further need for it; so it's...

Q. When you say "there was no further need," did Dr. Frankel tell you that your course of ECT treatment was concluded?

A. No, he did not. I'm a bit confused.

Q. Sure. Let me reask it.

Since your last treatment of ECT was on March 4, 2013, was there any reason why you didn't undergo any further ECT after that date?

A. I don't remember why I stopped, but I believe it wasn't working and -- yeah.

Q. What makes you think it wasn't working?

A. Because -- I don't remember, but I think that there were side effects that I was not able to endure.

It just wasn't worth it to go through that.

Q. Can you recall any of the side effects you were experiencing?

A. Memory loss, lots of pain in my body, bleeding, just pain all over. It was just like, having difficulty walking, having complete confusion of where I was or which city I was in, what time and date it was. It was just a nightmare.

Q. Did you tell Dr. Frankel you were experiencing any of these problems?

A. Yes, I did.

Q. What did he say?

A. That it would be temporary. It would last about a month and a half to 2 months.

Q. Did you experience any of these symptoms after --

A. Sorry?

Q. I interrupted you. Go ahead, Mrs. Benjamin.

A. I couldn't remember holidays or anything. I lost a lot of memories and it just wasn't worth it.

Q. Did you experience these problems, memory loss, pain in your body, bleeding, and difficulty walking beyond a month and a half after you completed ECT treatment?

A. Yes, I did.

to Dr. Gudeman to receive additional treatment from him?

A. I don't remember.

Q. Do you remember going back to Dr. Gudeman to receive additional treatment?

A. I remember going back to Dr. Gudeman to ask what to do, yes.

Q. And do you remember what he told you?

A. He suggested another form of treatment called TMS.

Q. Transcranial magnetic --

A. TMS is usually used for depression but because my case was anxiety he was going to do it anyways.

Q. TMS, did he tell you that that stands for transcranial magnetic stimulation?

A. Yes, he did. He had a unit in his office.

Q. So is he the doctor that administered TMS to you?

A. Yes.

Q. How many sessions of TMS did you undergo?

A. I don't remember.

Q. Were you taking any medication at the same time you were receiving TMS treatment?

A. I don't remember. My apologies, I don't remember.

Q. Do you recall what he told you about the risks

Q. (BY MR. BENKNER) Dr. Hirt is spelled H-i-r-t?

A. Correct.

Q. So I'm going to show you a new document now which we're going to mark as Exhibit No. 6.

(Exhibit 6 marked.)

Q. (BY MR. BENKNER) I'll represent to you that this is a progress note I received from Dr. Hirt pursuant to a subpoena.

Have you ever seen this document before?

A. No.

Q. So it's my understanding that this is the first time that Dr. Hirt visited with you, or at least it's the first progress note that he provided to our office. There's a date at the bottom of 10/28/2014. Do you see that there?

A. Um-hmm.

Q. Do you have a recollection of meeting with Dr. Hirt at any point prior to October 28, 2014?

A. No. I never knew Dr. Hirt before then.

Q. He was referred to you by Dr. Armstrong after you completed their program?

A. Correct.

Q. Why did you start treating with Dr. Hirt?

A. I didn't have a GP. And even though I had completed the program, I was still in a wheelchair and I

had trouble, like I had tremors, I was still having problems with my gait and not walking and feeling exhausted. I just needed, I just wanted a new doctor that could help me from then on.

Q. Let's back up a little bit. I don't think we talked about when you first started having problems with walking. Do you remember when that first started?

A. I don't remember. It was I believe -- I don't remember. I believe it was when I had a high dosage of Klonopin. I'm not sure. I really don't remember.

Q. Did any of your doctors ever tell you what the cause of your difficulty with your walk and gait were attributed to?

A. No. That's why I went to see Dr. Hirt. I believe I wanted, like, answers to, if that was -- what was that, if he could help me go back to my normal self.

Q. At the time you were referred to Dr. Hirt, were you still having problems with your memory?

A. Yes.

Q. Were you still having problems with concentration?

A. What was your question again?

Q. Were you still having problems with your concentration?

A. Yes, I was having problems with concentration,

Q. Yeah, because I don't know the size of the screen that you're looking on, it's on, so we may have different vantage points.

A. Um-hmm.

Q. Do you know what this document is, Exhibit No. 9?

A. I believe it's the following up to those documents. Yes, I do know what that is.

Q. Okay. Is this another letter that you drafted?

A. Yes, it is.

Q. In the letter, the first sentence you reference a Frank Iannaccone.

A. Yes.

Q. Do you know who that is?

A. Um-hmm.

Q. Who is that?

A. That is a lawyer in the area. I was seeking representation for malpractice of what I believe I received the wrong treatment and diagnosis and treatment at the time.

Q. And a new document now, Exhibit No. 10.

A. What we're talking there is that Dr. Frankel, I believe he released my medical records to somebody who was not representing me.

Q. You're referring to the substance of Exhibit No. 9.

A. Back to the previous one. I cannot read this one. Is this the previous one?

Q. Yes, I'm now showing you again Exhibit No. 9.

A. Yeah. So yeah, what happened was I was in conversation with Mr. Iannaccone, when he somehow got a copy of the medical records without my permission, and Dr. Frankel released to him, and I don't know how that was possible. Never signed anything, never -- I was in conversation with him, I had one or two at the most with his assistant. So Dr. Frankel released my medical records without my permission.

Q. Did Dr. Frankel ever respond to this letter?

A. Never responded to any of my letters.

Q. And did Mr. Iannaccone ever release the medical records to you that he received?

MS. ALARCON: Objection; calls for speculation.

THE WITNESS: Mr. Iannaccone, when I confronted Mr. Iannaccone, he put the medical records in the mail. But it was not upon my request. He put that in the mail because he decided to do that. I don't know why.

Q. (BY MR. BENKNER) My question was a little

you posted here is a link to another page that pops up. Does that sound right?

A. Correct. Um-hmm.

Q. So I'm going to show you what came up when I clicked on it, Exhibit No. 15, is an article. Do you see that on your screen?

A. I do.

Q. Have you ever seen this article before?

A. Yes, I have.

Q. Is this the article that you linked to your Facebook page on --

A. I'm not sure because he has so many articles.

Q. Okay. But you do recognize Exhibit 14 -- let me go back to it. Sorry. I'm having computer problems.

A. I do. I'm interested in reading about psychiatry and different types of treatments. Yes, I do.

Q. This one it says, the name of it is: "A Prescription for Love: An introduction to Toxic Psychiatry." Do you see that?

A. Yeah, I do.

Q. For the record, I'm referring to Exhibit No. 14. And then I want to go back -- strike that. Hold on one second.

MS. ALARCON: I'm freezing, just FYI.

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

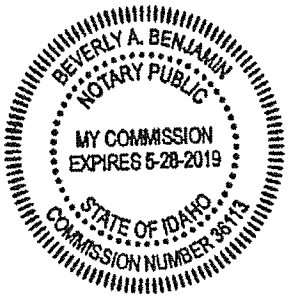

EXHIBIT 3

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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

Plaintiffs,

vs.

SOMATICS, LLC,

Defendants.

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

REMOTE VIDEOTAPED DEPOSITION OF PAUL HIMES

March 22, 2021

Job No. CS4487241
Reported by: Maryann Matthews, CSR #737

Q. And what are their names?

A. From oldest to youngest, [redacted], [redacted], [redacted], and [redacted].

Q. And can you give me their dates of birth, please.

A. [redacted] was born on February [redacted] 2008 -- or excuse me -- 2011; [redacted] was born November 24th of 2014; [redacted] was born [redacted] July, 2016; and [redacted] and [redacted] were born January [redacted] of 2020.

Q. And they're twins?

A. Yes, sir.

MS. ALARCON: Paul, I'm going to just ask you to take a beat after Mr. Benkner's questions so I can make my objections.

THE WITNESS: Yes, ma'am.

MS. ALARCON: Thank you.

Q. (BY MR. BENKNER) And I understand that you currently reside in Oak Harbor, Washington; is that right?

A. Yes, sir.

Q. When did you first move into your residence in Oak Harbor?

A. December of 2016, sir.

Q. Have you lived in the same residence that

entire time?

A. Yes, sir.

Q. Prior to living in Oak Harbor where did you live?

A. We -- prior to here we were living in Camarillo, California.

Q. When did you first move to Camarillo?

A. We moved to Camarillo in September of 2013.

Q. Prior to Camarillo where did you live?

A. So prior to Camarillo Michelle was living in Las Vegas while I resided in South Korea.

Q. Okay. How long was Mrs. Himes in Las Vegas?

A. About 13 months, sir.

Q. So sometime between 2012 and 2013?

A. Yes, sir.

Q. Do you know what month?

A. We -- I left for Korea in late August, so I believe she would have been there early August of 2012. So we would have moved here, like I said -- or we would have moved to Camarillo -- sorry -- September of 2013.

Q. And when you moved to Camarillo, did you come directly from Korea or did you come back at some point before that?

A. I came home for two weeks at the halfway point.

Q. And how do you know him?

A. He was another one of Shelly's proceeding doctors for behavior health.

Q. And it's my understanding that Dr. Fidaleo recommended and administered ECT to Mrs. Himes. Is that your understanding as well?

A. Yes, sir.

Q. Were you present with Mrs. Himes when Dr. Fidaleo first recommended ECT?

A. No, sir.

Q. Did you ever interact with Dr. Fidaleo while he was treating Mrs. Himes?

A. Yes, sir.

Q. And during that first meeting, what was the context of you meeting him?

A. So the first time I met Dr. Fidaleo was at his office, you know. It was just kind of a meet-and-greet, This is who I am.

She had been recommended over to his care, was just told that he was the best of the best for what he does at the hospital in mental health; and we went to just do a meet-and-greet -- well, I went to do a meet-and-greet.

Q. Was this before Mrs. Himes started her ECT treatment?

visits.

Q. Yeah. Bad question again.

Prior to Mrs. Himes undergoing ECT did anybody at the hospital discuss with you or in your presence what ECT was, what the procedure was, and any of the risks of treatment?

A. So prior to the first one I remember going in with -- with Michelle, and we kind of got this promo video shown to us.

It was very '90's infomercial, kind of Sunday, you know, after-school thing, telling us how great ECT was, all the things it could do for us, a lot of great imagery of people -- I -- I -- the thing I remember is, like, people riding down the street on a bicycle in the sunshine.

There was a couple pamphlets. I can't remember or recall specific things from the pamphlets, but there was some pamphlets.

But the first time anybody brought ECT up to me, in my recollection, was Michelle when I went to go see her at an inpatient thing. She brought it up to me, saying that it was brought up to her that this might be the wonder fix for her.

Q. Okay. The promo video that you watched, did it discuss any of the risks of treatment?

A. Not that I recall -- or, I mean, define risks.

Q. Well, it's just a broad term because I'm not sure what the video has on it. I guess, any side effects or complications from the treatment?

A. So everything in the promo video said that there would be short-term memory loss, nothing more than that.

Q. Did the video define what short term was?

A. Not really. There was not a specific timetable on that.

Q. Who showed you the video?

A. It was from Dr. Fidaleo.

Q. Was this during your one-on-one initial meeting with him?

A. No. This would have been later, once Michelle decided that she -- this was what she wanted to have done with her.

Q. So at some point do you recall a second meeting with him and he showed you this video?

A. Well, yeah, I was in the room, but it was mainly for Michelle. Yes.

Q. Right. And during that meeting, did Dr. Fidaleo discuss any of the risks, side effects or complications of treatment?