
MedWatch Reporting Guide

LifeAfterECT.com

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Basics

- You have 4,000 characters to explain your injuries.
- I recommend writing what happened in Microsoft Word or Google Docs before you start the form. This gives you time to think about what to write and tools to check character count.

Word Processing Shortcuts

Word Count

- Google Docs - **Ctrl+Shift+C**
- Microsoft Word - **Ctrl+Shift+G**

Copy & Paste

When done writing,

- **Highlight text** with mouse or **Ctrl+A** to “select all” text
- Cut - **Ctrl+C**
- Paste - **Ctrl+V**

What to Write

One way is to compare an aspect of your life before ECT to problems you have after treatment.

Examples:

- “Before ECT I read all the time. After ECT I get lost after a few sentences. Or “I can’t pay attention long enough to read.”
- “Before I could run the household, now I can’t remember how to do laundry.”
- “I ran a small business. Now I need my kids to help me do basic tasks.”
- “I worked full time before ECT. Now I’m applying for disability.”

Additional Details to Include:

- Number of treatments if known.
- Timeframe of treatments if known.
- Any formal testing including cognitive or physical diagnosis relating to ECT injuries.
- If you were coerced or forced to have ECT.
- If you weren’t fully informed of or were misled about risks.
- If your doctor dismissed or ignored you when reporting serious known ECT side-effects.
- If your doctor encouraged you to have more ECT after reporting serious side-effects or concerns.
- If you received ECT **since December 26th 2018**, did your hospital have a sign posted stating **“Long-term safety and effectiveness of ECT treatment has not been demonstrated, and long-term follow-up may be needed.”**

List of Possible Symptoms

Sleep Problems

- Insomnia
- Central apnea
- Other sleep disorder
- Sundowning

Dental Problems

- Cracked teeth
- Dislocated jaw
- TMJ or other craniofacial pain
- Teeth grinding
- Jaw clenching

Speech Problems

- Recalling words
- Holding on to words long enough to speak them
- Organizing speech
- Slurred speech when tired
- Shuddering when overwhelmed
- Diagnosed acquired speech disorder

Vision Problems

- Eyes not working together
- Changes in vision, blurred, distorted
- Headaches from using vision
- Sensitivity to lights, screens
- Distorted vision
- Difficulty recognizing people who should be familiar
- Photosensitivity to flashing or moving lights (if they cause you distress, trigger seizures, etc)
- Motion sensitivity (if it causes you headaches, nausea, triggers seizures, etc)
- Problems with depth perception
- Visual neglect (not seeing or recognizing part of the area within your field of vision)
- Problems with hand/eye coordination
- Reading causes seizures

Cardiac Problems

- Irregular heart beat
- Arrhythmias
- Heart palpitations
- Heart attack
- Other heart changes
- Pulmonary embolism

Hearing Problems

- Problems retaining information you hear
- Problems understanding what you hear (auditory processing)
- Ringing/tinnitus
- Unable to ignore noise or filter out unnecessary noise
- Hyperacusis (sound sensitivity)
- Unable to enjoy music as you did before ECT
- Sirens or other loud noises trigger nausea or seizures

Memory Problems

- Memories don't return after 6 months (or other time frame your doctor told you)
- Long-term memories
- Short-term memory
- Working memory (the ability to recall and hold information in mind so you can work with it. examples: mental math, rehearsing a phone number till you can dial it or write it down, etc)
- Visual-memory (mind's eye)
- Remembering directions
- Remembering education
- Remembering work experience

Attention Problems

- Shorter attention span
- Inability to pay attention
- More easily distracted after ECT than before
- Difficulty multitasking
- Multitasking causing seizures
- Difficulties completing basic tasks or following up on longer tasks

Unexpected Unusual Reactions to Previously Safe Medications

- Lidocaine
- Albuterol
- Novocaine
- Proparacaine
- OTC drugs that act on sodium/calcium/magnesium blockers (antacids, acid reducers, stool softeners, certain allergy meds like Allegra)
- Drugs mentioned may cause: Transient hemiplegia, stuttering or loss of speech (signs of tetany seizures), heart palpitations, irregular heart beat, tachycardia, or cardiac arrest

Emotional Problems

- Trouble regulating emotions
- Emotional outbursts (Especially when overwhelmed with sensory input (noise, lights, etc)
- Emotional numbness, trouble feeling emotions, feeling meaning

Difficulty with Daily Tasks

- Housework
- Driving
- Working
- Attending school
- Making and keeping plans
- Cooking
- Planning meals/grocery shopping
- Cleaning
- Managing self-care
- Caring for family or pets
- Remembering where you live and how to get places
- Make and keep a budget
- Having conversations

Nervous System Problems

- Body temperature regulation difficulties
- Muscle stiffness
- Episodes of dystonia (cervical, oromandibular, etc)
- Muscle twitching
- Coordination problems: bumping into things, misjudging distance, not reacting fast enough when injured
- Balance problems, falling
- Episodes of Paralysis
- Motor Neuron Disease (i.e. ALS)
- Multiple Sclerosis
- Myoneural Disorder
- Non-diabetic neuropathy
- Acquired channelopathies or other electrical injury related conditions
- Coordination problems (walking, talking, breathing swallowing)
- Trouble walking, talking, controlling limbs
- Easily overwhelmed by sights, sounds, changes in plans
- Bladder problems, urinary retention, incontinence, frequent UTI infections
- Seizures
- Breathing problems
- Swallowing problems
- Kidney problems

Neurological Problems

- Hemorrhage
- Chronic microbleeds
- Stroke
- Migraines
- Hemipelagic migraines
- Lesions
- Seizures
- Acquired Apraxia
- Mild Cognitive Impairment
- Early-onset dementia
- Multiple Chemical Sensitivity

Step By Step Instructions

1. Visit [MedWatch website](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm) MedWatch Online Voluntary Reporting Form (URL) <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>
2. Select the red button that says "[report a problem](#)"
3. Select **Consumer/Patient (FDA Form 3500B)** button
4. On **PROBLEM PAGE: "Tell us what happened"** section: **Enter details describing what happened.** See tips if unsure what to write.
5. On **PROBLEM PAGE (CONTINUED)**: select the box "for problems with a medical device"
6. On **DEVICE PAGE**: Where it states "**enter the name of the medical device**" enter: **ECT machine.** (You don't the need specific name or model, just the device type)
7. On **REPORTER PAGE** enter **your first and last name**
8. **Optional:** Chose whether or not to allow the device manufacturer to contact you to follow-up
9. **Review your answers.** If everything looks correct **click submit.**
You're done!
10. **Please forward your confirmation email to contact@lifeafterECT.com so we can track submission numbers.**



Finding Your Report in The MAUDE Database

1. After submitting your report you should get a confirmation email thanking you for your submission.
2. Eventually you'll get a **2nd email** with an **access number** to view your anonymized report in the MAUDE database. Visit [MAUDE – Manufacturer and User Facility Device Experience \(fda.gov\)](https://www.fda.gov/maude)
3. **Copy/Paste** your **Access Number** in the **Search Database** box.
4. **Select the year** you submitted your report or **“ALL YEARS”**.
5. Click **“search”**
6. Your report should come up.

More Resources

[Video Tutorial](#)

[Interactive Slideshow](#)

[Blog Post](#)



Notes & Citations

“The MAUDE database houses medical device reports submitted to the FDA by **mandatory reporters 1** (manufacturers, importers and device user facilities) and **voluntary reporters** such as health care professionals, patients and consumers.”

1. “Manufacturers and importers **must submit reports when they become aware of information that reasonably suggests** that one of their marketed devices may have **caused or contributed to a death or serious injury** or has malfunctioned and the malfunction of the device or a similar device that they market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Manufacturers must send reports of such deaths, serious injuries and malfunctions to the FDA. Importers must send reports of deaths and serious injuries to the FDA and the manufacturer, and reports of malfunctions to the manufacturer.”

[MAUDE - Manufacturer and User Facility Device Experience \(fda.gov\)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm)

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm>

Symptom lists derived from formal & informal patient reports and the following electrical injury research:

1. [Morse MS, Berg JS, Ten Wolde RL. Diffuse Electrical Injury - A Study of 136 Subjects. Annu Int Conf IEEE Eng Med Biol - Proc. 2003;2\(March\):1694-1697. doi:10.1109/iembs.2003.1279716](#)

2. Morse MS, Berg JS, TenWolde RL. Diffuse electrical injury: A study of 89 subjects reporting long-term symptomatology that is remote to the theoretical current pathway. IEEE Trans Biomed Eng. 2004;51(8):1449-1459. doi:10.1109/TBME.2004.827343