Technical Requirements for Home-Use Transcranial Direct Current Stimulation

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Soterix Medical Inc. produces tDCS and High-Definition tDCS. Marom Bikson is founder and has shares in Soterix Medical. Some of the clinical data presented may be supported by Soterix Medical.

Soterix Medical, Neuroconn, and Thync are developing home-use tDCS.
Why go home?

Because we can
- tDCS is deployable, simple and safe

Because patient demand
- Burden of travel for repeated sessions

Because we should
- Lack of good options leads to unfortunate substitutions (“DIY-tDCS”)

To advance science
- High volume and naturalistic testing
Why worry?

Is current tDCS technology suitable for home use?

Reliability of electrode
- Poor design / preparation can lead to skin burns, pain

Electrode position
- Position of electrodes important for outcomes

Dose limitations
- Safety data based on tested protocols

Compliance
- Outcomes rely on prescription
Things that are NOT debated

✓ In most developed countries (including USA) tDCS is regulated by federal / state laws
  Does not matter if for medical treatment or neuro-enhancement

✓ Even low intensity electrical current can cause harm when applied using bad technology
  Not all devices are equal

✓ More clinical trials are needed to establish efficacy
  In many countries clinicians may already prescribe tDCS off-label

✓ It is natural for human to seek self-improvement
  Special consideration required in medical care
Expertise of operator

Home-use
Self application or Supervised

Clinic
Trained operator

Medical center or University
Increased automation

**Home**: Fully automatic, No flexibility

**Clinic**: Semi-automatic, Some flexibility

**Medical Center**: Customization, flexibility, integration with other equipment
Is more risk acceptable in any case?
Current home use

USA FDA home-use devices
Current home use

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Compliance
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A. Prescription – Dose limited
B. Dose stored on physical module (battery)
C. Single use electrodes
D. Single position head-gear
E. Simple activation (one button)
F. Storage of compliance (time of use, resistance)
G. Clinical supervision
Current home use

Contact Us

Hi, doctor! I have electrode #32

Great! Your code is #22

CODE?

PAIN LEVEL?

HIGH

MILD

Completion Code #724

#724

Great! Thanks
Is more risk acceptable in any case?
tDCS technology specifically designed for home-use + clinical supervision (remote) = flat risk
Things to address

- Who should prescribe
  - On or off-label, by indication
  - Who should provide the device
- Existing models
  - Insulin, sleep apnea....
- Compliance that exceeds pharmacotherapy
  - Patient training (selection)
- Level of evidence for off-label
  - Professional standards, protocols, guidelines
  - Liability (insurance) – for misuse
- Studies for home-use
  - Home-use vs. self-use
  - Dealing with related and unrelated adverse events
  - Devices approved specifically for home use
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