ELEVATE TMS

USER MANUAL

For model

Elevate TMS – v2024a

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Chapter 1: Introduction

Welcome to Elevate TMS!

Our Elevate device is often referred to as a "controllable" TMS, or cTMS and is one of the most advanced TMS systems in the world. It gives you the ability to generate new TMS pulses and more control over parameters such as pulse width and directionality. It represents many years of work by the inventor, Dr. Peterchev as well as at Rogue Research in evolving the device from a prototype to the functional device you have now. We hope the device helps you to further the state of the art in neuroscience and in TMS.

1. SCOPE

This document should be used by whoever needs general instructions or specifications on the Elevate TMS model CTMS001 (the "**device**"). It may as well be referred to as a baseline for future improvements.

2. HOW THIS DOCUMENT IS ORGANIZED

This document is intended to give you all the information you need to take advantage of all the features of the device. The overall structure is designed to present the information in a logical order from a primer in TMS and cTMS, a description of the system and its components and how you can use the system for your neuroscience experiments. There are occasions where some background information that will be useful throughout the document will be presented. These will be given in the first place where they will be needed, and usually highlighted by being in a grey box.

2.1 Document formatting

In numerous places where you will be instructed to interact with the system's touch screen, you will be instructed to select menu items, or tap on buttons. Rather than describing these in a "long winded " way (e.g. "touch the Open... button with your finger"), a more concise shorthand will be used. For example, "tap **Open**" will be used for button presses (e.g. tap the button labeled "open" on the screen) and "swipe left" will be used to move to the next screen.

3. HOW TO GET HELP (or HOW YOU CAN HELP US MAKE ELEVATE TMS BETTER FOR YOU)

CTMS001 was designed and assembled using high standards in product planning, hardware design, software coding and testing. It is our expectation that on the whole, the system will work without major issues, however, you may use the device in ways that we did not foresee, and encounter new issues. You can provide us with valuable feedback in the following ways:

- **Software crash reporting**
  If the device crashes (reboots, or becomes unresponsive), a diagnostic file may be generated by the system that we can use for diagnosis. In these cases, we may ask you to download the file on to a USB key to then send to us via email.
- **mail support@rogue-research.com.**
  Several experienced people (the engineers that actually develop the device) get the support e-mail so you should get a reply as soon as possible from someone who can help out in a meaningful way.
- Phone: +1 514 284 3888

4. ACRONYMS AND ABBREVIATIONS

cTBS	continuous Theta Burst Stimulation
cTMS	Controllable pulse parameters Transcranial Magnetic Stimulator
iTBS	intermittent Theta Burst Stimulation
PW	Pulse Width
QPS	Quadripulse

5. DEFINITIONS

M-Ratio	M-Ratio describes the relative amplitude of each phase of the pulse. It is the ratio of the voltage of the of the negative phase capacitor ("VC2") divided by the voltage of the positive phase capacitor (VC1). It is an indicator of the directionality of the pulse.
Essential Performance	Performance of a clinical function, other than related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

6. SAFETY SYMBOLS

	Advice. This symbol denotes advice to obtain the best results using the system.
	Attention! This symbol denotes information regarding the safe use of the equipment to prevent injury or damage the equipment.
	High voltage warning.
	Consult instructions for use.
	Separate collection for electrical and electronics equipment.
	Consult the User Manual
	Type BF applied part
	Earth Terminal Ground

	Indicates the medical device manufacturer
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Indicates the manufacturer serial number so that a specific medical device can be identified.
	Indicates the date when the medical device was manufactured.

7. BASIC DESCRIPTION

Transcranial magnetic stimulators (TMS) work by inducing electrical currents in tissue using a non-invasive coil. The stimulator coil is placed near the intended site of stimulation and the device generates brief magnetic pulses which can pass through clothing, tissue and bone to reach otherwise inaccessible areas.

The Elevate TMS device is a transcranial magnetic stimulator and enables manipulation of certain parameters that define the shape of the magnetic field pulse that are fixed in a conventional TMS device. It generates near rectangular electric field pulses with control over the pulse duration, pulse directionality and pulse type including monophasic and biphasic. It can administer sets of pulses in distinct modes common to neuroscience research including single pulse, paired-pulse, quadripulse and repetitive pulse.

The Elevate TMS system was tested according to the recommendations of IEC TS 60601-4-2:2024, Medical Electrical Equipment – Part 4-2: Guidance and Interpretation – Electromagnetic Immunity: Performance of Medical Electrical Equipment and Medical Electrical Systems."

8. INTENDED USE

The magnetic stimulator is intended for the non-invasive stimulation of nerves in the central and peripheral nervous system. It is approved in Canada for diagnostic purposes and intended for examining motor pathway and/or peripheral nerve conductivity. It should be used as a stimulation tool in conjunction with a suitable EMG device, where the examination and interpretation of the EMG results are performed by a qualified clinician. The device is intended to be used for diagnostic procedures on any patient where nerve conductivity measurements are required. Outside Canada the device is intended for scientific research only and is not approved for diagnostic or therapeutic use.

Typically, a stimulation coil (applied part) is placed in contact with the subject scalp or surface of a limb near a peripheral nerve (healthy skin) for a short period of time (generally a few minutes).

The device is intended to be installed in medical and/or research centres conducting TMS related studies. The work environment is non-sterile and both the operator and subject must wear suitable hearing protection.

The device is also intended to be used by clinicians and researchers in the field of neuroscience, neurology and motor control who require a device to non-invasively stimulate central and peripheral nerves to assess their function.

The expected life-time of the device is 7 years from the date of manufacture.

9. WARNINGS AND CAUTIONS

	Do not use the device on subjects who have an implanted device that is activated or controlled in any way by physiological signals (examples: pacemakers, implantable cardioverter-defibrillators [ICD's], vagus nerve stimulators [VNS] and wearable cardiovascular-defibrillator [WCD's], ocular implants, deep brain stimulators, implanted medication pumps, intra-cardiac lines), even when they are removed
	Do not use the device on subjects having conductive, ferromagnetic or other magnetic-sensitive materials implanted in the head or within 30cm of the stimulation coil (examples: cochlear implants, implanted electrodes /stimulators, aneurysm clips or coils, stents, bullet fragments, jewelery and hair barrettes, sutures, magnetic dental implants or implanted insulin pumps).
	Elevate TMS should not be operated nearby any other electronic equipment. The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
	Patients and those operating the device must always wear earplugs or similar hearing protection devices with a rating of 30dB of noise reduction during rTMS treatment.
	Inspect all components of device with particular attention to the stimulation coil and its cable. All cables including coil cables and input power cables should be exempt from exposed wires. Pay attention to exposed wires, cable insulation wearing, bent pins on connectors or enclosure damage. Report any issue to Rogue Research for relevant repair/replacement.

	The control software is developed using a quality management system to ensure safety and performance within the specifications. Updates to the control software will be made from time to time to add new functionality and address performance or safety issues. If any issue is discovered, report it to Rogue Research promptly.
	As with any device, system performance will change over time. The device contains an integrated current monitor and the measured output is displayed along with the expected output on the screen for every pulse. Report any significant discrepancy to Rogue Research promptly.
	Make sure the cables are well managed to prevent the subject or others around the subject from tripping on them and that they may be quickly disconnected in an emergency.
	The equipment is not protected against liquid spills. Liquids shall be avoided near the machine at all times. Do not immerse any parts in water or any other conductive liquid. If any liquid is spilled on the equipment, turn the main switch OFF and disconnect all (3) power input cords.
	Do not modify the equipment in any way. Modifying the equipment in any way may introduce potential safety hazards.
	The rear panels have several grills for air flow required to maintain correct operating temperatures for the internal components. Do not block any of the grills and make sure the rear of the device remains at least 30cm from any wall.

	The Elevate TMS device should not be operated nearby any magnetic card. The magnetic field created could demagnetize any magnetic card such as credit card or key card.
	The device must be turned off prior disconnecting the coil. The system should not be turned on without any coil properly connected. Strong pushing and pulling force is required to connect or disconnect main coil cable connector.
	The stimulation coil is intended for short-term subject contact where single or cumulative contact does not exceed 24 hours.
	The coil (applied part) should be moved off the head immediately if there is an overheat fault and/or if the coil temperature exceeds 41˚C.
	Make sure to always store the coil on the intended coil hook at the front of the stimulator when not in use
	Make sure to disarm the stimulator prior to storing/placing the coil.
	The stimulation coil and its cable are heavy (~1-2kg). Hold the coil using the handle and take care not to drop it on the subject or the floor. Dropping the coil on the subject may result in injury and dropping the coil on the floor may result in damage to the coil.

	The operator shall not leave the subject alone while being stimulated.
	The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If used in a residential environment (for which CISPR 11 Class B is normally required), this equipment might not offer adequate protection to radio-frequency communications services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment
	Patients who have a history of seizure, or potential alteration in seizure threshold, should be closely monitored when the device is used. This includes patients with a history of seizure or epilepsy, stroke, head injury, high intra-cranial pressure, severe headaches, or presence of other neurological disease that may be associated with an altered seizure threshold, or concurrent medication use as such as tricyclic antidepressants, neuroleptic medications or other drugs that are known to lower the seizure threshold, secondary conditions that may significantly alter electrolyte balance or lower seizure threshold, or where a quantifiable motor threshold cannot be accurately determined.
	User is responsible for ensuring safeness of use of the Elevate TMS device when connected to an external trigger.
	The user is responsible for selecting the correct input voltage prior to connecting the device to the mains power.

	It is recommended to limit the number of connection/disconnection cycles of the coil connector. The stimulation coil should remain connected between studies and during system storage. If removed, inspect the pins for signs of damage (e.g. bent pins). Report any damage to Rogue Research.
	The device can be moved, but it is not intended to be moved when the system is in use. The wheels should be locked whenever the system is in the desired position. The system should be moved using the handles (front or rear) and any excessive force on the cable should be avoided. The system should not be moved or stored on a slope or uneven floor.
	After a shutdown, always wait for 20-30 seconds before restarting the device.
	Elevate TMS should not be operated on metallic objects and/or anything other than the subject's scalp.
	The device's monitor can be adjusted in the range of +17° to -7° from the neutral position which is at 90° from the top surface of the stimulator. Any excessive force on the monitor should be avoided.
	Make sure to only connect the device to a secure network.
	The provided EMG electrodes are single-use and have a restricted shelf-life. They should not be used later than 45 days after being taken out of their package or past their expiration date as shown on the package.

	Only use coils manufactured by Rogue Research with the system.
	The USB key used for retrieving system data should be either FAT32 or exFat. Any other file system may have compatibility issues.
	Never use the coil cable to handle the coil. The coil shall be lifted only by its handle.
	When installing the coil handle (CCHV) on the coil (CL70), make sure it is properly locked in place. Failure to do so could result on the coil falling on the subject's head or on the floor.
	If the system is used with devices not covered by this User Manual, it is the user's responsibility to make sure that devices, both individually and together, meet applicable regulations
	Before performing a stimulation, make sure the coil is in contact with the subject's scalp.

10. CONTRAINDICATIONS

Elevate TMS and its accessories should not be used on or in the vicinity of subjects or users with cardiac demand pacemakers, implanted defibrillator and/or implanted neurostimulators.

11. SYSTEM DESCRIPTION (PHYSICAL)

Fig. 1-1 illustrates the main components of the Elevate TMS unit.

The touch screen interface is the main point of interaction with the device.

Selecting and modifying pulses and pulse sequences are done by manipulating the controls displayed on the screen. Device status can also be viewed on the screen. The screen is fixed to a swivel base and the tilt angle of the screen can be adjusted by grasping the screen with two hands (one on each side) and tilting the screen to the desired orientation.

The control panel contains the standby button, charge status indicator, disable button and USB port.

The handles (front and rear) are used to move the device.

The coil is connected to the main unit via the coil connector. Connecting and disconnecting the coil is done by pushing the coil connector into the receptacle on the main unit. Disconnecting is done by pulling on the coil connector handle. Note that some force may be required to connect and disconnect the coil.

When not in use, the coil may be stored on the front of the unit using the storage hooks.

The controller module contains the embedded computer that operates the device. The rear panel contains the input/output signal connectors (e.g. trigger in and out) as well as the network interface. These are described in more detail in subsequent chapters.

The powertrain module contains the heart of the cTMS device including the two main capacitors and all the electrical and electronic hardware required to generate the pulses and send them to the coil.

The power supply module contains the chargers that convert the AC mains to DC voltage required to charge the capacitors and the electrical power outlets to power the capacitors and the control module.

12. SPECIFICATIONS

12.1 Power Requirements

All power supplies, used inside the device are IEC 60601-1 compliant. A total of three (3) power inputs are required for proper operation of the device. The three (3) power inputs should be plugged into independent circuits.

- Main power input 100/120/220/230/240 VAC, 50-60Hz (**selector switch on rear panel**), current: 1.17A at 100VAC, 1.0A at 120VAC, 0.55A at 220VAC, 0.50A at 240VAC , 100 Watts (nominal), 120W (max).
  - For main input at 100/120 VAC, make sure the fuse is P/N is 0217002.MXP with Marking 2x F2A L250V or P/N 0213002.MXP with Marking 2x T2AL250V.
  - For main input at 220/230/240 VAC, make sure the fuse P/N is 0217001.MXP with Marking 2x F1A L250V fuses or P/N 0213001.MXP with Marking 2x T1A L250V fuses.
- Charging power supply input VC1: 208-240 VAC, 16A, 1500 Watts (nominal), 3500W (max).
- Charging power supply input VC2: 208-240 VAC, 16A, 1500 Watts (nominal), 3000W (max).

The mode of operation of the Elevate TMS device is classified as “intermittent”.

12.2 Environment Conditions

For safe use, the device must only be used indoors in the following conditions:

- Operation temperature range: 5˚C to 30˚C
- Operation coil internal temperature range: 5˚C to 41˚C
- Storage and transport temperature range: -19˚C to 60˚C
- Storage and transport relative humidity range: 10% to 80% Non-Condensing
- Atmospheric pressure: 50kPa-106kPa.

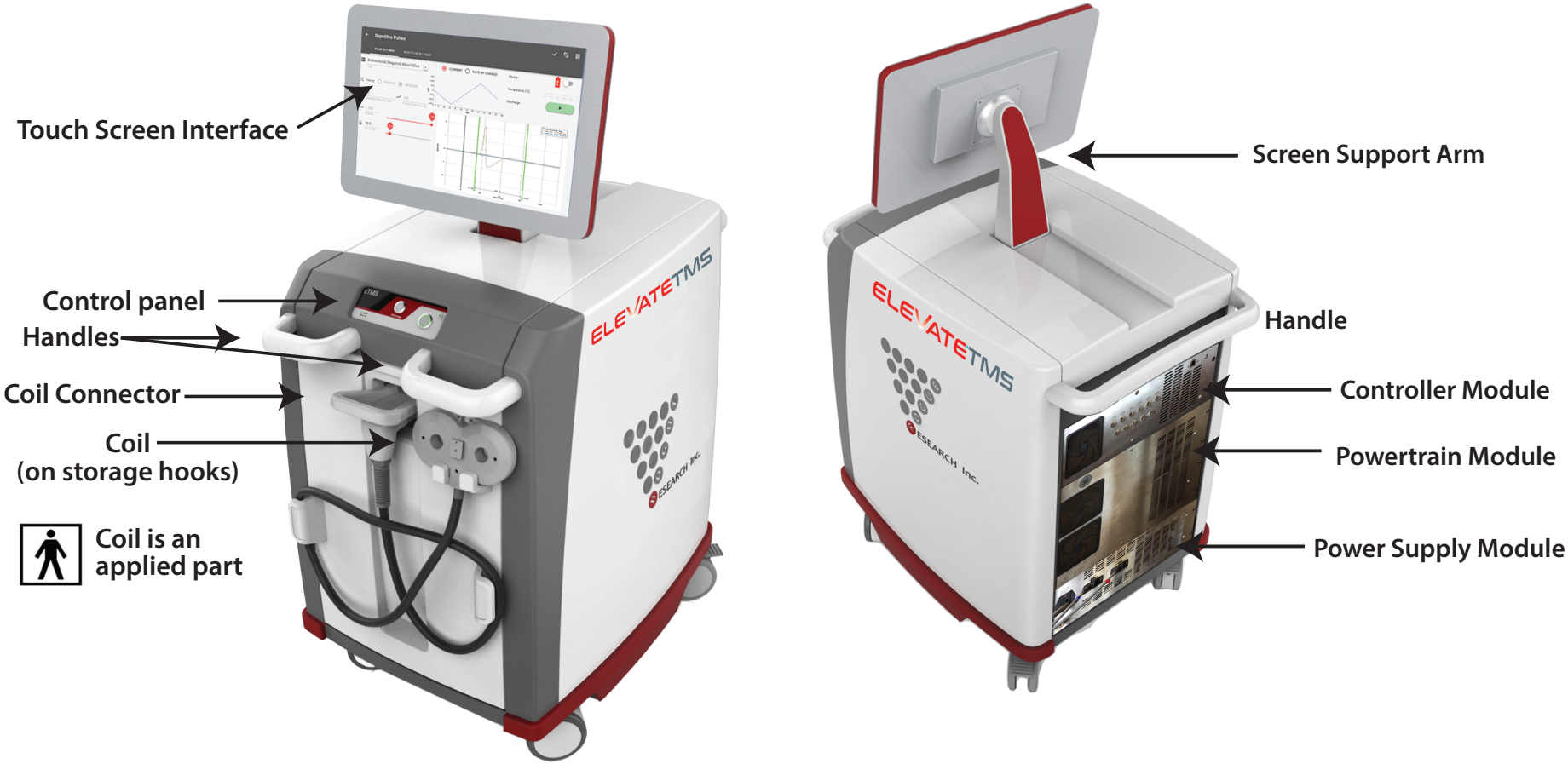


Fig. 1-1

cTMS device overview

12.3 Parts List

Description	Model
ETMS Stimulator	CTMS001
ETMS Firmware	CSFW002
ETMS 70 mm coil High, medium or low inductance, AP or PA direction-ality	CL70001
ETMS 70 mm Cooled Coil High, medium or low Inductance	CC70001
ETMS 70 mm EBOT Cooled Coil High, medium or low Inductance[1]	CE70001
Vertical Coil Handle for CL70	CCHV001
Xtronics Footswitch	MED-100-5(E)
Ethernet cable 10ft	C6ASPAT10BL (Startech)
10 ft. BNC cable	115101-19-120 (Amphenol RF)
EMG device[1,2]	MEPP-v2025a
Power Cables	
Power Cable North America 18A 250VAC C19 (x2)	86632060 (Interpower)
Power Cable North America 10A C13	86610810 (Interpower)
OR	
Power Cable Australia 16A C19 (x2)	693-6051.205 (Schurter)
Power Cable Australia 10A C13	86210140 (Interpower)
OR	
Power Cable Europe 16A C19 (x2)	86235000 (Interpower)
Power Cable Europe 10A C13	86230110 (Interpower)
OR	
Power Cable UK 13A C19 (x2)	6051.2048 (Schurter)
Power Cable UK 10A C13	86240060 (Interpower)

1 For research purposes only

2 Refer to page 56 for more details.

12.4 General system specifications

The display touch screen can be tilted from +17 to -7º from the vertical position.

Hardware version 1.3.X

Maximum Peak Coil Current	+/-7 kA
VC1 min voltage	82.5 V
VC1 max voltage	2750 V
VC2 min voltage	82.5 V
VC2 max voltage	1175 V

Hardware version 1.4.X

Maximum Peak Coil Current	+/-10 kA
VC1 min voltage	74.25 V
VC1 max voltage	2700 V
VC2 min voltage	74.25 V
VC2 max voltage	1350 V

12.5 Essential Performance

The system shall deliver the planned stimulation protocol any time a trigger is received from any source. The system shall not deliver a pulse or protocol when the user has taken no action to send a trigger. The degradation of the function could lead to delay/miscalculation in the diagnosis under clinical use or to the patient receiving an unwanted pulse.

The system shall send a trigger out from the Trig OUT BNC port when a pulse or protocol is initiated. A temporary loss or degradation of the function to send a trigger out when a pulse or protocol is initiated would prevent the user from synchronizing the device with an external EMG acquisition device. Which could therefore lead to delay/miscalculation in the diagnosis under clinical use.

Exposure to Portable Wireless Equipment as per Table 9 of IEC 60601-1-2 may cause a false positive Overheat Error. (Distancing of system from Portable Wireless Equipment advisable to clear the error)

12.6 Acceptable Degradation of Essential Performance (Known Issues)

- Exposure to RFID equipment near the front/bottom of the cTMS console enclosure may cause a false positive Coil Overheat error. (Distancing of console and RFID equipment advisable to clear the error)
- Exposure to equipment operating in the ISM bands below 80MHz when using the CE70 coil may cause a false positive Coil Overheat error. (Distancing of CE70 coil cable and other electronics advisable to clear the error).
- Exposure to Electrical Fast Transient coupled on the AC Power Port(s) or I/O Cables may cause noise on the EMG readings. (Repeat measurements once free of transient disturbances is advisable to reduce the noise on EMG readings)

12.7 Usage with other devices

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, the equipment and other equipment should be observed to verify they are operating normally.

Portable RF Communications Equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12") to any part of the Elevate TMS system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the Elevate TMS system." The list is here:

- A double-shielded Cat6a ethernet cable no longer than 10ft
- A BNC cable no longer than 10ft using commercial grade RG-58 coaxial cable

12.8 Product Lifetime

The expected lifetime for the device is 7 years. Lifetime is estimated taking into account normal degradation of materials and performance of components. Contact Rogue Research for instructions on the disposal or re-testing to prolong the device working life.

13. MAINTENANCE

13.1 Cleaning and Disinfecting

The exterior of the main unit enclosure and computer may be cleaned using a water moistened cloth.

The cTMS coil is intended to be cleaned using an Isopropyl alcohol moistened cloth in between each session of stimulation.

It is recommended for the user to wash their hands before and after a cTMS

session.

Ensure that the equipment is turned off during cleaning and has dried thoroughly before use. None of the parts of the Elevate TMS device can be sterilized. Never put the device main unit or coils in an autoclave.

Do not allow any parts of the system to become contaminated with body fluids or other contaminant.

13.2 Servicing and Inspection

The Elevate TMS device does not contain any user-serviceable parts. If repair or service is needed, it must be performed by trained personnel or by personnel deemed by Rogue Research to qualified to perform the task with sufficient instruction and support by Rogue Research. Contact Rogue Research for any assistance regarding the device prior to attempting any form of repair at support@rogue-research.com.

Visually inspect the device once per year, checking for obvious signs of wear such as rust, corrosion, or loose components. If you notice anything unusual, please contact Rogue Research at support@rogue-research.com for further assistance.

13.3 Packaging instructions

If maintenance is required and the system has to be sent back to Rogue Research, appropriate packaging and instructions will be provided at that time.

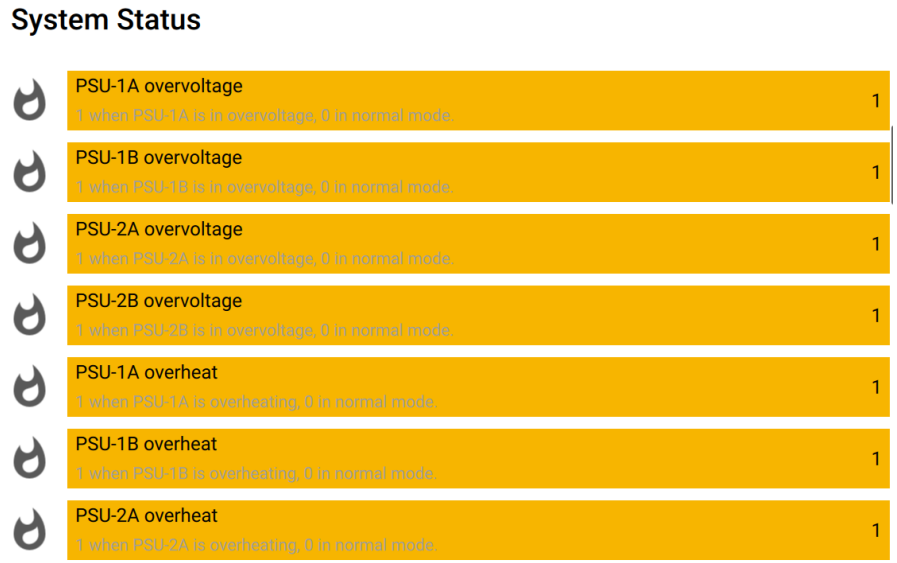
13.4 Product disposal

The Elevate TMS device contains recyclable materials and electronic components that contain hazardous substances that may lead to emission of toxic substances.

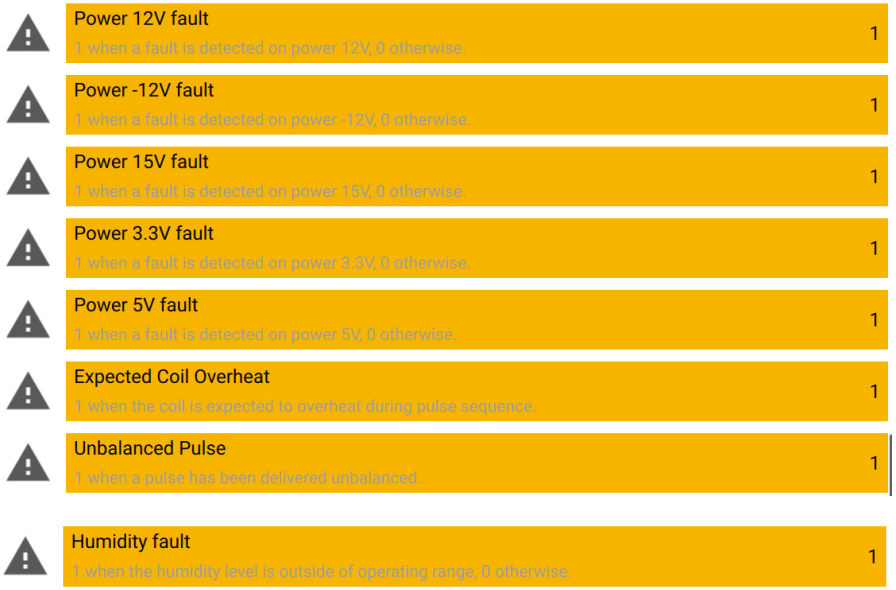
Disposal should be coordinated with Rogue Research. Any users that wish to dispose of the device should send it back to Rogue Research where the disposal will be done in accordance with the local provincial requirements.

14. FAULT LIST

The computer in the Elevate TMS device includes the ability to monitor the health of the components within the device. If an error or fault is detected, the system status icon on the right of the status bar will change to an attention icon (see Fig. 2-11). Click on the icon to view the status screen and note the fault (will be highlighted in yellow). **If a persistent hardware related fault is noted (other than a transient coil temperature fault), discontinue use and contact Rogue Research for assistance.**



PSU-2B overheat	1 when PSU-2B is overheating, 0 in normal mode.	1
PSU-1A presence	1 when PSU-1A is not detected, 0 in normal mode.	1
PSU-1B presence	1 when PSU-1B is not detected, 0 in normal mode.	1
PSU-2A presence	1 when PSU-2A is not detected, 0 in normal mode.	1
PSU-2B presence	1 when PSU-2B is not detected, 0 in normal mode.	1
Stop switch fault	1 when there is a stop switch fault, 0 in normal mode.	1
Trigger stop switch fault	1 when there is a trigger stop switch fault, 0 in normal mode.	1
Gate driver 12 fault	1 when there is a gate driver 1-2 fault, 0 in normal mode.	1
Gate driver 34 fault	1 when there is a gate driver 3-4 fault, 0 in normal mode.	1
Coil overheat fault	1 when there is a detected coil overheat, 0 in normal mode.	1
Powertrain overheat fault	1 when there is a powertrain overheat, 0 in normal mode.	1
Power supply overheat fault	1 when there is a power supply overheat, 0 in normal mode.	1
Coil connection fault	1 when there is a coil communication error, 0 in normal mode.	1
Powertrain connection fault	1 when there is a powertrain communication error, 0 in normal mode.	1
Power supply connection fault	1 when there is a power supply communication error, 0 in normal mode.	1
Coil memory fault	1 when there is a coil memory error, 0 in normal mode.	1
Powertrain memory fault	1 when there is a powertrain memory error, 0 in normal mode.	1
Power supply memory fault	1 when there is a power supply memory error, 0 in normal mode.	1
IGBT-1 overvoltage fault	1 when overvoltage is detected on IGBT 1, 0 otherwise.	1
IGBT-2 overvoltage fault	1 when overvoltage is detected on IGBT 2, 0 otherwise.	1
IGBT-3 overvoltage fault	1 when overvoltage is detected on IGBT 3, 0 otherwise.	1
IGBT-4 overvoltage fault	1 when overvoltage is detected on IGBT 4, 0 otherwise.	1
Gate driver 1 fault	1 when a fault is detected on gate driver 1, 0 otherwise.	1
Gate driver 2 fault	1 when a fault is detected on gate driver 2, 0 otherwise.	1
Gate driver 3 fault	1 when a fault is detected on gate driver 3, 0 otherwise.	1
Gate driver 4 fault	1 when a fault is detected on gate driver 4, 0 otherwise.	1
Discharge relay 1 fault	1 when a fault is detected on discharge relay 1, 0 otherwise.	1
Discharge relay 2 fault	1 when a fault is detected on discharge relay 2, 0 otherwise.	1



15. COMPLIANCE INFORMATION FOR EACH EMISSIONS AND IMMUNITY STANDARD OR TEST

Phenomenon	Basic EMC standard or test method	IMMUNITY TEST LEVELS Professional healthcare facility environment
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4kV, ± 8kV, ± 15kV air
Radiated RF EM fields	IEC 61000-4-3	3 V/m [1] 80 MHz – 2.7 GHz [2] 80% AM at 1kHz [3]
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table 6
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50Hz or 60Hz
Proximity magnetic fields	IEC 61000-4-39	See Table 7

1 Refer to IEC 60601-1-2:2014+A1:2020 Table 4 for more details
2 Refer to IEC 60601-1-2:2014+A1:2020 Table 4 for more details
3 Refer to IEC 60601-1-2:2014+A1:2020 Table 4 for more details

Table. 1-1

IMMUNITY TEST LEVELS for enclosure port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V [1] 0.15 MHz – 80 MHz 6 V [2] in ISM bands between 0.15 MHz and 80 MHz [3] 80 % AM at 1 kHz [4]
Voltage dips	IEC 61000-4-11	0 % ; 0.5 cycles [5] At , , , , , , and [6] 0 % ; 1 cycle And 70 % ; 25/30 cycles [7] Single phase: at
Voltage interruptions	IEC 61000-4-11	0 % ; 250/300 cycle [8]

1 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
2 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
3 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
4 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
5 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
6 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
7 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details
8 Refer to IEC 60601-1-2:2014+A1:2020 Table 5 for more details

Table. 1-2

IMMUNITY TEST LEVELs for input A.C. Power

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0.5 kV, ±1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V [1] 0.15 MHz – 80 MHz 6 V [2] in ISM bands between 0.15 MHz and 80 MHz [3] 80 % AM at 1 kHz [4]
Electrical transient conduction long supply lines	ISO 7637-2	N/A

1 Refer to IEC 60601-1-2:2014+A1:2020 Table 6 for more details
2 Refer to IEC 60601-1-2:2014+A1:2020 Table 6 for more details
3 Refer to IEC 60601-1-2:2014+A1:2020 Table 6 for more details
4 Refer to IEC 60601-1-2:2014+A1:2020 Table 6 for more details

Table. 1-3

IMMUNITY TEST LEVELS for input D.C. Power port

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4kV, ± 8kV, ± 15kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V [1] 0.15 MHz – 80 MHz 6 V [2] in ISM bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz

1 Refer to IEC 60601-1-2:2014+A1:2020 Table 7 for more details

2 Refer to IEC 60601-1-2:2014+A1:2020 Table 7 for more details

Table. 1-4

IMMUNITY TEST LEVELS for Patient coupling PORT

Phenomenon	Basic EMC standard	IMMUNITY TEST LEVELS Professional healthcare facility environment
ELECTROSTATIC DISCHARGE	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4kV, ± 8kV, ± 15kV air
Electrical fast transients / bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	±2 kV

Table. 1-5

IMMUNITY TEST LEVELS for Signal input/output PORT

Test frequency (MHz)	Band (MHz)	Service	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse Modulation 18 Hz	27
450	430 – 470	GMRS 460 FRS 460	FM ± 5 kHz deviation 1kHz sine	28
710 745 780	704-787	LTE Band 13, 17	Pulse Modulation 217 Hz	9
810 870 930	800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse Modulation 18 Hz	28
1720 1845 1970	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse Modulation 217 Hz	28
2450	2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7	Pulse Modulation 217 Hz	28

Table. 1-6

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	N/A	N/A
134.2 kHz	Pulse modulation (50% duty cycle square wave) 2.1 kHz	65 (r.m.s. before modulation)
13.56 MHz	Pulse modulation (50% duty cycle square wave) 50 kHz	7.5 (r.m.s. before modulation)

Table. 1-7

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

16. FIRMWARE CHANGE LOG/KNOWN ISSUES

2.8.1

- Changes
  - No major changes.
- Bug Fixes
  - Fixed an issue allowing user to set a pulse sequence containing more than 65535 pulses in a sequence
  - Fixed an issue where changing to a supported pulse preset would disarm the system
  - Fixed an issue where the power was not updated in the GUI to respect the power restriction after changing the m-ratio
  - Fixed an issue where the inter pulse interval was not rounded
  - Fixed an issue where losing the USB connection with the FPGA would not disable the GUI
- Known Issues
  - The mouse cursor may be displayed on some monitors.
  - In Multi pulse page, the inter-pulse interval can be edited during a pulse sequence. *Note: it will not affect the ongoing pulse sequence.

2.8.2

- Changes
  - Added trigger per pulse on GP output 1.
  - Added support for CTMS001 v1.2.x.
  - Disabled ability to charge the system to a power lower than 3%.
  - Updated message displayed when no USB key is found.
- Bug Fixes

- Fixed an issue where the mouse cursor would be displayed on some monitors.
- Updated display of coil version to show all 3 digits.
- Fixed issue allowing to change pulse interval during a pulse sequence in Multi pulse page.

- Known Issues
  - No known issues.

2.8.3

- Changes
  - No major changes.
- Bug Fixes
  - No bug fixes impacting the users.
- Known Issues
  - In Multi pulse page, changing the number of pulses during a sequence might cause a GUI crash.
  - Leaving the pulse page during a sequence might cause a GUI crash.

2.9.0

- Changes
  - Reduced power fault active time from 1s to 350ms.
  - Allowed single pulse in Multi pulse page.
  - Added pulse waveform export to USB key.
- Bug Fixes
  - Fixed GUI crash when changing the number of pulses during a sequence in Multi pulse page.
  - Fixed GUI crash when leaving the pulse page during a sequence.
- Known Issues
  - No known issues.

2.9.1

- Changes
  - Allowed the use of "-" and "_" while exporting a pulse waveform and forbade the use of "%" and "/" as part of the waveform file name.
- Bug Fixes
  - No bug fixes impacting the users
- Known Issues
  - An inaccurate "ready" signal may be shown.

2.10.0

- Changes
  - Added the ability to export the log from a previous boot.
  - Added the ability to save the protocol and pulse parameters.
  - Added a progress bar for rTMS.
  - Added a validation of system fault status and pulse sequence status before arming the system.
  - Addition of an error message when trying to export a pulse waveform without USB key mounted on the system.
  - Modification of the lock screen message to give more information about the status of the device.
  - Prevented closing the keyboard dialogs when pressing outside of the dialogue.
- Bug Fixes

- Updated high voltage calibration method to use an average of multiple samples instead of the maximum value.
- "Invalid sequence file" fault will be shown when the file is not located at the root of the USB key.
- Fixed inaccurate "ready" signal from PSU.

- Known Issues
  - A blinking of the "ready" LED may happen. This is due to a premature "ready" state. Only pulse when the "ready" LED is steadily light up.
  - The exported waveforms may contain duplicates which would make some waveforms missing.
  - The display may show the coil temperature is at 41.0ºC and still allow pulse delivery. In such cases, the coil temperature is still below 41.0ºC (ex.: 40.96ºC) but the GUI rounded the temperature value.
  - A short fault might disarm the stimulator without reporting the fault to the GUI.
  - In Single pulse page, a bug might cause an unbalanced pulse warning to appear, even though this sort of warning is impossible in single pulse.
  - There's a bug causing unexpected temperature fault for the given hardware version.

2.11.0

- Changes
  - Added humidity measurement.
  - Added remote control.
  - Added support for more USB disk partition types.
  - Added support for cooled coil.
  - Added decay quantification.
  - Added protection for unbalanced pulses.
  - Added control to auto-balance pulse width.
  - Added EMG data acquisition.
  - Added display of module information.
  - Added display of first pulse waveform from rTMS.
  - Updated display of high voltage pulse waveform.
  - Added option to display snubbing from pulse monitoring.
  - Updated protocol progress display.
  - Updated pulse monitoring display to always display the last pulse.
  - Added verification of firmware compatibility with system hardware versions.
  - Added warning for pulse model accuracy for pulse with phase duration shorter than 30us.
- Bug Fixes
  - Fixed blinking of the "ready" LED.
  - Fixed duplicates in exported waveforms.
  - Adjust coil temperature limit to avoid mismatch between GUI and device behaviour.
  - Fixed issue with very short fault duration that was not reported on the GUI.
  - Fixed bug that caused an unbalanced pulse warning to appear in single pulse.
  - Fixed bug causing unexpected temperature fault for the given hardware version.
- Known Issues
  - No known issue for this version so far.

Chapter 2: Setting up the CTMS001 Device

1. INTRODUCTION

This chapter will cover the setup and basic operation of the CTMS001 device. Before operating the device, take the appropriate time to review the introduction and the cTMS primer to become familiar with safe use of the device and understand the basics of controllable pulse design.

2. UNPACKING

The Elevate TMS device is shipped packed in a wooden crate. Inside the crate, the main components are packed in a combination of bubble and plastic wrap and cardboard boxes to protect them from damage during the shipping process.

2.1 Needed tools:

To unpack and assemble the system, you will require a wide flat screwdriver to straighten the metal clips holding the crate panels together and a knife or scissors to remove the protective wrapping from the main components. A pair of protective gloves is also advised while opening the crate as some of the metal clips may have sharp edges.

2.2 Opening the crate and unpacking the components

• Using the flat screwdriver, straighten each of the metal clasps along the top edges of the crate (Fig. 2-1). When a clip is straightened, examine the slit in the metal frame of the lid from which the clip protrudes and ensure it is wide enough for the clip to slide through when the lid is to be removed and if needed, use the screw driver to pry the slit wider. When all clips are straightened, remove the cover.

• Note the orientation of the main unit chassis within the crate and identify the wall of the crate adjacent to the front of the chassis (Fig. 2-2A). Use the screwdriver or small crowbar to straighten the metal clasps holding the panel to the crate. Remove the panel to expose the front of the chassis.

• Remove all the individually wrapped items from the box except for the main unit chassis. Fig. 2-3 shows the items in their protective wrap.

• Using the scissors or knife, remove the protective wrapping from the chassis (while in the crate to expose the handles needed to roll the chassis out of the crate. Take care not to scratch the chassis with the sharp object (Fig. 2-2B). Note the additional packing spacers in the handles of the main chassis (Fig. 2-3). Unwrap the plastic wrap and remove the cardboard and foam spacers.

• Verify that the wheels are unlocked (the lever should be up). With at least 2 people, roll the chassis out of the crate, taking care to keep the unit level while the front wheels exit the crate and lowering the front wheels to the ground after the unit has been pulled far enough out that the underside of the unit will not come into contact with the bottom edge of the crate. Lift the rear of the chassis and continue rolling the chassis completely out of the crate and lower the rear wheels to the ground.

• Using the knife or scissors, remove all the wrapping material from all remaining components, taking care not to scratch or otherwise damage the individual components.

3. ASSEMBLY

The CTMS001 device is shipped as a unit with the touch-screen removed. Assembly consists of attaching the screen mount to the main unit and connecting the monitor cables, then connecting the unit to the mains.

3.1 Mounting and connecting the touch-screen monitor

Unpack the monitor and mounting arm. The monitor itself may already be attached to the metal arm.

- Note the 4 screw holes on the top of the main unit. Place the monitor arm on the main unit and align the holes of the mount with the holes on the main unit taking care to route the monitor cables through the hole in the

Fig. 2-1

Retaining clip after being folded straight

A

B

Fig. 2-2

A: Crate with the top removed. Yellow arrow indicates the front of the chassis.

B: Chassis with the protective wrap removed.

Main Unit Chassis

Monitor

Monitor stand

Accessory Box

Hex Keys

Monitor
Ground Strap Nut

Montor
mounting screws

Fig. 2-3

Items from the packing crate in their protective packaging

Fig. 2-4

Main chassis with locations of protective spacers indicated in yellow

base of the metal arm mount (Fig. 2-5).

- Insert one of the 4 screws into one of the holes, taking care not to drop the screw into the cable access hole. Using the hex key, tighten the screw, but leave it a little loose. Take care to ensure the screw is straight when tightening. If you notice that the screw stops tightening after less than one full turn, loosen the screw again and ensure it is inserted straight into the threaded receiver hole in the main unit chassis. You may need to slightly move the monitor (jiggle) to correctly align the hole in the monitor mount with the threaded receiver hole.
- Screw the other 3 screws. Use the same care regarding aligning the screws as you did for the first one.
- Tighten all 4 screws to ensure the monitor is securely mounted on the main unit chassis.
- Connect the HDMI cable to the appropriate receptacle in the rear of the monitor taking care to align the connectors correctly.
- Connect the power and USB cables.
- Insert the monitor neck insert into the monitor neck by pushing it from the rear until fully inserted and the screw holes are aligned.
- Using the hex tool, secure the insert using the 4 screws (Fig. 2-4).
- Insert the front plate cable cover under the monitor against the front of the monitor base and secure with two of the screws.

3.2 Plugging the unit into the mains

The CTMS001 device includes three power cables. One to supply power to the controller module and the others to power the capacitor chargers. It is required that the charger cables be connected into independent circuits with sufficient capacity according to the specifications listed in “12. Specifications” on page 7. Note the connector for the controller module power cable also has a

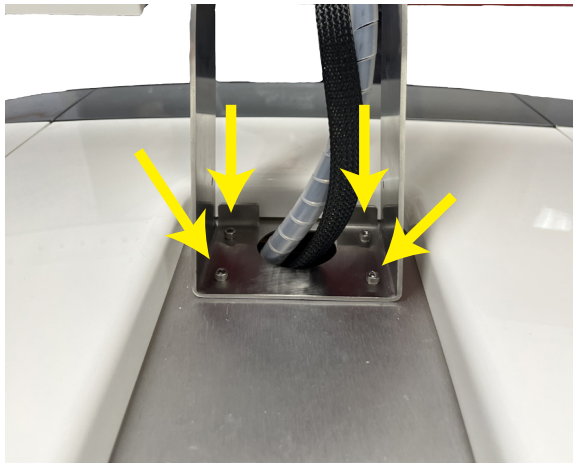
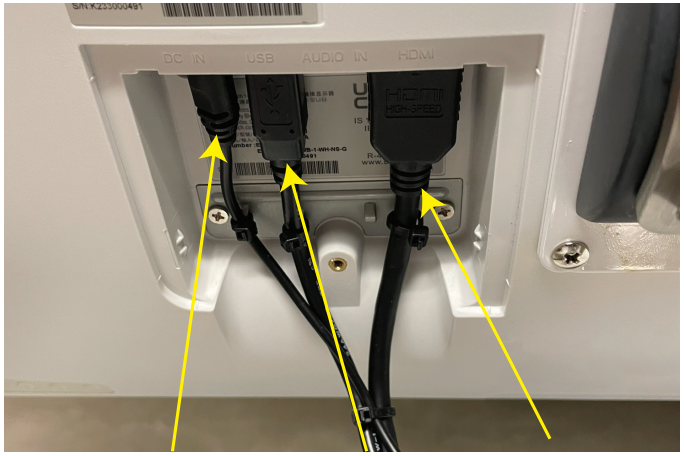


Fig. 2-5:**Monitor arm mounted on the chassis. Mounting screws are identified by the yellow arrows.**



Monitor power cable **USB Cable** **HDMI Cable**

Fig. 2-6:**CTMS001 monitor connections.**

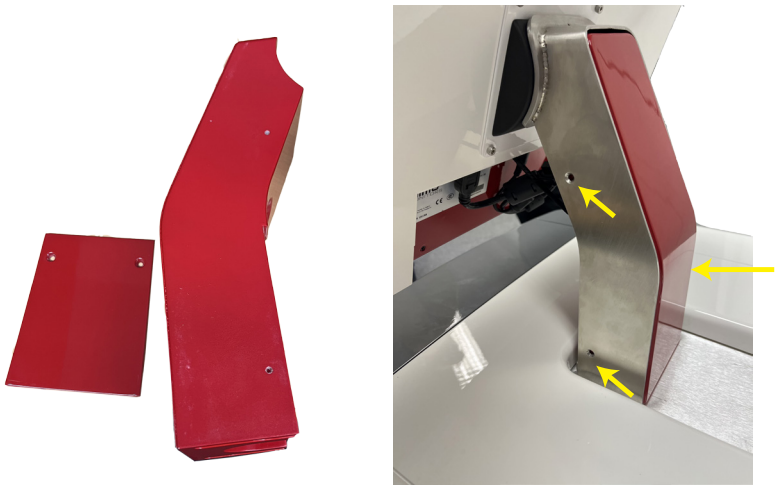


Fig. 2-7 :Monitor neck insert

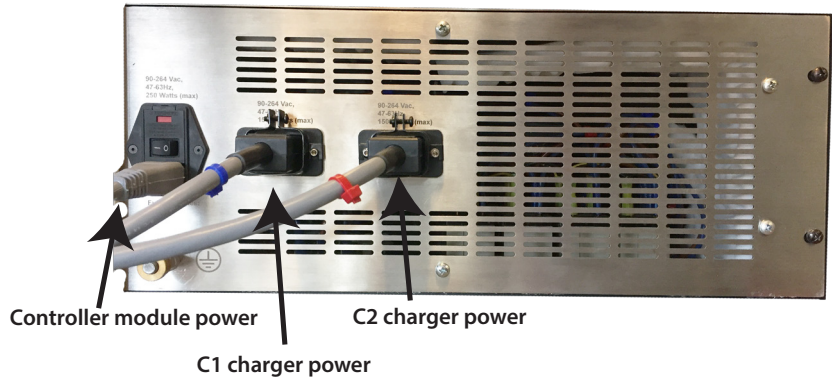


Fig. 2-8:Closeup of the power module panel.

switch. Turn that switch on. The touch screen will momentarily turn on and display a logo from the screen manufacturer, then turn off.

3.3 Preparing the coil

Plug in the coil by inserting the connector into the receptacle (Fig. 2-9). Note that some force may be required to insert it fully and take care to use the handle and not apply force to the cable itself. Only use coils manufactured by Rogue Research. Other coils are not compatible and can cause damage to the coil and stimulator.

4. TURNING ON THE SYSTEM AND BASIC OPERATION

Once the power cables are connected, turn on the system by pushing the power button on the right of the main control panel (Fig. 2-10). The green power indicator light will illuminate and the system boot process will begin. After the system has booted, the main screen will appear.

Tapping on any blue button will select that menu item and the sub-menu will appear. On the top-right of the screen (Fig. 2-11), you can access the System status screen and the coil information screen.

4.1 Viewing the system and coil status

Tap on the **system status** button to view the status screen (Fig. 2-12). The system status includes items that reflect the current status during normal operation (e.g. capacitor charge status, coil temperature) as well as internal system health information that can indicate a fault in the system. Scroll through them by dragging the list up/down using your finger. Close the window by tapping **Close**.

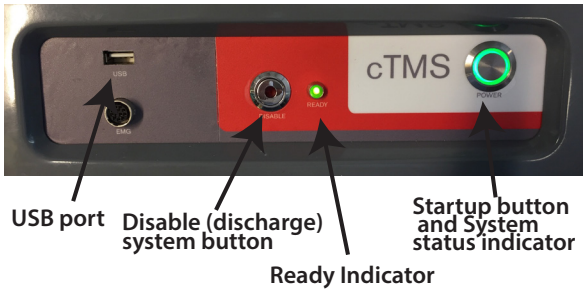
Tap on the coil status button to view the coil model, inductance, serial number and manufacture date (Fig. 2-13).

4.2 Updating the system firmware

The software running the CTMS001 device is designed to enable you to create

Fig. 2-9: Coil connector.

Fig. 2-10: Main control panel



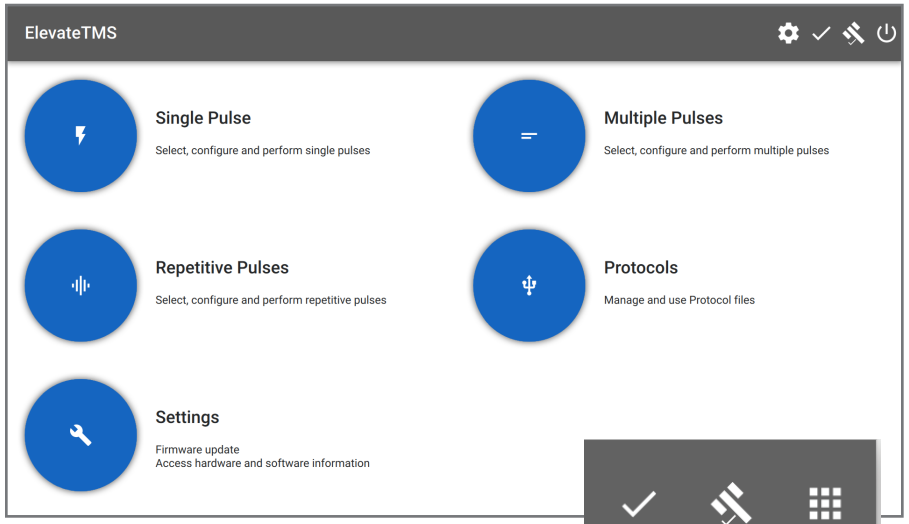


Fig. 2-11: Top: cTMS main screen.
Right: status and main menu buttons.

Bottom: System status in error condition

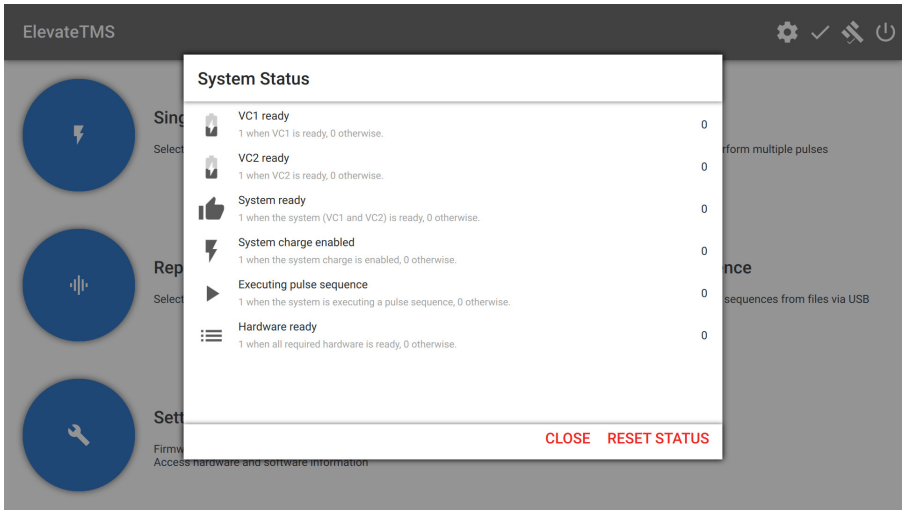


Fig. 2-12: System status screen. Scroll down to view all items.

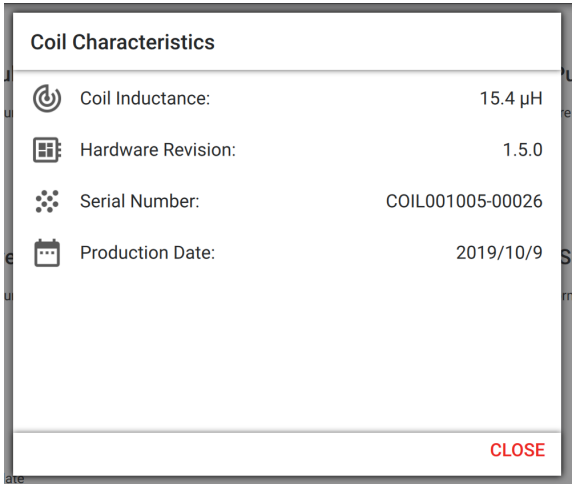


Fig. 2-13

Coil status display.

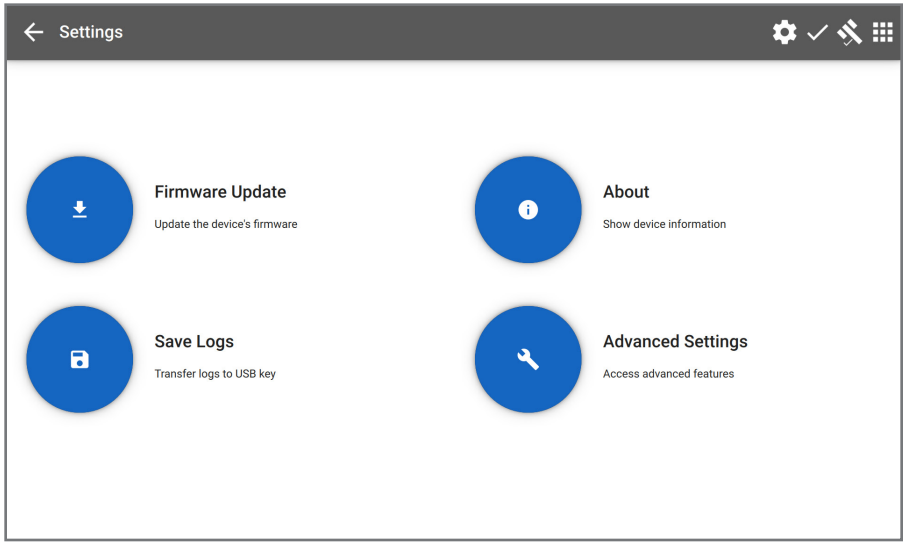
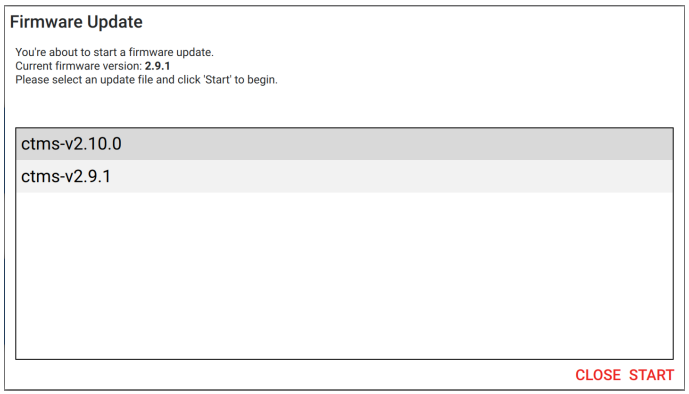


Fig. 2-14: Settings main menu screen.

Fig. 2-15: Firmware update screen.



a variety of pulses and pulse sequences while ensuring that the device is kept within its operating limits. The software is designed to only allow pulses and sequences that have been validated by Rogue Research. We are continuously working to unlock more of the capabilities in the hardware and addressing customer issues by releasing newer versions of the firmware that can be downloaded from our server and easily installed by you. To install an updated firmware:

- Go to our web site (www.rogue-research.com) and click on the downloads tab.
- Enter your device serial number in the serial number field and click View Eligible Downloads. This will show a list of software related to the cTMS device that can be downloaded. Click the desired software to initiate the download.
- Once downloaded, copy the file onto a USB key (the device should have come with one).
- Place the USB key in the USB port of the control panel.
- From the main menu, tap Settings. The main settings window should appear (Fig. 2-14). Tap Firmware Update to open the firmware update window (Fig. 2-15).
- Tap Start to begin the process. An "in progress" indicator will appear and remain until the update process is complete. After it completes, the system will shutdown to apply the new firmware which will be in effect when the system is activated.

4.3 Saving system logs

The CTMS001 device maintains an internal log while in operation, including pulse parameters being used as well as multiple parameters describing the health of the system. Should the device incur an error condition, be it a software crash or hardware error, the logs may be helpful in isolating the issue and determining the best path forward. If the system crashed or is reporting a hardware error condition, it may be helpful to save the logs to a USB key. To do so:

- Insert a USB key into the port of the control panel.
- Tap Settings from the main menu window
- Tap Save Logs. After a moment, the logs will be copied to the USB key.

5. USING THE TRIGGER IN & OUT PORTS

TMS is often performed in alongside with other devices (e.g. stimulus presentation, EMG recording etc...). It is often important to carefully synchronize these devices. For example, a visual stimulus may be presented to the subject at a specific time and a TMS pulse may be delivered at a specific time after the stimulus to disrupt a region of the brain thought to be important in processing the stimulus. Another more common example is to record the muscle evoked

Fig. 2-16: Trigger I/O panel

potential (MEP) elicited by stimulating a location on the motor cortex. In the former example, an external agent needs to initiate the TMS pulse at a precise time, so an external trigger input is needed. In the latter example, a trigger signal out is needed to allow the EMG recorder to define the epoch of data being measured.

The CTMS001 device has several general purpose input/output (GPIO) ports to allow for complex scenarios of I/O, however, not all of it has been implemented in the software at the moment. The most commonly used are the **Switch IN**, **Trig IN** and **Trig OUT**. All triggers are connected using standard BNC connectors. It is recommended that the protective caps be used when the port is not in use.

Footswitch IN is meant for the included foot switch. When the connection is closed and the TMS unit is charged and ready to deliver a pulse, it will fire.

Trig IN acts similarly to the Switch IN except it expects a standard TTL signal. This is commonly generated by stimulus presentation systems (e.g. EPrime).

Trig Out sends a TTL pulse out whenever the coil fires in single pulse mode or initiates a sequence. This can be used to trigger data acquisition.

If **Stopswitch IN** receives a TTL pulse, it will stop any active sequence and disarm the system.

In addition, system status information is output as continuous TTL 0 or 1 values for:

- A TTL 1 from the GPtrig OUT1 indicates the system delivered a pulse.
- A TTL 1 from the GPtrig OUT2 indicates the sent pulse was decayed.
- A TTL 1 from the GPtrig OUT3 indicates the sent pulse was unbalanced.

*** The last two outputs are limited to single pulse mode but will work with other modes only for the first unbalanced and first decayed pulse of a sequence.

All the trigger ports are designed to have a fast response to minimize introducing timing lag between the devices.

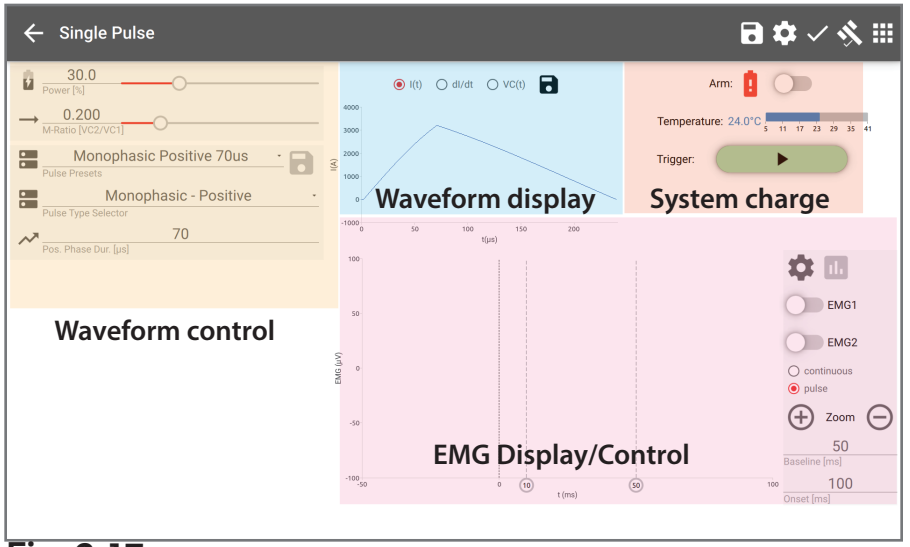


Fig. 2-17: Single pulse screen

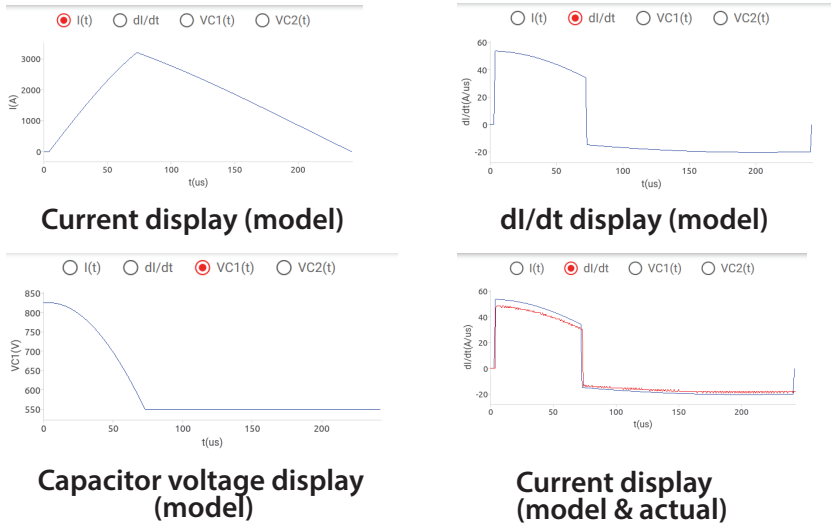


Fig. 2-18: Pulse waveform display

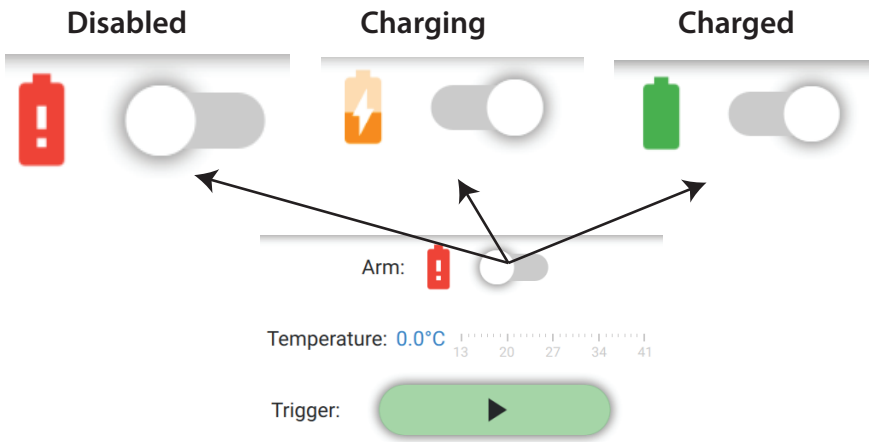


Fig. 2-19: **Charge status control. Left: System is discharged. Middle: System is charging. Right: System is charged and can be fired using the foot switch, coil trigger button or tapping the discharge button.**

6. PERFORMING A BASIC SINGLE PULSE EXPERIMENT

This section will present the steps to perform simple single pulses. The purpose is to introduce you to the various UI elements used to configure a pulse and manage the process of delivering pulses.

- If not already done, connect a coil to the system, then turn on the cTMS unit.
- From the main menu, tap Single Pulse. Fig. 2-17 shows the single pulse window. The window can be divided into three zones.

6.1 The single pulse screen

The waveform control area allows you to select the waveform type and manipulate certain parameters. For single pulses, you can change the pulse type (monophasic vs. biphasic), positive vs. negative pulse (first phase), the M-ratio and pulse intensity.

The waveform display (Fig. 2-18) shows the expected pulse waveform based on the waveform control parameters. The graph can show either the current waveform for the pulse or the derivative (di/dt) which is related to the expected induced e-field. The software uses a mathematical model taking into account the coil inductance as well as the response of the system components to model the expected waveform, which is shown in blue. The device also has an embedded current measurement tool so the actual pulse delivered is shown in red. These lines should generally agree however the measured wave will have some signal noise that may distort the signal slightly.

The system charge area allows you to charge the system and initiate a pulse. It also displays the current coil temperature.

6.2 Perform a single pulse

This simple experiment will generate a pulse that is similar to one typically encountered with a traditional monophasic stimulator, then we will manipulate the pulse width to see how this changes the stimulation effect.

- Tap the arrow next to the waveform type and select **Positive monophasic** (if not already selected) and tap **OK**.
- While observing the waveform display, tap **Negative monophasic** and the **Positive monophasic** again to see how the waveform differs.
- Set the positive pulse duration to 80µsec by tapping on the number in the field (which opens a numeric keypad window), then typing 80 and tapping **OK** to save the entry.
- Set the M-ratio to 0.2 by sliding the M-ratio slider to 0.2 or by tapping on the number and entering the value explicitly when the number input box appears. To gain an understanding of how the waveform looks, move the

M-ratio slider back and forth while watching the waveform display. Switch the waveform display from current to E-field by tapping **rate of change** and move the M-ratio slider again to see the effect. Slide the M-ratio back to 1.0 and set the waveform display back to Current.

- Set the pulse intensity to 40% by dragging the intensity slider (or tapping on the number itself, which will open the numeric keypad).
- Arm the system by tapping on the charge (the short slider next to the battery indicator) button. You should notice the system start to charge and the charge status display will change to the charging state (see Fig. 2-19). After a second or two, the status should change to charge.
  NOTE: The system will automatically disarm after 5 minutes of inactivity.
- Take the coil out of the holder and hold it away from anything metallic or anything that may be sensitive to EM pulses (e.g. watch, credit cards). Tap the discharge button or step on the foot switch or push the button on the coil handle (when present) to fire the coil.
- If you have a volunteer, place the coil on the head (e.g. left side) over where you expect the motor cortex to be. Fire the coil while observing the contra-lateral hand to see a finger twitch. If none is observed, move the coil around the region in 1cm increments to find a motor response. If none is found, increase the intensity to 50% and search again. Note that you can change the intensity with the system charged however the status will change briefly from ready to charging and then back to ready. This is normal as the system charges the capacitor to reflect the new setting.
- If you observed a motor response, keep note of the location. While keeping the coil in the same location, change the pulse width to 40µsec and fire the coil. Note the different (lower) sound and lower motor response.
- Set the pulse width to 120µsec and fire the coil again. Note the louder pulse sound and greater motor response. This illustrates the effect of pulse width on stimulation effect.

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Chapter 3: Introduction to cTMS

1. INTRODUCTION

The purpose of transcranial magnetic stimulation is to use changing magnetic fields to non-invasively induce electric currents within the brain. How these electric currents interact with the neurons will dictate the effect. In traditional TMS, many parameters of the magnetic pulse (and thus the nature of the induced current) are fixed and a property of the device itself (and different for different TMS devices and different coils). Many of these parameters are thought to play an important role in how the neurons react to the TMS pulse and access to these parameters can play an important role in understanding this effect and will be the topic of research for years to come. The ultimate goal is to improve the predictability and efficacy of non-invasive brain modulation yielding a more powerful tool for neuroscience research and more effective clinical interventions.

The overall approach of cTMS provides a much wider range of control over the nature of the TMS pulse. This additional set of capabilities brings along with it new parameters to manipulate and requires new nomenclature to describe them. The additional control offered by the CTMS001 device are not absolute or infinite. Understanding the capabilities of the device using this new nomenclature is important in making the most effective use of the device. It would be very useful to take some time to review this chapter carefully to learn the new terms used to describe the cTMS pulse and how the device works to generate these pulses.

Before describing cTMS, it would be worthwhile to have a short review of the traditional forms of TMS so we can expand from that base to describe cTMS in that context.

This discussion is meant to educate you on the general principles of TMS and cTMS and not specific to the CTMS001 device alone.

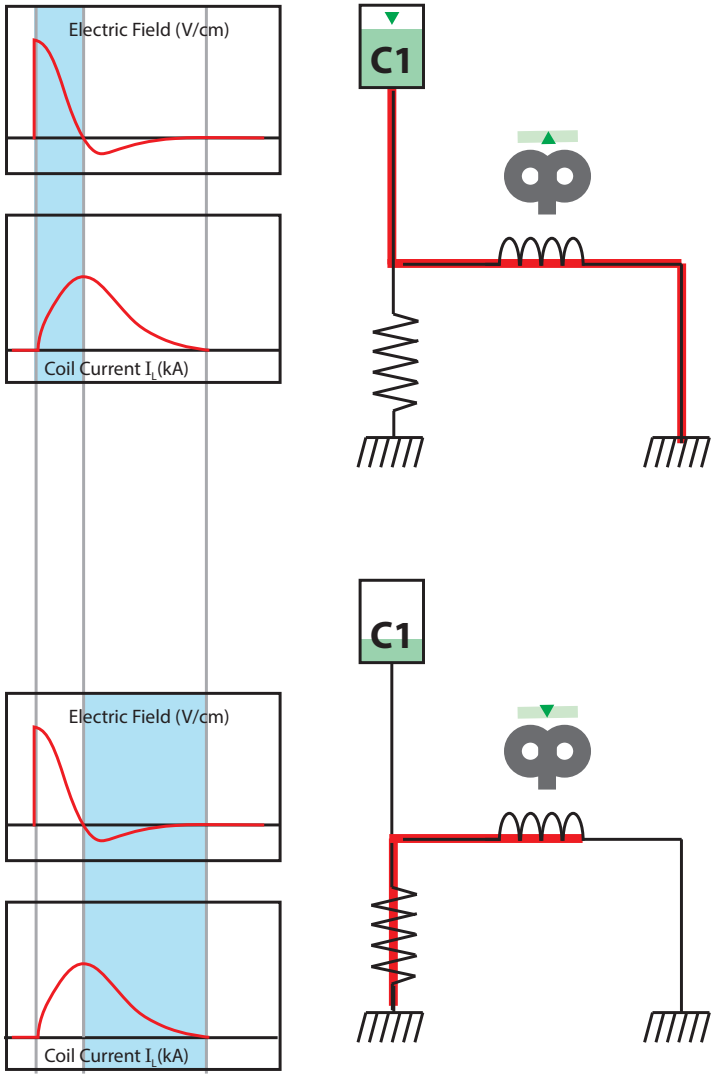


Fig. 3-1: **Monophasic TMS illustration**

2. TRADITIONAL TMS

2.1 Monophasic TMS

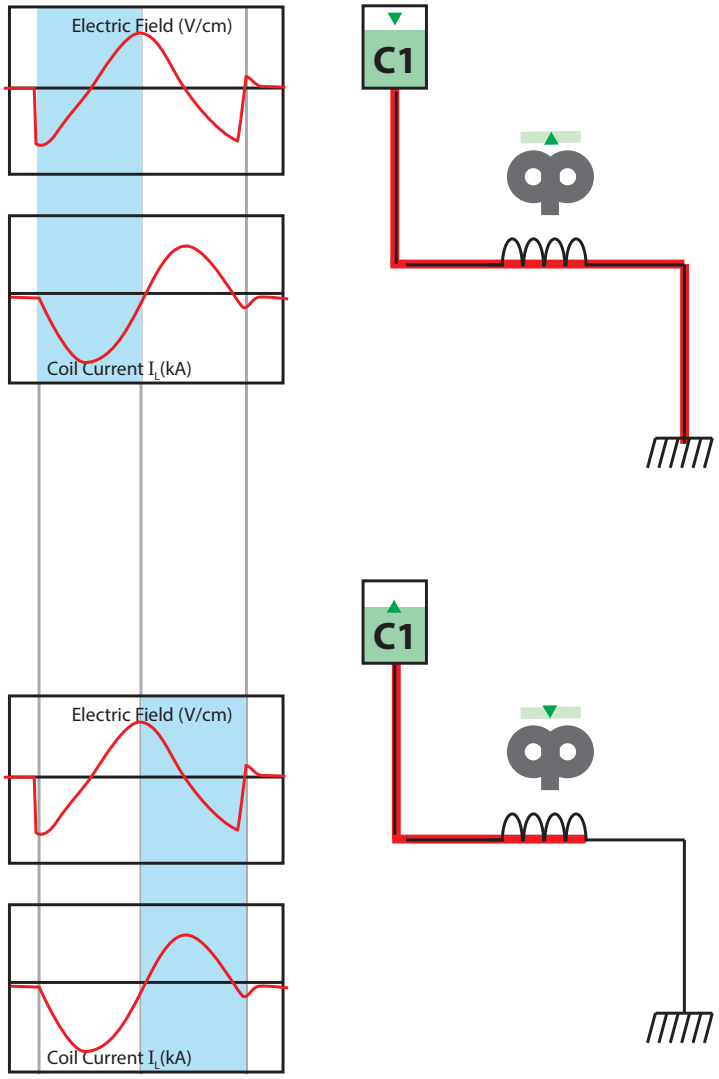
Monophasic TMS was the first and is the simplest form of TMS. The device essentially consists of a single capacitor, a thyristor switch, the coil and a discharge resistor. A charging circuit charges the capacitor. When the coil is fired, the capacitor discharges through the coil to the ground. Electrically, the TMS coil can be treated as an inductor. Some of the electrical energy going through the coil is converted to magnetic potential. When the capacitor is discharged, there is residual magnetic potential in the coil (which has to go somewhere) to the thyristor switch connects the coil to a discharge resistor. The coil then discharges to ground, converting the energy stored in the coil to heat within the resistor.

- The advantage of the monophasic pulse is that the stimulating effect is uncomplicated in that the induced current is always positive.
- The disadvantage is that the system is inefficient in that the capacitor is discharged and must be recharged before the next pulse. Typical monophasic machines require recharge times on the order of a second so repetitive pulses are generally not practical.
- **The only parameter that can be manipulated is the pulse intensity.**

2.2 Paired pulse (and quadripulse)

There is a special class of monophasic pulses that can be delivered repetitively. The most common is paired pulse. This is achieved by using two (or four for quadripulse) independent monophasic units with a combining box that routes the output of both devices to a single coil.

The advantage of paired pulse is the ability to deliver two closely spaced monophasic pulses with independent intensity and delay between pulses. This is useful in investigating intercortical inhibition and facilitation.



2.3 Biphasic TMS

Biphasic TMS attempts to address the inability of monophasic TMS of providing repetitive pulses with a more sophisticated circuit. Instead of dumping the energy stored in the coil to the ground, the switching circuit allows the energy to get dumped back into the capacitor. At the end of the pulse, the capacitor has recouped most of the energy and thus only requires a "topup" to recharge.

The resulting waveform is different than the monophasic pulse. There is negative and positive phase in the current so the interaction between the induced current and the neuron may be more complex.

Repetitive TMS is used routinely to generate longer lasting inhibition or facilitation in specific neuronal circuits.

- The advantage of biphasic pulses is the ability to generate rapid sequences of pulses.
- The disadvantage of biphasic TMS is the complex waveform interacting with the neurons. It is still unclear if the waveform can reliably produce cortical inhibition or facilitation and seems to vary with different coils and manufacturers likely due to different (and uncontrollable) waveforms generated by the different equipment.
- **The parameters that can be manipulated in biphasic (rTMS) are the pulse amplitude (intensity) and the repetitive pulse sequences (pulse frequency).**

3. CONTROLLABLE TMS (CTMS)

cTMS introduces a very different design to accomplish its goals. cTMS uses two independent capacitors and a complex switching circuit to move power around through the coil. One capacitor is charged in the positive direction and the other negative. This gives us three voltage levels to manipulate. The capacitors can either discharge energy through the coil to ground, or be charged by the energy stored in the coil from the previous phase. This allows great flexibility in designing complex pulses.

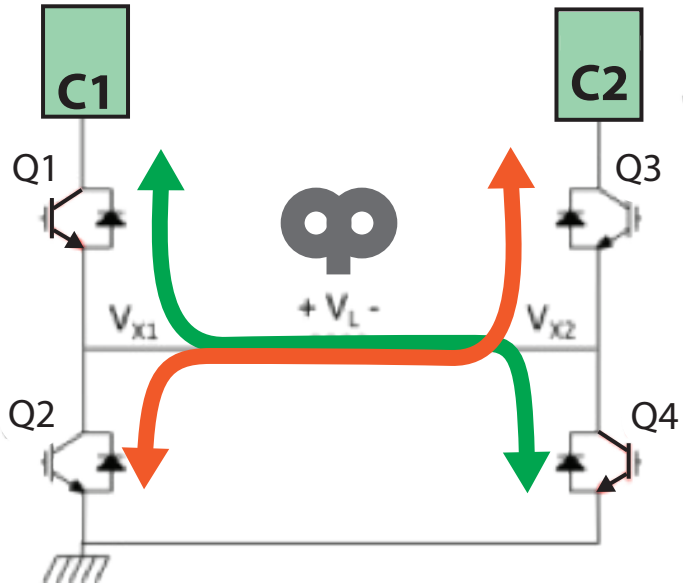
In order to describe this, some new terms are required to describe the new parameters that can be manipulated.

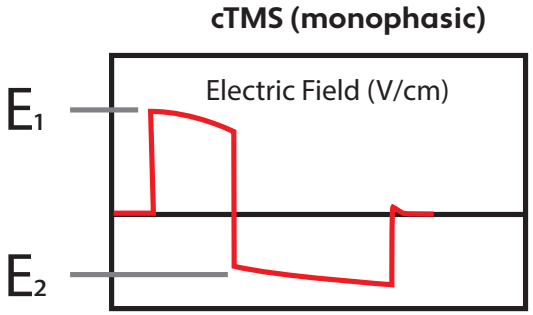
VC1, VC2: The voltages of the two capacitors

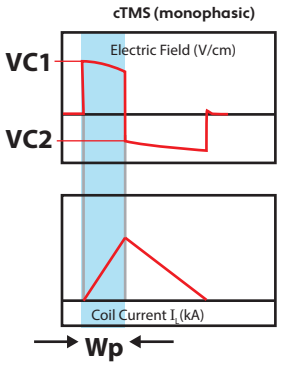
IGBT: Integrated bipolar transistors: The electronic switches that connect the capacitors to the coils.

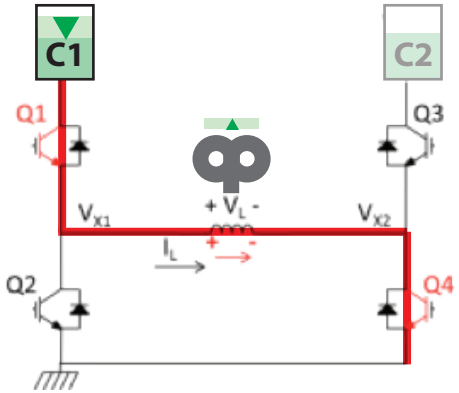
Pulse width (or duration): The duration of a particular phase of the pulse. In biphasic pulses, there will be a positive phase duration and a negative phase duration.

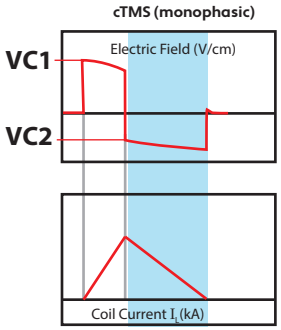
M-ratio: An important new parameter that describes the relative amplitudes of each phase of the pulse. It is **the ratio of the -ve capacitor voltage to the positive capacitor voltage** which is related electric field amplitude of the negative phase divided by the electric field amplitude of the positive phase (although not exactly). It controls (and describes) the directionality of the pulse. For example, a symmetric pulse where the -ve and +ve phase amplitudes are equal has an M-ratio of 1 while a predominantly +ve pulse would have a low M-ratio (e.g. 0.5). In general, the amplitude of the phases of the pulse (e.g. VC1 & VC2) are manipulated by setting the stimulator power and the M-ratio (rather than manipulate VC1 & VC2 directly), This makes it easier to define a specific pulse waveform and increase/decrease the intensity (e.g. to a % of the motor threshold) by simply changing the stimulator power.

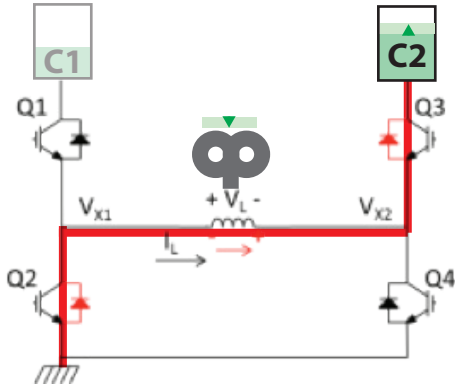












3.1 Monophasic cTMS pulse

A monophasic cTMS pulse is similar to a traditional monophasic pulse in that the current waveform is similar to a half-sine. For a positive monophasic pulse:

Before the pulse starts, C1 and C2 are charged.

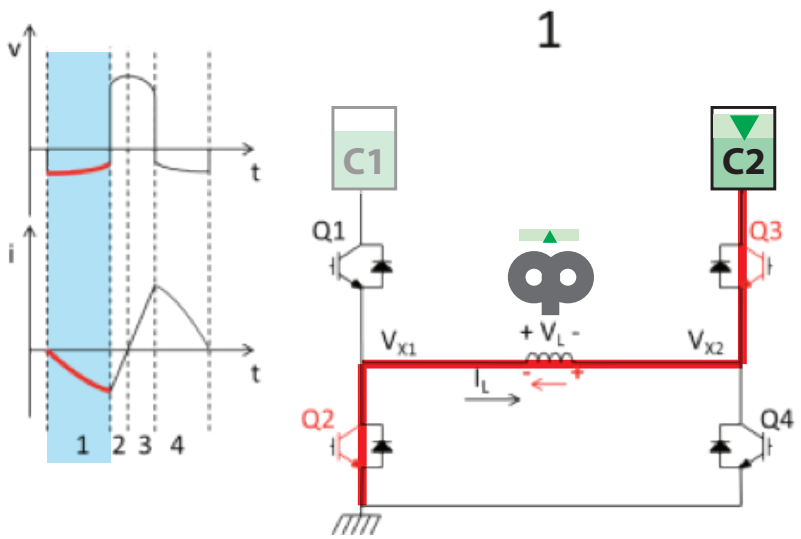
In the first phase, Q1 and Q4 are closed (conducting). C1 now has a discharge path through Q1 to the coil and through Q4 to ground. As C1 discharges, some of the energy is converted to magnetic potential in the coil. The duration that C1 is allowed to discharge is controllable, so the intensity is set by setting the voltage of the capacitor (VC1) and the duration is set by the pulse width (Wp).

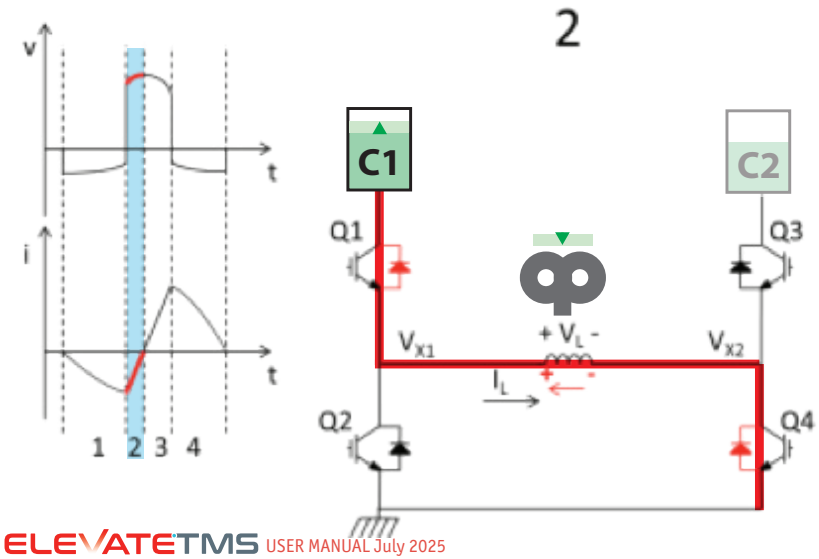
The second phase is started by closing Q1 & Q4. The coil becomes connected to C2 via 2 diodes that are in parallel with Q2 & Q3. This allows the coil's energy to be discharged into C2 until all the energy has been dissipated.

From the user-interaction perspective, the intensity setting influences how much to charge C1. The pulse width sets the duration of the first phase. The M-ratio influences how high to charge C2 (to set the intensity of the second phase) and the duration of the second phase is not explicitly controllable but is a function of the level of energy in the coil and the inductance of the coil (and connected cables).

Once the pulse is complete, C1 must be recharged (since it sent energy into the coil) and C2 must be discharged (since it received energy from the coil). This is why monophasic pulses cannot be used in repetitive TMS since it takes a long time to recharge C1 and discharge C2 (it takes longer to discharge C2 than charging C1). This limitation is partially addressed in clever biphasic pulse designs that are asymmetric (so they appear monophasic to the neuron) while being biphasic (balanced) pulses allowing for fast recharge.

A negative monophasic pulse is similar except that C2 is discharged into the coil in the first phase (by opening Q2 & Q3 instead of Q1 & Q4), then allowing the coil energy to discharge into C1 in the second phase.





3.2 Biphasic cTMS pulses

Biphasic pulses are controlled using the same components as the monophasic pulses. The main difference is that the energy is sent back and forth between the capacitors via the coil. Recalling monophasic pulses, one capacitor end discharged while the second ends "overcharged". The goal (to allow repetitive use) is to have the end state of both capacitors as close to the original state as possible and both being slightly discharged as opposed to one being overcharged (since recharging is much faster than discharging). Pulses that end with both capacitors only needing a slight recharge is called a **balanced pulse**. Remember this term. It plays an important role in repetitive pulse design.

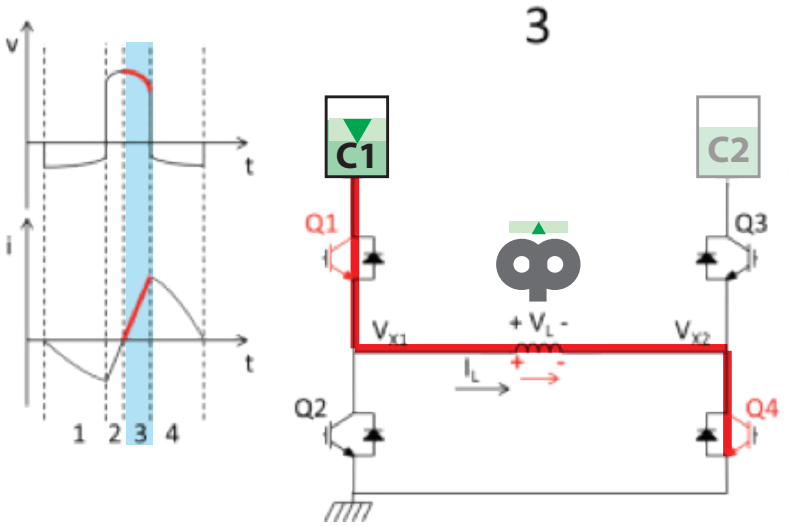
In the example on the left, the pulse starts (phase 1) by opening Q2 & Q3 to allow C2 to discharge through the coil to ground. The negative phase duration sets the width of the first phase of the pulse.

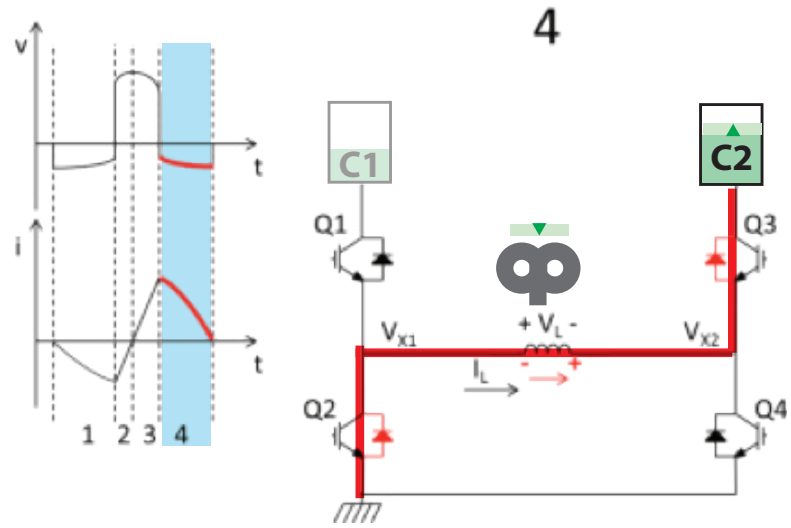
Phase 2 closes Q2 & Q3 and allows the coil's energy to be sent into C1. Note that VC1 goes up slightly as the coil current heads to 0. Up to now, this is identical to a negative monophasic pulse.

Phase 3 starts by opening Q1 & Q4. This allows C1 (which has received some energy from the coil) to start discharging into the coil. The positive phase duration is the sum of phase 2 (discharge into C1) and the discharge of C1 into the coil.

Phase 4 is started by closing Q1 & Q4 to allow the energy in the coil to discharge back into C2.

If the pulse is a balanced pulse, then the voltages of C1 & C2 will be lower than their initial values and re-charing them will prepare them for the next pulse. This juggling of energy between the capacitors via the coil is the art of good pulse design. The goal is to create pulses that achieve the desired stimulation effect while being balanced to allow for repetitive pulses.





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Chapter 4: Repetitive Protocols

1. INTRODUCTION

The Elevate TMS device is capable of delivering a wide variety of pulses, either as single pulses and in a repetitive mode (rTMS). This chapter will cover the basic of rTMS as implemented in cTMS. It is expected that you have carefully reviewed "Chapter 3: Introduction to cTMS" and paid particular attention to the concept of a **balanced biphasic pulse.** These are the only pulses that can be delivered in a repetitive protocol.

In the context of TMS, repetitive protocols typically refer to sequences of identical pulses delivered at frequencies of 1Hz or above. This is an arbitrary threshold that is largely historical and based on the intent of the use of the pulse. For example, single pulse TMS (typically using monophasic pulses) is usually used to either generate a supra-threshold current to induce the neuron to fire eliciting a spontaneous, short lasting (millisecond scale) activation of a neuronal circuit. This can be measured using EMG (in the case of motor circuits) or observation if activating a circuit interrupts the subject's ability to perform a task. The intent of rTMS is to induce sub-threshold, longer lasting excitation or inhibition of a circuit (on the order of minutes or an hour) to allow for more complex activities to be influenced by the excitation or inhibition, or for this effect to influence neuronal plasticity.

Common rTMS protocols include continuous 1Hz pulses to inhibit a circuit, bursts or 10Hz for excitation and more recently, theta burst to deliver similar excitation or inhibition using shorter protocols.

This chapter will describe how to implement these protocols using the device and describe the variety of pulse shapes that can be used in repetitive protocols.

Note that the list of available pulses will grow with future software updates and a custom pulse editor will be implemented in the future. In the meantime, additional custom pulses can be implemented via a text file and the USB interface (see "Chapter 7: Complex Sequences"). Contact Rogue Research to validate the desired pulse and pulse sequence and help generate the pulse sequence file.

2. IMPLEMENTING AN rTMS PROTOCOL

Delivering an rTMS protocol is done in three steps. Selecting the pulse to be delivered, selecting the repetition settings and triggering the start of the sequence.

2.1 Selecting the pulse

- From the system main menu, tap Run Repetitive Pulses to move to the rTMS screen (Fig. 4-1). Tap on the pulse selector to open the list of available pulses (Fig. 4-2) and select the desired pulse.

The default list of pulses have been pre-tested to ensure that they are balanced. You may also have created and saved additional pulses and you can change parameters here as well. Note that any pulse that is not balanced will generate a "pulse is not balanced" message and system will not allow itself to be armed or for any sequence to be started.

- Set the power output by either sliding the red control or tapping the power value and typing the number directly into the numeric entry screen (and tapping **OK**).

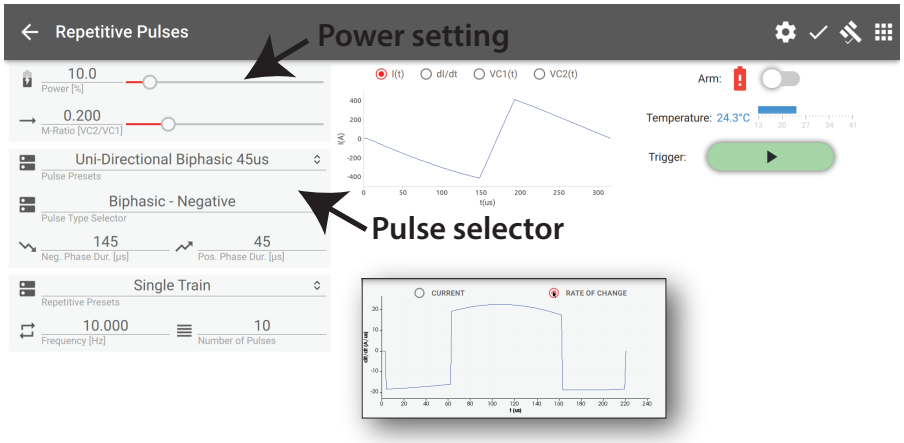

Fig. 4-1: Repetitive pulse selection screen. Note the ability to switch the pulse shape display from current to rate of change (inset).

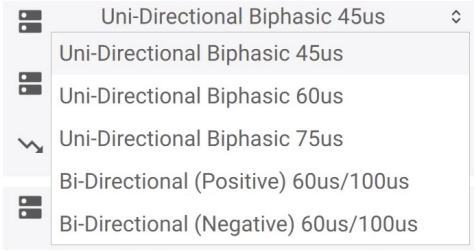

Fig. 4-2: Default pulse list.

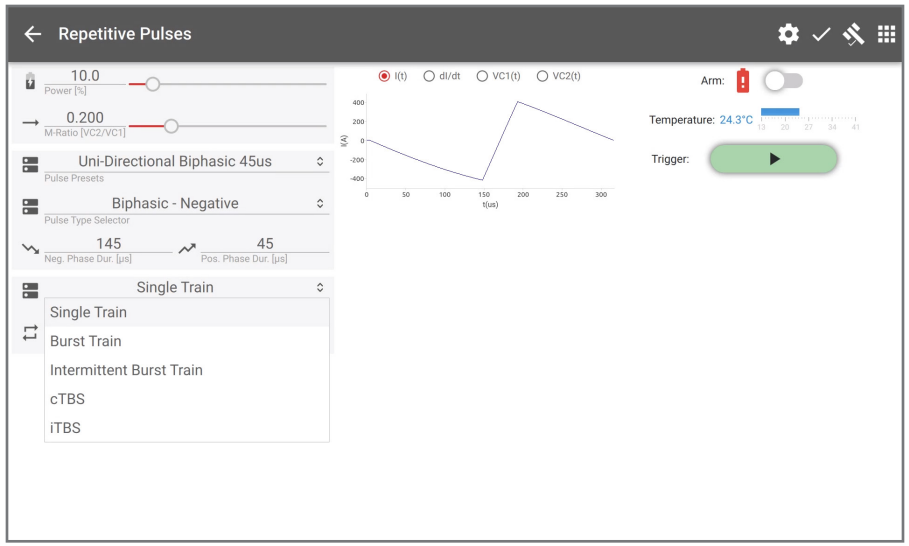

Fig. 4-3: Repetitive Settings screen.

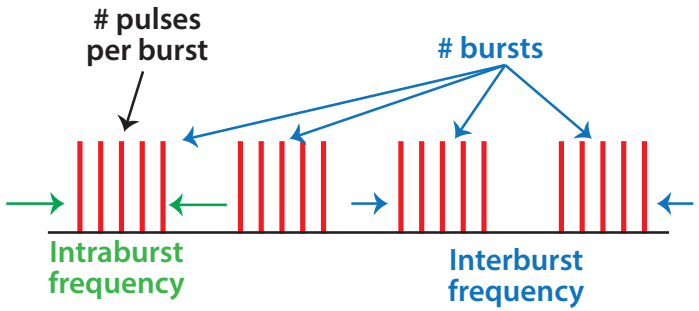

Fig. 4-4: Illustration describing the parameters to define a repetitive TMS sequence.

2.2 Entering the repetition settings

Once you have selected the pulse, you can enter the repetition settings (Fig. 4-4). Enter the desired parameters by tapping on each number (to open the numeric entry window), enter the number and tap **OK**.

For example, a simple 1Hz protocol for 60 seconds could be implemented by entering a 1Hz **intraburst** frequency, 60 **Pulses Per Burst**, 1Hz **Interburst Frequency** and 1 burst. A typical cTBS protocol would be implemented by entering 50Hz **Intraburst Frequency**, 3 pulses per burst, **Interburst Freqency** of 5Hz and the overall duration determined by the **Total number of Bursts**.

2.3 Delivering the sequence

Once the pulse and repetition parameters have been entered, the sequence can be initiated.

- Set the desired output power (if not already done so), then tap the charge button.
- Once the system has charged, the sequence can be initiated by either clicking the green play button, stepping on the foot-switch, pushing the trigger button on the coil handle (when present) or sending a TTL trigger pulse into the Trigger-In port.
- Once initiated, the sequence will automatically stop when complete. The sequence can also be stopped at any time by tapping again on the charge button or pushing the **Disable** button on the control panel (Fig. 2-10).

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Chapter 5: Paired Pulse, Quadripulse and “n” Pulse

1. INTRODUCTION

Most of the TMS protocols described in the scientific and clinical literature are designed to be used in a specific or specific class of experiments. They often implement standard pulses but the protocol in applying them are unique and thus treated separately than other protocols. Paired and Quadripulse are two examples and being unique, merit their own protocol specific user interface. Additional protocols may yet be introduced that are similar to these but use a different number of pulses, so we will call them n-pulse protocols.

2. PAIRED PULSE

Paired pulses are often used in experiments that involve the measurement of intra-cortical inhibition. The two pulses are referred to as the conditioning and test pulses. As the names imply, the first pulse elicits a reaction in the neuronal circuit and the second pulse generates an EMG response that can be measured.

In traditional paired pulse, changing the amplitude and the interval between the conditioning and test pulse can elicit a change in amplitude (inhibition or facilitation) and latency in the EMG. The Elevate TMS device performs paired pulse in a different way by enabling the pulse width of each pulse to be modified (rather than the amplitude) as well as the inter-pulse interval. This technique is not strictly equivalent to what is traditionally referred to as “paired pulse” however it achieves the same outcome and the term paired pulse should be understood to now include this version (and we will refer to it as such n this manual).

2.1 Enter the paired pulse settings and firing the coil

As with repetitive TMS, paired pulses are limited to balanced pulses. From the main menu, tap **Paired Pulse** to enter the paired pulse screen.

- Select the pulse type by tapping the pulse name and selecting it from the menu. Note that as with repetitive pulses, this list will grown with new updates in the control software.

- Set the width (duration) of the first and second phase of the second pulse by tapping each one and entering the new number in the numeric entry screen and tapping **OK**.
- Set the inter-pulse interval by tapping on the value, typing a new value and tapping **OK**. The minimum spacing is currently limited to 1.5msec.
- Set the M-ratio by sliding the **M-Ratio** control or by tapping the number, typing a new value and tapping **OK**.
- Set the stimulator power by sliding the **Power** control or by tapping the number, typing a new value and tapping **OK**.
- Note that in cases where the combination of power, waveform, M-ratio an inter-pulse Interval do not allow the device to fully recharge before the second pulse, a "Potential decay" warning will appear. The second power value will show what the software model predicts the second intensity will be. If the value is too low, change the pulse settings until an appropriate set of parameters is found.
- Tap the charge button.
- Once the system has charged, the sequence can be initiated by either clicking the green play button, stepping on the foot-switch or sending a TTL trigger pulse into the Trigger-In port.

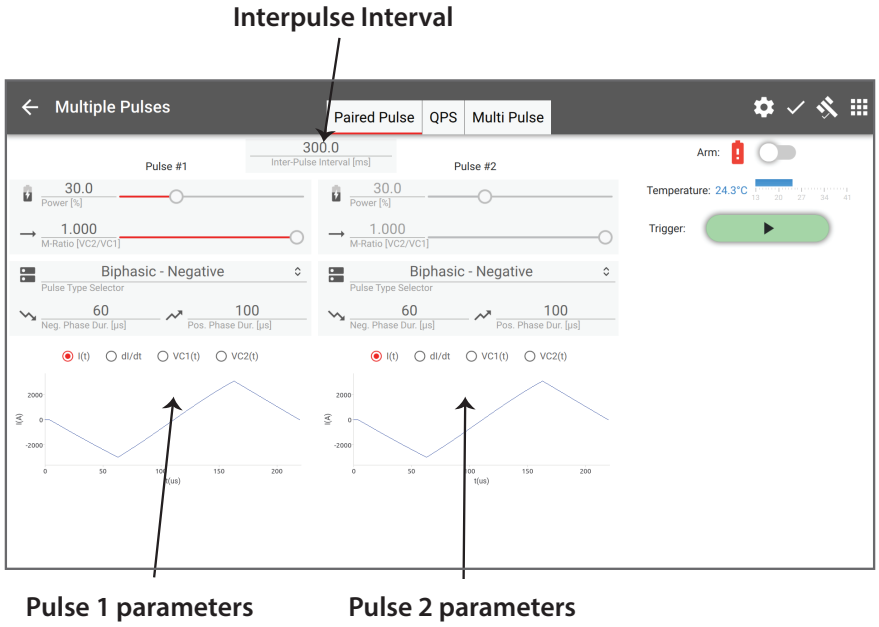


Fig. 5-1: Paired pulse selection screen. Note the ability to switch the pulse shape display from current to rate of change (inset).

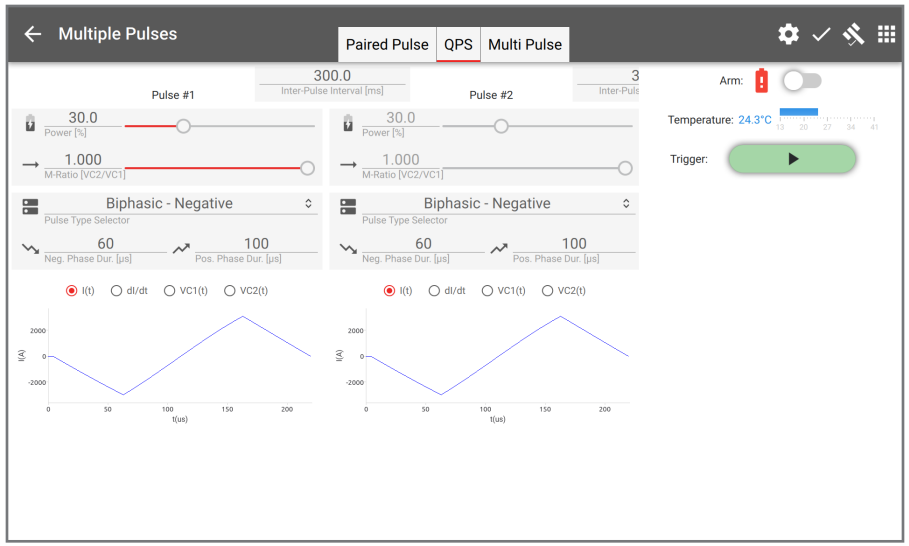
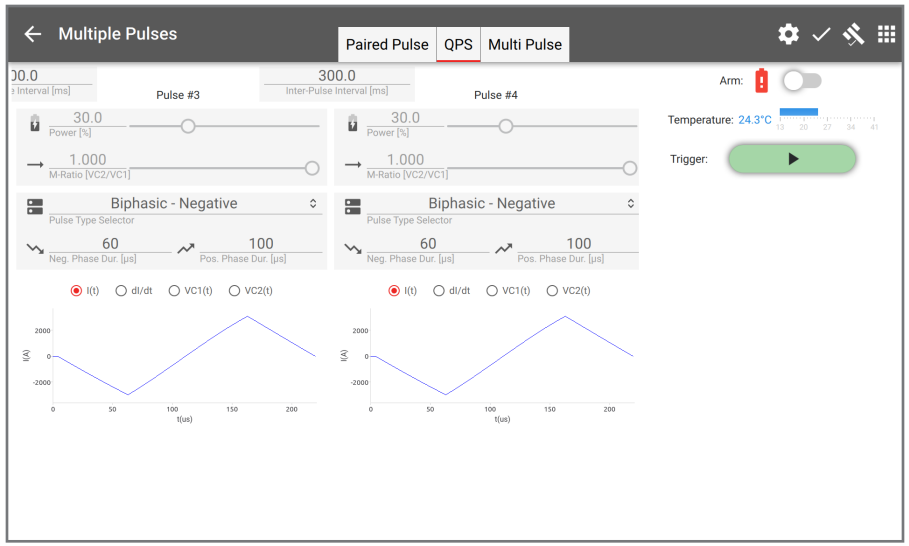


Fig. 5-2: **Quadripulse Settings screens.**



3. QUADRIPULSE PULSE

Quadripulse is a specific TMS technique where 4 pulses are delivered in a short train (analogous to the 3 pulses in Thetaburst). CTMS001 is capable of a specific version of quadripulse by firing 4 biphasic unidirectional pulses. As with rTMS and paired pulse, the quadripulse pulse needs to be a balanced pulse.

3.1 Configuring the quadripulse in cTMS

From the main menu, tap **Quadripulse** to enter the quadripulse pulse screen(Fig. 5-2).

- Set the width (duration) of the first and second phase of the first pulse by tapping each one and entering the new number in the numeric entry screen and tapping **OK**.
- Set the inter-pulse interval between each pulse by tapping on the value, typing a new value and tapping **OK**. The minimum spacing is currently limited to 1.5msec. To access the interval between the 3rd and 4th pulse, scroll the screen to the left by swiping to the left with your finger on the screen.
- Set the M-ratio by sliding the **M-Ratio** control or by tapping the number, typing a new value and tapping **OK**.
- Set the stimulator power by sliding the **Power** control or by tapping the number, typing a new value and tapping **OK**.
- Note that in cases where the combination of power, waveform, M-ratio an inter-pulse Interval do not allow the device to fully recharge before the second pulse, a “Potential decay” warning will appear. The power values at each pulse will show what the software model predicts the intensity will be. If the value is too low, change the pulse settings until an appropriate set of parameters is found.
- Any of the pulses can be disabled (to deliver a triplet or pair) by tapping

Enable Pulse checkbox to select/deselect it.

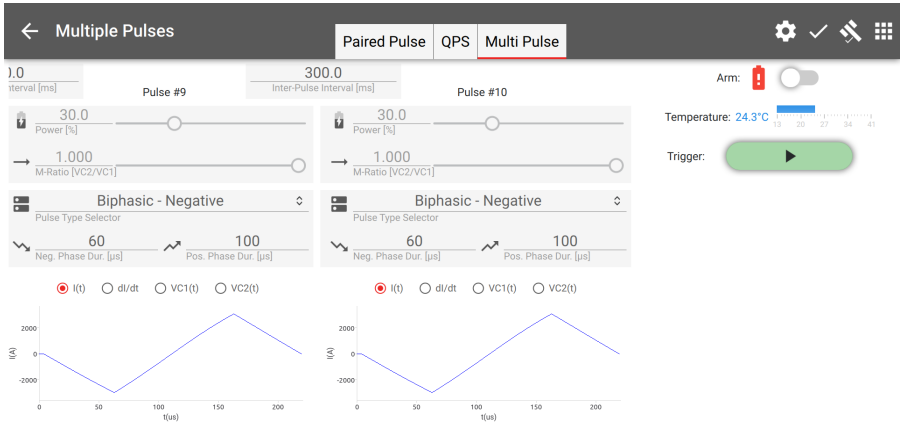
- Tap the charge button.
- Once the system has charged, the sequence can be initiated by either clicking the green play button, stepping on the foot-switch or sending a TTL trigger into the Trigger-In port.

4. N-PULSE

n-pulse sequences can be used for cases where multiple pulses with varying interpulse intervals. Enter n-pulse mode by selecting the **Multi Pulse** tab.

- Enter the number of pulses by touching the pulse count field, entering a number when the number keypad appears and touching **OK**.
- Select the pulse type by tapping the pulse name and selecting it from the menu. Note that as with repetitive pulses, this list will grown with new updates in the control software.
- Scroll through the list of pulses and set the individual timings by touching the number, entering the desired value on the keypad and touching **OK**.
- Tap the charge button.
- Once the system has charged, the sequence can be initiated by either clicking the green play button, stepping on the foot-switch or sending a TTL trigger into the Trigger-In port.

Fig. 5-3: n-Pulse screen



Chapter 6: EMG Pod

1. INTRODUCTION

The Elevate TMS electromyography (EMG) acquisition device is designed to measure the voltages generated by muscle activity and provide that information for display. The voltages are measured on the skin using disposable, self-adhesive surface electrodes. Typically, it is used to measure the motor evoked potential (MEP) generated by a TMS pulse, for example during motor threshold determination **(for research purposes only**).

2. SAFETY NOTES

2.1 Statement of intended use

This device is intended for use in teaching and research applications only. This device is not intended nor should be used for medical applications. It is not intended to treat, diagnose or monitor a subject.

The EMG device comes pre-calibrated. No adjustment is needed throughout the life of the device.

2.2 Safety Symbols

The following symbols are used throughout this manual to highlight important safety information, or information that is especially important to obtain best results in using the apparatus.

	This symbol is used to denote advice to refer to the user manual for proper operating procedures and safety information.
	Attention! This symbol denotes information regarding the safe use of the equipment to prevent injury or damage to the equipment.

	This symbol is used to denote advice to obtain the best results using your Brainsight EMG system.
	Type BF Applied part. This means that the input connectors are suitable for connection to humans. There is no direct electrical connection to the earth.
	This symbol is used to denote a high voltage warning.

2.3 Safety Tips

	Keep the subject out of reach from the TMS device or any other non-isolated device or other person touching non-isolated parts. The subject should only be able to reach and touch all BF applied parts including electrode leads, the differential sensor and isolation unit.
	Use disposable surface electrodes. Do not use implanted electrodes. Do not use electrodes beyond their expiration date as shown on the package.
	Make sure the cables are well managed to prevent the subject or others around the subject from tripping on them.

	To avoid temporary discomfort when applying the electrodes, snap the disposable electrodes to the electrode leads prior to applying the electrodes to the skin. Otherwise, the pressure required to snap the leads to the electrodes while on the skin may cause minor, transient discomfort.
	If the equipment fails to perform as expected, immediately discontinue use and contact Rogue Research for customer support or repair/replacement of the unit.
	This device may cause electrical disturbances in sensitive equipment within its operating environment
	Connection of a PATIENT to high frequency (HF) surgical equipment and to an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT simultaneously may result in burns at the site of the ELECTRODES and possible damage to the APPLIED PARTS
	Do not modify the equipment in any way. Modifying the equipment in any way may lead to data quality degradation, introduce potential safety hazards and void conformity to safety standards.
	Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the APPLIED PARTS.
	Ensure that all components are kept away from sources of electromagnetic radiation. Failure to do so may result in data with additional noise.

	Avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
	Examine the paths of all the wires, particularly the ones from the amplifier to the isolation box, and from the isolation box to the TMS device Try to avoid loops in the wire as they may pick up noise. Keep the wires away from the TMS coil and cable. To minimise noise from the input, short electrodes leads can be twisted. This will reduce the loop area and it's likely to induce less noise on the inputs.
	The TMS is plugged into the electrical mains. Use caution when connecting or disconnecting the device power cable.
	Do not attempt to service this device while in use.
	To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

	Do not modify this equipment without authorization of the manufacturer.
	If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
	Do not replace any components that require tools to perform that are not explained in this manual. Other replacements should be performed by authorized personnel only.
	Only connect items to that have been specified as part of this ME system, or listed in this manual as compatible with this ME system.
	The operator should not simultaneously touch any part of the system (e.g. TMS main unit) and the subject.
	Do not connect any multiple-socket outlet or extension cable to the ME system.

2.4 Contraindications

- Do not use on patients with implanted electronic devices of any kind, including pacemakers, implanted defibrillators, electronic infusion pumps, implanted stimulators or any similar electronic assistive devices.
- Do not use on irritated skin or open wounds.

3. OPERATING, TRANSPORT AND STORAGE ENVIRONMENT

3.1 Operating

- Temperature Range: min=15˚C, max=30˚C
- Humidity Range: 10%-80%
- Use indoors
- Keep away from direct sunlight

3.2 Transport

- Temperature Range: min=-20˚C, max=40˚C
- Maximum humidity: 95%, non-condensing
- Handle with care

3.3 Storage

- Temperature Range: min=15˚C, max=30˚C
- Humidity Range: 40%-60%
- Store indoors
- Keep away from direct sunlight

3.4 Expected Product Lifetime

- 5 Years

4. MAIN COMPONENTS:

The EMG device consists of several components. Some of which are to be used near the subject and are electrically isolated while some are near and connected to the computer. The two are linked by an analog cable.

4.1 Differential amplifier.

The differential amplifier has a shielded 3-pin mini connector to accept a twin electrode lead. A cable connects the amplifier to the isolation unit via a push/pull-style connector. It performs an analog subtraction of the signal from one surface electrode from the other. The amplifier is small enough to be worn near

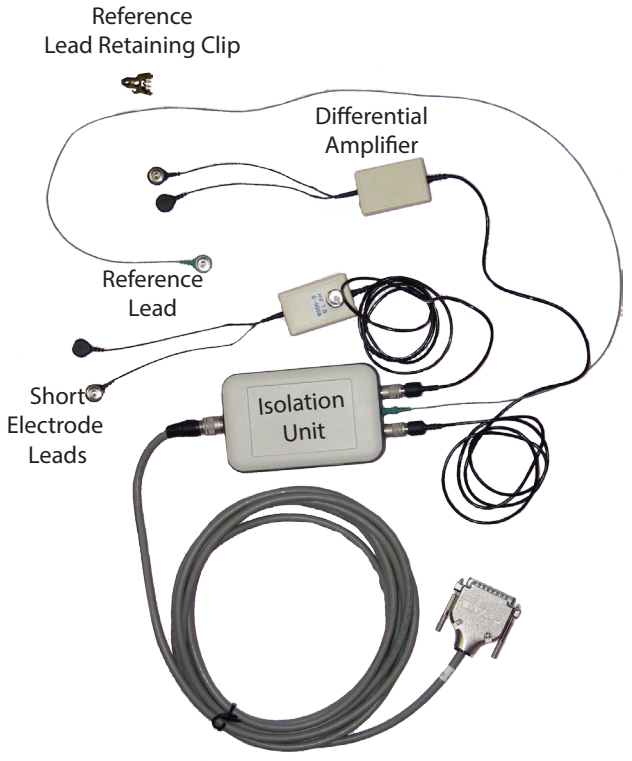


Fig. 6-1

Device overview: Parts used near the subject.

the measurement site (e.g. wear it on the wrist to measure finger muscles). A snap connector is fixed to the case to allow you to snap it to a velcro strap (e.g. to be worn on the wrist).

Short electrode leads

The electrode lead is specially designed to minimise signal contamination from external electrical sources (e.g. 50-60 Hz mains). It is shielded and uses a single mini 3-lead plug for the two electrode signals and the shield ground. The electrode connector is a standard snap style to ensure compatibility with a variety of surface electrodes (e.g. MEDI-TRACE™ Mini 130 Pediatric Foam Electrodes or equivalent).

Reference electrode lead

The reference electrode lead is connected directly to the isolation box using a 1.5mm mini-din connector. The reference electrode is connected to the lead by a snap connector. You can use the same surface electrode as with the other electrodes, however a larger reference electrode is preferred when availble. You can also use disposable reference electrodes (e.g. Ambu® Neuroline Ground electrodes).

Isolation unit.

The isolation box can accommodate the signals from two differential amplifier pods. The front of the box has two push/pull style connectors, one for each amplifier pod and a 1.5mm mini-din receptacle for the reference lead. The rear of the box (Fig. 6-5, right) has a larger push/pull connector for one end of the analog cable which links to the analog receiver.

The connectors leading to the amplifier and the reference lead are Type BF applied parts.

Analog Cable

The Analog cable connects the isolation unit to the cTMS device.

CLEANING THE EMG DEVICE

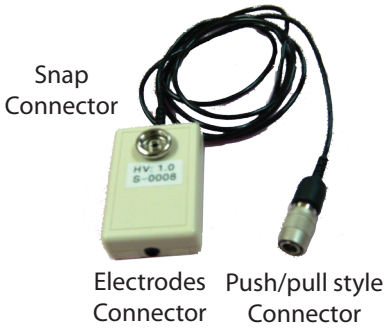


Fig. 6-2

Differential amplifier and connector cable.

Fig. 6-3

Twin-electrode lead.

Fig. 6-4

Reference electrode lead.

Fig. 6-5

Isolation unit: Left: viewed from the front. Right: Viewed from the rear.

If you need to clean peripherals likely to be in contact with different subjects, they can be cold-sterilised with an appropriate sterilizing agent. No part of the system can be placed in an autoclave. Shut down and disconnect all cables before

Fig. 6-6

Analog Receiver Cable

Push-pull to Push-pull cable.

cleaning. Use a damp, soft, lint-free cloth and mild detergent, with isopropyl alcohol swabs, or with a 70% isopropyl alcohol solution to clean the exterior of the enclosures. Avoid getting moisture in any openings. Do not spray liquid directly the enclosures. Do not use aerosol sprays, solvents, or abrasives.

The elastic/Velcro straps holding the amplifier to the subject may be cleaned by unsnapping it from the amplifier and soaking it in a mild detergent, rinsed and hung to dry.

5. INSPECTING THE EMG DEVICE

All components should be visually inspected before each use to ensure that no mechanical deterioration has occurred. It is important to periodically visually examine the covering of the cables for cuts and tears as well as checking the connectors for bent pins, exposed wires or any other damage.

6. PREPARING THE EMG DEVICE FOR USE

Before using the device, make sure that you have enough unused surface electrodes (two per channel) and a reference electrode. Review Fig. 6-1 for a complete wiring diagram.

6.1 Connecting the EMG Parts to the Elevate TMS unit

1. Connect one or both amplifiers to the isolation box by plugging in the connector(s) into the receptacle(s) labelled “CH 1” or “CH 2” on the isolation unit by holding the connector by the black plastic portion, gently pushing the connector into the receptacle while rotating the connector until it clicks into the receptacle (i.e. they are correctly aligned).

   If only one channel is used, unplug the unused channel to prevent accidental contact with non-isolated device or undesirable voltage source.

2. Connect the analog cable to the isolation box by plugging the appropriate connector into the receptacle of the isolation unit labelled “To Analog Receiver” (the Elevate TMS unit has an analog-digital converter built-in and the is referred to as an analog receiver) using the same method as with the amplifier connector above.

3. Connect connect the push-pull connector of the cable into the connector labelled “EMG” on the ELevate TMS device.

7. USING THE EMG DEVICE

7.1 Connecting hardware

1. Make sure the subject is kept far enough away from the TMS to prevent touching it.

2. Decide on your measurement location. Typically one electrode goes on a muscle and the other on a bony location near the first electrode. Fig. 6-7 shows a typical electrode configuration.

3. Place the isolation box near the subject. The box comes with a belt clip to allow the subject to wear it on the waist.
4. Using the Velcro strap, attach the differential amplifier to the subject close enough such that the short leads can reach the electrodes. The Velcro strap has a snap on it that snaps into a receptacle on the amplifier. For a finger twitch (using TMS) exercise, placing the strap around the wrist is a good choice.
5. Connect the snap end of the short electrode leads to the surface electrodes, and the shielded mini-din into the amplifier pod. **Note that disposable electrodes should only be used once. A "flat line" may result if the electrodes are reused or have expired.**
6. Prepare the skin surface according to the instructions that came with the surface electrodes.
7. Apply the electrodes to the skin following the instructions that came with the electrodes.
8. Repeat steps 4-7 for the second channel if you are planning to use it.
9. Attach the reference lead to the subject, usually on a bony surface or other reasonable neutral location (e.g. away from muscle).
10. Connect the other end of the reference lead into the reference connector on the isolation unit.

7.2 Configuring and viewing the EMG data display

Once connected, you can configure the acquisition and display of the EMG using the on-screen controls. In general, you can view the EMG data live as it is acquired, or you can view it as individual epocs showing individual MEPs for individual pulses, or as a running average of the last n pulses. Fig. 6-8 shows the EMG display and relevant controls. The right side of the display can be configured to show/set the acquisition **settings** or to **display statistics** of the acquisition.

Fig. 6-7

Example of electrode placement (the electrode on the index finger would actually be better if it were on the knuckle).

Settings Mode Selector

Tap the gear icon to expose the settings controls. You can enable either EMG channel 1 or 2 by tapping their respective enable/disable buttons. The display mode can be set to either continuous or pulse mode by tapping on the corresponding mode button. The Zoom + & - buttons allow you to increase or decrease the vertical (voltage) axis of the EMG display. The duration of the epoch (individual EMG sample) is set by entering values in the Baseline and Trial durations fields. The Baseline value represents the duration of EMG to be stored before the pulse onset (e.g. to evaluate baseline EMG activity) and the trial duration determines how much to record after the pulse onset. The total epoch duration is the sum of the baseline and trial durations.

Display Statistics

Tap the bar graph icon to expose the EMG data statistics display. The data shown will depend on the display mode.

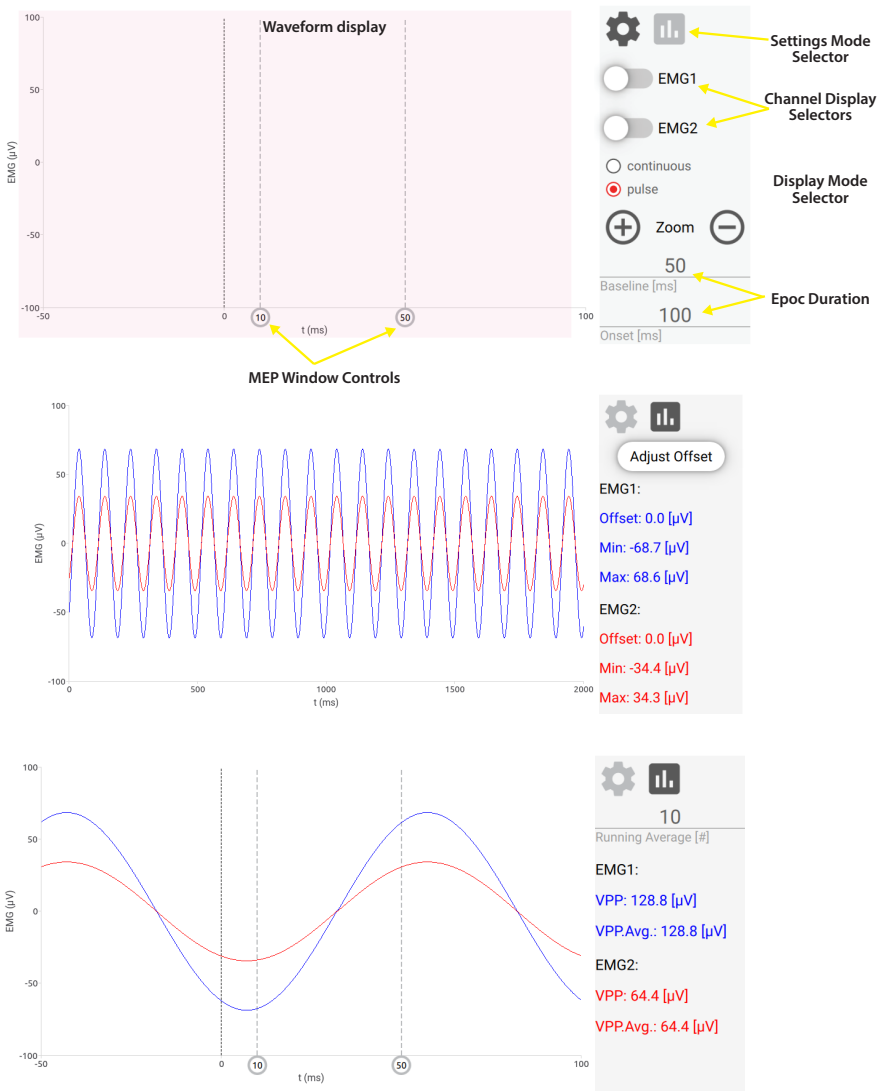


Fig. 6-8

Top: EMG Display with controls. Centre: EMG in continuous display mode. Bottom: EMG display in pulse mode.

In continuous mode, the offset, min and max values of EMG for each channel will be displayed. The values are calculated for the time window displayed. The offset is the average value of all samples in the time window and can represent the DC offset of the data. Tap on **Adjust Offset** to automatically subtract the offset from the incoming EMG to better centre it on the 0 axis to simplify evaluation of the waveform (it is easier to see it centred on the 0mV axis).

In pulse mode, the waveform display will either show the most recent EMG sample recorded, or, if a number higher than 1 is entered in the **Running Average** field, both the latest sample and the average of the N previous samples (N being the value entered in the running average field) will be displayed

When in use, the EMG data is also exported via the network interface to any connected clients.

SAFELY TERMINATING USE OF THE EMG DEVICE

The Brainsight EMG device was designed to operate in a safe and reliable manner. If for any reason, the use of the device needs to be terminated quickly and safely, simply do ANY of the following:

- Remove the electrodes (both the signal electrodes and the reference electrode) from the subject. The electrodes are self adhesive and are easily removed. They can be removed at any time.
- Disconnect the differential amplifier and reference lead. You can either disconnect the electrode cable from the amplifier by pulling out the connector, or the amplifier from isolation unit by pulling out the connector. Disconnect the reference lead cable from the isolation unit by pulling the connector out of the receptacle.

8. TROUBLESHOOTING

Your EMG unit was designed to be easy to use and to provide accurate results. Nevertheless, some problems may occur.

The EMG is being triggered, but the resulting waveform is flat, random noise.

Check that the surface electrodes and reference electrode are properly fixed to the subject's skin, and in the case of disposable electrodes, that they are fresh. Make sure that the electrode leads are correctly plugged into the amplifier and that the reference lead is correctly plugged into the isolation box. Check that the amplifier(s) are plugged into the isolation box and that the isolation box is connected to the analog receiver. Make sure you are stimulating an area that should elicit an MEP response in the muscle being monitored. Check that you have configured the EMG to sample the same amplifier (e.g. channel 1 or 2) that you are using.

The EMG is being triggered and we see a waveform, but we are also getting a lot of noise.

Make sure that the electrodes are well secured on the skin, and that the skin was prepared before fixing the electrodes (e.g. rubbed with an alcohol wipe, etc.). Make sure the locations of the electrodes are correct. Make sure that the reference lead is well placed and properly fixed to the skin. Make sure that the cables are not near the TMS coil when in use. Keep the cables away from large sources of electromagnetic radiation and prevent loops in the cables.

8.1 Further Assistance

If your problem was not solved with the above information, you can contact us directly by e-mailing us at support@rogue-research.com. We can also be reached at +1 514 284-3888 (or toll free in North America at 1-866-984-3888).

9. ELECTROMAGNETIC COMPATIBILITY

Medical electrical equipment requires special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

The EMG unit should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the EMG unit should be observed to verify normal operation in the configuration in which it will be used.

The use of Accessories, transducers, and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the EMG unit.

10. EMG SYSTEM SPECIFICATIONS

10.1 Overall System:

- Overall EMG Amplification:
  Model 3 amplifiers 4444 V/V:
- Input range: **Model 3,** 4.5 mVpp
- Overall Bandwidth: 16-470 Hz
- Overall Noise: **Models 1 & 2**: <5.33 µVpp (R.T.I),
  Model 3: <20 µVpp (R.T.I)
- ADC resolution: 12 bit
- ADC sampling rate: 3kHz per channel
- Power Consumption: 9Vdc, 1.5 A and USB 5Vdc, 500mA
- BF Applied part Isolation Voltage: 5300 VRMS

10.2 Sensors:

- Bandwidth: 16-550 Hz
- CMRR (60Hz): -115 dB (typical)
- Input Impedance: 300 (minimum), 1250 (Typical) GΩ//1.6pF

11. PARTS LIST

- 2x Differential amplifier SENS003: Rogue Research Inc.
- 1x Isolation unit BELT003: Rogue Research Inc.
- 1x Analog Cable ANAH002 (version 2.1.0 and higher): Rogue Research Inc.
- 1x Reference electrode Lead Green 1.5mm DIN 441273X25036001
- 2x Short electrode Leads ELEC001: Rogue Research Inc.
- Clip, Lapel: 38031: PI Technologies
- ECG Electrode: 31112496: Cardinal Health
- Neuroline Ground: 71410-M-1: Ambu Inc.

12. DISPOSAL

Dispose of the product in accordance with your local government requirements. Contact your local recycling centre for more information. For more information about product content contact Rogue Research Inc.

Chapter 7: Complex Sequences

1. INTRODUCTION

In traditional rTMS, a pulse sequence can be described as a series of evenly spaced pulses (e.g., 1Hz, 10Hz) or a series of bursts of simpler sequences (e.g. theta burst where a short sequence of 3 pulses at 50Hz is repeated in a higher-level sequence of 5Hz). One common thread for all these sequences (or sequence of sequences) is all the pulses are identical in shape and intensity (assuming no unintended decay). The CTMS001 device introduces the possibility of performing pulse sequences where certain parameters may be changed from pulse to pulse. In order to accommodate this new capability, The device can read a file that describes these **complex** sequences, validate the contents and execute the sequence.

In addition to complex sequences where the pulses may vary, CTMS001 once supported the additional concept of either combining the outputs of two machines into one coil (to allow even greater flexibility in varying the nature of each repetitive pulse), or to reverse the polarity of the pulse. These were accomplished using a **combining box** or **phase reversal** box respectively. The sequence file format includes commands to control these external devices to select which machine to use and/or the polarity of the pulse. These units are currently unsupported however they remain described here for clarity.

This chapter will explain how to write a pulse sequence file and how to run the sequence on the CTMS001 device.

High familiarity with TMS experimental and pulse design, the cTMS system's capabilities, and the information contained in the other chapters of this manual are recommended in order to plan an appropriate sequence that can be delivered by the hardware. It is recommended that you confer with us to validate your sequence to ensure it can be performed successfully on your hardware.

2. WRITING A PULSE SEQUENCE FILE

The Pulse Sequence File is an ascii text file (we use the .psf extension) can be

written and viewed in most text editors. After a header and universal settings, the file contains a list of objects, including **pulses**, **repetitions** (essentially a short sequence which defines a simple repetition pattern) and **sequences** (which can describe a sequence of distinct pulses and/or repetitions to be carried out in order). The definitions are made in order of use, meaning simple objects are defined first, more complex objects (which refer to the simpler objects) are defined second. The order is pulses first, repetitions (which are optional) second, followed by the sequence which implements the pulses and repetitions into something concrete to be delivered by the device.

Each line contains what is known as a **key-value** pair. The **key** is a setting to alter and is followed by the **value** to assign to that setting. The key is always one word (or more than one connected with an underscore "_" character). The value may be one or more words separated by a space and is specific to the key (see list below). Note, there should be no spaces after the last value of each line.

The psf file is written on an external computer with a text editor and then copied via USB key to the CTMS001 device.

2.1 Overview of a pulse sequence file

The overall structure of a sequence file includes a header section followed by universal settings (constant for the entire sequence), pulses, repetitions and a single sequence definition (that uses the pulses and repetitions).

Note that some key-value pairs can have multiple parameters and these will often be preceded by a key-value pair specifying the number of parameters (e.g. number_items). This number must match the actual number of items subsequent related key_value pairs (e.g. item_uids & item_onsets).

Header:

The first line simply has the word "rogue". The CTMS001 computer uses this to recognize that the file is a sequence file. The second line of the header is the key "version" and the value is 1 (to state that this is version 1 of the sequence file format).

Universal settings:

The Power and M-Ratio values are set for the entire sequence. They are referred to as **primary_power** and **primary_mratio** to signify that the primary machine is being set. In cases where a combining box is used, the second machine is set using the **secondary_power** and **secondary_mratio** keys.

Inputting the power and m-ratio values for the primary device in the sequence file is optional if you only have one CTMS001 device. If these values are not set, the default is 0. The power and m-ratio settings can be changed in the "Complex Sequence" window on the CTMS001 device (see Fig. 7-1 and see section "4. Running the pulse sequence").

At this time, the Power and M-Ratio values from each device cannot be changed between pulses.

Pulses

Before a sequence of pulses can be described, the actual pulses must be declared and described. Think of them as the building blocks of a sequence. The table below gives the details however in short, a pulse is defined by a unique name, polarity, number of phases and their duration and the hardware is present, the machine to deliver the pulse and the phase direction.

Repetitions

This is a simple definition of a repetitive sequence using one or more pre-defined pulses. In a repetition block, we define the number of repetitions (within the repetition block, sorry for the confusing nomenclature!), the pulses to implement in the repetition block and the onsets (see example below).

Sequence

There can only be one sequence in a sequence file and represents the complete implementation of one or more pulses and/or repetitions.

Universal Settings Parameter Description

Keys	Description	Range
primary_power	Power used by the primary stimulator for the whole sequence	1 to 100 (%), with increments of 0.1
primary_mratio	M-ratio used by the primary stimulator for the whole sequence	0.01 to 1, with increments of 0.001
secondary_power	Power used by the secondary stimulator for the whole sequence (only valid with a combining box)	1 to 100 (%), with increments of 0.1
secondary_mratio	M-ratio used by the secondary stimulator for the whole sequence (only valid with a combining box)	0.01 to 1, with increments of 0.001

Pulse Parameter Description

Keys	Description	Range
uid	Pulse name	Any unique name, no spaces
polarity	The polarity of the first phase of the pulse	“positive” or “negative”
number_phases	Selecting between a monophasic or biphasic pulse, respectively	1 or 2
phase_duration_us	The duration of a phase	10 to 400 us, with increments of 1 us
stimulator	Selecting the stimulator to deliver the pulse (only valid with a combining box)	“primary” or “secondary”
current_direction	The current direction for the pulse (only valid with a phase reversal box)	“regular” or “inverted”

Repetitions Parameter Description

Keys	Description	Range
uid	Repetition name	Any unique name, no spaces
number_repetitions	The number of times the repetition will run	1 to 65535
repetition_interval_us repetition_interval_ms repetition_interval_s	The interval between the start of each repetition	1 ms to 1800 s, with increments of 1 us
number_items	The number of different pulses used in the repetition	1 to 65535
item_uids	The list of pulse uids to be used in the repetition	Any previously defined pulse uid
item_onset_us item_onset_ms item_onset_s	The list of onset times to be used for each pulse in a repetition	0 s to 14400 s, with increments of 1 us

Sequence Parameter Description

Keys	Description	Range
uid	Sequence name	Any unique name, no spaces
number_repetitions	The number of times the sequence will run (optional)	1 to 65535
repetition_interval_us repetition_interval_ms repetition_interval_s	The interval between the start of each sequence (optional)	1 ms to 1800 s, with increments of 1 us
number_items	The number of different items used in the sequence	1 to 65535
item_uids	The list of pulse uids and/ or repetition uids used in the sequence	Any previously defined uid
item_onset_us item_onset_ms item_onset_s	The list of onset times to be used for each item_uid in a sequence	0 s to 14400 s, with increments of 1 us

2.2 Example File(s)

The following example will detail a file called “rogue.psf”. The Power and M-Ratio values will be set, then two pulse types will be defined, two repetition types will be defined, and finally, the sequence will be defined.

---

rogue
version 1

primary_power 56.3
primary_mratio 0.427

type pulse
uid pulse1
polarity positive
number_phases 1
phase_duration_us 100

type pulse
uid pulse2
polarity negative
number_phases 2
phase_duration_us 120 120

type repetition
uid repetition1
number_repetitions 3
repetitions_interval_s 1.5
number_items 2
item_uids pulse1 pulse2
item_onsets_ms 0 300 1000

type repetition
uid repetition2
number_repetitions 2
repetitions_interval_ms 750
number_items 2
item_uids pulse1 pulse2
item_onsets_ms 0 300

type sequence
uid sequence
number_items 2
item_uids repetition1 repetition2
item_onsets_s 0 5

The file should be saved using the extension ".psf". The filename itself should not have any spaces (e.g. use **rogue_version1.psf** instead of **rogue version 1.psf**).

The following second example shows how to set parameters when there are two CTMS001 devices, a combining box, and a phase reversal box.

---

rogue
version 1

primary_power 56.3
primary_mratio 0.427
secondary_power 43.0
secondary_mratio 0.687

type pulse
uid pulse1
stimulator primary
current_direction regular
polarity positive
number_phases 1
phase_duration_us 100

type pulse
uid pulse2
stimulator secondary
current_direction regular
polarity negative
number_phases 2
phase_duration_us 80 120

type pulse
uid pulse3
stimulator secondary
current_direction inverted
polarity negative
number_phases 2
phase_duration_us 120 120

type repetition
uid repetition1
number_repetitions 3
repetitions_interval_s 1.5
number_items 3
item_uids pulse1 pulse2 pulse3
item_onsets_ms 0 300 1000

type repetition
uid repetition2
number_repetitions 2
repetitions_interval_ms 750
number_items 2
item_uids pulse1 pulse2
item_onsets_ms 0 300

type sequence
uid sequence
number_items 2
item_uids repetition1 repetition2
item_onsets_s 0 5
---

3. IMPORTING THE .PSF FILE TO THE cTMS DEVICE

Copy your sequence file onto a USB stick and then plug the USB into the front of the CTMS001 device. If not already done, connect a coil to the device, then turn on the main unit. From the main menu, tap Complex Sequence (Fig. 2-10 on page 24). Tap the file selector button (downward arrow near the top left of the screen) and select your sequence from the list.

Once the file loads, note the power and M-ratio controls will be set to the values from the sequence file.

4. RUNNING THE PULSE SEQUENCE

Once the file has been imported, if needed, you can adjust the power and M-ratio values for your sequence in the Primary and/or Secondary Stimulator section.

This will override the power and m-ratio values set in your .psf file.

If the file has incompatible pulse sequences, the .psf may not run and a warning message will appear. The file will need to be modified in your text editor.

Arm the CTMS001 device by tapping on the charge button and wait for the charging to complete (typically a few seconds).

Place the coil over the desired location and when ready to execute the sequence, either tap the Discharge button , use the foot switch or external trigger. Either of these will run/execute the entire pulse sequence.

5. TERMINATING THE PULSE SEQUENCE

Once initiated, the complex pulse sequence will automatically stop when complete. The sequence can also be stopped at any time by pushing the Disable button on the control panel or touchscreen.

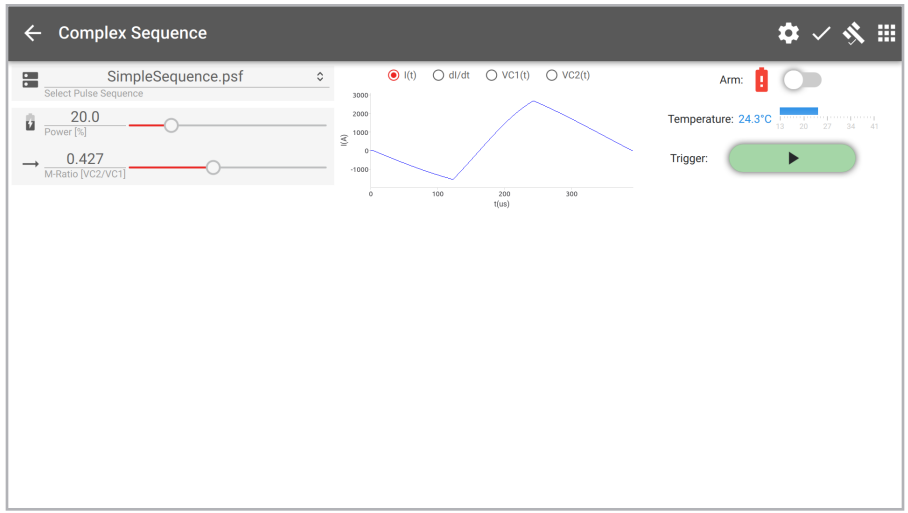


Fig. 7-1: Paired pule selection screen. Note the sequence file selector button (downward arrow icon) and the primary (and optionally secondary) power and M-ratio controllers.

Chapter 8: Network Protocol

1. INTRODUCTION

The Elevate TMS device allows you to control its functionality in many ways. The multi-touch screen allows you to configure and operate all features of the device. The TTL interface allows you to, among other things, synchronize the onset of pulses and pulse trains with external devices in your lab to enable multiple devices to behave on a coordinated fashion. For example, you may use a visual stimulus presentation system to display a specific image to the subject and send a TTL trigger to the stimulator at a very specific time in relation to the stimulus onset. The complex sequence script language support allows you to define a set sequence of pulses in a simple text file and the Elevate TMS device can carry out this sequence with minimal interaction.

Many of these types of use are static in that many aspects of the experiment are predetermined, fixed and sequential. For example, the pulse used when triggered by the stimulus device must be either configured on the touch-screen or defined by the complex sequence file. It is becoming more common in neuroscience to design experiments that are dynamic, meaning that certain parameters need to be determined as the experiment is carried out with data acquired to dictate these decisions in real-time. For example, one may investigate statistical methods of accelerating the determination of the subject's motor threshold where the MEP acquired by one or more pulses dictate what the next pulse intensity might be. To accomplish this , a real-time control of the device is required.

As with many pieces of equipment commonly found in a neuroscience research lab, the Elevate TMS device includes a TCP-based connection and protocol to connect to the device using an external program (e.g. Python or Matlab®) and query it for information as well as send it commands to configure the device's operation. For example, one may develop a program that communicates with the Elevate TMS device as well as with a physiological acquisition device (e.g. EMG, EEG, fNIRS) to configure the TMS pulse, send a TMS pulse, acquire response data

Fig. 8-1: Protocol Manager screen.

from the acquisition device and decide on the parameters of the next pulse based on that response.

Note the device supports two levels of external control. The first level supports arming/disarming and triggering while the second level supports full control of the device. Note in the second level of control, the user interface screen will be disabled to prevent conflicting parameters from being entered from two sources.

The typical workflow for such an experiment might resemble the following general steps:

1. Connect all devices to a common network (closed network preferred to minimize network traffic and simplify network configuration).
2. On the ElevateTMS device, select the Settings screen, then tap **Advanced**, then **enable external control** and finally tap **start external sequence**. Note that this will have the side-effect of essentially disabling the UI of the ElevateTMS device to prevent the UI and the external program conflicting with settings (only one controller at a time)
3. On the control computer, input the IP address of the ElevateTMS system (or use the xxx.local nomenclature where xxx is th serial# of the Elevate device), or use an automatic discovery protocol (e.g. autoconf) to detect the device on the network.
4. Establish a connection to the device (control socket) and establish the notification and data sockets and ensure yo are able to receive data and send commands.
5. Connect to any other relevant devices (e.g. Physiology equipment or navigator).
6. Carry out your experiment.

2. SPECIFICATIONS AND/OR SPECIFICATION DEVELOPMENT

2.1 Protocol specifications

2.1.1 Overview

The hardware communication protocol between clients and the embedded computer (server) uses Ethernet with TCP protocol. The protocol should be able to detect lost data. Therefore, the data should be sent in a way that it could be checked for its integrity.

2.1.2 Packets

Packets are sequences of bytes exchanged between the client and the server. In what follows we describe the different types of packets used in the ETMS protocol. We refer to such packets as “ETMS packets”.

All ETMS packets consist of a fixed-length header optionally followed by additional data. This additional data constitutes the DATA segment of the packet. From a high-level view, a ETMS packet has the following structure:

0	16	...
HEADER	**DATA**	

Note that the HEADER segment is always 16-bytes in length, while the length of the DATA segment is variable and depends on the packet type.

The header of a ETMS packet has the following structure:

0	4	8	12	14	16
Name	**MC**	**SIZE**	**PUID**	**Command ID**	**Sub Command**
Type	Unsigned 32	Unsigned 32	Unsigned 32	Unsigned 16	Unsigned 16

Table 1: Packet structure

In the ETMS protocol, whenever a numerical value spanning more than 1 byte is sent over the network, it is encoded as little endian. Even if the standard for the

networking is in big endian , most of the computers now use little-endian CPUs. Therefore, it is easier to encode and decode data in the native endianness. This is mainly important when performance is an issue.

The **magic number (MC)** represents a 4-byte sequence of predefined values, which are used to identify the packets used in this protocol. The 4 bytes are chosen to reduce the possible de-synchronisation between the client and the server.

The 4 characters that are defined are not ASCII characters, meaning common visible one, and not UTF-8, meaning not following UTF-8 rules (http://en.wikipedia.org/wiki/UTF-8). The characters are:

<0xEF><0xCD><0xAB><0x89>

The order of those characters needs to be send starting with <0x89> respecting the little endianness. An **MC** of 0xFFFFFFFF (4294967295) is reserved for "uninitialized" status. This makes packet introspection possible and allows packet validation and protocol testing.

For a reason of redundancy these characters will be replace by **<MC>** in this document.

The **number of bytes (SIZE)** is an unsigned 32-bit integer. It represents the length in bytes of the **DATA** segment of the packet. A **SIZE** of 0xFFFFFFFF (4294967295) is reserved for "uninitialised" status.

The **PUID** is a unique identifier that is used to associate a command to its reply. The reply to a message should contain the same **PUID** as the command. A **PUID** of 0 is reserved for data packet or notification messages (INFO message in that are not a reply to a GET message). A **PUID** of 0xFFFFFFFF (4294967295) is reserved for "uninitialized" status.

The **Command ID** is an unsigned 16-bit integer representing the type of the packet. The value 0xFFFF (65535) is reserved for "uninitialized".

The **Sub Command** is an unsigned 16-bit integer representing the specific command in relation with the **Command ID**. The value 0xFFFF (65535) is reserved for "uninitialized".

The **DATA** segment of the packet contains SIZE bytes, and the content depends on the type of the packet. In what follows we define the types of ETMS packets and the structure of their corresponding data.

2.1.3 Constants

Some constants are used in the communication protocol to indicate some states or key points in the protocol. The constants are based on the ASCII code characters.

Constants	Value	Description
ACK	0x0006	Acknowledge: Indicates a success of a request.
NAK	0x0015	Negative acknowledge: Indicates an error of a request.
NUL	0x00	NULL: Used to indicate invalid data or unavailable data.
MC	0xEFCDAB89	Magic number: Represents the magic number starting each packet.
SET (">")	0x003E	">": Used to indicate that the specified parameter is set, sub command type.
GET ("<")	0x003C	"<": Used to indicate that the specified parameter is requested, sub command type.
INFO ("=")	0x003D	"=": Used to indicate that the specified parameter is followed with Data, sub command.

Constants	Value	Description
UNINITIALIZED	0xFF, 0xFFFF, etc.	Uninitialized data: Used to indicate that a field was not initialized. This allows packet introspection (a packet can detect if it is valid or not)

Table 2: Constants

2.1.4 Sockets

The ETMS communication protocol uses 3 sockets:

- Control socket (bidirectional);
- Notification socket (client read-only);
- Data socket (client read-only).

The **control socket** should be used by the client to send requests to set or get parameters of the system, or to initiate an action. The server will then respond with an ACK packet if a SET request was successfully received, an INFO packet if a GET request was successful, or a NAK packet if the request failed. A PUID is used to link the request with the associated reply. Note that unless specified otherwise, every reply to a command on the control socket is expected to be replied to within 1 second after being processed. Note however that if sending N continuous packet, the 1-second timeout starts once the previous packet is processed. Therefore, sending 10 packets at once might take up to 10 seconds before the last one is replied to.

The **notification socket** is used by the server to send asynchronous packets when the internal state of the device changes. This could be the case when an unexpected error occurred, or when there is an update of a parameter. This socket is the mechanism to notify connected client(s) of critical values that are changed.

The **data socket** is used (and reserved) by the server to stream data from the device (e.g. EMG data).

2.1.5 Ports

The following ports are used by the system:

Control socket: 19213

Notification socket: 19214

Data socket: 19215

2.1.6 Workflow

Initialization State

State	Connection State	Dependency
Booted	Daemon is launched and no connection is granted.	None
Initialized USB	Daemon is attempting to established connection with the FPGA Once the daemon has established the connection with the FPGA, it will read the device configuration from the FPGA and accept packet from USB	USB
Initialized Socket	Daemon **accept client connection** and network packets. The following packet are sent when a new client connects to the daemon • PACKET_INFO_DEVICE_CONFIGURATION • PACKET_INFO_SYSTEM_STATE • PACKET_INFO_FIRMWARE_VERSION • PACKET_INFO_TEMPERATURE	Network
Initialized Finished	Daemon **accept client connection** packet with daemon and USB scope.	Client

Control Parameters

Example of a successful control packet

Control Socket	Notification Socket	Data Socket
-> PACKET_SET_CHARGE_STATUS	N/A	N/A
<- PACKET_INFO_ACK	N/A	N/A

Example of a failed control packet

Control Socket	Notification Socket	Data Socket
-> PACKET_SET_CHARGE_STATUS	N/A	N/A
<- PACKET_INFO_NAK	N/A	N/A

Asynchronous Notifications

Example of an asynchronous status packet

Control Socket	Notification Socket	Data Socket
N/A	<- PACKET_INFO_SYSTEM_STATE	N/A

Asynchronous Data

Example of an asynchronous data packet

Control Socket	Notification Socket	Data Socket
N/A	N/A	<- PACKET_INFO_HIGH_SPEED_MONITORING_DATA

Control Socket	Notification Socket	Data Socket
N/A	<- PACKET_INFO_SYSTEM_STATE	N/A

Setting up and executing a pulse sequence

Example of a successful pulse sequence

Control Socket	Notification Socket	Data Socket
-> PACKET_SET_PULSE_SEQUENCE		
-> PACKET_INFO_ACK		
-> PACKET_SET_CHARGE_STATUS		
-> PACKET_INFO_ACK		
	<- PACKET_INFO_SYSTEM_STATE	
-> PACKET_SET_PULSE_SEQUENCE_STATUS		
-> PACKET_INFO_ACK		

2.2 Packet specifications

2.2.1 Acknowledge (PACKET_INFO_ACK)

This packet is usually sent on the control socket in response of a PACKET_SET request.

<MC><SIZE><PUID><ACK><INFO>

2.2.2 Negative Acknowledge (PACKET_INFO_NAK)

This packet is usually sent on the control socket in response (failure) of a PACKET_SET_ or PACKET_GET_ request.

<MC><SIZE><PUID><NAK><INFO><ERROR><N><Param0>...<ParamN>

ERROR is an error code, encoded as an unsigned 32 bits integer. See Annex I for a list of supported error codes.

N is the number of optional parameters associated with the specific error code (encoded as an unsigned 32-bit integer). See Annex I for the number of optional parameters associated with a given error code.

ParamX is an optional parameter. Its type is defined in Annex I according to the specific error code.

2.2.3 Set Password (PACKET_SET_PASSWORD)

This packet is used to identify as an authorized client to the device.

<MC><SIZE><PUID><0x0034><SET><LENGTH><PASSWORD>

LENGTH is the length of the password, encoded as unsigned 32-bit.

PASSWORD is the password to identify, encoded as <length> of byte.

PACKET_INFO_ACK is returned if the password is accepted, PACKET_INFO_NAK otherwise.

2.2.4 Set Lock (PACKET_SET_LOCK)

This packet is used to identify as the lock administrator of the device, which grant greater access to the device. Only one client can have access to the lock at a time.

<MC><SIZE><PUID><0x002C><SET><STATUS>

STATUS is the status of the lock, 1 is to acquire the lock and 0 to release it, encoded as unsigned 32-bit.

PACKET_INFO_ACK is returned if the lock status was accepted, PACKET_INFO_NAK otherwise.

2.2.5 Set Pulse Sequence Status (PACKET_SET_PULSE_SEQUENCE_STATUS)

This packet is used to start/stop a pre-loaded pulse sequence.

<MC><SIZE><PUID><0x0102><SET><STATUS>

STATUS is 1 to start the previously loaded pulse sequence, 0 to stop it.

PACKET_INFO_ACK is returned if the pulse sequence can be started, PACKET_INFO_NAK otherwise.

2.2.6 Set Charge Status (PACKET_SET_CHARGE_STATUS)

This packet is used to enable/disable the charge on the stimulator. When charge status is enabled, any change to **POWER** or **MRATIO** will be updated automatically.

<MC><SIZE><PUID><0x0103><SET><STATUS>

STATUS is 1 to charge the stimulator, 0 to discharge it.

PACKET_INFO_SYSTEM_STATE can be used to monitor the current value of the charge status.

2.2.7 Set Power (PACKET_SET_POWER)

This packet is used to set the power of the next pulse/sequence to be executed, it's the same power as the one set by PACKET_SET_PULSE_SEQUENCE.

<MC><SIZE><PUID><0x0103><SET><POWER>

POWER is the target power value, in %, for the stimulator, encoded as double (64-bits), valid range is from 0 to 100.

2.2.8 Set Pulse Sequence (PACKET_SET_PULSE_SEQUENCE)

This packet is used to set the next pulse/sequence to be executed when the pulse sequence status is set to 1.

<MC><SIZE><PUID><0x0105><SET><OWNER_ID><POWER_0><MRATIO_0><POWER_1><MRATIO_1><ONSET><N_REP><REP_INT><N><TYPE_0>...

If <TYPE_0> is 0:

<ONSET><N_REP><REP_INT><N><TYPE_0>...

If <TYPE_0> is 1:

<ONSET_0><ISAUX_0><AUX_IDCODE_0><IS_REVERSED_0><POSITIVITY_0><NPHASE_0><T_0>...

OWNER_ID is a user provided ID that can be used to identify the pulse sequence.

Encoded as unsigned 8-bit.

POWER_i is the target power value, in %, for the ith stimulator (0-based), encoded as double (64-bit). Valid range is from 0 to 100.

MRATIO_i is the target M-Ratio value, in %, for the ith stimulator (0-based), encoded as double (64-bit). Valid range is [0.0 – 1.2].

ONSET is the onset in us at which the following item in the sequence will begin, encoded as double.

N_REP is the number of repetitions of the following sequence, encoded as unsigned 32-bit.

REP_INT is the interval in us between each repetition of the following sequence, encoded as double

N is the number of items in the following sequence, encoded as an unsigned 32-bit integer.

TYPE_i is the type of the ith item in the current sequence, encoded as unsigned 8-bit. It can be either 0 if the following item is another pulse sequence, or 1 if the following item is a pulse.

ONSET_i is the onset in us at which the ith pulse (or sequence) in the sequence will begin, encoded as double.

ISAUX_i is 1 if the pulse is to be delivered by an auxiliary stimulator, 0 if delivered by the master. Encoded as unsigned 8-bit.

AUX_IDCODE_i is the ID code of the auxiliary to deliver the pulse if **ISAUX_i** is 1. Encoded as unsigned 8-bit.

ISREVERSED_i is 1 if the pulse is to be delivered in the opposite current direction, 0 in normal direction. Encoded as unsigned 8-bit.

POSITIVITY_i indicates if the first phase of the pulse is positive (1), or negative (0). Encoded as an unsigned 8-bit integer.

NPHASE_i is the number of phases in the pulse (e.g. 1 for monophasic, 2 for biphasic) Encoded as unsigned 32-bit.

T_i is a series of durations for all phases of the pulse, in microseconds. It is encoded as double 64-bit. Therefore, if **NPHASE_i** is 4, then there are 4 x a double 64-bit values.

2.2.9 Info Pulse Sequence (PACKET_INFO_PULSE_SEQUENCE)

This packet is used to notify the pulse/sequence to be executed when the pulse sequence status is set to 1.

<MC><SIZE><PUID><0x0105><INFO><OWNER_ID><POWER_0><MRATIO_0><POWER_1><MRATIO_1><ONSET><N_REP><REP_INT><N><TYPE_0>...

If <TYPE_0> is 0:

<ONSET><N_REP><REP_INT><N><TYPE_0>...

If <TYPE_0> is 1:

<ONSET_0><ISAUX_0><AUX_IDCODE_0><IS_REVERSED_0><POSITIVITY_0><NPHASE_0><T_0>...

OWNER_ID is a user provided ID that can be used to identify the pulse sequence. Encoded as unsigned 8-bit.

POWER_i is the target power value, in %, for the ith stimulator (0-based), encoded as double (64-bit). Valid range is from 0 to 100.

MRATIO_i is the target M-Ratio value, in %, for the ith stimulator (0-based), encoded as double (64-bit). Valid range is [0.0 – 1.2].

ONSET is the onset in us at which the following item in the sequence will begin, encoded as double.

N_REP is the number of repetitions of the following sequence, encoded as unsigned 32-bit.

REP_INT is the interval in us between each repetition of the following sequence, encoded as double

N is the number of items in the following sequence, encoded as an unsigned 32-bit integer.

TYPE_i is the type of the ith item in the current sequence, encoded as unsigned 8-bit. It can be either 0 if the following item is another pulse sequence, or 1 if the following item is a pulse.

ONSET_i is the onset in us at which the ith pulse (or sequence) in the sequence will begin, encoded as double.

ISAUX_i is 1 if the pulse is to be delivered by an auxiliary stimulator, 0 if delivered by the master. Encoded as unsigned 8-bit.

AUX_IDCODE_i is the ID code of the auxiliary to deliver the pulse if **ISAUX_i** is 1. Encoded as unsigned 8-bit.

ISREVERSED_i is 1 if the pulse is to be delivered in the opposite current direction, 0 in normal direction. Encoded as unsigned 8-bit.

POSITIVITY_i indicates if the first phase of the pulse is positive (1), or negative (0). Encoded as an unsigned 8-bit integer.

NPHASE_i is the number of phases in the pulse (e.g. 1 for monophasic, 2 for biphasic) Encoded as unsigned 32-bit.

T_i is a series of durations for all phases of the pulse, in microseconds. It is encoded as double 64-bit. Therefore, if **NPHASE_i** is 4, then there are 4 x a double 64-bit values.

2.2.10 Info Device Configuration (PACKET_INFO_DEVICE_CONFIGURATION)

This packet is sent on the notification socket by the server to all authorized clients when the device's internal or external configuration changes.

<MC><SIZE><PUID><0x0108><INFO><ID><N><INTERNAL_CONFIGURATION><N><EXTERNAL_CONFIGURATION><N><CONTROLLER_CONFIGRATION><N><POWERSUPPLY_CONFIGURATION><N><STIMULATOR_CONFIGURATION>

ID is the device ID from which the configuration is coming from. Encoded as an unsigned 8-bit integer.

N is the number of bytes read from the internal configuration. Encoded as an unsigned 16-bit integer.

INTERNAL_CONFIGURATION is a series of bytes read from the internal device's configuration. See ETMS-SPEC-ConfigurationFormat.

N is the number of bytes read from the external configuration. Encoded as an unsigned 16-bit integer.

EXTERNAL_CONFIGURATION is a series of bytes read from the external device's configuration. See ETMS-SPEC-ConfigurationFormat.

N is the number of bytes read from the controller configuration. Encoded as an unsigned 16-bit integer.

CONTROLLER_CONFIGURATION is a series of bytes read from the controller device's configuration. See ETMS-SPEC-ConfigurationFormat.

N is the number of bytes read from the power supply configuration. Encoded as an unsigned 16-bit integer.

POWERSUPPLY_CONFIGURATION is a series of bytes read from the power supply device's configuration. See ETMS-SPEC-ConfigurationFormat.

N is the number of bytes read from the stimulator configuration. Encoded as an unsigned 16-bit integer.

STIMULATOR_CONFIGURATION is a series of bytes read from the power supply device's configuration. See ETMS-SPEC-ConfigurationFormat.

2.2.11 Info System State (PACKET_INFO_SYSTEM_STATE)

This packet is used by the server to notify connected clients of the system state. It is sent to authorised clients periodically every second on the notification socket.

<MC><SIZE><PUID><0x01A0><INFO><HW_STATES><HW_FAULTS><FW_STATES>

HW_STATES is an unsigned 64-bit integer value, where each bit is used to represent a different state of the hardware part of the system. (refer to ETMS-SPEC-SystemStatesAndFaults).

HW_FAULTS is an unsigned 64-bit integer value, where each bit is used to represent a different fault of the hardware part of the system. (refer to ETMS-SPEC-SystemStatesAndFaults).

FW_STATES is an unsigned 64-bit integer value, where each bit can be used to represent a different state of the firmware part of the system.

- **B0**: 1 when the USB connection is successfully initialized, 0 otherwise.
- **B1**: 1 when the daemon system cache has been synchronized with FPGA values, 0 otherwise.
- **B2**: 1 when the daemon has successfully sent all PACKET_INFO required by the client (the bit is unique per client), 0 otherwise.
- **B3**: ID-Code (bit 0) that specifies the pulse sequence ID.
- **B4**: ID-Code (bit 1) that specifies the pulse sequence ID.
- **B5**: ID-Code (bit 2) that specifies the pulse sequence ID.
- **B6**: ID-Code (bit 3) that specifies the pulse sequence ID.
- **B7**: ID-Code (bit 4) that specifies the pulse sequence ID.
- **B8**: ID-Code (bit 5) that specifies the pulse sequence ID.
- **B9**: ID-Code (bit 6) that specifies the pulse sequence ID.
- **B10**: ID-Code (bit 7) that specifies the pulse sequence ID.

2.2.12 Info Temperature (PACKET_INFO_TEMPERATURE)

This packet is used by the server to send the current reading to the temperature sensors to all connected clients on the notification socket. This packet is sent periodically every second to connected clients with authorized password.

<MC><SIZE><PUID><0x01A1><INFO><N><T0>...<TN>

This packet is sent periodically every second.

N is the number of temperature sensors (should be 15), encoded as an unsigned 32-bit integer.

T0 is the temperature (Celsius) from the 1st powertrain temperature sensor, encoded as float.

T1 is the temperature (Celsius) from the 2nd powertrain temperature sensor, encoded as float.

T2 is the temperature (Celsius) from the 3rd powertrain temperature sensor,

encoded as float.

T3 is the temperature (Celsius) from the 4th powertrain temperature sensor, encoded as float.

T4 is the temperature (Celsius) from the 5th powertrain temperature sensor, encoded as float.

T5 is the temperature (Celsius) from the 6th powertrain temperature sensor, encoded as float.

T6 is the temperature (Celsius) from the 7th powertrain temperature sensor, encoded as float.

T7 is the temperature (Celsius) from the 8th powertrain temperature sensor, encoded as float.

T8 is the temperature (Celsius) from the 1st power supply temperature sensor, encoded as float.

T9 is the temperature (Celsius) from the 2nd power supply temperature sensor, encoded as float.

T10 is the temperature (Celsius) from the 3rd power supply temperature sensor, encoded as float.

T11 is the temperature (Celsius) from the 1st coil temperature sensor, encoded as float.

T12 is the temperature (Celsius) from the 2nd coil temperature sensor, encoded as float.

T13 is the relative humidity level (%) from the powertrain humidity sensor, encoded as float.

T14 is the relative humidity level (%) from the controller humidity sensor, encoded as float.

2.2.13 Data High-Speed Monitoring (PACKET_DATA_HIGH_SPEED_MONITORING)

This packet is used by the server to send the current reading to the high-speed monitoring to all connected clients on the data socket.

<MC><SIZE><PUID><0x01D0><INFO><IDX><DATA>

This packet is sent only during/after pulses with the monitoring data recorded during a pulse.

IDX is the index of the pulse in the current sequence, encoded as unsigned 16-bit.

DATA is a series of values, encoded as unsigned 16-bit.

2.2.14 Info High Voltage Monitoring (PACKET_INFO_HIGH_VOLTAGE_MONITORING)

This packet is sent on the notification socket by the server to the primary simulator when info high voltage monitoring serial packet is received by the server.

<MC><SIZE><PUID><0x01D2><INFO><VC1><VC2><Filtered_VC1><Filtered_VC2>

VC1 is the measured value of VC1, encoded as double.

VC2 is the measured value of VC2, encoded as double.

Filtered_VC1 is the processed and averaged measured value of VC1, used to regulate the power supply, encoded as double.

Filtered_VC2 is the processed and averaged measured value of VC2, used to regulate the power supply, encoded as double.

2.2.15 Monitoring Data (PACKET_DATA_MONITORING)

This packet is sent on the data socket by the server to the primary simulator when monitoring status is set to 1. Packet is then sent at 5kHz.

<MC><SIZE><PUID><0x01D3><DATA><TIMESTAMP><VC1><VC2><EMG0><EMG1>

TIMESTAMP is an incremental timestamp that can be used to identify any missing packets (e.g. overflow). It is encoded as unsigned 32-bit.

VC1 is the measured value of VC1, encoded as double.

VC2 is the measured value of VC2, encoded as unsigned 16-bit.

EMG0 is the processed and averaged measured value of VC1, used to regulate the power supply, encoded as unsigned 16-bit.

EMG1 is the processed and averaged measured value of VC2, used to regulate the power supply, encoded as unsigned 16-bit.

2.2.16 Set Monitoring Status (PACKET_SET_MONITORING_STATUS)

<MC><SIZE><PUID><0x01D4><SET><STATUS>

This packet is used to allow/disallow the FPGA to send monitoring packet.

STATUS is 1 to allow FPGA Board to send monitoring data packet. 0 to disallow. Encoded as unsigned 8-bit.

2.2.17 Info Firmware Version (PACKET_INFO_FIRMWARE_VERSION)

<MC><SIZE><PUID><0x0109><INFO><IDCODE><MAJOR><MINOR><PATCH>

This packet is used to send the firmware version of a given device.

IDCODE is the ID code of the device, encoded as unsigned 8-bit.

MAJOR is the major version of the device firmware version, encoded as unsigned 32-bit.

MINOR is the minor version of the device firmware version, encoded as unsigned 32-bit.

PATCH is the patch version of the device firmware version, encoded as unsigned 32-bit.

2.2.18 Info Client List (PACKET_INFO_CLIENT_LIST)

<MC><SIZE><PUID><0x01D7><INFO><N><LENGTH_N><HOSTNAME_N>

This packet is used to send the list of clients connected to the device.

N is the number of clients connected to the device, encoded as unsigned 32-bit.

LENGTH_N is the length of the hostname N, encoded as unsigned 32-bit.

HOSTNAME_N is the hostname of client N, encoded as LENGTH_N of unsigned 8-bit.

Error Code	Description
0	**ERROR_UNDEFINED** Undefined error code.
1	**ERROR_INVALID_COMMAND_ID** Usually used when a packet is received on the control socket with an unsupported command ID.
2	**ERROR_INVALID_SUB_COMMAND** Usually used when a packet is received on the control socket with an unsupported sub-command.
3	**ERROR_INVALID_PUID** Indicates an invalid PUID (0) value received on the control socket.

Error Code	Description
4	**ERROR_SYSTEM_NOT_INITIALISED** Indicates that the system is not ready to process any packets from a client.
5	**ERROR_NOT_AUTORISED** Indicates that the received packet cannot be processed because the client didn't previously send a successful PACKET_SET_PASSWORD packet.
6	**ERROR_LOCK_REQUIRED** Indicates that the received packet cannot be processed because it requires a lock status to be processed.
7	**ERROR_SYSTEM_ALREADY_LOCKED** Usually used in reply of a PACKET_SET_ADMIN_LOCK when the lock status is already taken by another client.
8	**ERROR_INVALID_PASSWORD** Usually used in reply of a PACKET_SET_PASSWORD packet to indicate that the given password is invalid.
9	**ERROR_INVALID_POWER** Usually used in reply of a PACKET_SET_POWER packet to indicate a power value out of the expected range [0-100].
10	**ERROR_INVALID_MRATIO** Usually used in reply of a PACKET_SET_MRATIO packet to indicate a value out of the expected range [0-1.2].

Error Code	Description
11	**ERROR_INVALID_PULSE_SEQUENCE_STATUS** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE_STATUS packet to indicate a status value out of range (0 or 1).
12	**ERROR_NO_PULSE_SEQUENCE** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE_STATUS packet with STATUS to 1 when there is no valid pulse sequence to perform.
13	**ERROR_CHARGE_NOT_ENABLED** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE_STATUS when STATUS is 1 but the stimulator charge is not enabled.
14	**ERROR_NOT_READY** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE_STATUS when STATUS is 1 but the stimulator is not ready.
15	**ERROR_INVALID_CHARGE_STATUS** Usually used in reply to a PACKET_SET_CHARGE_STATUS packet to indicate a status value out of range (0 or 1).
16	**ERROR_INVALID_EMG_DATA_STATUS** Usually used in reply to a PACKET_SET_EMG_DATA_STATUS packet to indicate a status value out of range (0 or 1).
17	**ERROR_INVALID_PULSE_SEQUENCE** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE packet to indicate that the given pulse sequence contains invalid parameters.

Error Code	Description
18	**ERROR_UNSUPPORTED_PULSE_SEQUENCE** Usually used in reply to a PACKET_SET_PULSE_SEQUENCE packet to indicate that the given pulse sequence is not supported by the system.
19	**ERROR_INVALID_EXTERNAL_DEVICE_CONFIGURATION** Usually used in reply to a PACKET_SET_COIL_CONFIGURATION to indicate that the given coil's configuration contains invalid parameters.
20	**ERROR_INVALID_INTERNAL_DEVICE_CONFIGURATION** Usually used in reply to a PACKET_SET_POWERTRAIN_CONFIGURATION to indicate that the given powertrain's configuration contains invalid parameters.

Table 3: Error codes

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