ELEVATETMS

USER MANUAL

for model

CTMS001

Hardware v1.3.7, Firmware v2.10.0

July 2023

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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

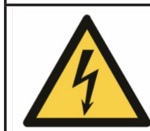
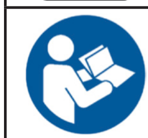
4. ACRONYMS AND ABBREVIATIONS

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

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.

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.
	Do not trash. Dispose of this product according to the disposal instructions described in this manual.
	Consult the User Manual
	Type BF applied part
	Earth Terminal Ground

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.

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 the user is not meant to wear any protective equipment while operating the device. It is recommended that the subject 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 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 other medical devices. 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 should 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.
i	The control software is developed using a quality management system to ensure safety and performance within the specifications. Updates to the control software will 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.
i	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. 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 the coil temperature exceeds 41˚C

	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 Ethernet port currently does not support any end-user applications and should only be used under the direction of Rogue Research.
	The operator shall not leave the subject alone while being stimulated.
	Caution: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.
	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. If necessary the system should be moved by two people and it 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.

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.

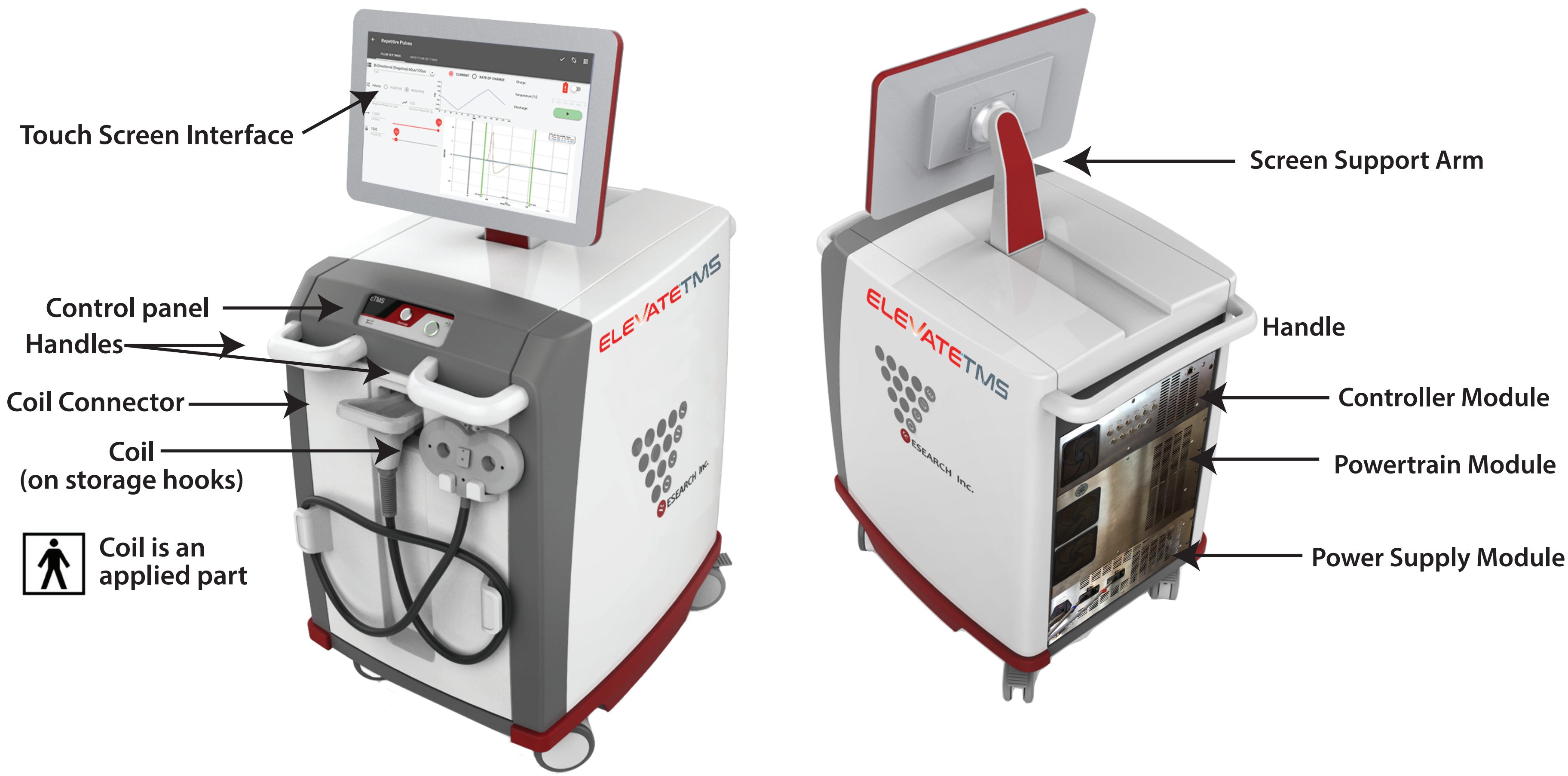


Fig. 1-1: **cTMS device overview**

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 100/120/220/240 VAC, 50-60Hz (selector switch on rear panel), current: 2A at 100VAC, 1.7A at 120VAC, 0.9A at 220VAC, 0.8A at 240VAC , 100 Watts (nominal), 120W (max)
- Charging power supply input PS1: 220-240 VAC, 20A, 1500 Watts (nominal), 3500W (max).
- Charging power supply input PS2: 220-240 VAC, 20A, 1500 Watts (nominal), 3000W (max).

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

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.

12.2 General system specifications

The display touch screen can be tilted from +15º to -5º from the vertical position.

Maximum Peak Coil Current	+/-7 kA
Maximum Voltage VC1 limit	2750 V
Maximum Voltage VC2 limit	1175 V

12.3 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.

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. 2-10). Click on the icon to view the status screen and note the fault (will be highlighted in yellow). **If a fault is noted, discontinue use and contact Rogue Research for assistance.**

15. KNOWN ISSUES:

- In Multi pulse page, the inter-pulse interval can be edited during a pulse sequence. *Note: it will not affect the ongoing pulse sequence
- In Settings page, connecting a USB key after pressing the save logs button might cause a GUI crash.

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

Discharge relay 2 fault 1 when a fault is detected on discharge relay 2, 0 otherwise.	1
Power 12V fault 1 when a fault is detected on power 12V, 0 otherwise.	1
Power -12V fault 1 when a fault is detected on power -12V, 0 otherwise.	1
Power 15V fault 1 when a fault is detected on power 15V, 0 otherwise.	1
Power 3.3V fault 1 when a fault is detected on power 3.3V, 0 otherwise.	1
Power 5V fault 1 when a fault is detected on power 5V, 0 otherwise.	1
Expected Coil Overheat 1 when the coil is expected to overheat during pulse sequence.	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

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

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

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

PSU-1A overvoltage 1 when PSU-1A is in overvoltage, 0 in normal mode.	1
PSU-1B overvoltage 1 when PSU-1B is in overvoltage, 0 in normal mode.	1
PSU-2A overvoltage 1 when PSU-2A is in overvoltage, 0 in normal mode.	1
PSU-2B overvoltage 1 when PSU-2B is in overvoltage, 0 in normal mode.	1

PSU-1A overheat 1 when PSU-1A is overheating, 0 in normal mode.	1
PSU-1B overheat 1 when PSU-1B is overheating, 0 in normal mode.	1
PSU-2A overheat 1 when PSU-2A is overheating, 0 in normal mode.	1
PSU-2B overheat 1 when PSU-2B is overheating, 0 in normal mode.	1

Chapter 2: Setting up the Elevate TMS Device

1. INTRODUCTION

This chapter will cover the setup and basic operation of the Elevate TMS system. 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 screw-driver 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. 2-1 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.

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.

3. ASSEMBLY

The device is shipped as a unit with the touch-screen removed. Assembly consists of mounting and connecting the screen to the main unit chassis, connecting a coil and then connecting the unit to the mains.

You will need one of the included hex keys as well as a small wrench (not included).

3.1 Mounting and connecting the touch screen

The touch screen monitor is attached to the main unit using 4 screws (found in the accessory box) and hex key.

- Carefully hold the monitor overt the top of the chassis (see Fig. 2-4). Line up the 4 mounting holes of the monitor base with the 4 holes of the chassis.

: **Package contents with wrapping (not to scale)**

Fig. 2-3: **Main chassis with handle protectors (yellow circles)**

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 monitor cable to the appropriate receptacle in the rear of the monitor (Fig. 2-5).
- 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 Elevate TMS device includes three power cables. One to supply power to the controller module and the others to power the capacitor chargers (Fig. 2-7). It is recommended that the plugs be connected into independent circuits with sufficient capacity according to the specifications listed in “12. Specifications” on page 7. Notably, the device is certified and will operate with maximum performance when both capacitor power inputs are connected to 220-240v 20A

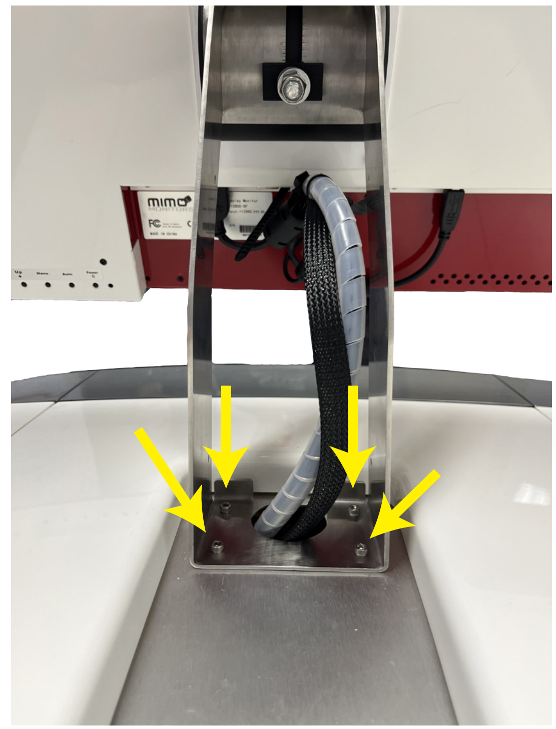


Fig. 2-4: **Monitor mount on the chassis. Mounting screws are highlighted by the yellow circles.**

outlets. Note the connector for the controller module power cable has a switch and an input voltage selector. Make sure the selector is set to the correct input voltage prior to connecting it to the power source (mains). Once conformed, turn the switch on. The touch screen may momentarily turn on and display a logo from the screen manufacturer, then go dark until the cTMS is turned on from the front panel.

3.3 Preparing the coil

Plug in the coil by inserting the connector into the receptacle (Fig. 2-8). Note that some force may be required to insert it fully. 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. 2-9). 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. 2-10), 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. 2-11). 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

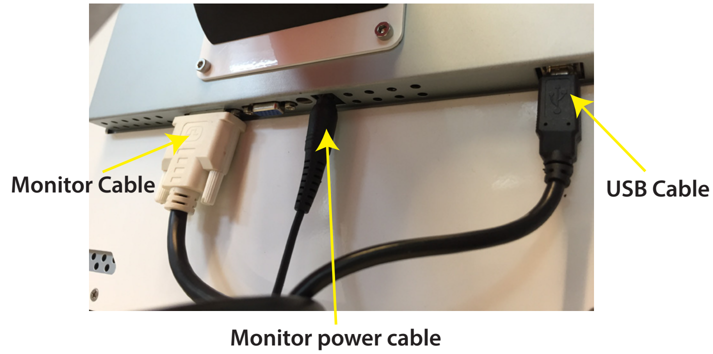


Fig. 2-5: **CTMS001 monitor connections.**

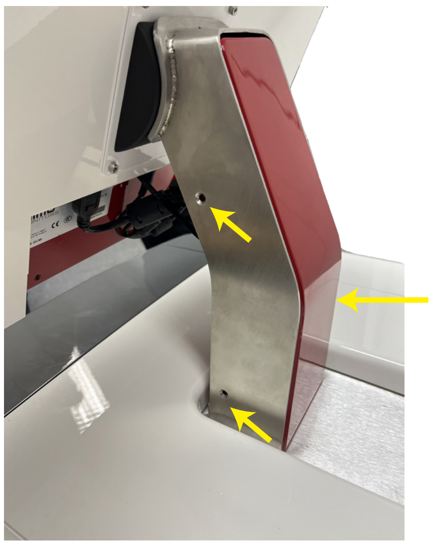


Fig. 2-6: **Monitor neck insert**

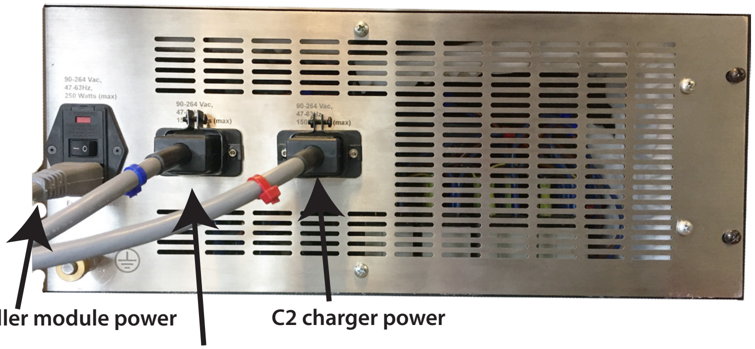


Fig. 2-7: **Closeup of the power module panel.**

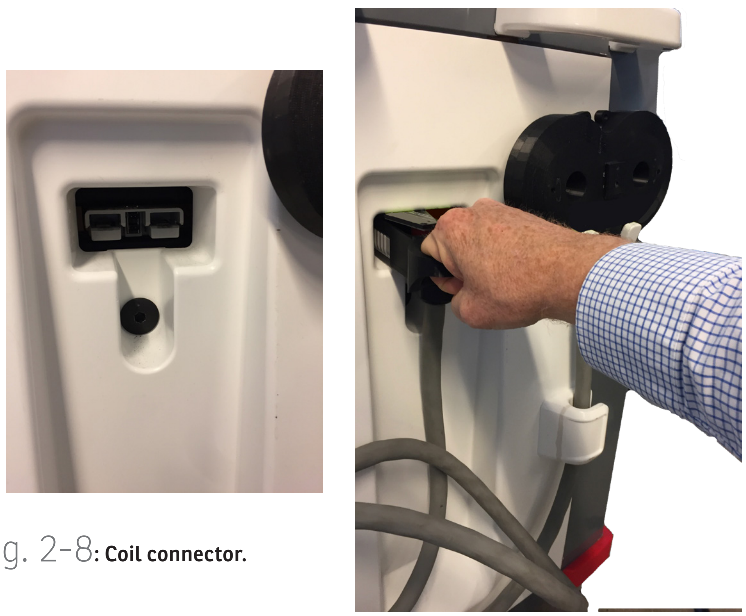


Fig. 2-8: **Coil connector.**

and manufacture date (Fig. 2-12).

4.2 Updating the system firmware

The software running the device is designed to enable you to create 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. 2-13). Tap Firmware Update to open the firmware update window (Fig. 2-14).
- Select the firmware you wish to apply and 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 shut down. Reboot the device by pushing the Startup button on the main control panel.

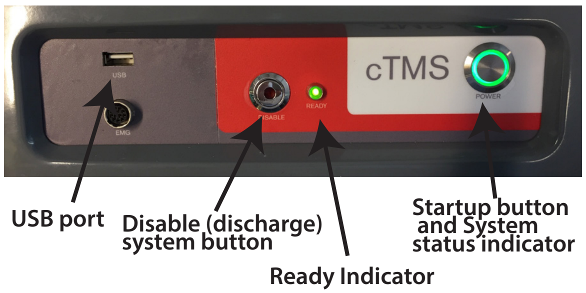


Fig. 2-9: **Main control panel**

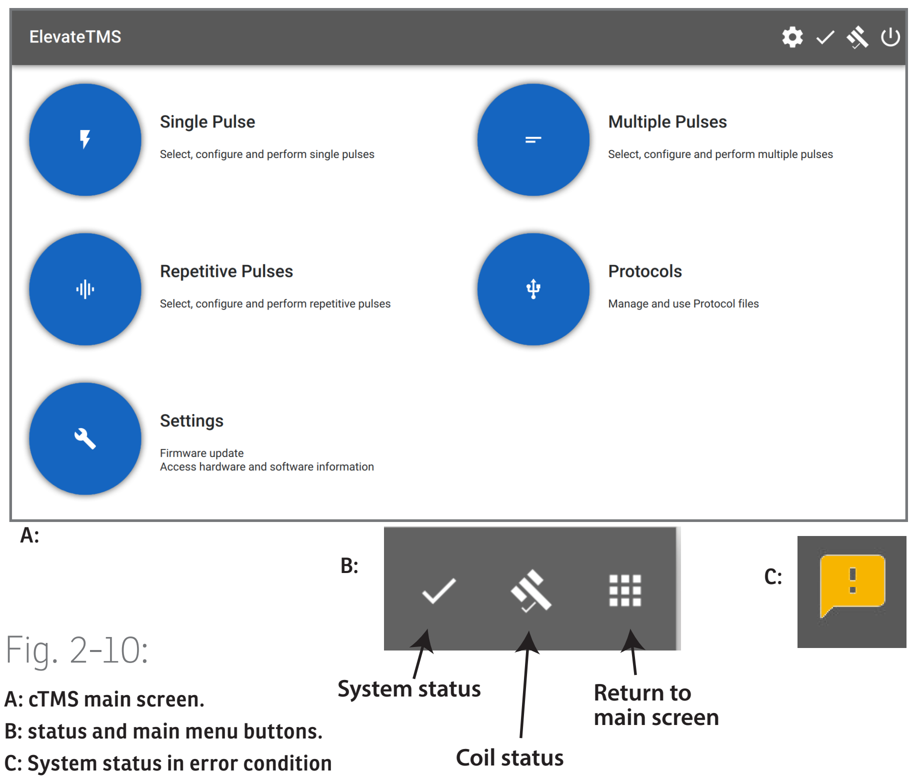


Fig. 2-10:

A: cTMS main screen.

B: status and main menu buttons.

C: System status in error condition

4.3 Saving system logs

The Elevate TMS 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 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 Elevate TMS device has several general purpose input/output (GPIO) ports to allow for complex scenarios of I/O (Fig. 2-15), 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.

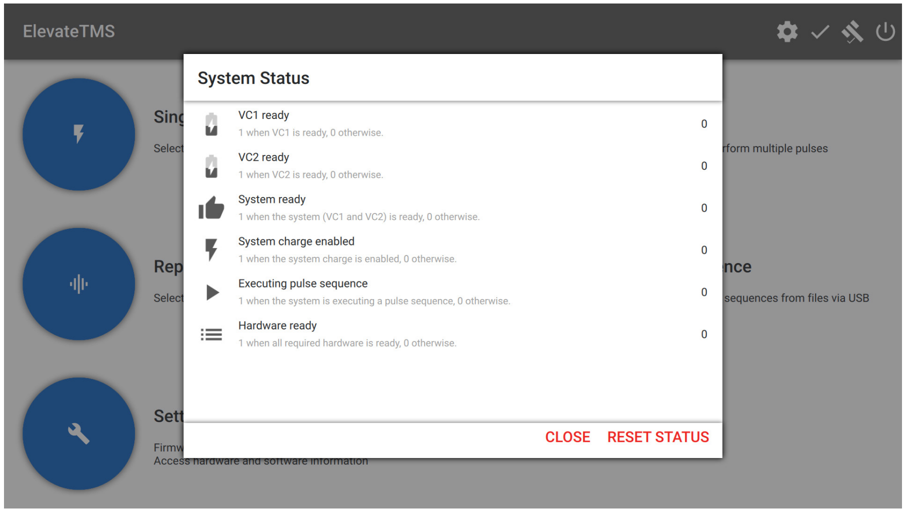


Fig. 2-11: **System status screen. Scroll down to view all items.**

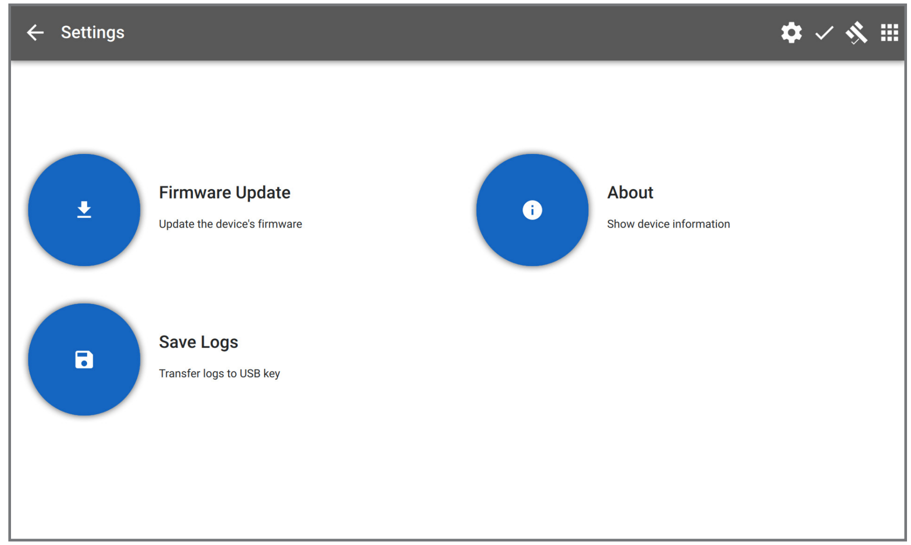


Fig. 2-13: **Settings main menu screen.**

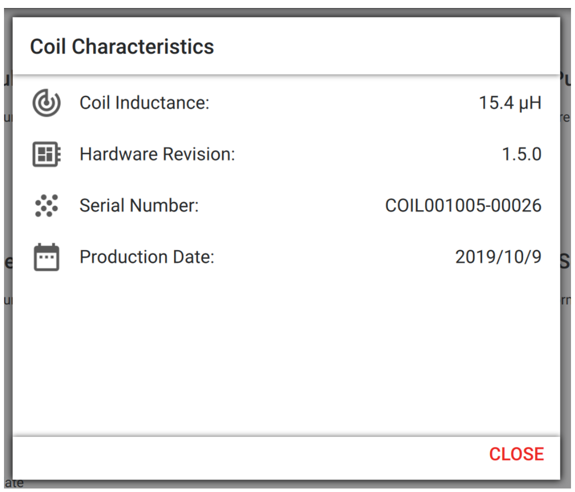


Fig. 2-12: **Coil status display.**

Fig. 2-14: **Firmware update screen.**

Switch 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. This can be used to trigger data acquisition (e.g. EMG or neuronavigation).

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 wasn't ready to trigger.
- A TTL 1 from the GPtrig OUT2 indicates the sent pulse was decayed.
- A TTL 1 from the GPtrig OUT3indicates the sent pulse was unbalanced.

*** The last three 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.

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. 2-16 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. 2-17) 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

Fig. 2-15: **Trigger I/O panel**

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 monophasic (if not already selected) and tap **OK**.
- Select **Positive** waveform. While observing the waveform display, tap **Negative** and the **Positive** 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 1 by sliding the M-ratio slider to 1.0. 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. 2-18). After a second or two, the status should change to charge.
- Take the coil out of the holder and hold it away from anything. Tap the discharge button or step on the foot switch 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

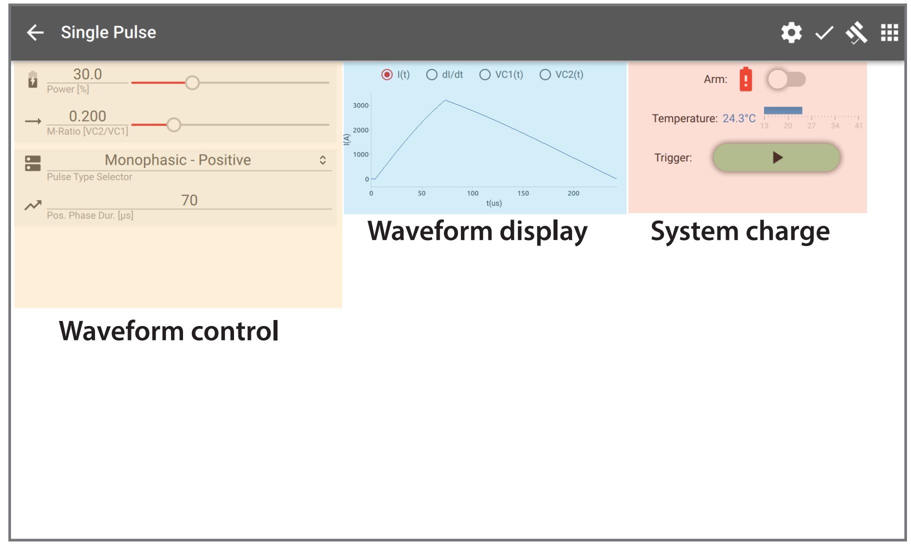


Fig. 2-16: **Single pulse screen**

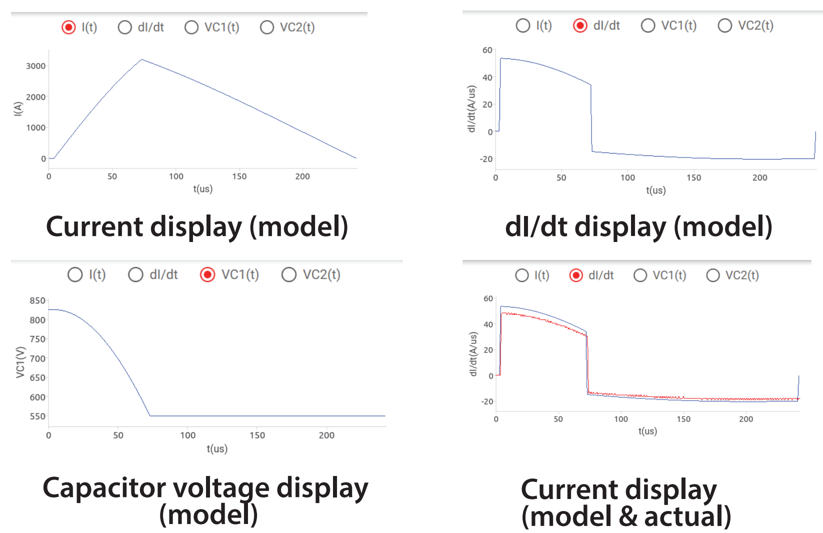


Fig. 2-17: **Pulse waveform display**

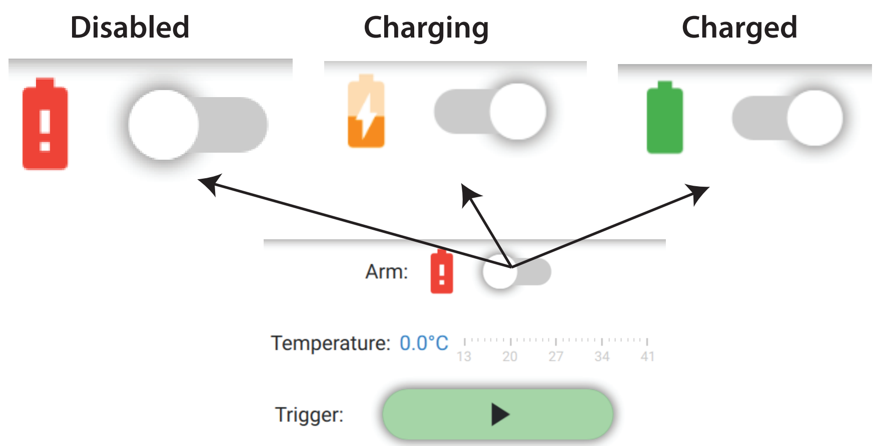


Fig. 2-18: **Charge status control. Left: System is discharged. Middle: System is charging. Right: System is charged and can be fired using the foot switch, coil trigger button or tapping the discharge button.**

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.

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 Elevate TMS 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 Elevate TMS device alone.

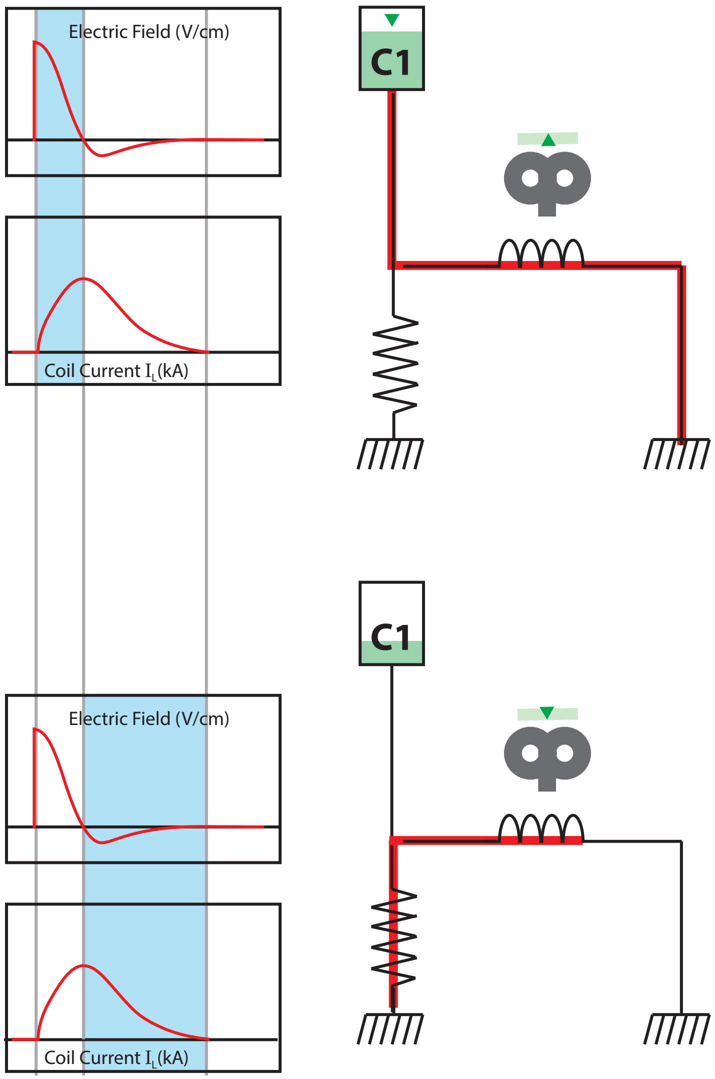


Fig. 3-1: **Monophasic TMS illustration**

2. TRADITIONAL TMS

2.1 Monophasic TMS

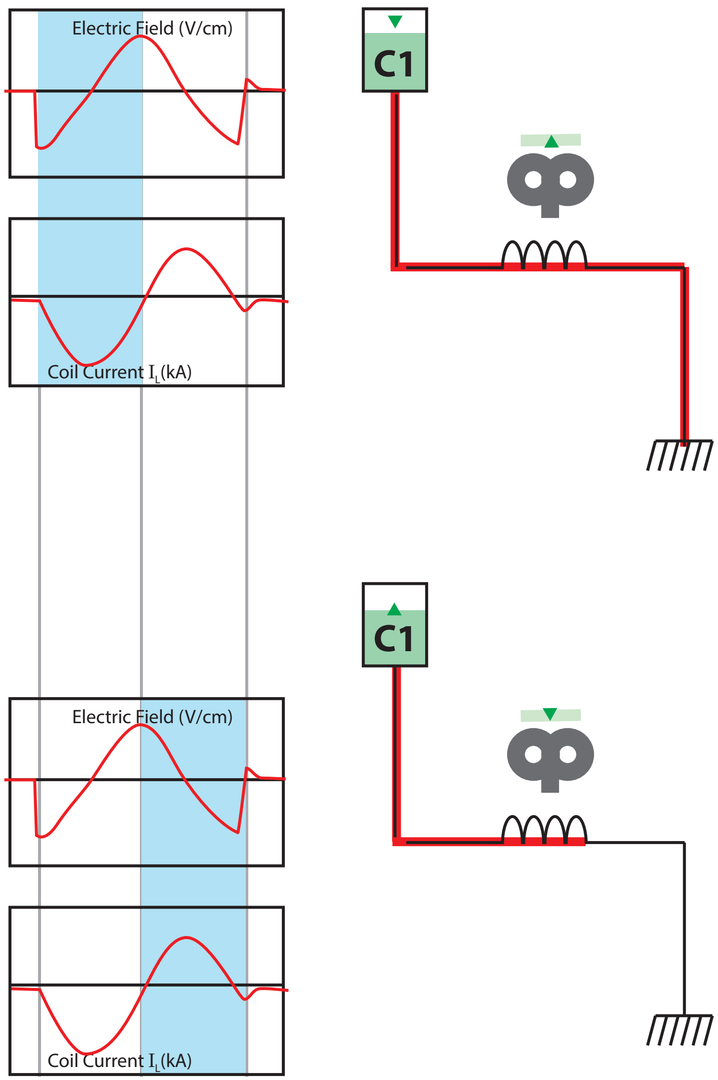
Monophasic TMS was the first and is the simplest form of TMS. The device essentially consists of a single capacitor, a thyristor switch, the coil and a discharge resistor. A charging circuit charges the capacitor. When the coil is fired, the capacitor discharges through the coil to the ground. Electrically, 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.

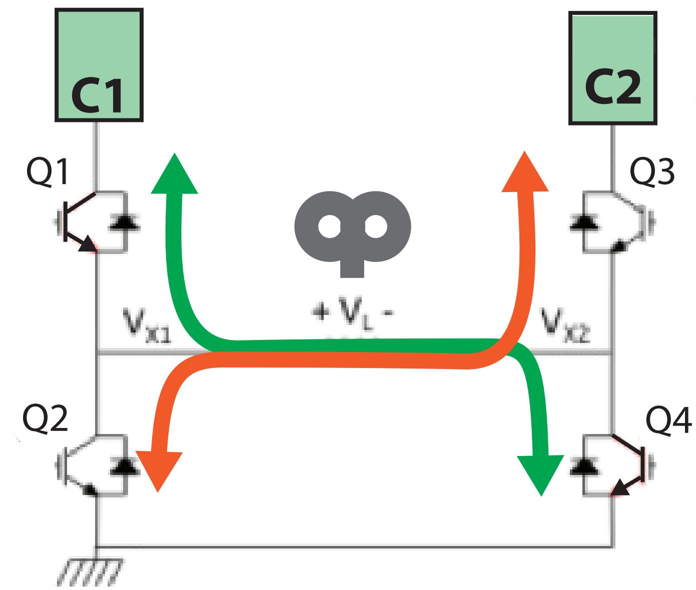
In order to describe this, some new terms are required to describe the new parameters that can be manipulated.

VC1, VC2: The voltages of the two capacitors

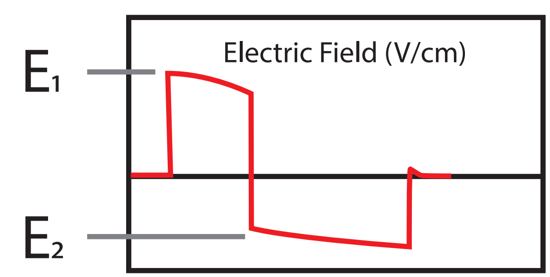
IGBT: Insulated-gate bipolar transistors: The electronic switches that connect the capacitors to the coils.

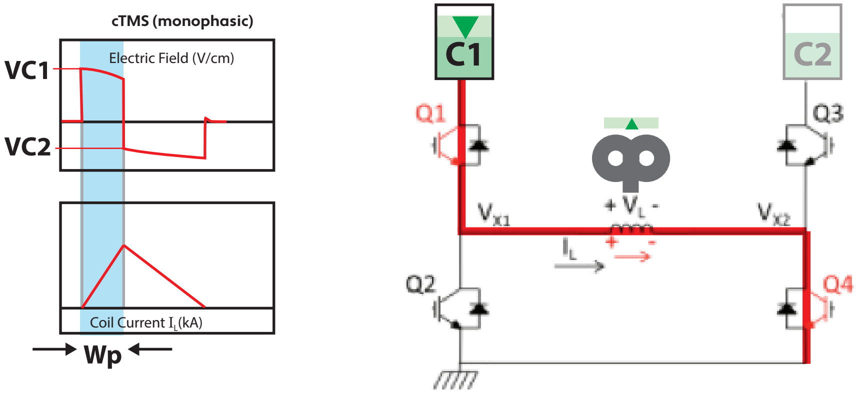
Pulse width (or duration): The duration of a particular phase of the pulse. In biphasic pulses, there will be a positive phase duration and a negative phase duration.

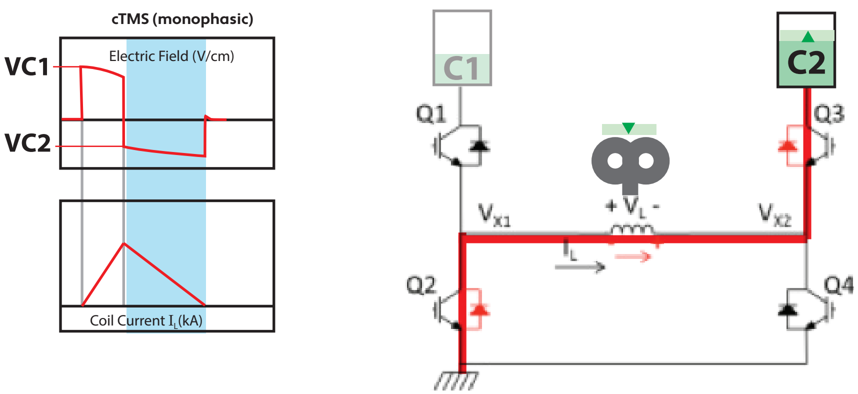
M-ratio: An important new parameter that describes the relative amplitudes of each phase of the pulse. It is **the ratio of the -ve capacitor voltage to the +ve capacitor voltage** which is related electric field amplitude of the negative phase divided by the electric field amplitude of the positive 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.



cTMS (monophasic)







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.

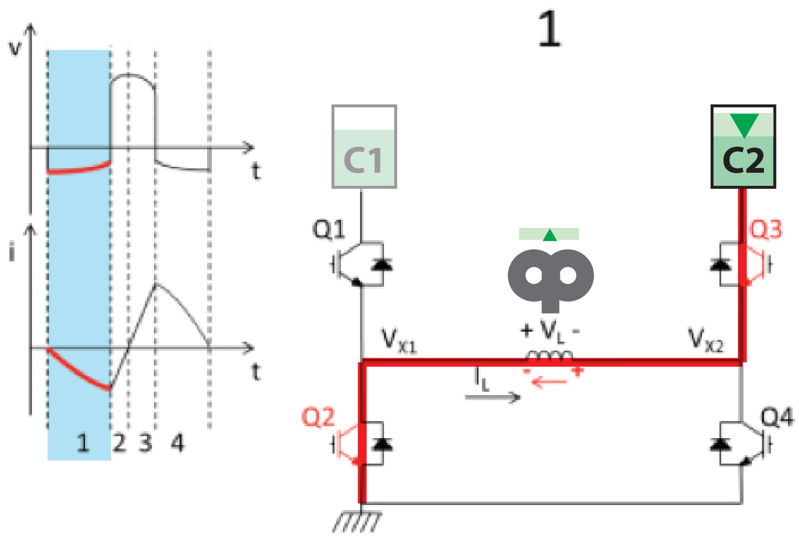
In the first phase, Q1 and Q4 are opened. C1 now has a discharge path through Q1 to the coil and through Q4 to ground. As C1 discharges, some of the energy is converted to magnetic potential in the coil. The duration that C1 is allowed to discharge is controllable, so the intensity is set by setting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

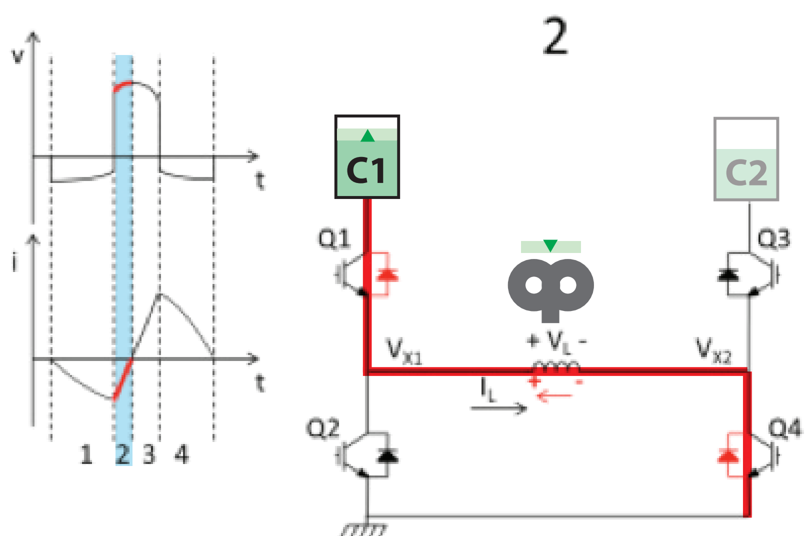
The second phase is started by closing Q1 & Q4. The coil becomes connected to C2 via 2 diodes that are in parallel with Q2 & Q3. This allows the coil's energy to be discharged into C2 until all the energy has been dissipated.

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.

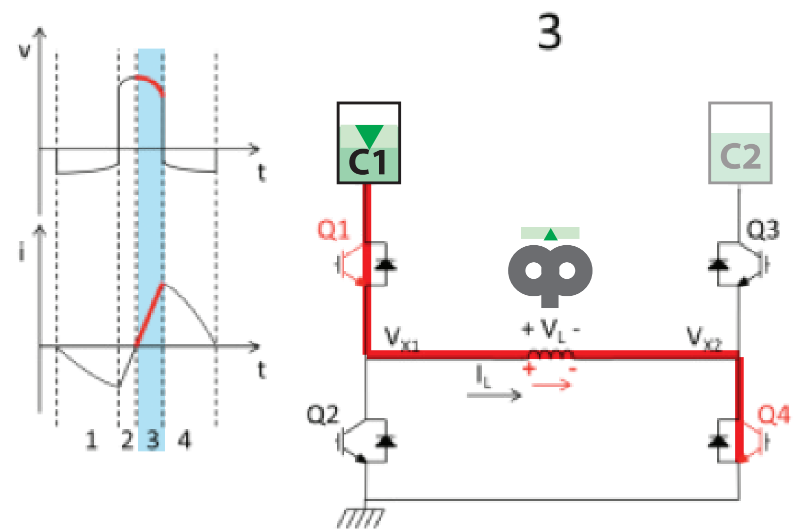
In the example on the left, the pulse starts (phase 1) by opening Q2 & Q3 to allow C2 to discharge through the coil to ground. The negative phase duration sets the width of the first phase of the pulse.

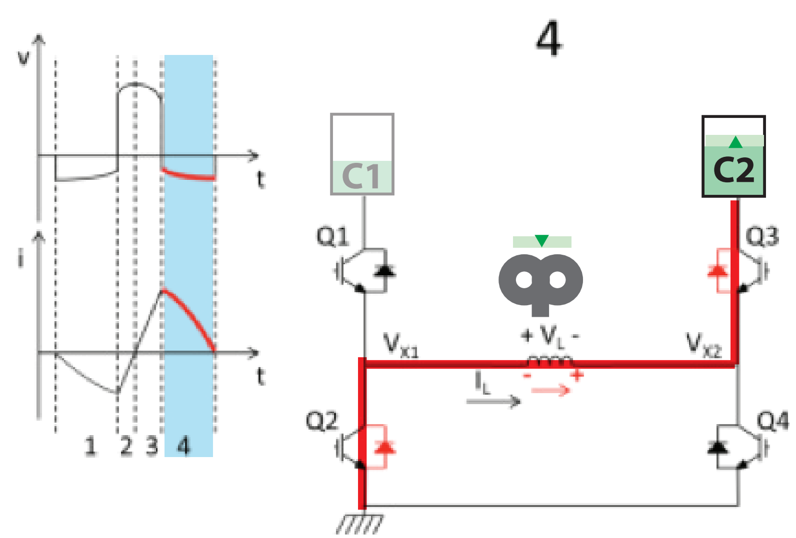
Phase 2 closes Q2 & Q3 and allows the coil's energy to be sent into C1. Note that VC1 goes up slightly as the coil current heads to 0. Up to now, this is identical to a negative monophasic pulse.

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.





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 th order of minutes of 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 6: 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.

Since these pulses have been pretested to ensure that they are balanced, parameters that are normally accessible in single-pulse mode are locked to ensure that they remain balanced.

- 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**).

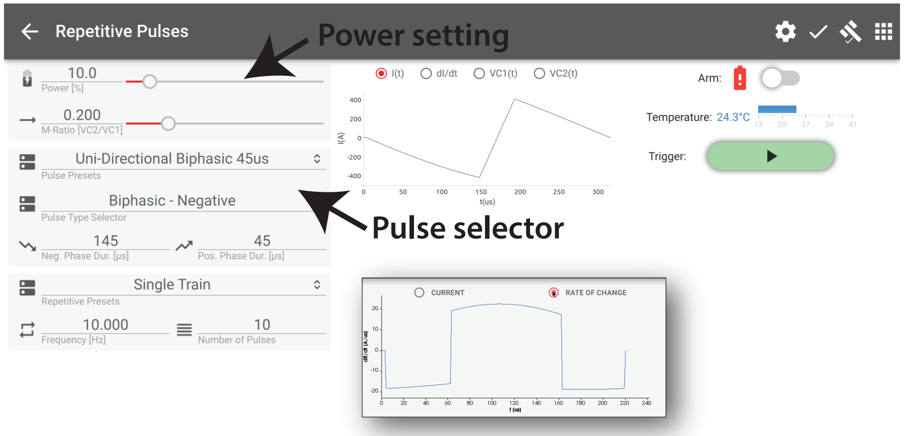


Fig. 4-1: **Repetitive pulse selection screen.** Note the ability to switch the pulse shape display from current to rate of change (inset).

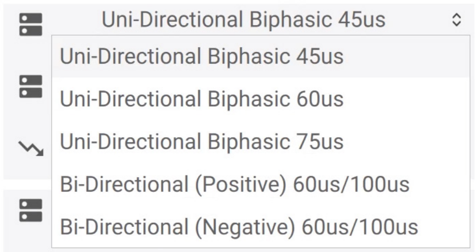


Fig. 4-2: **Currently available pulse list.**

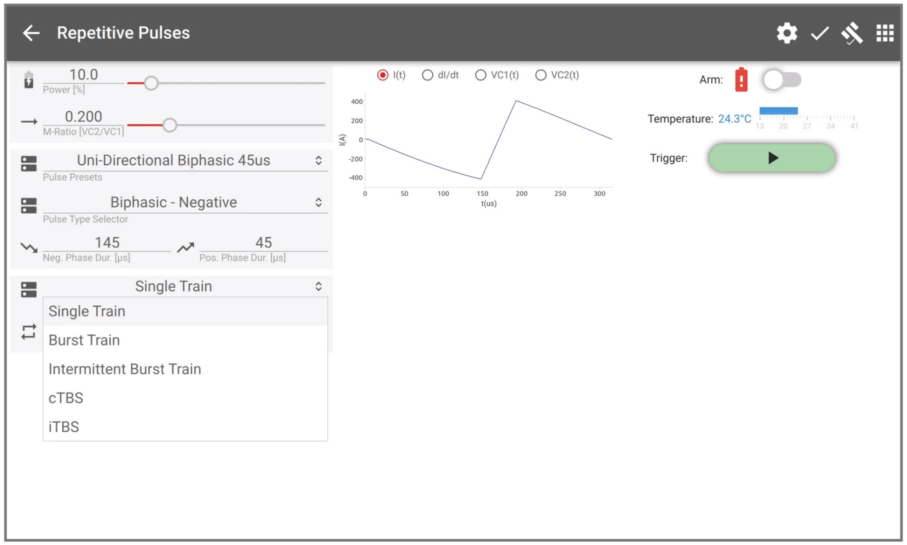


Fig. 4-3: **Repetitive Settings screen.**

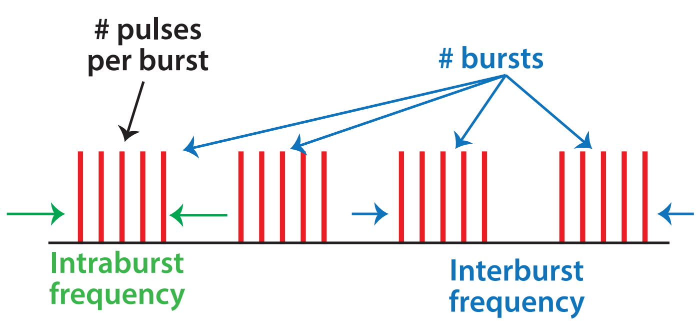


Fig. 4-4: **Illustration describing the parameters to define a repetitive TMS sequence.**

2.2 Entering the repetition settings

Once you have selected the pulse, you can enter the repetition settings.

- Tap **REPETITION SETTINGS** to move to the repetition settings screen (Fig. 4-3).

The meanings of the parameters used to define the repetitive sequence is illustrated in 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. 2-4).

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.

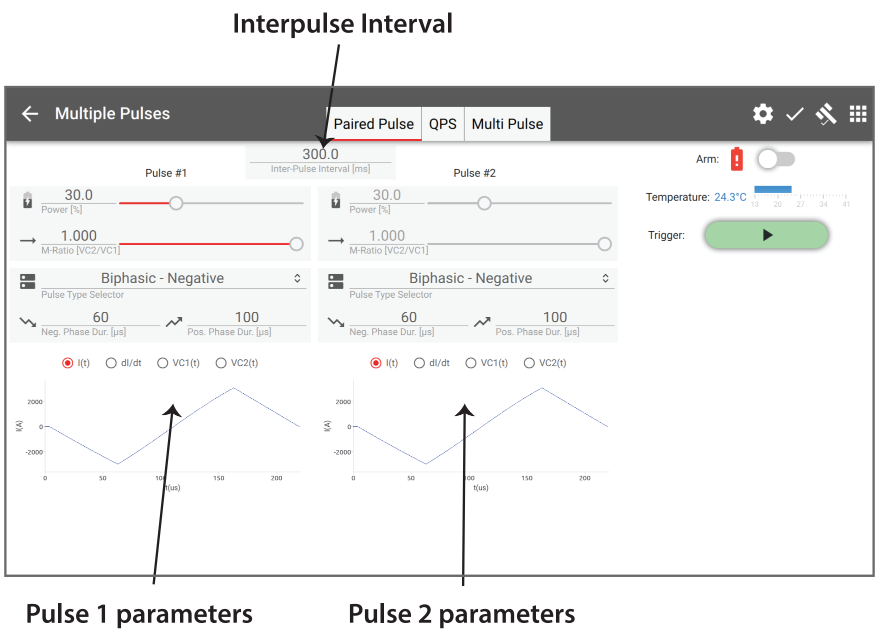


Fig. 5-1: **Paired pulse selection screen.** Note the ability to switch the pulse shape display from current to rate of change (inset).

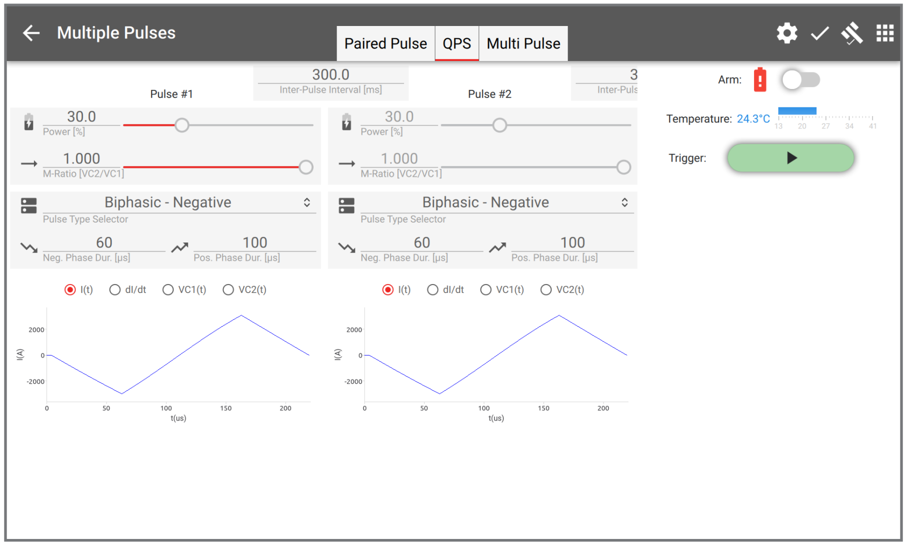
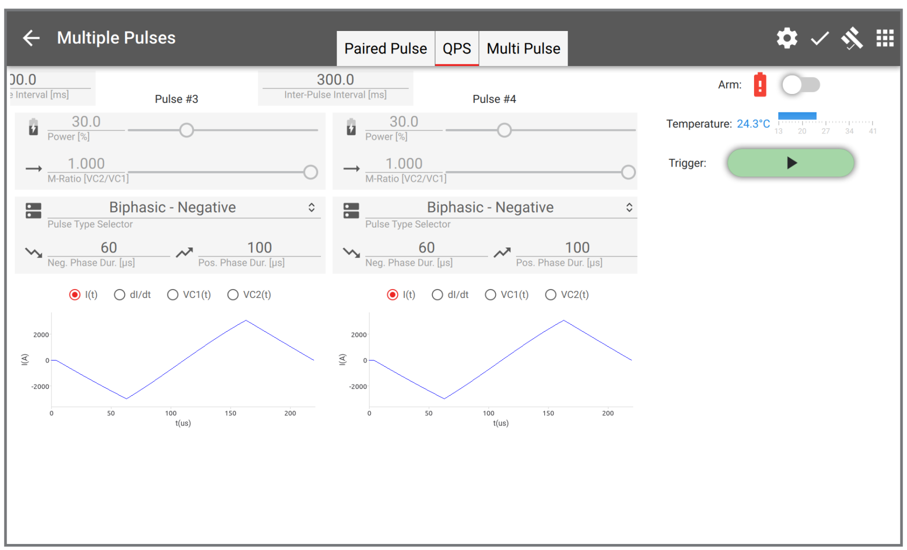


Fig. 5-2: **Quadripulse Settings screens.**



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).

- Note that only one unidirectional pulse is currently available, so you cannot select a pulse type other than the negative biphasic (unidirectional version, so it is similar to a monophasic pulse).
- 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.

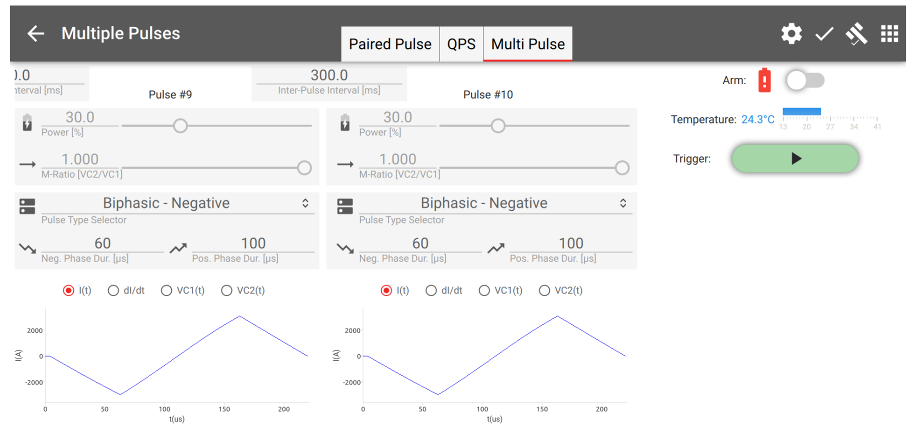
- Any of the pulses can be disabled (to deliver a triplet or par) by tapping **Enable Pulse** checkbox to select/deselect it.
- Tap the charge button.
- Once the system has charged, the sequence can be initiated by either clicking the green play button, stepping on the foot-switch or sending a TTL trigger 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: 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 Elevate TMS 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 protocol file that describes these **complex** sequences, validate the contents and execute the sequence.

In addition to complex sequences where the pulse shapes may vary, the device supports 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 are 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.

This chapter will explain how to write a protocol and how to run the sequence on the Elevate TMS 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 PROTOCOL FILE

The Pulse Sequence File (PSF) 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 the name identifier of 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 device. 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**).

2.1 Overview of a protocol file

The overall structure of a protocol 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 Elevate TMS computer uses this to recognize that the file is a protocol file. The second line of the header is the key "version" and the value is 2 (to state that this is version 2 of the protocol file format). Note version 1 sequence files are still supported, but it is recommended to use version 2 when possible. Note that we previously referred to this file as a sequence file. We use the more general term protocol file to reflect the more comprehensive nature of the file.

Protocol type:

Each PSF should contain the protocol type of the sequence described in the file. This type dictates which key-value pairs to use in the file. Only one protocol type is permitted per file and only version 2 files can have a protocol type.

Keys	Description	Range
protocol_type	Gives the type of protocol used in the file single_pulse, repetitive, multipulse or complex	single_pulse, repetitive, multipulse or complex

single_pulse: Protocol containing only one pulse. Therefore, only the pulse object should be used.

repetitive: Protocol containing a repetitive sequence of a single pulse. This repetitive sequence can have up to 3 levels of repetition at various frequencies. Therefore, a pulse needs to be defined using the pulse object and the repetition levels are defined using the repetition object. The first level of repetition written in the file will repeat the pulse. The second repetition level written in the file will repeat the first repetition level and the third repetition level written in the file will repeat the second repetition level.

multipulse: Protocol containing a sequence of different pulses. This protocol can have from 1 to 10 pulses in it and they can be different from each other and the inter-pulse interval can be adjusted. Therefore, the pulses must be defined with the pulse object and the inter-pulse intervals are defined with the intervals object.

Complex: Protocol containing a complex sequence. A complex sequence is a collection of pulses, repetitions and sequences. It can be defined using the pulse, repetition and sequence objects.

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 Elevate TMS device. If these values are not set, the default is 0. At this time, the Power and M-Ratio values from each device cannot be changed between pulses.

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

Objects:

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.

Pulse Parameter Description

Keys	Description	Range
uid (only required for complex protocol type)	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: 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).

Repetitions Parameter Description

Keys	Description	Range
uid (only required for complex protocol type)	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
repetition_frequency_hz	The repetition frequency in Hz. Cannot be used if any of the repetition_interval keys above are used.	From 0.001 to 1000 Hz (resolution of 0.001 Hz)
number_items (only required for complex protocol type)	The number of different pulses used in the repetition	1 to 65535
item_uids (only required for complex protocol type)	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: There can only be one sequence in a sequence file and represents the complete implementation of one or more pulses and/or repetitions.

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

Intervals: Insert an interpulse interval to pause between two pulses

Keys	Description	Range
interpulse_intervals_ms **Interval Parameter Description**	Inter-pulse interval, in ms. Relative to the last pulse, meaning this is the time between 2 successive pulses. The number of pulses and inter-pulse intervals must match. The first interval is the time between the start of the sequence and the first pulse.	From 1 to 10 000 ms (except for the first interval that can be 0) (resolution of 0.1 ms)

2.2 Example File(s)

The following examples implement:

single pulse

------

rogue
version 2

protocol_type single_pulse

primary_power 30
primary_mratio 0.2

type pulse
polarity positive
number_phases 1
phase_duration_us 70

Repetitive Pulses

rogue
version 2

protocol_type repetitive

primary_power 45
primary_mratio 0.55

type pulse
polarity positive
number_phases 2
phase_duration_us 45 145

type repetition
number_repetitions 7
repetition_frequency_hz 40

type repetition
number_repetitions 10
repetition_frequency_hz 5

type repetition
number_repetitions 10
repetition_interval_ms 5000

Multipulse protocol:
rogue
version 2

protocol_type multipulse

primary_power 30
primary_mratio 0.87

type pulse
polarity negative
number_phases 2
phase_duration_us 60 110

type pulse
polarity negative
number_phases 2
phase_duration_us 63 102

type pulse
polarity positive
number_phases 1
phase_duration_us 85

type intervals
interpulse_intervals_ms 0 250 75

Complex Protocol:
rogue
version 2

protocol_type complex

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 primary
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
repetition_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
repetition_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. MANAGING PULSES AND SEQUENCES ON THE CTMS DEVICE

The protocols manager allows you to copy pulses and sequences to/from a USB stick. Pulses and sequences can also be created using the pulse and sequence UI by tapping the disk icon next to the pulse display and the disk icon along the toolbar at the top of the screen. Once saved, they will appear in the protocol list.

To view the protocols (pulses and sequences) stored on your device, from the main menu, tap protocols (Fig. 6-1). Pulses and sequences on the device's internal memory will appear on the left. Read-only built in pulses and sequences will appear first, and pulses and sequences loaded by you will appear below.

Insert your USB stick with your protocol(s) and they should appear on the right box. Select any protocol you which to copy onto the device and tap the **<-** arrow. If you wish to save any pulses or protocols on the device to the USB key, select it on the list (in the left box) and tap the **->** arrow.

Pulses and sequences that were copied from USB can be deleted from the device by selecting the pulse or sequence and tapping the trash icon below the list. Similarly, pulses and sequences stored on the USB can be deleted by selecting the item from the items on the USB list and tapping the trash icon below that list.

4. RUNNING THE PULSE SEQUENCE

Select any protocol on the left box (protocols stored on the device) and tap the play button.

Arm the 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.

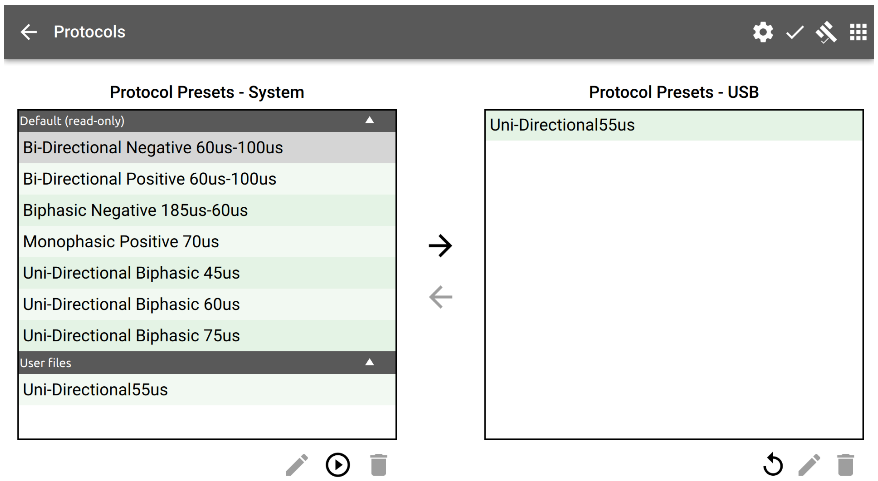


Fig. 6-1: **Protocol Manager screen**.

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.