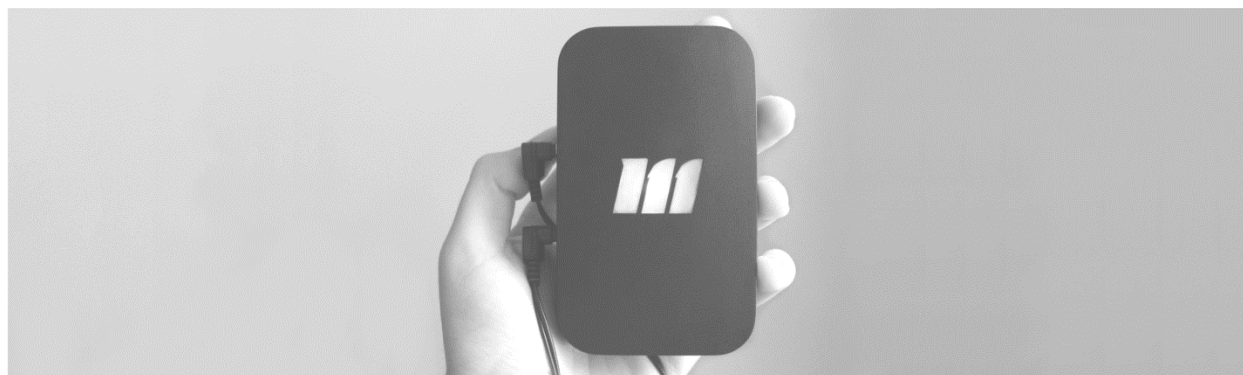




mTrigger® Biofeedback System User Manual



Please read the entire User Manual before attempting to operate this device.

If you have any questions or problems with this device, please contact:

mTrigger® Customer Service:

101 Lukens Drive

Suite A

New Castle, DE 19720

Phone: 302-502-7262 ext 1

Email: customerservice@mtrigger.com

Manual Part Numbers:

863712000337 | SKU BI2612 - Individual Unit + Accessories

863712000382 | SKU BK2613 - Clinical Bundle

Effective Date: 1 November 2017

Table of Contents

1 Glossary and Abbreviations.....	4
Table 1.1: Glossary.....	4
Table 1.2: Abbreviations	4
2 Safety	4
2.1: Conventions Used in this Manual	4
3 System Set-Up	5
3.1: Location	5
3.2: Unpacking and Initial Set-up	5
3.3: Battery Use and Charging	6
3.4: Battery or Power Malfunction.....	7
4 Device Description	7
4.1: Indications for Use (Purpose of the Device)	8
4.2: Contraindications	8
4.3: Biofeedback System Unit.....	8
4.4: Accessories	9
5 Operation.....	11
5.1: Safety Precautions.....	11
5.2: Patient Preparation	11
5.3: Device Operation	11
6 Maintenance and Calibration.....	20
6.1: Cleaning	20
7 Quality and Regulatory	21
7.1: Quality Environment	21
7.2: Regulatory Compliance	21
8 Specifications and Environmental Conditions.....	21
8.1: Specifications.....	21
Table 8.1 System Specifications	21
8.2: Accessory Details.....	22
Table 8.2 Accessory Specifications.....	23
9 Warranty Information	23



9.1: Terms and Conditions.....	23
9.2: Before You Call—Troubleshooting	24
9.3: Return Procedure	24
10 Labeling.....	25
11 Contact Information	26
11.1 Customer Service	26

1 | Glossary and Abbreviations

Table 1.1: Glossary

Table 1.2: Abbreviations

Abbreviation	Term
EMC	Electromagnetic Compatibility
FDA	Food and Drug Administration
US or USA	United States

2 | Safety

This section provides safety guidelines and safety-related statements to operate this biofeedback system safely and effectively. Additional guidelines, statements, and protocols appear throughout this manual. Follow all printed guidelines, warnings, cautionary statements, and protocols when using this biofeedback system.

2.1: Conventions Used in this Manual

Various Warnings, Cautions, Recommendations and Notes are presented throughout this manual. Explanations and the corresponding symbols are:



Warning: Specific or potential danger. If ignored or compromised, the situation could result in harm. Warning statements are preceded with a yellow symbol.



Caution: Possible problem with the device associated with its use or misuse. Problems include, but are not limited to, device malfunction, device failure, or damage to the device. Caution statements are preceded by a black-and-white symbol.

Recommendation: Offers guidance for the optimal application and usage of the device. Recommendation statements are in a shaded box.

Note: Describes the conditions or exceptions that may apply to the subject matter presented.

3 | System Set-Up

3.1: Location

The mTrigger® Biofeedback System can be used in virtually any location, so long as there is sufficient space to perform appropriate therapy exercises. Locations with high levels of electrical or Bluetooth activity may cause minor signal interference, but do not pose risks to the system or users.

3.2: Unpacking and Initial Set-up

- Step 1.** Using the mTrigger® Biofeedback System packing list, carefully unpack the system and its accessories from the shipping box.
- Step 2.** Check for any missing or damaged parts.
- Step 3.** If items are missing or damaged, call mTrigger® Customer Service. Notify the carrier if the damage occurred during shipping and retain shipping packaging for evidence.
- Step 4.** Fully charge the battery via the USB port and provided charger before using the device(s). See figure 3.1

Fig. 3.1: Micro USB charging port setup

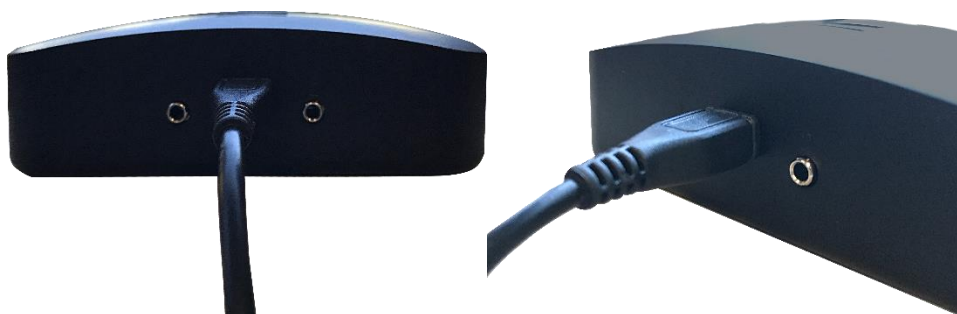


Fig 3.3: Charging state LEDs

green = fully charged, red = actively charging, white = not charging/in use



Recommendation: Charge the device before use. The system ships with the device battery only partially charged.

Recommendation: Turn devices off before any method of charging. When the device is on, the LEDs cannot indicate a full charge and full charge will take longer.

3.3: Battery Use and Charging



Warning: Do not modify the battery or attempt to remove it from device.



Warning: Do not immerse the battery in water or get the battery wet.



Caution: mTrigger hardware cannot establish a Bluetooth connection while in a charging state. Do not attempt to use the mTrigger device/system while charging.



Caution: DO NOT leave device charging overnight; charging time in excess of 6 hours can cause over-charging and impact battery life and device performance.



Caution: The temperature range for charging this battery is -10° C to 45° C (14° F to 113° F). Do not charge, store, or attempt to use the battery outside of this range.



Caution: Do not store the battery over a long period of time at temperatures above 30° C (86 °F), such as inside a car on a hot day or in direct sunlight; this may damage the battery.



Caution: Do not disassemble or open, crush, bend, deform, puncture, shred or burn the battery.

Note: When the device is plugged in to charge, it will be illuminated in red. Green illumination indicates full charge. When in use, it will be illuminated in white. See figure 3.3.

3.4: Battery or Power Malfunction

If the battery is not charging or device is not powering on as expected, contact mTrigger® Customer Service to determine if a replacement charger or device is needed. The battery cannot be removed from the unit or replaced except by the manufacturer.

4 | Device Description

The mTrigger® biofeedback system includes:

- *mTrigger* biofeedback device (qty 1 for Individual Unit; qty 3 for Clinical Bundle)
- Sensing cables (qty 2, IU; qty 6, CB)
- Sensing electrodes, 4 per pouch (qty 10 pouches, IU; qty 50 pouches, CB)
- User interface software application (free download to mobile device)

A custom user interface software application allows the operator to pair with a specific device via Bluetooth and set exercise parameters, complete training sessions, track progress, play games, and calculate neuromuscular deficit. Once the operator has selected the desired exercise parameters, complete training session and save output to the tracking module. These steps are detailed in Section 5.



Warning: Do not use any accessories and/or cables not specified or sold by mTrigger, LLC as replacement parts. Use of unauthorized accessories and/or electrodes not specified or sold for use with this system may result in ineffective signal transmission or damage to the system.



Warning: DO NOT attempt to gain access to any internal component. Doing so may cause injury and/or device damage. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this device.

4.1: Indications for Use (Purpose of the Device)

This biofeedback system is indicated for:

- Biofeedback, muscle re-education
- Deterrence of atrophy due to lack of voluntary muscle activation
- Increasing voluntary muscle control and activation via real time display of muscle activity
- Stroke rehab by muscle re-education
- Visual feedback to supplement physical therapy exercises performed for the purpose of rehabilitating musculoskeletal injury

4.2: Contraindications

None.



Caution: Use of the mTrigger® Biofeedback System simultaneously with an electrical muscle stimulation system may impact signal quality.

4.3: Biofeedback System Unit

Top View:

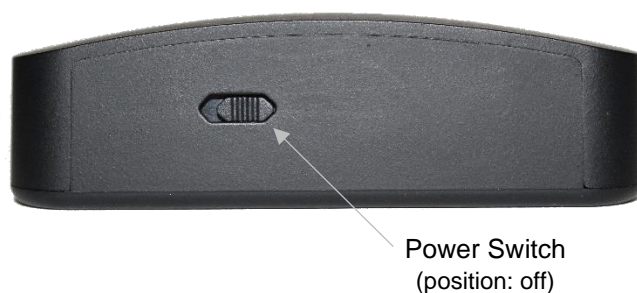


Bottom View:

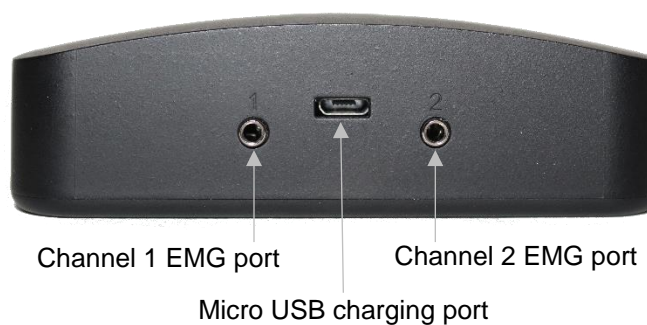


Serial Number

Right Side View:



Left Side View:



4.4: Accessories



Warning: Use of unauthorized accessories and/or electrodes not specified or sold for use with this system may result in ineffective signal transmission or damage to the system.

Micro USB Charger:



Sensing Electrodes:



Cable connector receptor

Sensing Cables:



Electrode connector pins

EMG port jack

5 | Operation

5.1: Safety Precautions



Caution: FAILURE TO COMPLY with the setup procedures and suggested application techniques listed in the manual may lead to ineffective treatment via improper signal transmission or device failure.

Take the following steps to secure the treatment area:

- Clear exercise area of any obstacles.
- If exercise is stationary, place device on a nearby table or other flat surface where it will not impede treatment. Prop phone or tablet on provided viewing stand where the application can be easily seen by the patient and provider, if desired. Secure device inside mTrigger Wearable Wrap if available.
- If exercise is mobile, secure the device in the mTrigger wearable band or a pocket if available; if neither option is available, hold the unit during exercise.

Note: For mobile exercises, either prop phone or tablet on provided viewing stand where the application can be easily seen by the patient and provider, or hold mobile device in hand.



Caution: DO NOT rest mTrigger unit on or touching other electronic devices (computers, printers, digital scales, etc.) as this may cause electronic interference and improper signal transmission.

5.2: Patient Preparation

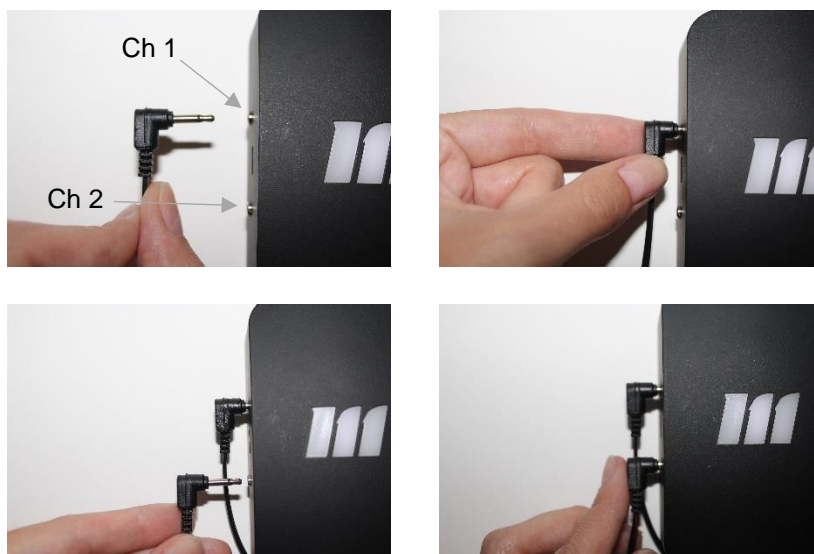
Before a treatment, perform the following preparation:

- Ensure that the skin on the treatment area is clean, dry, and free of surface dirt or oils for proper electrode adherence and signal reception. See instructions on electrode packaging.
- Ensure that Bluetooth permissions on mobile device are set to On to enable connection.

5.3: Device Operation

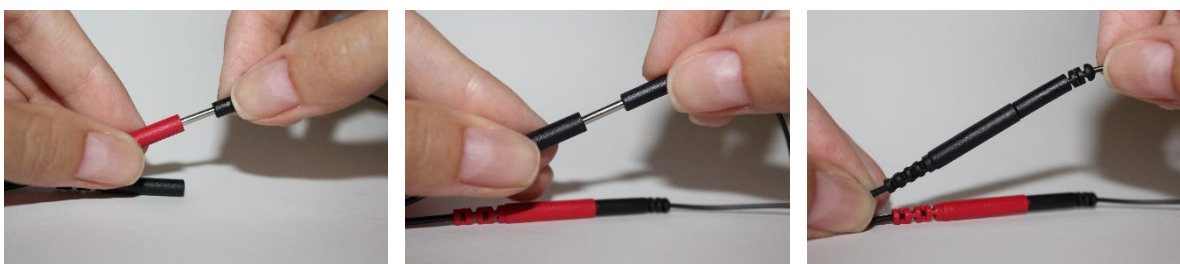
Additional content: [Quick Startup Guide](#) (included in your order or available online)

- 1) Search “mTrigger biofeedback” on the Apple Store or Google Play Store and download the mTrigger Biofeedback App to your mobile device. Native app and separate game apps are available across Android and iPhone phones and tablets.
- 2) Attach electrode connector cable(s) to mTrigger EMG ports.



Caution: For single channel use, only data from Channel 1 will be read. Please insert channel 2 cable **ONLY** for dual channel use.

- 3) Attach sensing electrodes to sensing cables



- 4) Place one pair of electrodes on target muscle. See [Electrode Placement Database](#) for suggested electrode placements.

Note: For dual channel use, i.e. monitoring of two muscular activity channels, place second electrode pair on a co-contracting or contralateral muscle.

- 5) Turn on device by sliding power switch on the right hand side as indicated. A white light will illuminate the logo *m* when the device is on.

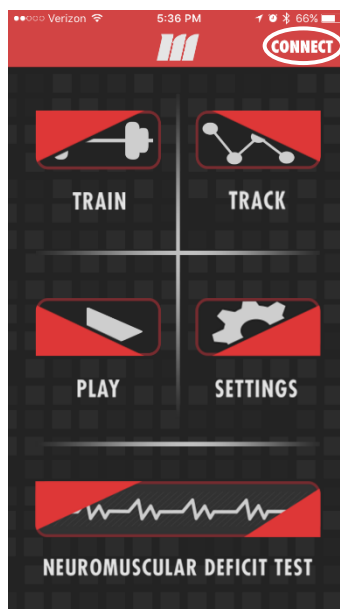


Note: If charging is necessary, any micro USB charger will work; active charging is indicated by a red light, charge complete is indicated by a green light. Very low battery level may impact the unit's ability to communicate data over the Bluetooth connection.

- 6) Open application on mobile device.



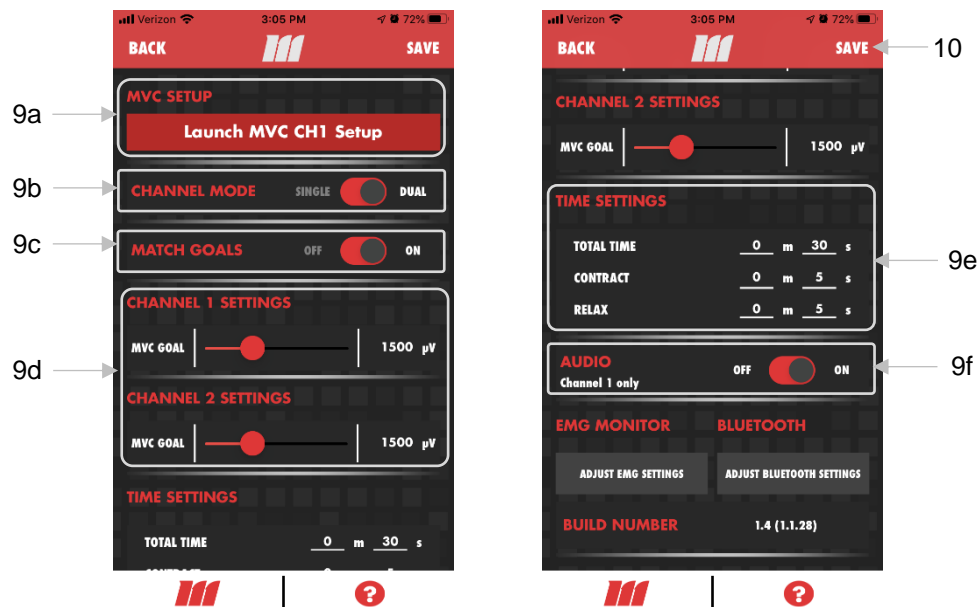
- 7) Select "CONNECT" in the upper right corner of the Home screen, or access "ADJUST BLUETOOTH SETTINGS" on the Settings page.



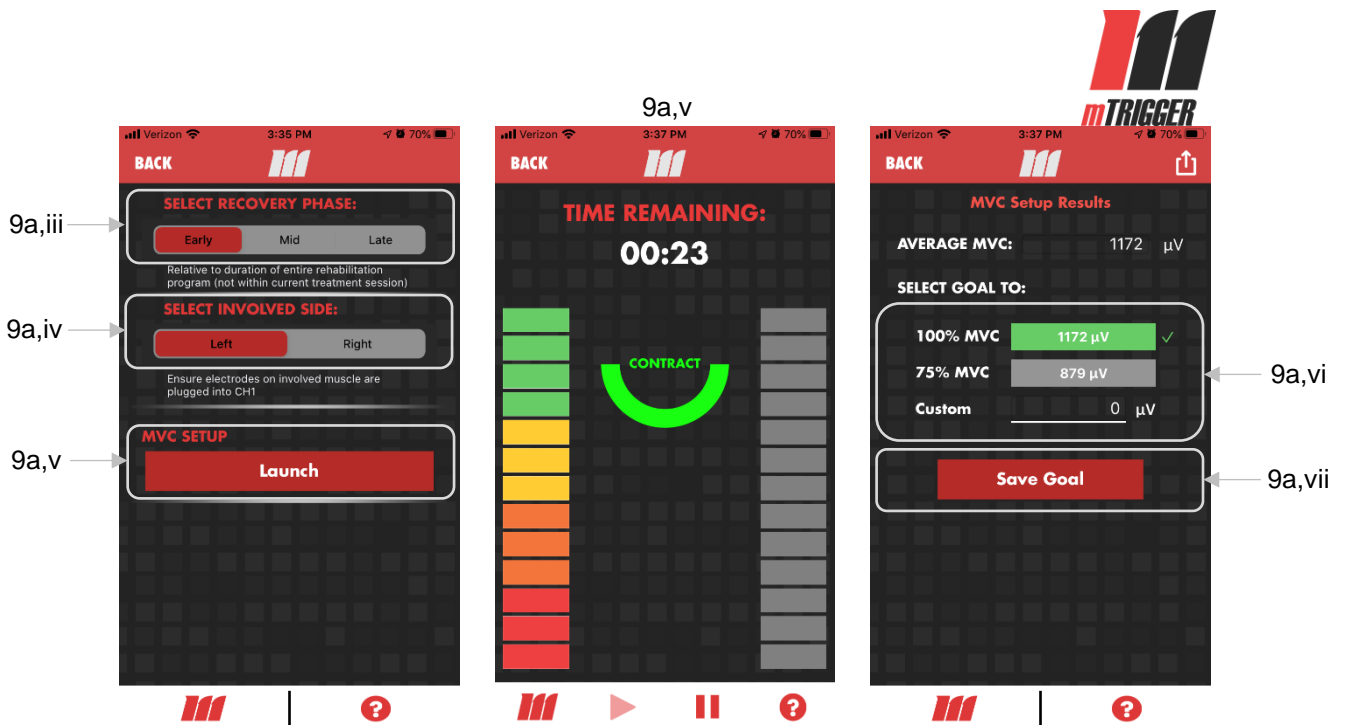
- 8) Locate the serial number on the sticker on the underside of the mTrigger device. Match the serial number to the numbers that appear in the scanned device list. Tap to select your device number and connect via Bluetooth. A “device connected” confirmation will pop up.



- 9) From the Home screen, go to Settings to set up treatment parameters:



- a) MVC Setup – Launch: Use this feature to assist with setting MVC goal level
 - i) Tap to launch the automatic maximum voluntary contraction setup protocol (setup for Ch 1 only, but turning Match Goals ON will ensure Ch 1 goal is synced across both channels if desired. See 9c.)
 - ii) Ensure electrodes and cables are plugged into Ch 1.
 - iii) Select recovery phase relative to duration of entire rehabilitation program, *not* within the current treatment session. This appropriately adjusts the visual display on the next screen.
 - iv) Select whether the target muscle plugged into Ch 1 is on the right or left side of the patient's body. This appropriately adjusts the visual display on the next screen.
 - v) Launch test and follow prompts to relax and contract maximally for 30 sec.
 - vi) Select goal based on Average MVC results. Goal can be set to 100% or 75% of MVC achieved during setup, or a custom goal can be typed in.
 - vii) Save to return to Settings; results of setup will be reflected in Ch 1 goal settings automatically.



b) Channel Mode Select: Select dual or single channel as desired.

- i) If in single channel mode, ensure you are plugged into Channel 1 only; Channel 2 will not display data in single channel mode.
- ii) Single channel mode is ideal for isometric exercise and basic activation training.
- iii) Dual channel mode is ideal for bilateral comparisons, A/B activation ratio monitoring, agonist/antagonist monitoring, or compensation monitoring.

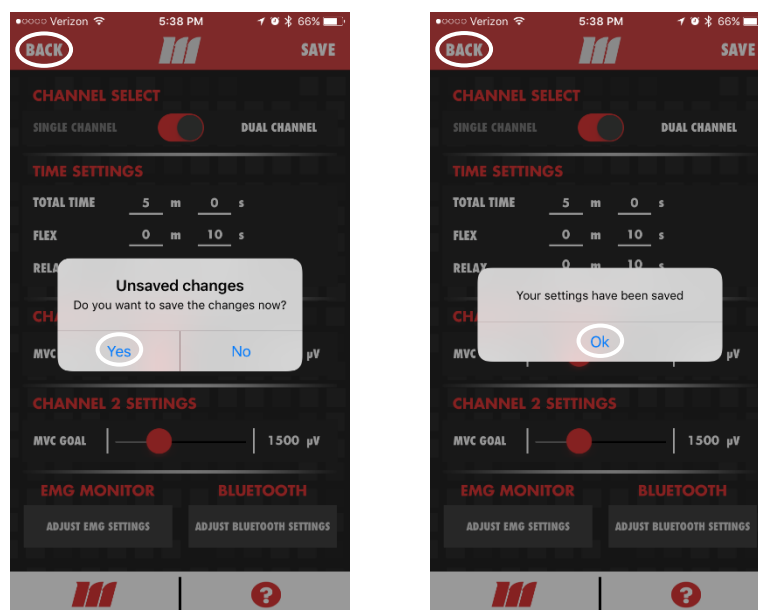
c) Match Goals Select: Toggle Match Goals ON to lock goals together for simultaneous adjustment, e.g. for comparison of muscles with current or goal similar MVC levels; Ch 1 goal is default. Toggle Match Goals OFF to adjust Ch 1 and Ch 2 goals independently, e.g. for comparison of muscles with different MVC levels.

d) Channel Goal Settings: Set the microvolt goal for each channel; this can also be set or adjusted in the Train module by assessing MVC in real time. Goal can also be modified by typing the exact desired uV level into the text bar (tap on the number before uV to type).

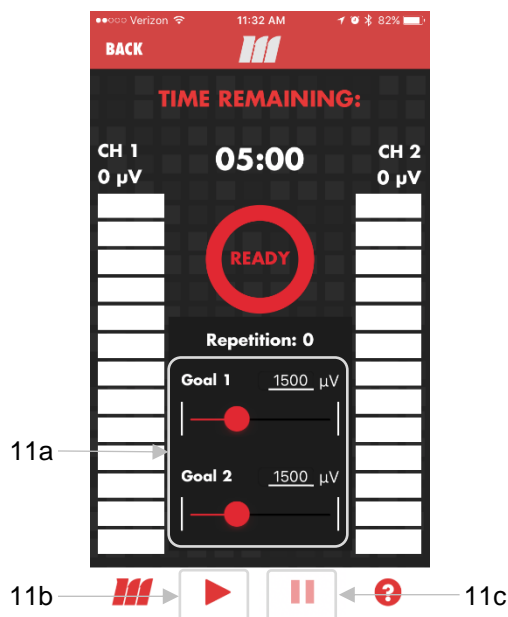
Note: 1000-1500uV is a good starting point to assess patient capability if setting goal manually

e) Time Settings: Modify total, contract, and relax time as desired. Both contract and relax times must be set or you will be notified of an error. Reps are calculated as $[\text{total time}] / [\text{flex time} + \text{relax time}]$. Every training session will begin with the relax period of the rep.

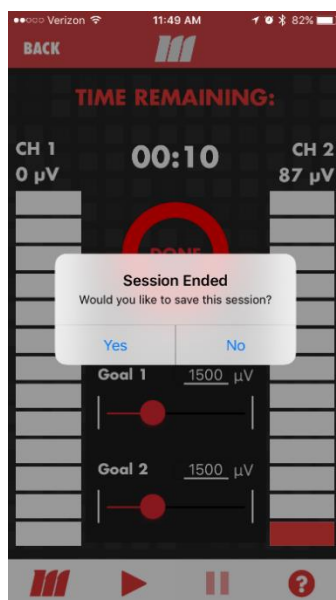
- f) Ch1 Audio Select: Toggle Ch 1 Audio ON to hear cues for relax and contract periods as well as a “success tone” when the contraction reaches the green zone. Audio is only reflective of Ch 1 activity. Toggle Audio OFF to mute.
- 10) Save settings by tapping SAVE in upper right corner. Tap “BACK” in upper left or *m* in lower left to return to home screen and accept “save settings” prompt upon exiting if settings have not already been saved.



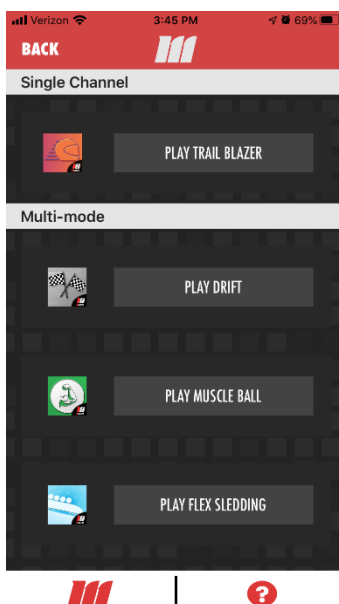
- 11) From the Home screen, tap to enter Train.



- a) Before beginning your session, modify the goal as necessary to match MVC using the slider bars or by typing.
- b) Hit the play button on the bottom bar to begin your session.
- c) Pause button pauses the session and will restart at the beginning of the relax time of the previous rep.
- d) Save results when prompted at session completion to see timestamped output in the Track module.

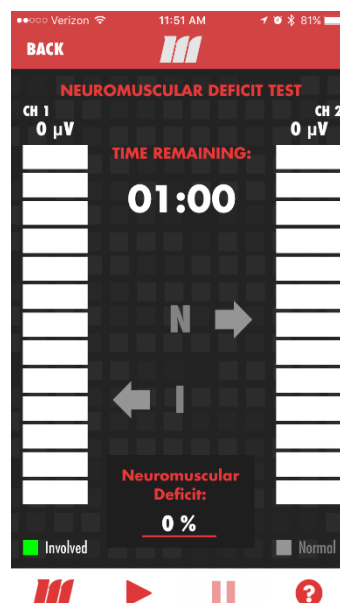


12) To Play: Tap Play from Home to launch the game list.



- a) Select the PLAY [GAME NAME] button to take you to the individual app for that game. There you will reconnect your mTrigger device and customize settings for that session of play; native app settings will not be affected.
- 13) Neuromuscular Deficit Test: First, enter settings and toggle to dual channel mode. Then ensure that the goals for CH1 and CH2 match exactly – you can tap the numbers to type. The goal should be set to both at the level of a normal max contraction on the healthy side to provide the most accurate deficit calculation.

Tap Neuromuscular Deficit Test to start the test. NDT assesses the deficit of the involved side as compared to the healthy side. The involved side will test on the left side of the screen (CH1), normal side on the right (CH2). Flex your involved muscle when indicated by the green “I” and left-pointing arrow; flex your normal muscle when indicated by the green “N” and right-pointing arrow. The test compares average microvolt activity on the healthy versus involved sides over a one-minute test period. See help button on bottom right of screen for further details.



Note: Ensure that your involved muscle is plugged into channel 1 during the NMDT. It is also critical that electrode placement be as identical as possible on both healthy and involved sides of the body. You will be prompted to ensure that Match Goals is ON. It is recommended to set the goal for both channels to the MVC of the healthy side to provide the most accurate percentage deficit. Failure of any of these steps will invalidate test results.

- 14) Tap Track and select a session to see actual EMG activity compared to goal per timestamped session. Tap an individual graph to see average maximum contraction for that session. You can also delete individual sessions using your mobile device's standard delete gesture.



- 15) Slide the power button up to shut down the device. Bluetooth will disconnect automatically upon powering device off or force closing app.

6| Maintenance and Calibration



Warning: DO NOT attempt to gain access to any internal component. Doing so may cause injury and/or device damage. THERE ARE NO USER-SERVICEABLE COMPONENTS inside this device.

6.1: Cleaning



Warning: Always turn off the device before cleaning and remove from charger.

Keep EMG ports and sensing cable jacks clear from dirt, dust, and debris. These substances will impact signal quality and device functionality and over the long term could cause device damage.

If cleaning is necessary, use a dusting cloth.



Warning: DO NOT use water or a damp cloth to clean any part of the mTrigger Biofeedback System; no component of the system is waterproof.



Caution: Water coming in contact with sensing electrodes may impact skin conductance and thereby signal quality.

7 | Quality and Regulatory

7.1: Quality Environment

- The mTrigger® biofeedback system production environment complies with 21CFR820.70
- The mTrigger® biofeedback system is manufactured in compliance with the United States Food and drug Administration's general manufacturing practices concerning medical devices.

7.2: Regulatory Compliance

According to the applicable standards, the mTrigger™ Biofeedback System is classified as follows:

- Class II Medical Device per USFDA 21CFR 882.5050
- 510(k) exempt

In order to safely perform its intended use, the system requires two accessories whose classifications and registrations are as follows:

- Custom Sensing Electrodes – Cutaneous electrodes classified as Class II (special controls; 510(k) exempt) per USFDA 21CFR Sec. 882.1320
- Custom Sensing Cables – not classified as a medical device or medical device accessory; tested as part of the mTrigger® Biofeedback System EMC and safety standards

Please see supplemental FDA Compliance Summary Report (Quality Document number Q-06) for further details.

8 | Specifications and Environmental Conditions

8.1: Specifications

Table 8.1 System Specifications

Model Name	mTrigger® Biofeedback System
-------------------	------------------------------



Model Number(s)	863712000337 - Individual Unit + Accessories 863712000382 - Clinical Bundle	
Device Classifications		
United States	Class II Medical Device per USFDA 21CFR 882.5050	
User Interface		
Mobile Application	mTrigger® Biofeedback	
Mechanical Specifications – Individual unit		
Dimensions	4 in x 2.4 in x 1.1 in	
Weight	0.25 lb	
Environmental Specifications		
Operation temperature	10 °C to 35 °C 50 °F to 95 °F	
Storage temperature	-20 °C to 70 °C -4 °F to 158 °F	
Electrical Specifications		
Input Voltage	See EMC testing	
Input Current	See EMC testing	

8.2: Accessory Details

Warnings & Precautions: *mTrigger* Custom Sensing Electrodes



- Keep electrodes out of reach of children.
- Electrodes are intended for single person use only.
- Electrodes are latex free and manufactured in the USA.
- Electrodes can be cut down to smaller size for specific applications if required.
- DO NOT remove electrode by pulling on the lead wire.
- DO NOT use generic electrodes with the *mTrigger* Biofeedback System, as damage to *mTrigger* accessories can occur.
- DO NOT use electrodes that have been incorrectly applied or damaged.
- Follow placement instructions carefully – electrodes should be separated on the skin and positioned as indicated for your treatment.
- DO NOT apply to broken skin. Should a skin rash or irritation occur, discontinue use and contact your physician.
- DO NOT use the *mTrigger* Biofeedback System while operating machinery, sleeping, or in close proximity to water.

Note: The life of electrode adhesive gel varies depending on skin condition, preparation, storage, and climate. Please refer and adhere to care and storage instructions on the electrode packaging.

Cleaning & Maintenance of *mTrigger* Custom Sensing Electrodes:

Skin and electrodes can be cleaned with alcohol wipes if needed. Performance should not be impacted by wiping either the gel adhesive or cloth overlay with an alcohol pad, but do not submerge in any solution. Let dry before application to skin or plastic backing. Excessive cleaning may lead to decreased hydration/adhesion of gel over time.

Table 8.2 Accessory Specifications

Device Classifications			
Item	Description	Classification	Image
Sensing Electrodes	2" square white cloth, sensing gel, self-adhering surface electrodes	Class II special controls; 510(k) exempt	
Sensing Cables	4' M/F AUX jack pin connector pigtail cable	Non-medical	

9 | Warranty Information

9.1: Terms and Conditions

The mTrigger Biofeedback system is warranted to be free from manufacturer defects in materials and workmanship for a period of 1 year, starting from the date of initial shipment. This warranty does not extend to incidental or consequential damages nor to damage caused by negligent or improper handling in use or storage; products on which the original identification markings or labels have been intentionally defaced, altered or removed are not eligible for warranty.

mTrigger, LLC reserves the rights of determining existence and cause of defect as well as the option to repair or replace products which prove to be defective as necessary during the warranty period. Claims may be submitted for review after the warranty period close; however, mTrigger does not guarantee repair or replacement after the close of the warranty period. This warranty extends only to the original purchaser of the equipment from mTrigger, LLC. The purchaser must notify mTrigger within 15 days of first detecting the defect and promptly return the defective product before expiration of the warranty period.



Return shipping costs will be covered by mTrigger, LLC within the warranty period. mTrigger will return repaired or replaced goods to purchaser within the Continental United States at no additional charge. mTrigger does not offer goods internationally at this time.

9.2: Before You Call—Troubleshooting

If you are having a problem with your biofeedback system, please check the list below of common conditions that can occur that you may be able to resolve without having to contact mTrigger® Customer Service.

If the device will not turn on:

Attempt to charge. If after attempted charge, the device does not show charging indicator LEDs or still does not turn on, call mTrigger® Customer Service to undergo troubleshooting exercises to determine if a replacement battery is required.

If there are problems with the battery:

Problems with the battery (e.g., battery will not charge, will not hold a charge, or depletes charge quickly) may not require battery replacement. Call mTrigger® Customer Service to undergo troubleshooting exercises to determine if a replacement battery is required.

If there are error messages:

Ensure that your phone's Bluetooth is turned on and that you are using only authorized accessories.

If you experience signal malfunction:

Note that during the first 5-10 seconds after powering on, your device may display what appears as hypersensitivity when viewing activity in Train. This is a calibration period. If hypersensitivity persists beyond 60 seconds, please document the issue and report it to mTrigger Customer Service.

If other signal anomalies occur, ensure that you are using new electrodes and the cables are in the proper channel inputs. Troubleshoot excess noise by observing resting activity on various muscles and/or persons. If the issue is inconsistent across these use cases, it is likely to do with the original subject and temporal/environmental conditions like fatigue, spasm, hydration, and humidity, which can all impact sEMG readings. If signal issues inconsistent with your clinical assessment and persist across conditions, please document the issue(s) and submit to mTrigger Customer Service at info@mtrigger.com.

9.3: Return Procedure

Step 1. Review the date of shipment to determine the validity of any warranty claim. Warranty claims should only be made for products within the terms of the warranty policy (see Section 9.1).



Step 2. Before contacting mTrigger Customer Service, be prepared to provide:

- Product Model and Serial Number (see Section 11.1)
- Purchase and Shipment Date
- Invoice number
- Reason for return with documentation of manufacturer defect
- Contact name, phone number, and email address for further communication

Note: Providing complete information as requested will expedite RMA evaluations.

Step 3. Complete our online contact form, or call or email Customer Service to obtain a Return Material Authorization (RMA) number and detailed return instructions.

Step 4. Complete and sign the RMA form and return to mTrigger Customer Service. Adhere to mTrigger's complete return instructions for transportation and packaging to ship the product (freight and insurance prepaid) with completed and signed RMA form to mTrigger.

Step 6. Once mTrigger receives and evaluates the product, mTrigger will advise the purchaser of the warranty service determination and any subsequent action, i.e. shipment of repair or replacement unit(s).

10 | Labeling

The label displays the model number and serial number, which encodes the date of manufacture as the lot number as well as the individual device's Bluetooth pairing number.

MTRIGGER UNIT SERIALIZATION PLAN				
Position	Section Data	# char	Alpha/Num	Notes
1	product key	1	alpha	M = main unit
2	Rev #	2	num	no punctuation
3	Job number	5	num	yy/ww
4	-	1	punctuation	
5	board serial #	4	num	

A	#	#	#	#	#	#	#	#	#	#	#	#	#
Product Key	Rev code		Job number					-	Serial number				

11 Contact Information

11.1 Customer Service

For immediate assistance, contact mTrigger® Customer Service directly.

If this biofeedback system does not function as expected and/or if the biofeedback system malfunctions, contact *mTrigger* Customer Service immediately.

Please have the device serial number so that Customer Service can provide you with the highest level of service. The Serial Number (SN) of the device are found on the black barcode sticker located on the bottom of the unit.



mTrigger Headquarters:

101 Lukens Drive
Suite A
New Castle, DE 19720

Customer Service:

Phone: 1-302-502-7262 ext. 1
Email: customerservice@mtrigger.com

Sales & Other inquiries:

Phone: 1-302-502-7262 ext. 0
Email: info@mtrigger.com