TWITCHVIEW SYSTEM OPERATING MANUAL

TwitchView® | blink DEVICE COMPANY

TWITCHVIEW SYSTEM
OPERATING MANUAL

Intended Use

The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography (EMG).

Caution

Federal law restricts this device to use by or on the order of a physician.

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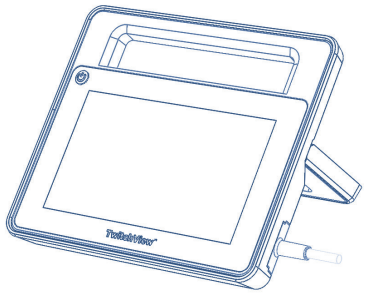
CE 2797

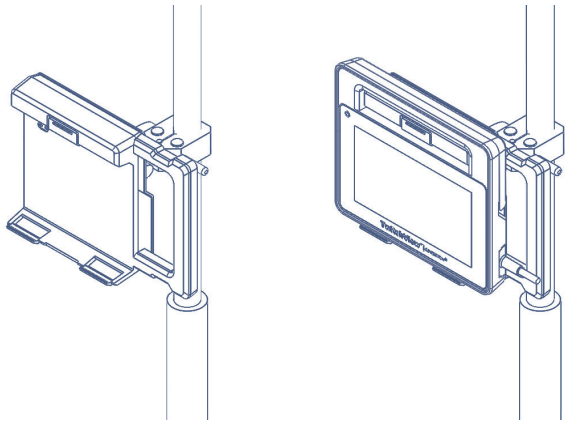
MONITOR

The TwitchView Monitor stimulates a peripheral nerve and measures the resulting electromyographic (EMG) response. The user interacts with the TwitchView Monitor via a touchscreen LCD and a Power button. The TwitchView Monitor includes a cable to connect the Electrode Array to the Monitor. When the Monitor is docked in the Charging Station, the Monitor's lithium ion battery is charged inductively, and the Monitor transmits neuromuscular monitoring data to the Charging Station by means of an infrared communications port.



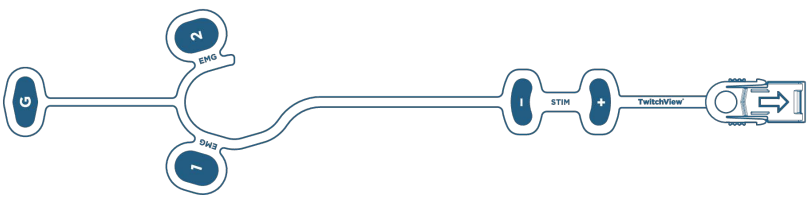
CHARGING STATION

The Charging Station charges the Monitor and outputs neuromuscular monitoring data from the Monitor via an RJ45 connector. The Charging Station plugs into a standard wall outlet and includes hardware for mounting to a pole or other piece of equipment.

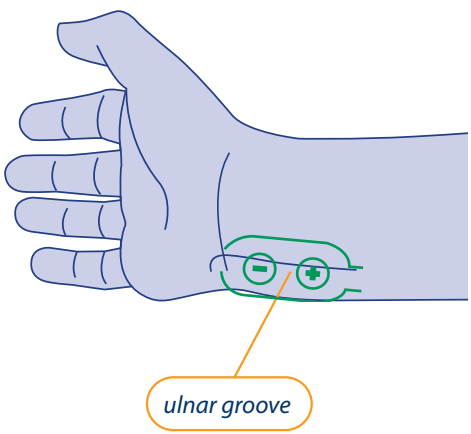


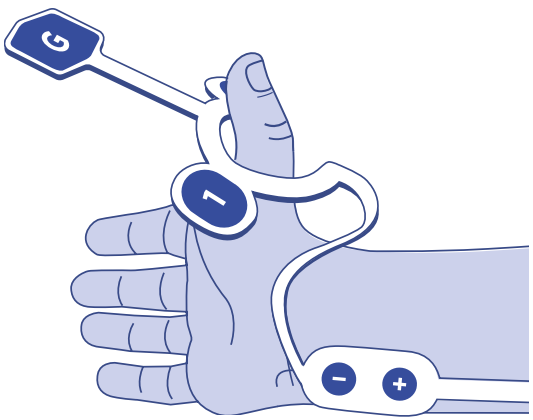
ELECTRODE ARRAY

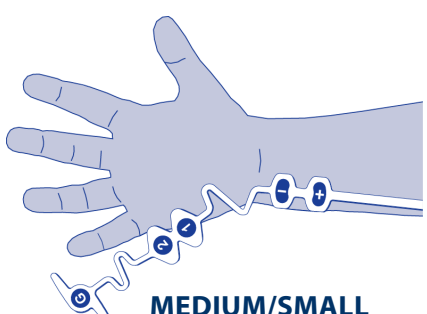
The single-patient use Electrode Arrays contain five independent electrodes— two for nerve stimulation and three for EMG. The Arrays have been designed to work on either the left or right hand. Use the Array size that best fits the patient's hand.

ARRAY SIZE		INTENDED POPULATION
LARGE TVLEA025		**ADULTS**
MEDIUM TVMEA025		**ADULTS & CHILDREN >10kg**
SMALL TVSEA025		**FULL TERM INFANTS >1 MONTH OF AGE**

1 Remove the release liner from the Stimulation portion of the Electrode Array and position the two stimulation electrodes over the ulnar nerve at the patient's wrist. Preparing the skin with an alcohol wipe or mild skin abrasion will improve signal quality. Placement over dense hair or scars should be avoided.



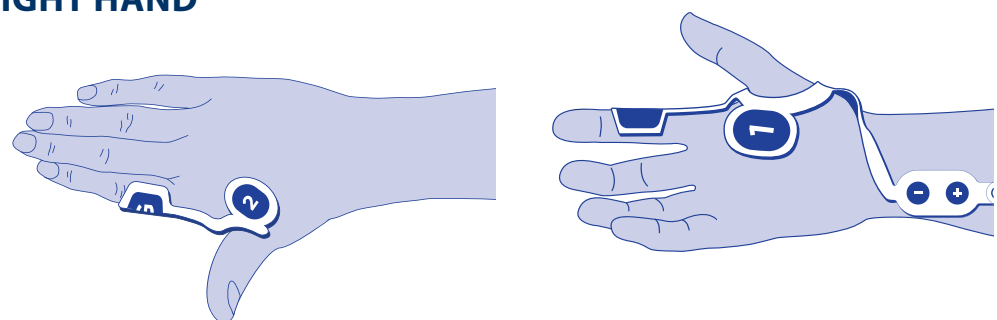




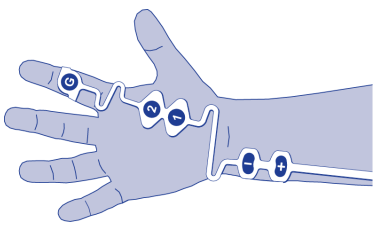
For optimal results, make sure to place the stimulating electrodes directly over the patient's ulnar nerve. To locate the ulnar nerve, flex the patient's hand back to expose the ulnar groove and place electrode centers directly over the visible/palpable groove. Ensure array has good contact throughout.

2 Remove the release liner from the EMG portion of the Electrode Array. For the large array, secure electrode 1 or 2 over the adductor pollicis, with the other electrode over the first dorsal interosseous muscle. The ground electrode (G) should be secured to the patient's index finger. For the medium/small arrays, secure electrode 1 and 2 over the adductor pollicis and the ground electrode (G) to the index finger.

RIGHT HAND

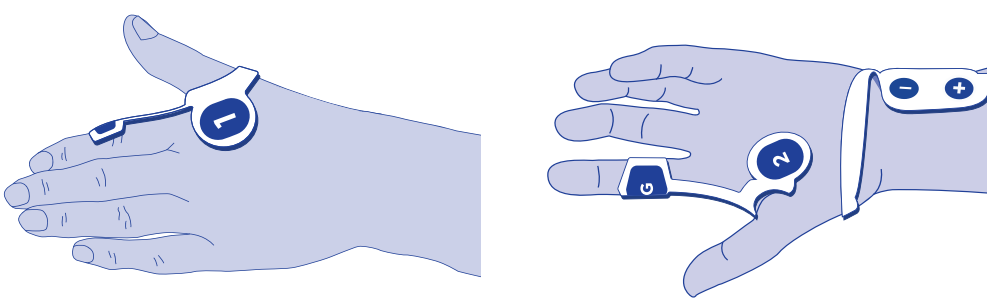


LARGE

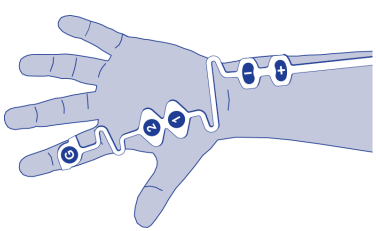


MEDIUM/SMALL

LEFT HAND

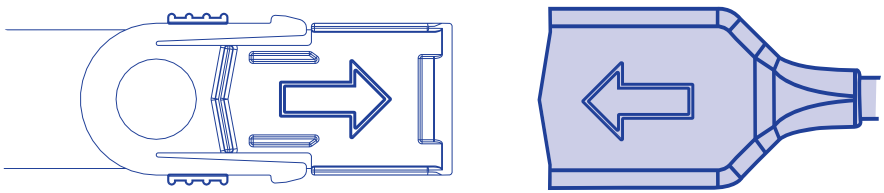


LARGE

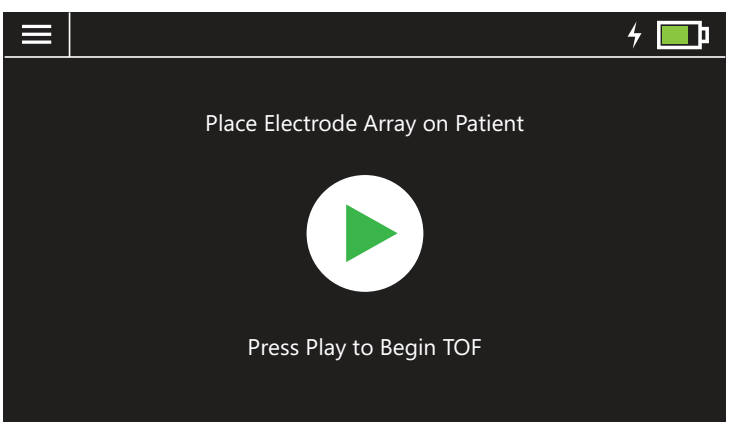


MEDIUM/SMALL

3 Insert the Electrode Array Tab into the Monitor Cable. Use tape to secure the array/cable connection to the patient's arm.

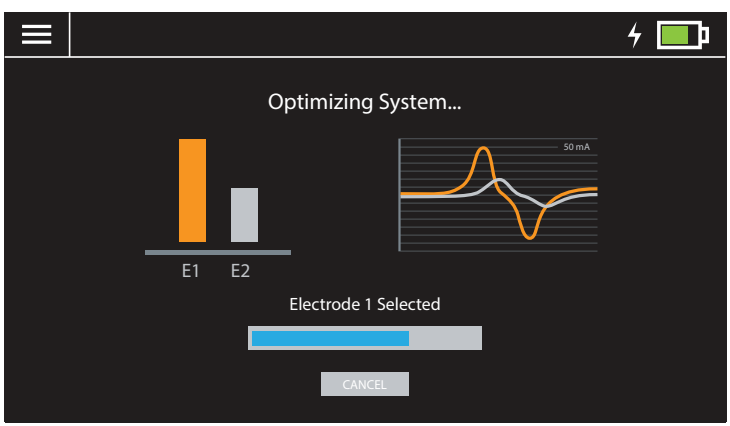


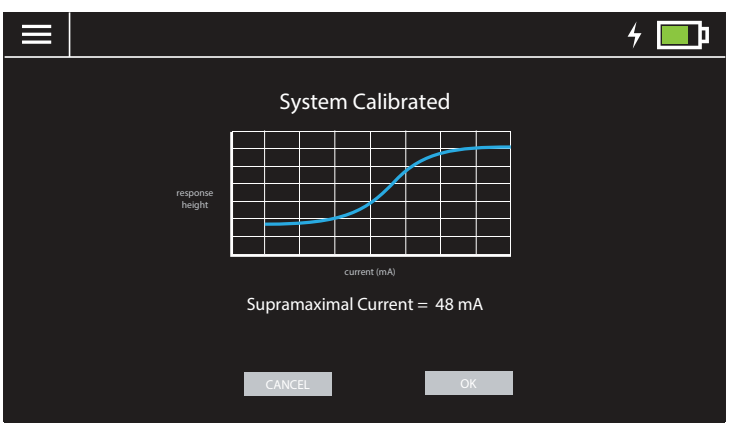
4 Touch anywhere on the Monitor screen to wake up the device and then press the **PLAY** button.



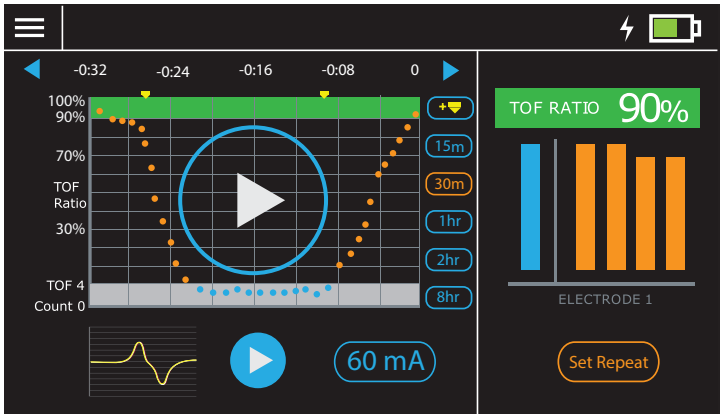
Note: Play button will be green if the electrode is attached to the patient, and red if an electrode is not attached to the patient or if there is poor contact.

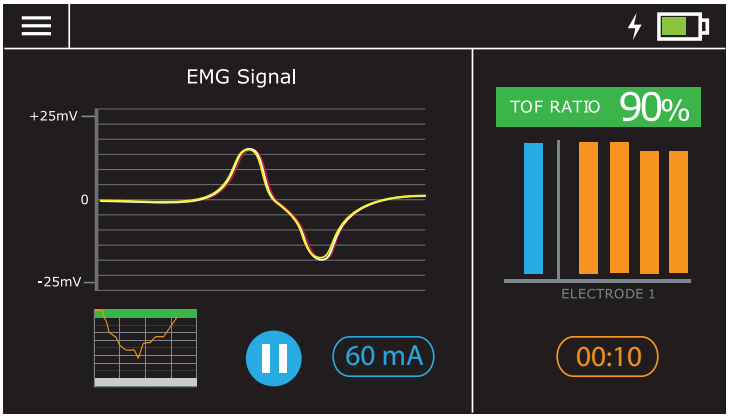
5 The system automatically selects the optimal EMG recording electrode and determines the supramaximal stimulation current. If the patient is already paralyzed, automated electrode selection and/or supramaximal current determination may not be possible, in which case the system uses default values.





6 The system begins Train-of-Four (TOF) monitoring. The user can toggle between a time plot (left panel below) and the EMG signal (right panel) by touching the screen over the smaller plot (lower left corner of screen). The stimulating current can be adjusted by touching the blue current icon, whereas the repeat frequency of the TOF and PTC sequence can be adjusted by touching the orange timer.

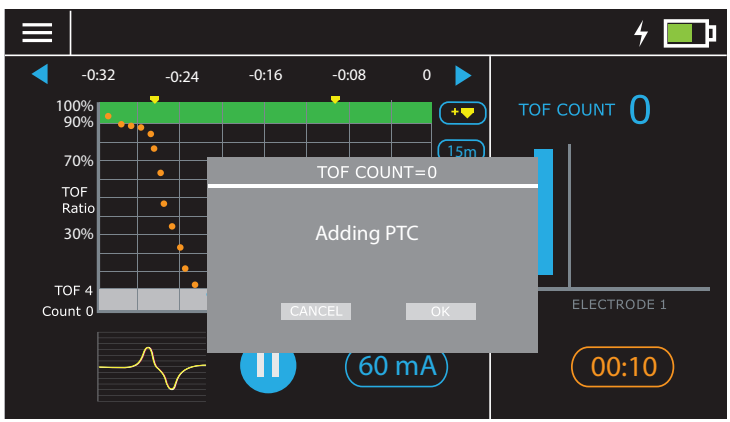


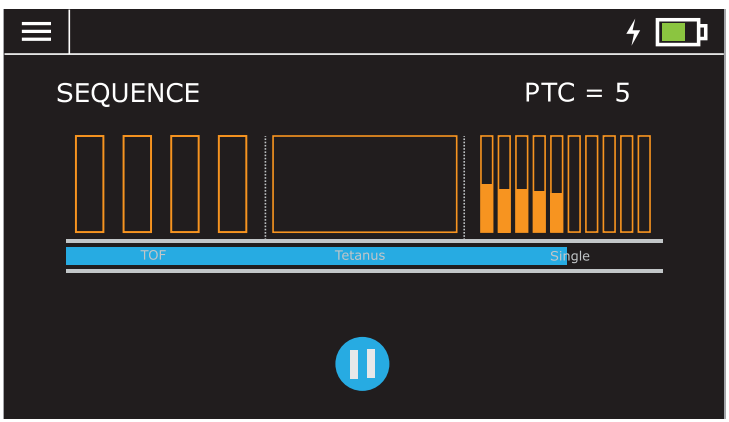


Note: If the supramaximal stimulating current has been determined, the height of the calibration pulse will be displayed in blue to the left of the train-of-four bars.

Note: If the signal quality is too poor to accurately determine a TOF count or a TOF ratio (e.g. due to excessive electrocautery noise or extreme physical motion), the screen will display "Excessive Noise."

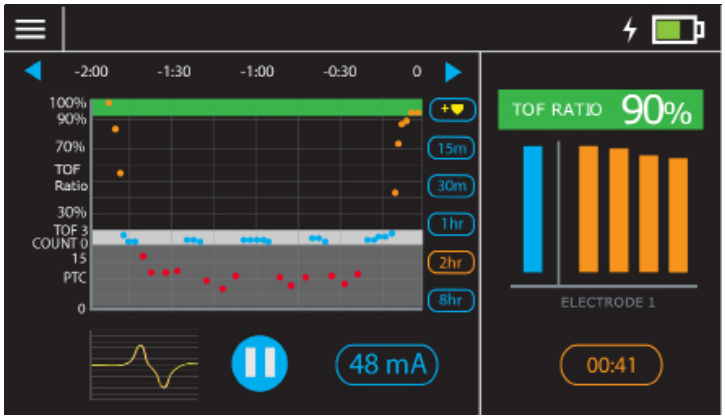
7 ***Auto PTC*** causes the system to switch between train-of-four stimulation and post-tetanic count (PTC) stimulation depending on the patient's degree of neuromuscular block. When enabled, if the TOF count decreases to zero during ongoing TOF monitoring, the user will be prompted to switch to PTC to monitor deep blockade.





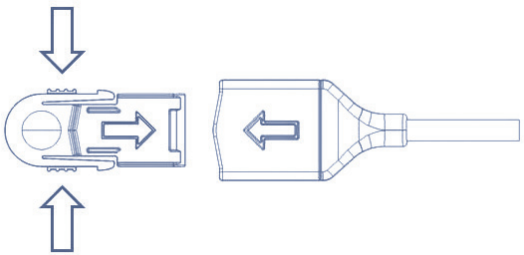
If selected, PTC is then repeated every 5 minutes as long as the patient continues to be in deep neuromuscular blockade (defined as a TOF Count of zero). If the TOF Count recovers to 1 or higher, the system switches back to TOF stimulation.

8 The x-axis (time) can be scaled using the five buttons (15m, 30m, 1hr, 2hr, 8hr) or shifted using the left and right scroll arrows. Events can be annotated on the time plot by pressing the event marker button( ) .



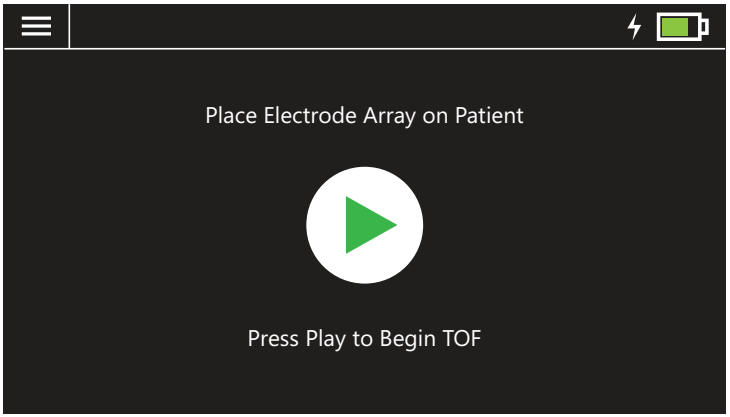
9 The Electrode Array is removed from the cable by compressing the two side grips on either side of the Array tab (see arrows in picture at left) and pulling the Array tab away from the cable.

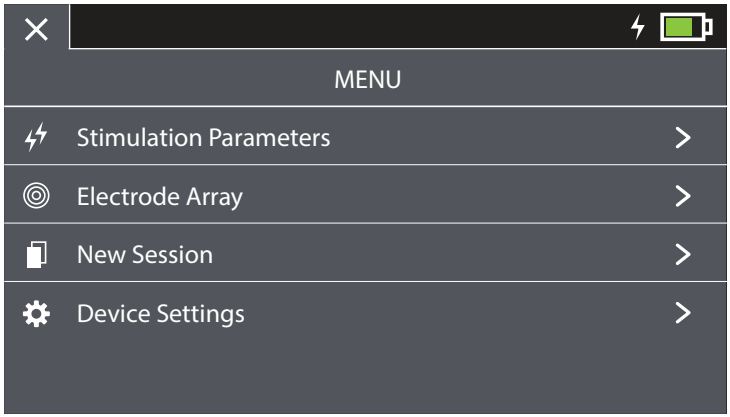
Note: The Electrode Array should be disposed of after use.



MENU

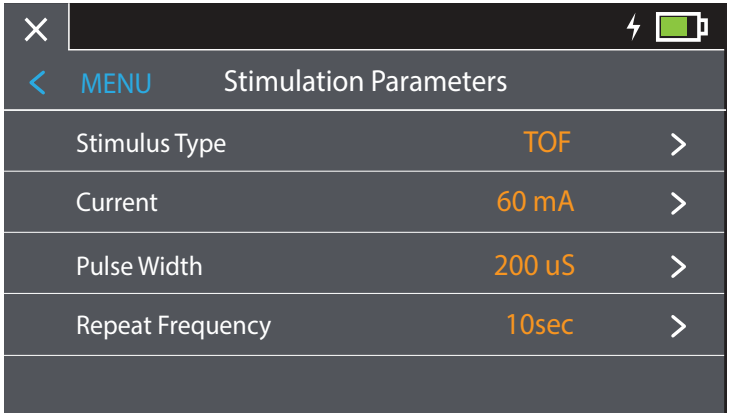
The menu can be accessed at any time by touching the menu icon in the upper left-hand corner of the display. Main menu choices include: **Stimulation Parameters, Electrode Array, New Session, and Device Settings.**





STIMULATION PARAMETERS

The user can select the **Stimulus Type** from the Stimulation Parameters menu, as well as adjust the **Current**, the **Pulse Width**, and the **Repeat Frequency**.

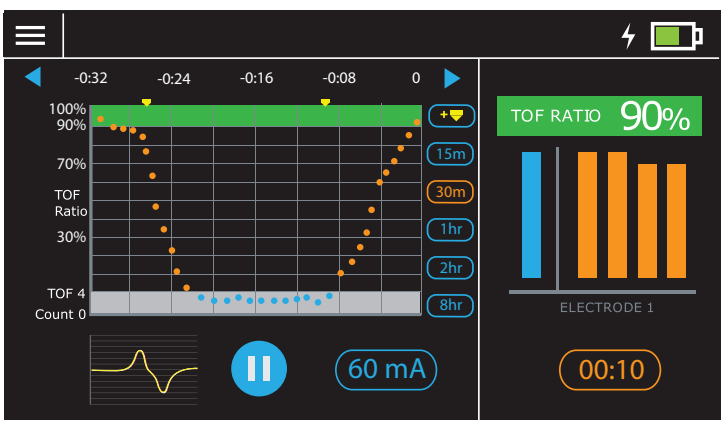


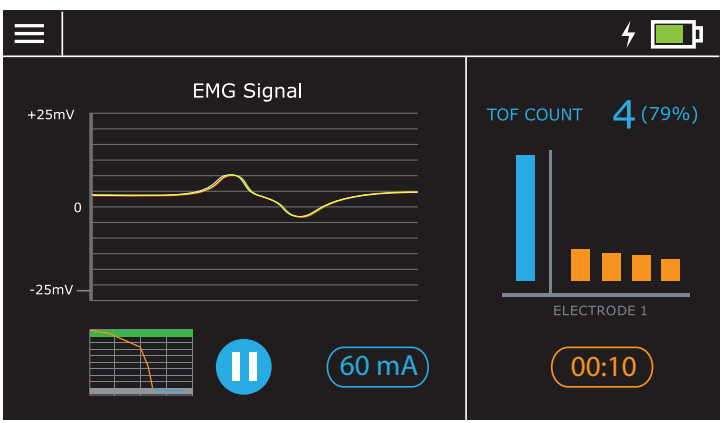
STIMULUS TYPE

Four stimulation sequences are available: **Train-of-Four**, **Post-Tetanic Count**, **Single Twitch**, and **Tetanus.**

Train-of-Four (TOF)

Four stimulation pulses are delivered at 0.5-second intervals. The muscle response is measured after each pulse and the ratio of the fourth to the first response (T4/T1) is calculated, resulting in a displayed **TOF Ratio** between 0–100%. If the fourth twitch is below the detection threshold, the **TOF Count** (the number of detectable twitches) will be displayed instead of the TOF Ratio.





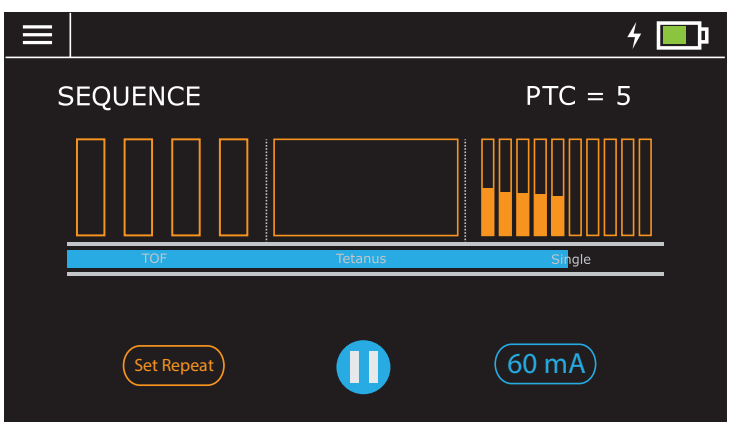
Note: When the TOF Ratio is ≥ 90% the screen surrounding the TOF Ratio will be displayed in green.

Note: If all four twitches are small, a TOF Count of 4 will be displayed with the TOF Ratio in parenthesis to indicate poor signal quality.

Note: If the displayed TOF data is over 15 minutes old, a timer will indicate the amount of time elapsed since the data was obtained.

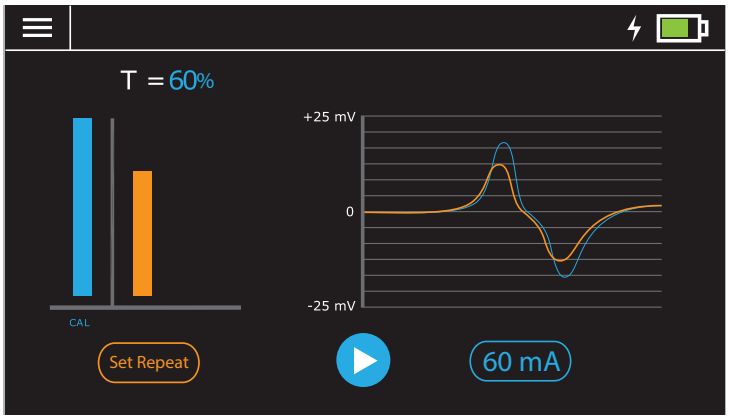
Post-Tetanic Count (PTC)

The PTC stimulation sequence, used to monitor deep neuromuscular blockade, consists of a 5-second, 50 Hz tetanic stimulation (to make the muscle more responsive) followed by a 3-second pause and then a series of single stimuli (up to 15 total) delivered once per second. The number of detectable responses to the single stimuli are counted and reported as the post-tetanic count. The fewer the detected responses, the deeper the neuromuscular blockade. To ensure PTC is only used in patients with deep neuromuscular blockade, a TOF is performed at the beginning of each PTC stimulation sequence. The tetanic stimulation is only delivered if the TOF Count is zero (no detectable twitches). Additional tetanic stimuli are prohibited for 2 minutes following the last tetanic stimulation. The progress of the PTC stimulation sequence is displayed dynamically during stimulation.



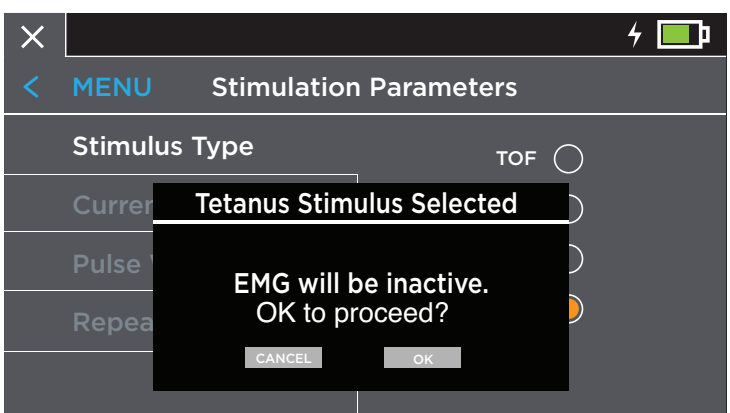
Single Twitch (ST)

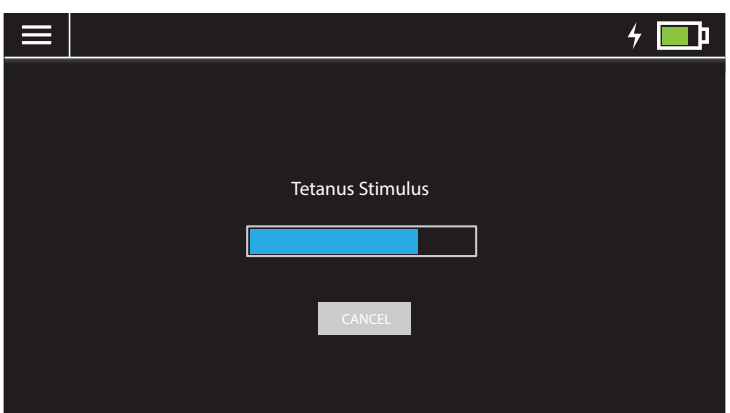
A single stimulation pulse is delivered, and the EMG response is measured and displayed. If the supramaximal current (supramax) has been determined, the supramax twitch height will be shown in blue and all subsequent single twitches will be scaled to the supramax value (0–100%). If supramax is not obtained, the response height is displayed on a fixed scale (0–100).



Tetanus

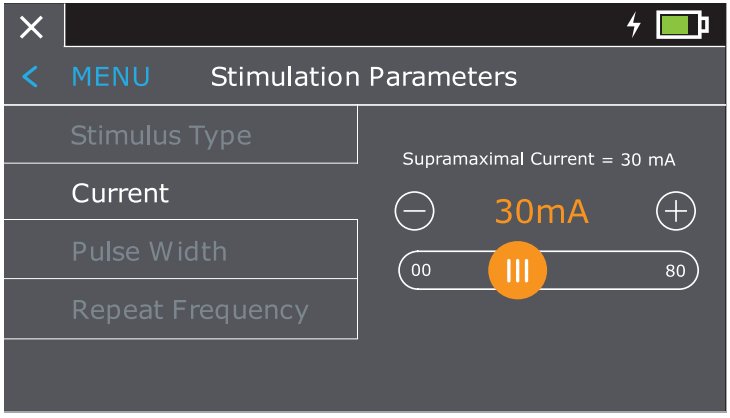
The system delivers a 5-second, 50 Hz tetanic stimulation. EMG is not active. Additional tetanic stimuli are prohibited for 2 minutes following the last tetanic stimulation.

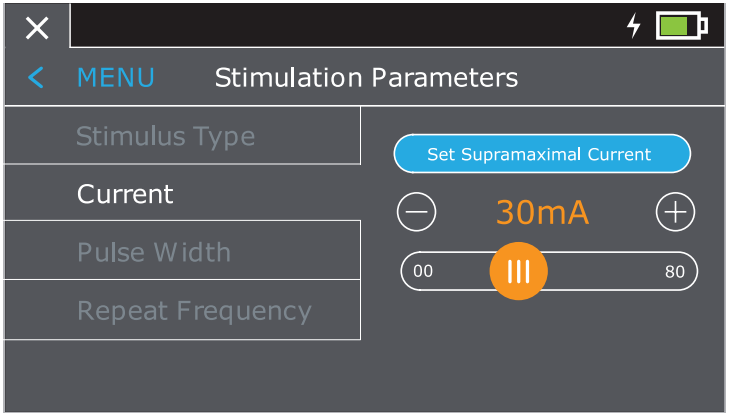




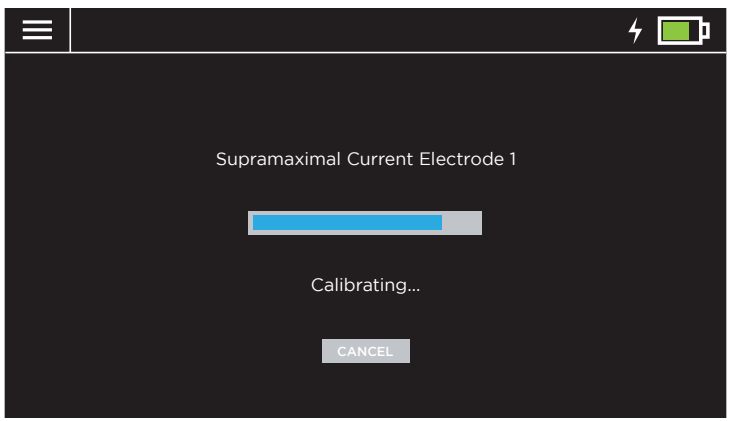
CURRENT

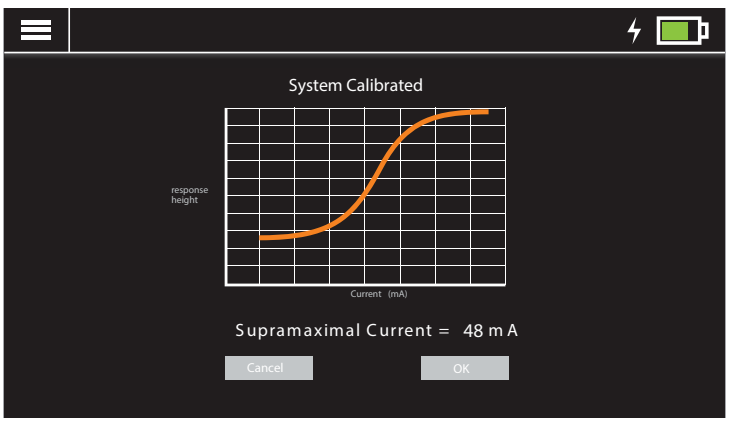
The stimulation amplitude can be adjusted from 0 mA to 80 mA in 1 mA increments. If the supramaximal current (the current required to activate the maximal number of fibers in the stimulated muscle) has been determined, the value will be displayed above the current adjustment slider (left figure below). If the supramaximal current has NOT been set, the user will be able to perform a supramaximal current determination by selecting the **Set Supramaximal Current** button (right figure below).





The **Set Supramaximal Current** sequence begins at 10mA and increases in 5mA increments until the increase in current does not increase the measured response. The selected current is increased by 20% resulting in a supramaximal current.

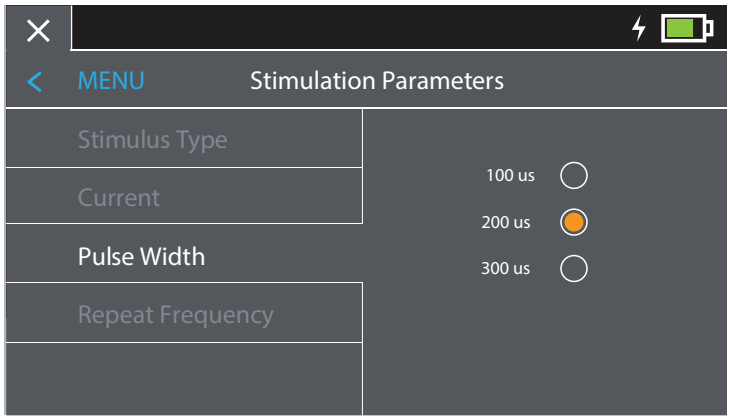




Note: The supramaximal sequence should be performed prior to the administration of neuromuscular blocking agents.
Note: The supramaximal sequence is aborted if the signal is unstable (e.g. the patient is paralyzed) and the current defaults to 65mA.
Note: Changes in hand or wrist position during patient positioning can alter the current required to elicit a supramaximal response. To prevent under stimulation, the monitor sets the minimum stimulation current to 48 mA if the supramaximal current is determined to be less than 48 mA.

PULSE WIDTH

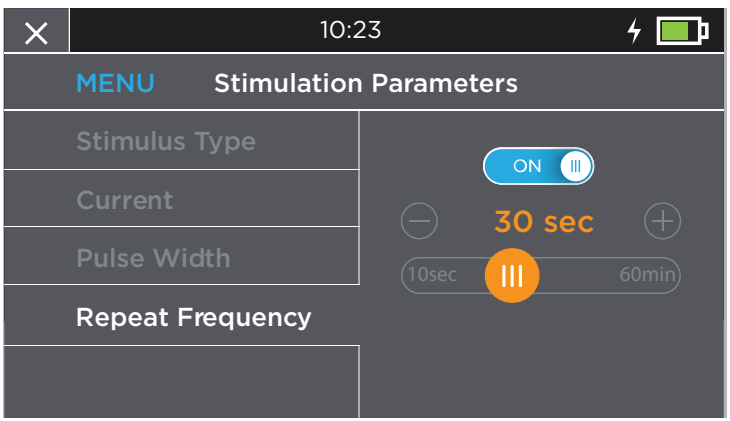
The pulse width can be selected as 100, 200 or 300 µs (default) using the **Pulse Width** menu.

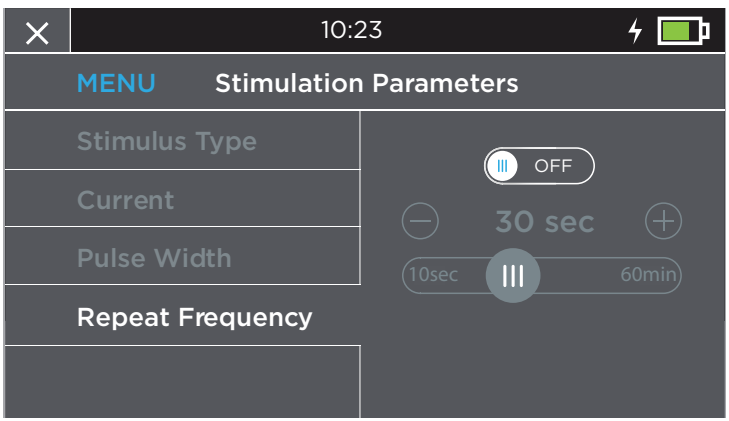


REPEAT FREQUENCY

The repetition frequency of the stimulation sequence can be adjusted (or turned off) in **Repeat Frequency**. The Repeat Frequency ranges are dependent on the specific stimulus type selected:

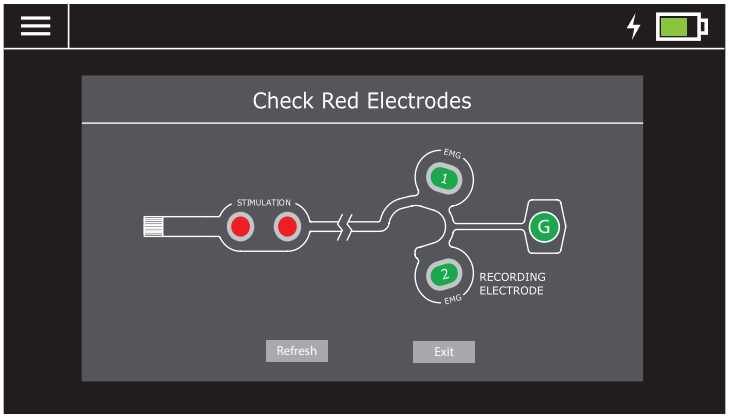
Sequence	Repeat Frequency Range
Train-of-Four	10 sec to 60 min
PTC	5 min to 90 min
Single Twitch	10 sec to 60 min
Tetanus	No repeat





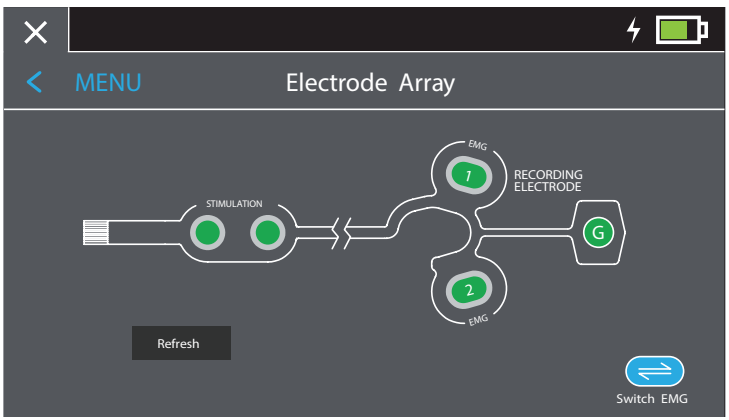
ELECTRODE ARRAY

The **Electrode Array** page shows the status of the electrode array (green indicates that the lead impedance is within expected values, whereas red means there is a problem with the electrode array). The electrode impedances are measured prior to each stimulation, and if a problem is detected, the system will automatically display the Electrode Array page.



The **Electrode Array** page also allows the user to select which of the two EMG recording sites to use (by pressing the blue toggle button). The currently selected EMG recording electrode is indicated on the screen.

Note: During Quick Start, the system selects the optimal EMG electrode recording site by measuring the EMG signal strength at each site and selecting the recording site with the largest signal.

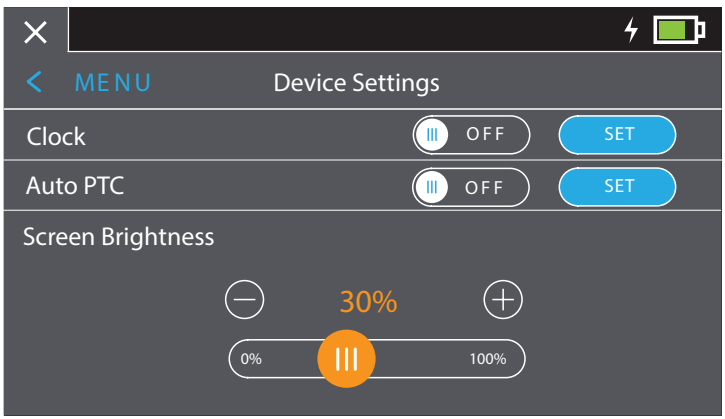


NEW SESSION

Selecting New Session clears all previous data and returns the system to the Start page.

DEVICE SETTINGS

The device settings menu has the following selections: Clock, Auto PTC, and Screen Brightness. Changes to device settings are not reset by a new session.



Clock

If the clock feature is enabled, the user will be prompted to set the date and time.

Screen Brightness

Screen brightness can be adjusted between 0 to 100%. Using a lower screen brightness will prolong battery life when the Monitor is not in the Charging Station.

DATA OUTPUT AND CYBERSECURITY CONTROLS

When the Monitor is docked in the Charging Station, data is output using a combination RS232 serial and Ethernet port implemented over an industry standard RJ45 connector. For data format and connectivity details, contact the manufacturer or your local sales representative.

The TwitchView System cannot be controlled or otherwise accessed via the external connection. The TwitchView does transmit data over its ethernet/serial cable, including the TOF Ratio, TOF Count, and PTC Count. The TwitchView System never contains or transmits Protected Health Information. Transmitted data could be intercepted by external devices. To avoid unauthorized access to the data, ensure that any external devices to which the TwitchView are connected are on a trusted network.

MONITOR CHARGING

The TwitchView System uses an inductive charging system that requires no direct electrical contact between the Monitor and the Charging Station. Charging begins automatically when the Monitor is docked in the Charging Station, and active charging is indicated by a charging symbol (ϟ).

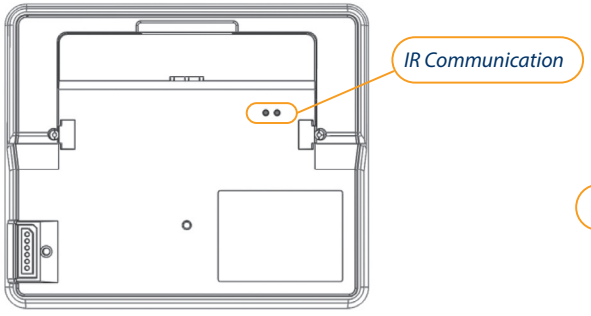
If the inductive charging fails, the user will notice the charging symbol does not appear on the Monitor. Reseat the Monitor in the Charging Station, and if charging does not resume, contact the Manufacturer.

POWER BUTTON

The Monitor has three power states (ON/OFF/STANDBY) that can be accessed via the Power button.
If the device is ON and the Power button is held down, the device enters either STANDBY (if docked in the Charging Station) or the OFF state (if undocked). If the screen is touched in STANDBY, the device enters the ON state. If the Monitor is removed from the charging station in STANDBY mode, it enters the OFF state if the screen is not touched within 30 seconds. If the device is OFF, pressing the Power button causes the unit to enter the STANDBY state.

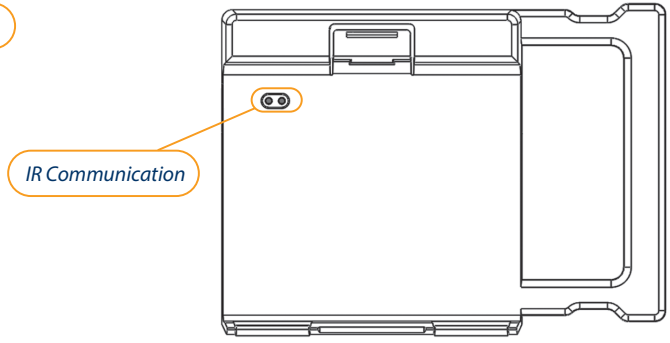
INFRARED DATA TRANSMISSION

When the Monitor is docked in the Charging Station, data is transferred from the Monitor to the Charging Station via an infrared data port. To ensure reliable data transmission, do not block the IR Communication Ports located on the back of the Monitor and the front of the Charging Station. If the IR Communication Ports are blocked or otherwise fail, data will not be transferred over the ethernet/serial cable. In the case of a failure of data transmission, check that the infrared communication ports are not blocked and that the cable connecting the Charging Station to the external device is intact. If communication does not resume, contact the Manufacturer.



Location of IR Communication
Port on the back of the Monitor

Location of IR Communication
Port on the front of the Charging Station



TECHNICAL SPECIFICATIONS

Stimulation

- Monophasic square wave, constant current
- Current Range: 0-80 mA
  - ±5% of full scale value above 20 mA
  - ±1 mA below 20 mA
- Pulse Width: 100µs, 200µs, or 300µs
- Maximum Stimulation Voltage: 300 V
- Maximum Load: 3.75 kOhm
- Frequency: 1Hz - 50Hz ±5%

EMG

- Accuracy: +/- 5%
- EMG amplitude determined using area under the curve

Battery

- Type: Lithium Ion, Rechargeable, 4.0 V, 3000 mAh
- Battery Life: At least 6 hours when fully charged

Input Power

- 0.25A/100-115VAC I 0.15A/230VAC I 50/60Hz
- Class II power supply with functional earth

Weight and Dimensions

- Approximately 1.3 kg with battery
- 200 x 175 x 75 mm

Safety and Efficacy Compliance

- IEC60601-1
- IEC60601-2-40 (EMG and Evoked Response Equipment)
- Class: Portable
- Type: Equipment
- Water Ingress Protection: IPXO (non-protected)
- Operation Mode: Continuous

EMC Compliance

- IEC60601-1-2

Cables

- TVCAB02 (12 ft Cable)
- TVCAB03 (14 ft Cable)

CLEANING

The case may be cleaned with a damp cloth. Thorough cleaning of the device can be achieved by using any of the following:

- Distilled water
- Methylated spirits
- 70% Isopropyl alcohol
- Non-bleach disinfectant
- Broad spectrum quaternary disinfectant
- Clorox Healthcare Fuzion cleaner disinfectant
- Bleach disinfectant

Other chemical cleaners may damage the case finish and are not recommended. Do not use abrasive cleaners as these will damage the surface. Do not allow liquid to enter the case.

CLINICAL BENEFITS

The TwitchView System is used for the quantitative monitoring of neuromuscular transmission by means of electromyography (EMG). The TwitchView System allows the clinician to assess the degree of neuromuscular blockade after neuromuscular blocking agents are administered to a patient. The measurements obtained by the TwitchView System are for diagnostic purposes, intended to aid in decision-making and supplement other patient management parameters; clinical decisions are not based solely on TwitchView System data.

Use of EMG leads other than those supplied with the TwitchView may result in serious injury.

Apply supplied electrode to patient's arm and hand as described in the IFU. Do not place the electrode on the patient's chest or allow the stimulating current to pass through the patient's chest. Do not apply stimulation across or through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.

Application of electrodes near the thorax may increase the risk of cardiac fibrillation.

Always make sure that no other equipment can touch the stimulation electrodes.

Electrodes should be applied only to normal, intact, clean skin. Electrodes should not be applied over open wounds or over swollen, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.). Placing electrodes over disrupted skin may lead to skin irritation, edema, or cellulitis.

Some persons may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

Never touch the electrodes unless the stimulation has been stopped.

Do not use in patients with implanted electrical devices, such as cardiac pacemakers, without first consulting an appropriate medical specialist.

Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.

Operation in close proximity (e.g. 1 m) to shortwave or microwave therapy equipment may produce instability in the stimulator output.

When removing electrode from patients with sensitive skin (e.g. infants or elderly patients) peel electrode off skin slowly and gently with a moisteneded gauze sponge. Rapid removal of electrode may tear the skin and increase the risk of cellulitis.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

SHIPPING, STORAGE, AND OPERATING ENVIRONMENT

The temperature of the TwitchView Monitor, Charging Station, and Electrode Array should be kept within the following limits:

	Shipping	Storage	Operation
Monitor	5˚C to +60˚C (41˚F to 140˚F)	5˚C to +60˚C (41˚F to 140˚F)	10˚C to +30˚C (50˚F to 85˚F)
Charging Station	5˚C to +60˚C (41˚F to 140˚F)	5˚C to +60˚C (41˚F to 140˚F)	10˚C to +30˚C (50˚F to 85˚F)
Electrode Array	5˚C to +60˚C (41˚F to 140˚F)	5˚C to +60˚C (41˚F to 140˚F)	10˚C to +30˚C (50˚F to 85˚F)

Humidity of all components should be kept between 15% to 85% (non-condensing). Protect the Monitor and Charging Station from sudden temperature changes that can lead to condensation within the instruments. To minimize condensation, avoid moving the system between heated buildings and outside storage.

SYMBOLS

Manufacturer
Indicates medical device manufacturer name and address
ISO 15223-1; 5.1.1

CE Mark - European conformity
Designates that the product labeled is authorized for sale in EU
Council Directive 93/42/EEC, 2017/745

Authorized European representative
Indicates authorized representative in EU
ISO 15223-1; 5.1.2

Prescription use only
Requires prescription for sale in US
21 CFR Part 801.1(c)(1)(i)F

Temperature limit
Indicates temperature limits to which medical can be safely exposed
ISO 15223-1; 5.3.7

Keep dry
Indicates medical device to be protected from moisture
ISO 15223-1; 5.3.4

Catalogue or model number
Indicates medical device manufacturer's catalogue number
ISO 15223-1; 5.1.6

Serial number
Indicates medical device manufacturer's serial number
ISO 15223-1; 5.1.7

Degrees of ingress protection provided by enclosure
Not protected against the effects of water ingress
IEC 60529

Caution
Indicates caution is necessary when operating device
ISO 15223-1; 5.4.4

WEEE wheeled bin
Indicates product should be separately collected and not disposed of as unsorted waste
Directive 2012/19/EU Annex 1X (WEEE)

Consult instructions for use
Indicates the need for the user to consult instructions for use
ISO 7010-M002

MR unsafe
Indicates device poses unacceptable risk within MR environment
ASTM F2503-13; 7.3.3

Class II equipment
Indicates device meets safety requirements according to IEC 61140
IEC 60601-1, IEC 60878

Type BF applied part
Indicates type B applied part per IEC 60601-1 (B=Body; F=Floating)
IEC 60601-1, IEC 60878

Non-sterile
Indicates device has not been subjected to a sterilization process
ISO 15223-1; 5.2.7

Medical device
Indicates item is a medical device
ISO 15223-1; 5.7.7

ISO 15223-1: Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

IEC 60529: Degrees of protection provided by enclosures (IP Code)

IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

ASTM F2503-13: Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

IEC 60878: Graphical symbols for electrical equipment in medical practice

ISO 7010: Graphical symbols - Safety colors and safety signs - Registered safety signs

21 CFR Part 801.1(c)(1)(i)F: Labeling - Medical devices, prominence of required label statements

DISPOSAL OF MONITOR AND CHARGING STATION

Contact Blink Device Company for a Return Materials Authorization (RMA) number. According to the WEEE Directive 2002/96/EC, all waste electrical and electronic equipment (EEE) should be disposed of and collected separately and treated according to the best available and environmentally friendly techniques. EEE contains hazardous substances to the (human) environment but also EEE is a valuable resource of new raw materials. Therefore, it is important to collect WEEE separately from other waste.

Blink Device Company urges you to dispose of the Monitor and Charging Station separately and make sure that it is treated at an electronics recycler. Please contact your municipality or the nearest collection site and dispose of waste equipment there and make sure the discarded equipment does not end up in the "normal" household waste.

ELECTROMAGNETIC COMPATIBILITY GUIDANCE

This section provides the appropriate specification tables for the TwitchView System per IEC 60601-1-2

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The TwitchView Monitor and Charging Station are intended for use in the electromagnetic environment specified below. The customer or user of the TwitchView System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment- User Guidance**
RF Emissions CISPR 11	Group 1	The TwitchView Monitor and Charging Station use RF energy only for their internal function. Therefore, the RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The TwitchView System is suitable for use in all environments, including those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes. The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals.
Harmonic Emissions IEC 61000-3-2	Class A	
Flicker Emissions IEC 61000-3-3	Complies	

Caution: The TwitchView System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the TwitchView Monitor should be observed to verify normal operation in the configuration in which it will be used.

Caution: Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the TwitchView System.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The TwitchView Monitor and Charging Station are intended for use in the electromagnetic environment specified below. The customer or user of the TwitchView Monitor and Charging Station should ensure that it is used in such an environment.			
Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment- Guidance
Electrostatic Discharge IEC 61000-4-2	Contact +/- 8kV Air: +/- 2kV, +/-4kV, +/-8kV, +/-15kV	Contact +/- 8kV Air: +/- 2kV, +/-4kV, +/-8kV, +/-15kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated Immunity IEC 61000-4-3 Conducted Immunity IEC 61000-4-6	3V/m 80MHz to 2.7GHz AC Mains: 3 Vrms & 6Vrms 150kHz to 80MHz IO lines: 3 Vrms & 6Vrms 150kHz to 80MHz	3V/m 80MHz to 2.7GHz AC Mains: 3 Vrms & 6Vrms 150kHz to 80MHz IO lines: 3 Vrms & 6Vrms 150kHz to 80MHz	Portable and mobile communications equipment should be separated from the TwitchView System by no less than the distances calculated below: D = (3.5/3)*(Sqrt P): 80 to 800 MHz D = (7/3)*(Sqrt P): 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. Field strengths from fixed transmitters as determined by an electromagnetic site survey[a] should be less than the compliance levels in each frequency range[b]. Interference may occur in the vicinity of equipment containing a transmitter.
Electrical Fast Transient Burst IEC 61000-4-4	AC Mains: 2kV, 100kHz PRF DC Mains: NA	AC Mains: 2kV, 100kHz PRF DC Mains: NA	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Mains: +/- 0.5kV and +/-1kV line to line DC Mains : NA IO Mains : NA	AC Mains: +/- 0.5kV and +/-1kV line to line	Mains power should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC 61000-4-8	30A/m; 50Hz and 60Hz	30A/m; 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage Dips and Interrupts IEC 61000-4-11	0% for 0.5 cycle 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles	No effect	Mains power should be that of a typical commercial or hospital environment.
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. *Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TwitchView system is used exceeds the applicable RF compliance level above, the TwitchView system should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the TwitchView System [b] Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.			

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the TwitchView System

The TwitchView Monitor and Charging Station are intended for use in the electromagnetic environment in which RF disturbances are controlled. The customer or user of the TwitchView System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TwitchView System as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	**Separation Distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz D=(3.5/3)*(Sqrt P)	80 MHz to 800 MHz D=(3.5/3)*(Sqrt P)	800 MHz to 2.5 GHz D=(7/3)*(Sqrt P)
.01	0.117	0.117	0.233
.1	0.369	0.369	0.738
1	1.167	1.167	2.334
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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TwitchView®

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