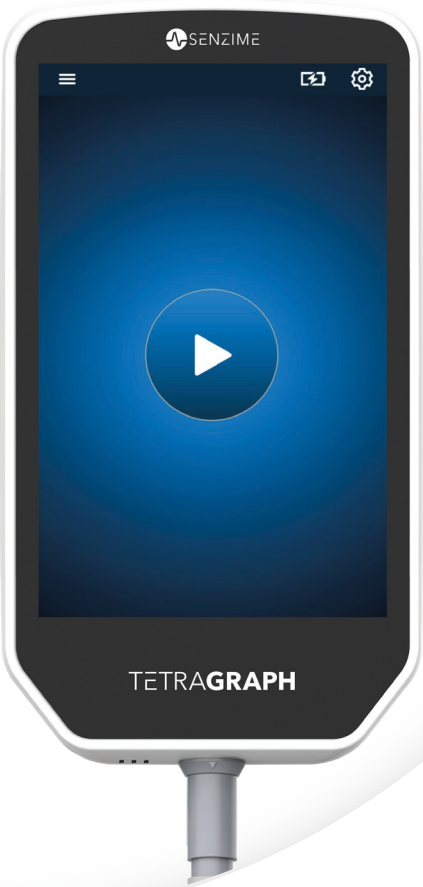
English



TETRAGRAPH

Rx Only

Neuromuscular Transmission Monitor

Operating instructions

SENZIME

Contents

1. Introduction

These instructions are intended to assist with the operation of the TetraGraph Neuromuscular Transmission (NMT) monitor and its TetraSens sensors.
The TetraGraph monitors neuromuscular block. Information from the TetraGraph is intended to complement clinical information obtained with other monitors and clinical judgment to determine if ventilation is adequate.
Always check the TetraGraph monitor and ensure it is able to complete the self-check sequence when first turned on. Inspect the device and associated accessories for any physical damage or missing parts.

2. Scope of Use and Contraindications

Intended Users

The TetraGraph system and monitor must be operated by trained and competent clinical staff and used in accordance with approved clinical practice and local guidelines and recommendations.

Intended Use

The Intended Use of the TetraGraph is to deliver stimulations to a nerve and record, measure, analyze and report muscle electrical activity to determine muscle function.
TetraGraph is a Neuromuscular Transmission (NMT) monitor intended for use in hospital settings including operating rooms, subsequent recovery areas and in critical care settings. The device is for use with patients (excluding neonates), and where the patient is or has been mechanically ventilated and when a neuromuscular block has been administered.
Neuromuscular Transmission is the transfer of an electrical impulse between a motor nerve and its associated muscle. NMT is blocked by neuromuscular blocking agents (NMBA) which cause transient muscle paralysis, preventing the patient from moving and breathing spontaneously.
Muscle relaxation is used during general anesthesia to enable endotracheal intubation and to provide optimal surgical conditions. In critical care, muscle relaxation may be used during mechanical ventilation. In these settings, TetraGraph can be used as an objective monitor of neuromuscular transmission.

NOTE TetraGraph is not for use in MRI environment (it is not MRI compatible).

WARNING Patients with an implanted electronic device such as a cardiac pacemaker must not be subjected to electrical stimulation until specialist medical opinion has been obtained.

WARNING Do not use in a flammable atmosphere or in places where flammable anesthetics may concentrate.

CAUTION Patients with pre-existing neuromuscular disease (Myasthenia Gravis, Dystrophy etc.) or patients with cerebrovascular accidents (CVAs or Stroke) may have unexpected electromyographic responses that may affect the results of the monitoring. Place the EMG responses in appropriate clinical context.

Indications for Use Statement

The TetraGraph Neuromuscular Transmission (NMT) monitor is indicated for monitoring the relaxation of the patient when neuromuscular blockade is administered.

Rx Only — Federal law restricts this device to sale by or on the order of a physician. (US only)

Clinical Benefits

The major benefit to the patient, provided by TetraGraph, is the ability to monitor the degree of neuromuscular block when NMBAs are administered in conjunction with surgery and/or mechanical ventilation.
Clinical decisions are never based solely on data from TetraGraph. Thus, information obtained from TetraGraph should be considered as supplementary for optimal patient management decisions. For that reason, specific clinical outcome parameters such as operation time, symptom reduction, time to discharge etc. cannot be directly attributed to the device, and clinical outcome must be related to the overall benefit of neuromuscular relaxation monitoring.

3. Modes of Operation

A Neuromuscular Transmission (NMT) monitor shows the presence of a neuromuscular block by stimulating a peripheral motor nerve and evaluating the evoked muscle response. TetraGraph undertakes this function by periodically applying electrical stimulation to the peripheral nerve and directly measuring the evoked electromyographic (EMG) response of the muscles. This provides a quantitative and automatic measurement of muscle response to a stimulus.

Train of Four (TOF), TOF Ratio (TOFR) and TOF Count (TOFC)

The TOF Mode involves the emission of a sequence of four stimuli, known as a Train of Four (TOF), where the ratio of the fourth to the first twitch, the Train of Four Ratio (TOFR) and TOF Count (TOFC), is calculated from the evoked EMG responses. The first response in the TOF sequence (T1) (before the administration of any neuromuscular block) is stored as a T1 baseline signal strength (response) against which further measurements may be compared. A T1 baseline signal strength above 5 mV indicates an adequate signal strength to provide a

good EMG measurement throughout the procedure.

Minimal and Shallow Level of Block

The baseline Train of Four Ratio (TOFR) is determined before administration of neuromuscular blocking agents, but after induction of general anesthesia. The baseline TOFR is displayed as 100%, representing a ratio of 1.0. During a partial non-depolarizing block, the ratio (percentage) decreases from 100% to 0% as the degree of block increases, indicating a minimal followed by shallow level of block. At ratio 0% the fourth response (T4) disappears.

Moderate Level of Block

TOF Count (TOFC) is displayed when three responses remain, indicating a moderate level of block. As depth of neuromuscular block increases the third (T3) and the second (T2) response disappears. When the last response in the train (T1) disappears the TOFC becomes 0.
When depolarizing agents such as succinylcholine (suxamethonium) are used, there is usually no fading. The response amplitude decreases simultaneously in all four responses and the TOFR remains close to 100% until all responses disappear. The use of Single Twitch (ST) may be an alternative to TOF when depolarizing agents are used.

Post-Tetanic Count (PTC)

Deep Level of Block

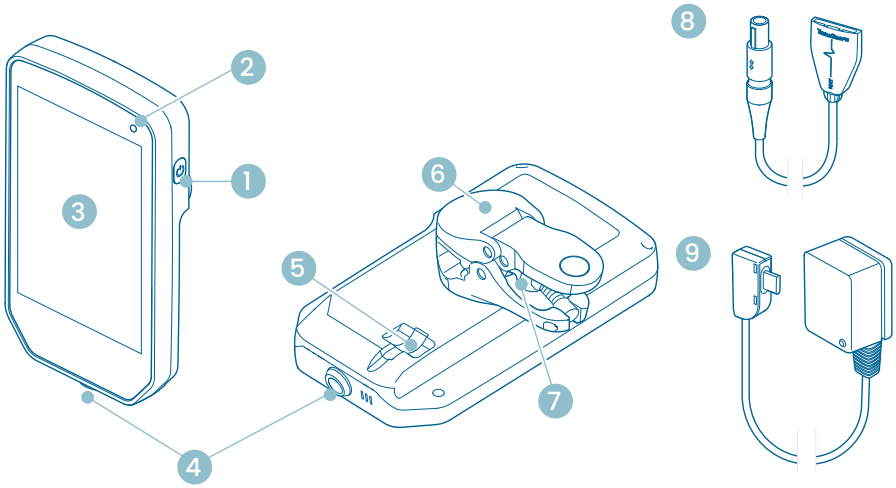
PTC mode is enabled when the TOFC is 0 and is used to monitor a deep level of block. PTC mode executes a tetanic stimulation protocol with a high frequency (50 Hz) tetanic stimulation lasting 5 seconds with the stimulation parameters (current (mA) and duration (µs)) automatically selected in Auto Start mode. If Manual Start mode is used, the manually selected stimulation parameters are used. The tetanic stimulation is followed 3 seconds later by up to 20 separate single stimulations at 1 Hz. PTC is the number of responses detected following tetanic stimulation and may be a number between 0 and 20, zero indicating a complete neuromuscular block.
After delivery of a PTC sequence, the TetraGraph disables PTC mode for at least 2 minutes. The selection of adaptive, manual or repeated PTC is made in the Settings menu. **Adaptive PTC™** is the TetraGraph's default setting for PTC. See more in PTC Options on page 23.

Single Twitch (ST)

The ST Mode delivers a single stimulation and displays a single response, repeated every 5 or 10 seconds. The first measurement, commonly determined before the administration of any neuromuscular block but after induction of general anesthesia, is stored as a baseline signal strength (Tref) against which further measurements may be compared. The TetraGraph Gauge displays the T1 amplitude in mV and T1/Tref Ratio in percent (%). A baseline signal strength above 5 mV indicates an adequate signal strength to provide a good EMG measurement throughout the procedure.

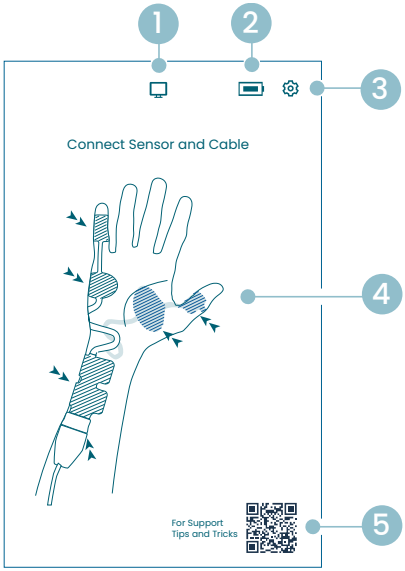
4. Getting to Know the TetraGraph

Device Layout



1. Power On-Off Button
2. Battery Charge Indication Light
3. Front glass with Touch Screen
4. Cable Connector for the TetraCord Patient Cable
5. Port for TetraGraph Power Supply Cable
6. Pole Clamp
7. Pole Clamp Grip Adjusting Screw
8. TetraCord Patient Cable
9. TetraGraph Power Supply Cable (USB-C)

Screen Layout



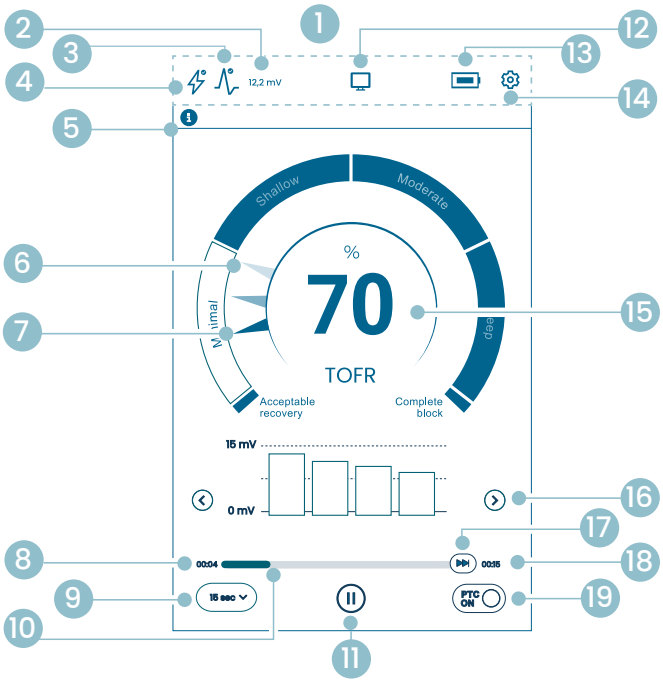
Sensor Positioning Screen

1. External Monitor Indication
2. Battery Capacity Indication
3. Button to Open the Settings Menu
4. Instructions for Sensor Positioning on the Ulnar Nerve, and ADM or AP Muscle
5. Support (QR code to access user manual, quick guides, and additional support)

Start Screen

1. Alternative Start
   a. Manual Start (Recovery Room)
   b. Single Twitch (Depolarizing)
2. External Monitor Indication
3. Battery Capacity Indication
4. Button to Open the Settings Menu
5. Auto Start Button

TetraGraph Main Screen



1. Information Bar
2. Signal Strength (T1 Baseline)
3. Signal Strength Icon
4. Stimulation Setting Icon
5. Notification Bar
6. Trend (1 minute)
7. Current Level of Block
8. Time Since Last Measurement
9. Time Interval
10. Measurement Time Bar
11. Pause Button
12. External Monitor Indication
13. Battery Capacity Indication
14. Button to Open the Settings Menu
15. Measurement Result
16. Display Mode Selection
17. On Demand Measurement
18. Time To Next Measurement
19. PTC Mode Indication and On/Off Button

TetraGraph icons

No	Icon	Name	Description
1.	-	Information Bar	Display icons and statuses for Stimulation, Signal Strength, Signal Strength (T1 Baseline) numeric, External monitor connection, Battery capacity. Location for the Settings menu button.
2.	12,2 mV	Signal Strength (T1 Baseline)	Indicates the established or estimated Signal Strength (T1 Baseline). It is recommended to strive for a mV response (Signal Strength) above 5 mV. If monitoring starts on an already muscle relaxed patient TetraGraph Adaptive Intelligence™ provides an estimated signal strength reading to help guide optimal sensor placement.
			12,2 mV — Established signal strength
			(~12,2)mV — Estimated signal strength (in parentheses).
3.		Signal Strength Icon (Supplemented with the T1 baseline mV, if established)	 The signal strength has not been evaluated. The icon is only visible in the auto setup gauge during Auto start.
			 Good signal strength has been detected (>5 mV)
			 Signals have been detected, but the signal strength is poor (<5 mV)
			 No signal detected since the start of the case.
4.		Stimulation Setting Icon	 The stimulation has not been set. The icon is only visible during the Auto start.
			 A supramaximal stimulation has been set. (Patient specific stimulation)
			 The maximum stimulation settings are used (in Auto start mode). The stimulation is set manually (in Manual Start mode)
5.		Notification bar	Always follow the instructions in the Notification bar. The Notification bar provides additional guidance through messages or questions/call for action displayed as notifications. Text notifications are accompanied with an icon indicating type and importance.
			 (Blue). Information. Visible until the next measurement, or any change of state.
			(Yellow) Important information and/or a call for action
			 (Green) Supramaximal stimulation has been set. A good signal strength has been detected.
			 (Red) No signal detected since start of case, or device error.

No	Icon	Name	Description
6.		1 Minute Trend	Display 1 minute trend view. The faded (transparent) needles in the Level of Block Gauge™ indicate direction of the trend. Old values fade out after 1 min. with increased transparency for the oldest value. A maximum of 4 needles are displayed on the screen simultaneously.
7.		Current Level of Block	The filled (opaque) needle indicates the current Level of Block
8.		Time Interval	The time interval button shows the current time interval for TOF (during TOF measurement), and for PTC (during PTC). The button can be pressed at any time to change the interval. See more detailed information and learn about adaptive and manual time interval in Measurement Time Interval on page 25.
9.		Time Since Last Measurement	Indicates the time since the last valid measurement. Always increasing. If the device is paused, or measurement failed, the values continue to increase.
10.		Measurement Time Bar	Progress bar that Indicates the elapsed time/ countdown to the next measurement. If the device is paused the bar is greyed-out.
11.		Pause Button (Play and Stop Buttons)	 Tap the Pause button to pause measurement.  Tap the Play button to resume measurement.  Tap Stop button to stop start up process
12.		External Monitor Indication	If no monitor has been connected: Empty.  External monitor connected.  Lost connection with external monitor.
13.		Battery Indicator	The battery level is indicated by an icon in combination with a color. Tap on the battery icon to display battery capacity % information.
14.		Settings	Tap to open the settings menu and access: New patient, Go to ST Mode / Go to TOF Mode, PTC mode, Stimulation, Device, and Data.

No	Icon	Name	Description
15.		Measurement Result	Displays the result from the last measurement (TOF Ratio, TOF Count, number of PTC responses, or Single Twitch response). The color of the number indicates the patient's level of block. (If monitoring is paused the value is displayed in faded dark grey.).
			White indicates a minimal to moderate level of block.
			Pink indicates a deep level of block.
			Green indicates acceptable recovery from neuromuscular block.
16.		Display Mode Selection	Tap the arrow to navigate between the available Bar Graph, EMG curve (wave), and Trend Graph view. (Trend Graph is only available in TOF mode).
17.		On Demand Measurement	On Demand measurement is enabled after 15 sec. when interval is set to > 15 sec. for TOF, or after 2 min. when interval is set to > 2 min. for PTC measurements. Tap the On Demand measurement button to start a measurement before the set time interval has passed.
18.		Time to Next Measurement	A countdown timer to the next measurement. If the device is paused no values are displayed and the time bar is greyed out.
19.		PTC Mode Indication	The PTC ON mode can be turned off at any time by pressing the PTC button. During PTC measurement, the PTC button changes to pink. See more detailed information about the different PTC modes in PTC Options on page 23.

Settings Menu Overview

	Level 1 menu	Level 2 menu		Level 3 menu
	Actions			
	New Patient			
	Go to ST Mode / Go to TOF Mode (Switch operating mode)			
	Settings			
	PTC Mode: • Adaptive (default) • Manual • Repeated			
	Stimuli	Stimuli Current: 30 mA (default) 10/20/30/40/50/60 mA		
		Stimuli Puls Width: 200 us (default) 200 / 300 us		
	Device		Brightness Adjustment	
			Sound	Volume Adjustment
				Low Battery Notification: On/Off
				Lead off Notification: On/Off
			Date/time	Enter Date/Time (HH/MM/SS)
			Communication: • OFF • General • IntelliVue	
			Configuration (Password protected)	
			Service (Password protected)	
			Info	Software version and Serial number
	Data		Upload	Select and send files.
			Delete/Manage	Select and delete files.
			Case Reference	Max 8 digits.

The Monitor System

The system as delivered includes the following items:

- SEN 2015 TetraGraph monitor with an attached Pole clamp
- SEN 2112 TetraCord Patient Cable
- 0715 Fixed Cable Power Supply (FRIWO model No. FW8002.1M/05)
- INFO0124 Operating Instructions (this document, markets outside of US)
- INFO0136 Welcome to Your New TetraGraph (US market only)

Accessories

Accessories for SEN 2112 TetraCord Patient Cable:

- SEN 2012 Box of 20 TetraSens electrodes (each SEN 1010)
- SEN 2013 Box of 15 TetraSens Pediatric electrodes (each SEN 1011)
- SEN 2016 Box of 15 TetraSensitive electrodes (each SEN 1013)

Associated Devices / Optional Accessories & Spare Parts

- SEN 2017 TetraHub
- SEN 2230 18ft TetraCord Patient Cable

On receipt and after periods of storage, clean and disinfect the TetraGraph before using it. Further instructions are detailed in section 9. Cleaning and Disinfecting on page 36.

WARNING Before use visually inspect the device and the patient cable for any loose or damaged parts. If the performance of the device changes from that specified, required or expected, take the device out of service immediately.

CAUTION Before use, ensure the monitor is intact and the battery is fully charged or connected to power supply.

5. Setting Up

Setting Up the SEN 2015 TetraGraph

Connect the TetraGraph to Power

1. Use the Fixed Cable Power Supply included in the system.
2. Connect the USB-C cable to the USB-C port on the back of the TetraGraph and connect the power supply to the mains electricity.
3. Alternatively charge the installed rechargeable battery before use with the supplied power supply.

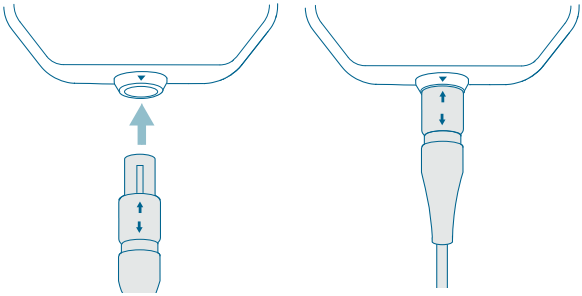
Battery Charging

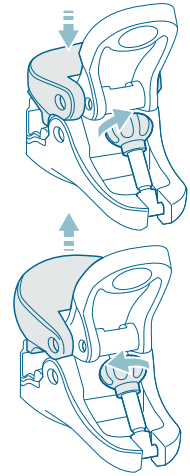
To charge the device, connect the power supply unit to the USB-C port on the back. The battery charge indicator light in the upper right corner of the device will light up. The LED lights orange when charging and turns green when the battery is fully charged. The LED indication will be off when the charger is not connected. See Device Layout on page 8.
If it is required to stop charging due to a malfunction, you should disconnect the USB cable and disconnect the power supply from the mains electricity. To facilitate disconnection, ensure the location is easy to access.

Connect the TetraCord Patient Cable to the TetraGraph Monitor

1. Connect the TetraCord cable to the monitor by inserting the cable straight into the connector.
2. The black arrow on the cable connector should be aligned with the black arrow on the connector/port in the monitor.

NOTE DO NOT TWIST the cable connector when inserting it into the connector on the monitor!





Pole Clamp

1. Adjust the pole clamp grip range by turning the grip adjustment screw clockwise or counterclockwise.
2. Attach the TetraGraph to the pole/post with the pole clamp.
3. Ensure that the clamp has a sufficient grip

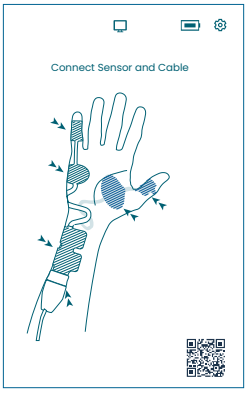
Turn On the TetraGraph

The power On-Off button is located on the right side of the monitor see Device Layout on page 8.

1. Press the On-Off button for 1 second.
2. A short beep sound confirms that the device has been switched on.
3. The screen illuminates, and the monitor performs a self-test.
4. After the self-test sequence, the Start-up screen will be shown.

The software version is shown at the bottom of the Start-up screen.

NOTE It takes about 5 seconds for the screen to light up after pressing the On-Off button. The complete startup process takes 20 seconds.



Sensor Positioning Screen

The sensor positioning screen is displayed after the Start-up screen.
The image on the screen shows the correct placement of the electrodes over the ulnar nerve and hand.
Proceed with applying the sensor to the patient and connect the sensor to the TetraCord cable in accordance with instructions in Preparation and Positioning of the Sensor on page 18.

Preparation and Positioning of the Sensor

WARNING Apply only to intact, dry, and clean skin with normal sensation.

NOTE Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins, etc.) or over, or in proximity to, cancerous lesions.

CAUTION Patients with pre-existing neuromuscular disease (Myasthenia Gravis, Dystrophy etc.) or patients with cerebrovascular accidents (CVAs or Stroke) may have unexpected electromyographic responses that may affect the results of the monitoring. Place the EMG responses in appropriate clinical context.

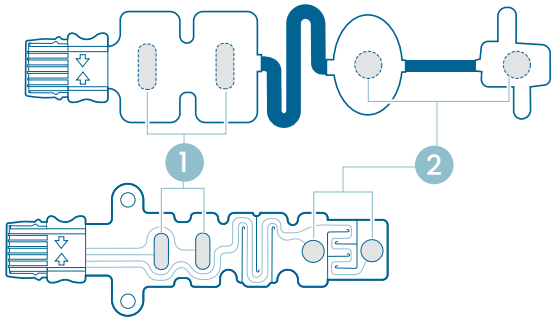
CAUTION Ensure that conductive parts of the sensor or patient cable are in contact with the patient only

Skin Preparation

The sensor can be applied to either hand or foot.

1. If necessary to remove hair, clip instead of shaving.
2. Lightly abrade with a clean gauze sponge.
3. Clean thoroughly and dry the skin area completely before application.

Description of Sensor Electrodes



1. Stimulating electrodes
2. Recording electrodes

Measurement on the Hand

Apply the stimulating electrodes over the ulnar nerve at the wrist, and the recording electrode on the hypothenar muscle below the little finger (abductor digiti minimi muscle), or the thenar muscle below the thumb (adductor pollicis muscle). The distal recording electrode is placed on the little finger or the thumb, as illustrated below.

Measurement on the Foot

Apply the stimulating electrodes over the posterior tibial nerve at the ankle (behind the medial malleolus), and the recording electrode on the flexor hallucis brevis muscle located on the foot adjacent to the plantar surface of 1st metatarsal (the bone just behind the big toe on the sole of the foot). The distal recording electrode is placed under the big toe, as illustrated below.

If surgery is being conducted on an arm/foot, place the TetraSens sensor on the opposite arm/foot avoiding nonsterile sensor in the proximity of the surgical site and in the case of high frequency (HF) electrocautery reducing the effect of potential interference.

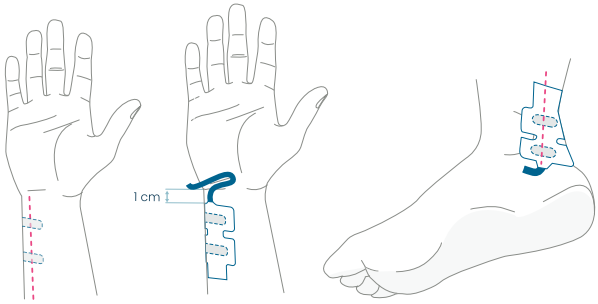
WARNING Patients with an implanted electronic device such as a cardiac pacemaker must not be subjected to electrical stimulation until specialist medical opinion has been obtained.

NOTE On patients with pacemaker, place the stimulation electrodes as far from the pacemaker as possible (on the lower extremity or the arm opposite the pacemaker location), and weigh the risks vs. benefits. If neuromuscular monitoring is deemed necessary, use as low a current as possible to induce an evoked response, and stimulate only as frequently as necessary.

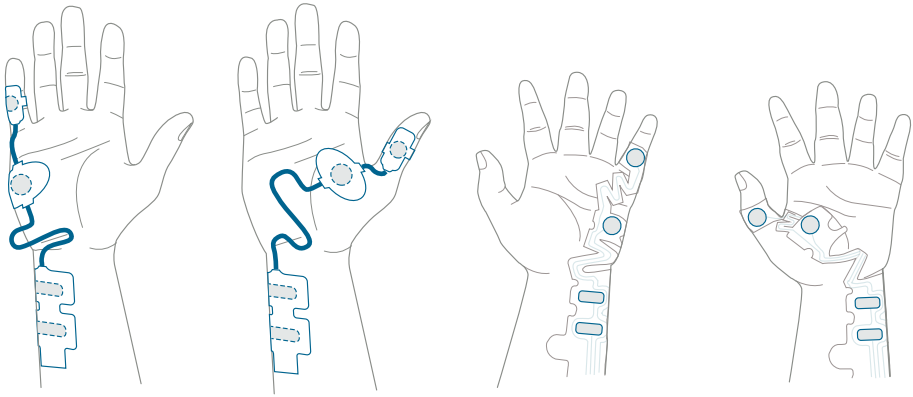
Positioning of the Sensor

Place the electrodes on the hand or foot before connecting the sensor to the TetraCord cable.

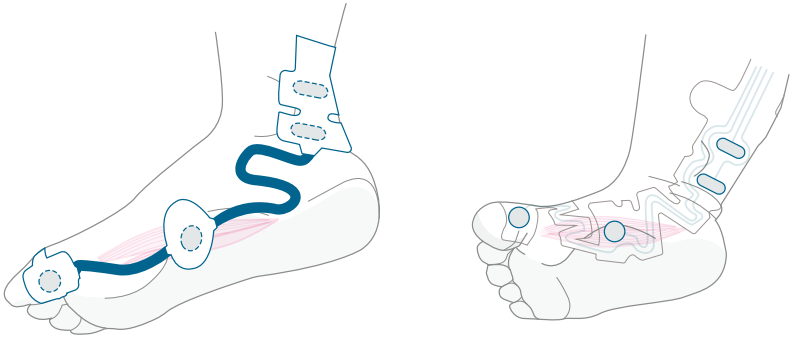
1. Tear the pouch open (do not use scissors) and remove the sensor from the pouch.
2. Remove the stimulating (proximal, square) electrodes from the liner by lifting the edge of the electrodes and then apply them over the ulnar nerve (nervus Ulnaris) at the wrist or over the posterior tibial nerve at the ankle as illustrated below.
3. Remove the recording (distal, round) electrodes from the liner by lifting the edge of the electrodes and then apply them on the abductor digiti minimi muscle, the adductor pollicis muscle, or the flexor hallucis brevis muscle as illustrated below.



On the hand: The stimulating electrodes are placed over the ulnar nerve, 1 cm below the wrist crease.
On the foot: The stimulating electrodes are placed over the posterial tibial nerve, next to Medial malleolus.



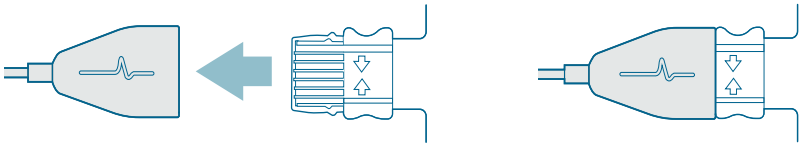
On the hand: *The recording electrodes are placed over the digiti minimi muscle or adductor policis muscle.*



On the foot: *The recording electrodes are placed over the flexor hallucis brevis muscle.*

Connect the TetraCord Cable to the Sensor

1. Insert the sensor connector into the cable connector.
2. Ensure correct orientation as illustrated. A click sound confirms the correct pairing.



Sensors must be discarded if they no longer stick firmly to the skin.

Ensure that no other equipment gets in contact with the stimulating or recording electrodes.

CAUTION Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrically conductive medium, such as clinical adhesive or hydrogel.

The irritation may be reduced by using an alternative foot or hand electrode placement.

Remove the Sensor

1. Turn the TetraGraph monitor off.
2. Disconnect the TetraCord cable from the TetraSens sensor by squeezing the tabs on the sensor.
3. Remove the sensor from the skin by gently peeling from the edge.
4. Remove possible gel residue from the skin.
5. Dispose of used sensors as clinical waste.

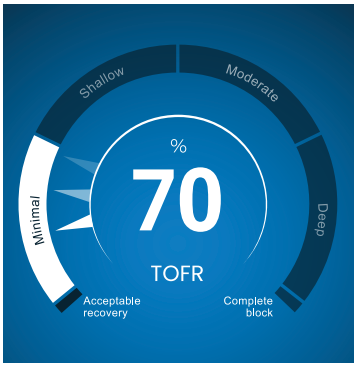
6. Operation

TetraGraph Adaptive Intelligence™

The TetraGraph monitor has several specialized algorithms to simplify and guide the user in optimizing the monitoring of neuromuscular blockade. Together they form **TetraGraph Adaptive Intelligence™** which consists of:

- Guidance for **Sensor Placement Optimization** with Stimulation and Signal strength Icons feedback supported with text notifications to aid in optimal sensor placement and signal strength. When monitoring starts on a patient who is already muscle relaxed or partially muscle relaxed, supramaximal stimulation (patient-specific stimulation) cannot be established, and no signal or unstable signal will be detected. When EMG responses are detected, **TetraGraph Adaptive Intelligence™** provides an estimate of the signal strength (shown in parentheses) to provide feedback on sensor placement.
- **Adaptive PTC™** where the TetraGraph enters PTC mode (deep block mode), and proceeds with tetanic stimulation and PTC measurements, automatically when two consecutive TOFC 0 have been confirmed. If conditions are not met, TOF mode continues. See PTC Options on page 23.
- **Adaptive Time Interval** which adjusts measurement intervals automatically based on neuromuscular response changes. See Measurement Time Interval on page 25.

Display of Measurement Data, Information and Call for Action



TetraGraph Level-of-Block Gauge™

The Level-of-Block Gauge™

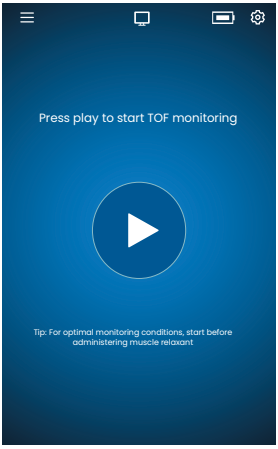
Measurement data is displayed in the **Level-of Block Gauge™** where color indication, a needle (pointer), number, and text together inform the user about the latest measurement data and 1-minute trend.

Information Bar

The Information Bar is found at the top of the screen. **TetraGraph Adaptive Intelligence™** guides sensor placement optimization and verify good electrode position through the color of the Stimulation icon (green or white) and Signal Strength icon (green, yellow, or red) in the Information Bar. See Screen Layout on page 9.

The Notification Bar

The Notification Bar is located directly below the Information Bar. Additional guidance is provided through messages or questions displayed as notifications.
During the initiation of Auto Start, the question/prompt for action message is displayed for a few seconds. If the user does not select (press) one of the options within this period, the Auto Start process continues and the TOF measurement starts.
Notifications are displayed when required during the measurement process to inform about the monitor, or measurement, status, and/or guide the user to a recommended action.

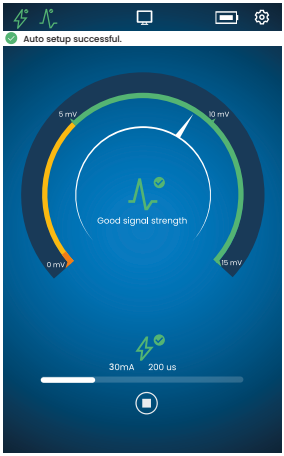


Auto Start

The Auto Start mode is the recommended mode of operation for the TetraGraph.

Initiate Auto Start Mode

1. Press the **Auto Play button** on the start screen to initiate Auto Start mode. The unit detects the maximal stimulation current and sets the current to 20% above the point of maximal response (supramaximal stimulation current level).
2. Notifications **Auto setup in progress** followed by **Auto setup successful**, before starting the first TOF measurement will be displayed.



View Parameters Selected Automatically

1. Tap on the Stimulation Icon in the Information Bar to view the auto selected parameters for stimulation in milliamperes (mA) and pulse width in microseconds (µs).

Green stimulation and signal strength icons indicates that:

- A supramaximal stimulation has been set (Patient specific stimulation)
- A good signal strength (above 5 mV) has been detected.

Monitoring on an Already Muscle Relaxed Patient

If monitoring starts on an already muscle relaxed patient, a supramaximal stimulation (patient specific stimulation) cannot be established, and no signal will be detected. Therefore:

- Maximum stimulation settings are used (60 mA, 300 µs).
- Notification Displayed: **Blocked Patient** or **Restart and reposition sensor** prompt the user to confirm blocked patient or select the option to restart.
- The Auto setup will proceed after 5 seconds if no option is selected.
- When EMG responses are detected **TetraGraph Adaptive Intelligence™** provides an estimated signal strength reading to provide feedback on sensor placement.

For more information and interpretation of the Stimulation and Signal Strength icons and recommended actions, see the Troubleshooting Charts on page 31.

PTC Options

Adaptive PTC™ where the device automatically switches between TOF and PTC measurements is the TetraGraph's default setting for PTC.

Changing PTC Mode

1. To change PTC mode, open the **Settings** menu and select **PTC mode** in the PTC Mode drop-down menu.

NOTE PTC ON mode can be turned off at any time by pressing the PTC button in the lower right corner of the display. The indication on the button will change to PTC OFF .

Adaptive PTC™ Mode

Adaptive PTC™ is the default setting for PTC.

- Indicated by the white (active) button, and the **PTC ON** text on the PTC button.
- PTC ON can be switched OFF at any time.
- The PTC ON button switches to pink when two consecutive TOFC 0 has been confirmed.

- The change to pink color indicates that PTC is active. Notification: **PTC will soon be initiated.**
- The default PTC interval is 2 minutes.
- If a TOFC is detected, the intervals will resume to 15 seconds, or the time interval previously selected for TOF.

Time intervals of 15 seconds (TOF) and 2 minutes (PTC) is default in Adaptive PTC™ mode and remains as long as the interval is not manually changed.

NOTE If the TOF or PTC time interval is changed manually, the user must continue to change the interval manually during further monitoring.

Repeated PTC Mode

- In Repeated PTC mode the PTC OFF button is greyed-out (inactive).
- Inactive mode remains during measured TOFR, and TOFC 3, 2 and 1.

- After confirmed TOFC 0, the PTC OFF button switches to white (active).

- The first PTC measurement is started manually by tapping the PTC button. The PTC button changes to pink, and the PTC measurements start.
- After the first start the PTC measurements are repeated every 2 minutes (default interval) until a TOFC 1 or higher is detected.

Manual PTC Mode

- In Manual PTC mode the PTC button is greyed-out (inactive).
- Inactive mode remains during measured TOFR, and TOFC 3, 2 and 1.

- After confirmed TOFC 0, the PTC OFF button switches to white (active).

- The first PTC measurement is started manually by tapping the PTC button. The PTC button changes to pink, and the PTC measurements start.

- PTC OFF mode (inactive) is resumed when one PTC sequence has been completed.

- The PTC OFF button changes to white (active), and a single PTC measurement can be started manually by pressing the PTC button when:
  - >2 minutes have passed since the last PTC measurement.
  - A TOF Count 0 has been confirmed.

Measurement Time Interval

The measurement interval settings button is accessed directly from the measurement screen. The button can be pressed at any time to change the interval or mode for time interval.

Adaptive Time Interval

Prerequisite: Repeated or Manual PTC mode has been selected in Settings.

Description of Adaptive Time Interval

- Time intervals of 15 seconds during measured TOFR and TOFC.
- If PTC measurements are not initiated when TOFC is 0:
  - If PTC measurements are NOT started (the PTC button is not pressed) TOF measurements continue, and time interval increases to 1 minute.
  - When a TOFC 1 or higher is recorded the device switches back to a 15 second interval.

- If PTC measurements are initiated:
  - If selecting PTC (the PTC button is pressed) the device enters deep block mode, performing PTC with 2 min intervals (Repeated PTC), or performs one PTC (Manual PTC).
  - If a TOFC 1 or higher is recorded the device adapts to TOF and switches to 15 seconds interval.

For instructions on how to select PTC mode see Changing PTC Mode on page 23.

Select Adaptive Time Interval

Selection of Adaptive time interval is done in the time interval pop-up window that appears after monitoring has started.

Prerequisite: Repeated or Manual PTC mode has been selected in Settings.

1. Tap on the Interval button located at the bottom left of the screen. The current mode is displayed at the top of the window.
2. Select **Adaptive.**
3. Press **OK.**
4. The measurement time interval will be adapted to the depth of neuromuscular block.

Manual Time Interval

Select Manual Time Interval:

1. Tap on the Interval button located at the bottom left of the screen to change interval.
2. Select **Manual**.
3. Options for time intervals are enabled.
4. Select the preferred time interval:
   a. TOF: 15 seconds, 1, 5, 15, or 60 minutes.
   b. PTC: 2, 3, 5, 10, or 15 minutes.
3. Press **OK**.

To change the time interval, repeat step 1, 4, and 5.

On Demand Measurement

On-demand measurement provides the possibility to start a measurement before the selected time interval has passed.
The On Demand button becomes visible:

- In TOF mode if intervals longer than 15 seconds are selected and >15 seconds have passed.
- In PTC mode if intervals longer than 2 minutes are selected and >2 minutes have passed.

Starting On Demand Measurement

1. Tap the **On Demand** button (double arrow symbol) located adjacent to the measurement time bar.

Trend View

Short Time Trend View - The Level of Block Gauge™

The Level-of-Block Gauge displays the latest measurement data and 1-minute trend through:

- Color indication
- A needle (pointer)
- Numbers and text

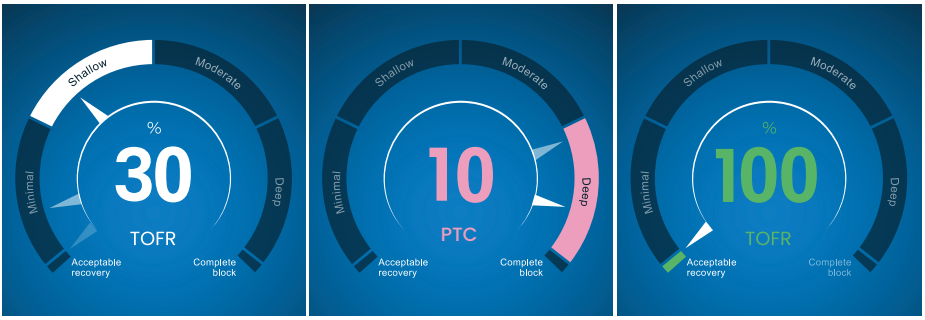
Numbers and text to visualize the latest measurement data and 1-minute trend.
The **Color of the Gauge** indicates the patient's level of block:

- White: Minimal to moderate level of block.
- Pink: Deep level of block.
- Green: Acceptable recovery from neuromuscular block. (Displayed when three consecutive measurements have an average result >90%.)

The **Needle** moves clockwise/counterclockwise pointing towards and moving through the sections labeled Minimal, Shallow, Moderate, or Deep. A measurement result will move the needle on the scale to indicate which depth of muscle relaxation is currently recorded/measured.

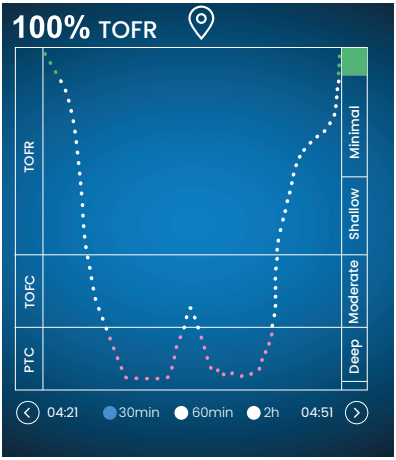
Current level of block	A filled (opaque) needle indicates the current level of block.
1 minute trend	The faded (transparent) needles display the direction and 1 minute trend.
Previous values	Previous values fade out after 1 min. with increased transparency for the oldest value. Maximum 4 needles are displayed on the screen

The **Text and Number** of the measurement result is displayed in the center of the Gauge. Text label "TOFR" together with "%" for a measured Train-of-Four Ratio, TOFC for a Train-of-Four Count, or "PTC" for Post Tetanic Counts.



Full Trend Graph View

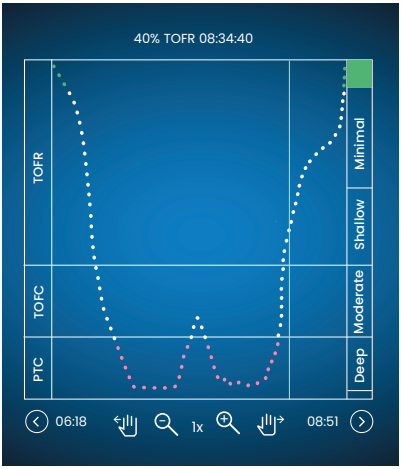
The full Trend Graph can be viewed in real-time and when the monitoring is paused. It is accessed by swiping right and left over the screen, or through the Display Mode selection buttons. See Screen Layout on page 9.



Real-time View

The real-time Trend Graph has a secondary y-axis that displays the Level of Block with the same color coding as the Level of Block Gauge.

- Time scale options to view the latest 30 min., 60 min., or 2 h.
- To set a marker, press the marker symbol placed above the trend graph.



Data Review in Pause Mode

- Use controls to zoom-in/-out.
- In pause mode a vertical orange line will appear.
- Tap on a selected measurement/time point to move the dynamic line and review data.

Display Modes

There are four available display modes:

- Level of Block Gauge™ and Bar Graph
- Level of Block Gauge™ and EMG Curve (waveform)
- Full Trend Graph
- Level of Block Gauge™

Select mode by tapping the arrow on the left or right side of the image to navigate between viewing modes.

Noise Notification

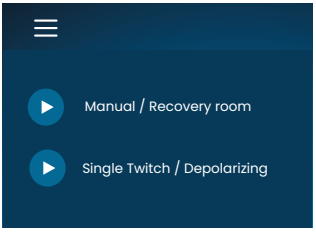
Noise disturbance may be caused by electrocautery (diathermy) or adjacent equipment and are displayed as followed:

During start	Stimulation icon	Icon is white. Supramaximal stimulation (patient specific stimulation) may not be established. Therefore, maximum stimulation settings are used (60 mA, 300 µs).
	Signal strength icon	The icon can be green, orange, or red, depending on the strength of the signal response.
	Notification	**Auto setup disturbed**
During or between two measurements	Level-of-Block Gauge™	The Gauge is shaded.
	Notification	**Noise, measurement postponed** (Noise detection in between measurements)
	Notification	**Noise, measurement invalid** (Noise detection during a measurement)

Monitoring resumes when the interference has ceased.

NOTE Ensure the TetraCord Patient Cable is well separated from other cables or electrical equipment.

Alternative Start Modes



For alternative start, tap on the **Menu button** in the upper left corner of the screen.
The two alternative start modes on TetraGraph are:

- Manual Mode (Recovery Room)
- Single Twitch (Depolarizing)

Manual Start (Recovery Room)

1. Tap on **Manual Start (Recovery Room)**.
2. Select **Pulse Width and Current.**
3. Select measurement mode, **TOF** or **ST.**
4. Tap **OK** to start measurement.

Signal Strength will be displayed after the first TOF.

Single Twitch (Depolarizing)

1. Tap on **Single Twitch (Depolarizing)** to start Single Twitch (ST) mode. An Auto set-up is performed, and ST stimulations starts.
2. Select time interval. Available time intervals are 5 or 10 seconds (10 seconds as default).

Signal Strength, Tref, will be displayed after the first ST. The Gauge displays the T1 amplitude in mV with T1/Tref Ratio in percent (%) below.
To switch to TOF Mode during ST measurement:

- Tap on the **Go to TOF Mode** button displayed in the lower right corner .
- Open **Settings** and tap on **Go to TOF Mode** .

Start New Measurement

1. To start a new measurement, open **Settings** and select **New Patient.**

Data Upload and Review

TetraConnect Data Management is a cloud-based service that runs on computers, tablets and smartphones intended for import, view, and search in data records generated with a TetraGraph system. TetraConnect provides an option to export data records in different file formats for storage/archival purposes or for offline analysis. For more information contact your Senzime sales representative.
For data export:

1. Turn the TetraGraph on.
2. Use a USB cable 2.0 or higher with the monitor and connect TetraGraph to the computer´s USB port.
3. Open **Settings** and tap on **Data** and select **Upload.**

Detailed instructions for data export are provided in the TetraConnect manual (INFO0017).

7. Troubleshooting

Troubleshooting Charts

Use these troubleshooting charts to resolve some of the most common issues identified when using a TetraGraph monitor.

Information Bar Icons during Auto Setup Process

Icon(s)	Description	Cause	Resolution
	• Stimulation Icon is green. A supramaximal stimulation (patient specific stimulation) has been set / found. • A good low signal strength (< 5 mV) has been detected.	Correct positioning of both stimulating and recording electrodes.	
	• Stimulation Icon is green. • Poor sensitivity. A low signal strength (< 5 mV) has been detected.	Possible Incorrect position of recording electrodes.	1. Check the position of the recording electrodes on the hand/foot. 2. Reposition recording electrodes and restart. 3. If position of electrodes is correct proceed monitoring.
	• Stimulation icon is white. A supramaximal stimulation (patient specific stimulation) has not been established. Therefore, maximum stimulation settings are used (60 mA, 300 µs).	The stimulation settings have been set manually.	1. Tap on Stimulation Icon for pop-up information. To change stimulation settings, tap on Settings symbol, and select “Stimulation”
		See causes in combination with Signal Strength icon indications below.	
	• Stimulation icon is white (See definition above). • Signal Strength icon is green (good signal strength >5 mV)	• Possible incorrect position of the stimulating electrodes. Risk of unstable results if the hand/foot are moved. • The patient’s anatomy or other conditions, e.g. obese patient, diabetic, or geriatric patient.	1. Check the position of the stimulating electrodes over the Ulnar nerve (if monitoring on the hand), or Posterior Tibial nerve (if monitoring on the foot). 2. Reposition stimulating electrodes and restart. 3. If position of electrodes is correct proceed monitoring.

Icon(s)	Description	Cause	Resolution
	• Stimulation icon is white (See definition above). • Signal Strength Icon is yellow (Low signal strength <5 mV). Poor sensitivity.	• Possible incorrect position of stimulating and/or recording electrodes. • The patient is partially blocked (neuromuscular blocking agents have been given).	1. Check the position of the stimulating and /or recording electrodes on the hand/foot. 2. Reposition stimulating and /or recording electrodes and restart. 3. If position of electrodes is correct proceed monitoring.
	• Stimulation icon is white (See definition above). • Signal Strength Icon is red (No response detected)	**Context:** Neuromuscular blocking agents have been administrated (the patient is blocked) prior to starting.	Continue measurement. **TetraGraph Adaptive Intelligence** will provide an estimated signal strength when starting post-paralytic.
		Context: Blocking agents have not been given (the patient is not blocked). • The setup is incorrect. • Incorrect position of the sensor (both stimulating and recording electrodes).	Reposition the sensor and restart.

Other Information Bar Icons

Icon(s)	Description	Cause	Resolution
	• Battery capacity is less than 15% (yellow icon) or 5% (red icon). • Notification: **Battery level is X %. Charge battery**	Device is not connected to power and the battery is close to being discharged.	• Connect the TetraGraph to power using the Power Supply supplied by Senzime.
	Lost connection with external device	Possibly the cable(s) between TetraGraph and the external device is loose, or the external device is turned off.	1. Make sure the cable(s) is/are connected properly between TetraGraph and the external device. 2. Make sure the external device is switched on and have power.

Information on the Display During Auto Setup or Ongoing Measurement

Display	Symptom description	Cause	Resolution
	Auto setup disturbed. Monitor display return to sensor positioning screen after a few seconds.	No leads detected. The sensor or patient cable is disconnected.	1. Ensure that the electrodes have good contact with the skin. 2. Check that the sensor is correctly connected to the patient cable as per 6. Operation on page 21.

Display	Symptom description	Cause	Resolution
	Uncertain value. (Measurement value within paragraphs).	Disturbance during measurement. Possibly due to movement or other equipment.	• Consider the measurement as not fully reliable and wait for the next measurement result.
	Measurement value is shaded. Notification: • **Noise, measurement postponed** or • **Noise, measurement invalid**	Too much noise to perform a measurement (e.g. electrocautery), or noise during or disturbing a measurement.	Visible until the next measurement. Monitoring will resume after the interference ceases. • Ensure the Patient Cable is well separated from other equipment.
	• Level-of-block Gauge is dark. • Notification: **Lost connection. Check sensor and connections**	The measurement is paused due to sensor or cable disconnection.	1. Ensure that the sensor electrodes have good contact with the skin. 2. Check that the sensor is correctly connected to the patient cable, and the patient cable is connected to the monitor as per 6. Operation on page 21.
	• Level-of-block Gauge is dark. • Notification: **Measurement is paused**	The pause button has been pressed and the measurement is paused.	• Press the play button to resume measurement.
	• Level-of-block Gauge is dark. • Notification: **Paused monitoring. No connection**	The sensor or cable is disconnected while the monitor is paused.	1. Ensure that the sensor electrodes have good contact with the skin. 2. Check that the sensor is correctly connected to the patient cable as per 6. Operation on page 21. 3. Press the play button to resume measurement.
	• Notification: **Device error. Code ###.**	Error in device.	• Remove the TetraGraph from service. Contact Senzime or a Senzime authorized service center.
	Device performance changes.		• Remove the TetraGraph from service. Contact Senzime or a Senzime authorized service center.

NOTE Any serious incident that has occurred to the user and/or the patient in relation to the device should be reported to Senzime and the competent authority of the Member State (for Europe) or relevant health authority (for other countries) in which the user and/or patient is located.

8. Maintenance and Battery Charging

To charge, connect the TetraGraph device to the charger via the USB port using only the Fixed Cable Power Supply. The TetraGraph can be used while charging. If the device is going to be stored for a long period it should be charged / discharged to 40% battery capacity before storage, checked every 12 months and recharged as required to maintain the 40% battery level.

The battery charging indicator light on the upper right of the front panel will glow orange when the device is charging and will turn to green once charging is complete. The TetraGraph unit can be turned off whilst charging to decrease charging time.

- Always check the battery level before commencing a surgical procedure.
- Check the device and cables for damage before use. Do not use the device if it is damaged or not operating as expected.
- The TetraGraph does not have any user serviceable parts and must not be modified.

WARNING Maintenance work including change of battery must be conducted by personnel certified by manufacturer. Unauthorized modification of the system could lead to fire, electric shock, or injury.

The following components can be replaced:

- TetraCord Patient Cable
- Fixed Cable Power Supply

Product Lifetime

The lifetime of the TetraGraph Monitor is 7 years.

Periodical Checks

WARNING Before use, visually inspect the device and the TetraCord cable for any loose or damaged parts. If the performance of the device changes from that specified, required or expected, take the device out of service immediately.

- Turn off the TetraGraph unit before performing the periodical checks.
- Visually examine the TetraGraph for these types of damage:
  - Cracking of the casing, screen, or pole clamp
  - Corrosion
  - Scores, dents or burrs
- Visually examine the TetraCord patient cable and any communication cables for these types of damage:
  - Cracks and kinks
  - Signs of wear or fretting of cables or wires
- Visually examine the electrical connectors on both TetraGraph and the cables for these types of damage:
  - Deterioration of insulation
  - Signs of overheating
  - Bent or damaged contacts
- If any of the above damage is observed during visual inspection contact Senzime or a Senzime authorized service center.
- When requesting service or maintenance, always quote the serial and reference numbers which are located on a label on the base of the device.
- Check the active service life of your device - the service life of the TetraGraph is 7 years after which the device should be decommissioned.
- Make sure that the device and cables are thoroughly cleaned and free from residues, especially on or in the close vicinity of the connectors.
- Check the USB connector on the TetraGraph. Make sure that there is good connection when inserting the USB cable (from the power supply) and verify that the connector itself is not loose.

It is recommended that these tests are performed once every 24 months.

Battery Check

The expected lifetime is 500 charging cycles (battery charging and discharging). Batteries normally degrade over time. If the battery life for your usage has degraded and is no longer sufficient, a replacement of the built-in battery is possible. Maintenance including battery change work must ONLY be conducted by Senzime or authorized service point. Contact a Senzime representative for questions regarding battery change.

WARNING Maintenance work including change of battery must be conducted by personnel certified by manufacturer. Unauthorized change of battery could lead to fire, electric shock, or injury.

Safety Test and Replacement of Power Supply Kit

It is recommended that the power supply be electrical safety tested on an annual basis in accordance with the clinical establishment's safety test policy.
If any part included in the Fixed Cable Power Supply is malfunctioning and needs to be replaced, contact your supplier or Senzime AB to acquire these spare parts.
When connecting to the TetraGraph unit, only use the supplied power supply.

CAUTION If the device performance changes from that specified, required or expected the device should be taken out of service immediately

9. Cleaning and Disinfecting

WARNING Before cleaning, disconnect the power unit from the mains electrical supply. The TetraGraph and its cables must NOT be immersed in water or other liquids during cleaning or disinfection.

WARNING Reuse of TetraSens electrode is prohibited and may lead to inaccurate measurement, cross-contamination and superficial burns.

CAUTION Do not use abrasive cleaners on the display.

- Cleansers and disinfectants must be indicated for use on medical devices and specify compatibility with use on plastics and metal surfaces.
- Only the TetraGraph monitor and TetraCord cable may be cleaned: the TetraSens Electrode is single-use and must be replaced with a new sensor for each patient monitoring session.

Cleaning and Disinfecting

The outer casing shall be manually cleaned and disinfected with surface cleaning agents and disinfectants, excluding solvents and abrasive material. Always perform cleaning and disinfection concurrently. Clean immediately after use and always before disinfection.

Manual Cleaning

1. Wipe all parts with cleaning wipes or a soft lint-free cloth moistened in soap and water or detergent-based disinfectant until visually clean.
2. Allow the surface to dry.

3. Wipe off traces of cleaning agent with a soft lint-free cloth moistened in water.

Visually inspect that the surface is clean. If not, repeat the cleaning procedure. When the surface is clean continue to connect the device according to 6. Operation on page 21.

Manual Disinfection

1. Be careful not to allow moisture into the device through connectors or the battery cover.
2. Clean the surfaces prior to manual disinfection.
3. Wipe all parts with disinfection wipes or a soft lint-free cloth moistened in disinfectant. Make sure the surface is wet during the specified time.
   a. Alcohol-based disinfectant (70%) - 3 minutes duration on surface
   b. Oxivir Excel wipe (0.36% Hydrogen peroxide) - 3 minutes duration on surface
4. Let the surface dry in air.
5. Wipe off traces of disinfectant with a soft lint-free cloth moistened in water. Make sure to use clean cloth for each part to avoid cross-contamination.

10. Performance and Technical Specifications

Stimulation Patterns

Single Twitch (ST)	Single pulse of 200 or 300 µs duration repeated at a user selected period time of 5s or 10s.
Auto Setup	Set of up to 15 pulses of 200 or 300 µs duration repeating automatically at 1 Hz.
Train-of-Four Ratio (TOFR & TOFC	4 pulses of 200 or 300 µs duration at 2 Hz repeated at user selected period time of 15 s, 1 minute, 5 minutes, 15 minutes or 60 minutes.
Post-tetanic Count (PTC)	Tetanic Stimulation, a set of 250 pulses (1 pulse at 50Hz over 5s); followed by up to 20 ST pulses at 1 Hz repeated at user selected period time of 2, 3, 5, 10 and 15 minutes.
Accuracy	Pulse amplitude and Pulse duration ±10%. Amplitudes within ±25% when tested according to IEC 60601-2-40. Pulse repetition frequencies ±5%.

Stimulation

Mode	Max. current (mA)		Max. voltage (V)		DC component
	RMS @ 1 kΩ	Peak	RMS @ 1 kΩ	Peak	(V)
ST (Single Twitch), 60 mA, 300 µs, 5 s	0.46	60	0.46	300	0
TOFR & TOFC (Train-of-Four), 60 mA, 300 µs, 15 s	0.54	60	0.54	300	0
Tetanic-Stimulation, 60 mA, 300 µs, 50 Hz	7.35	50	7.35	300	0
Stimulus Calibration, 60 mA, 300 µs, 1 s	1.04	60	1.04	300	0

Stimulation current options: 10, 20, 30, 40, 50, 60 mA

Stimulation Voltage 300V Peak. Electrode / Patient resistance 50-5000 ohm maximum. High skin impedance may result in selected current not being achieved.

Accuracy of Measurement

TOF Ratio	±10% of full scale compared to theoretical value with 100% as maximum. (E.g. 85% is between 75 – 95%)
TOFC Values	90% of the results equal to the theoretical value and within a count of 1 in the remaining 10%
mV Values	± 15% or ± 1 mV, whichever is greater, specified due to variability of skin impedance.

Power Supply

Battery	8 hours continuous operation with a new battery in good condition
Power Unit	EN 60601-1 power supply 5V DC USB connection
Ratings	Input: 100 -240 V ~, 50 to 60 Hz, 160-80 mA Output: 5 V DC, 1400 mA
Branch circuit breaking capacity	Max. 35A

Graphics

Display	Color LCD, Brightness control, Touch Screen interface
MAP (Muscle Action Potentials)	Display of waveforms
TOF values	Bar of four pulse amplitudes and %, EMG curves, trend of successive TOFR
TOFC	TOF Count, integer and trend
PTC	Number of post-tetanic ST responses
ST	Amplitude of response, mV, series of response amplitudes as bars
Level-of Block-Gauge™	Dynamic illustration of level of block

Settings

Setup	Automatic detection of maximal current. Supramaximal current 20% above maximal current.
Date format	YY/MM/DD
Case reference number	Up to 8 characters, numeric
Audible stimulus indication	On/Off
Audible low battery indication	On/Off
Audible lead off indication	On/Off
Data interface	USB-C file transfer to PC

Dimensions

Length	215 mm
Width	116 mm
Thickness	38 mm, 85 mm including pole clamp
Weight	573 g (including battery) 748 g including pole clamp

Communication interface

USB-C connector	Connected equipment USB-C 2.0 or higher

Defibrillation Protection

TetraCord connector	BF Defibrillation-proof applied part
Defibrillation Recovery Time	Continuous. No required delay between adjacent defibrillation attempts and continued use of the TetraGraph.

Restriction on other Equipment or Network/Data Couplings to be Connected with this Device

External equipment intended for connection to signal input, signal output or other connectors, shall comply with relevant IEC standard (e.g., IEC 60601 series for medical electrical equipment). In addition, all such combinations of systems shall comply with the standard IEC 60601-1-1, Safety requirements for medical electrical systems, alternatively IEC 60601-1 ed.3 §16, ME SYSTEMS. Any person who connects external equipment to signal output, or other connectors, has formed a system and is therefore responsible for compliance of the system with these requirements. If in doubt, contact a certified technician, or alternatively, a Senzime representative or technical support.

Applied Part

The parts that are intended to come in contact with patients during normal operation. All electrodes (TetraSens, TetraSens Pediatric and TetraSensitive) are considered Applied Parts and are connected to the BF Defibrillation-proof port on the TetraGraph. The patient cable interconnecting the TetraGraph to the applied part (the sensor) is considered an Applied Part.

Standards and Regulations Applied

- IEC 60601-1:2005/AMD1:2012/AMD2:2020
  - Class II protection against electric shock.
  - Type BF applied part
  - For continuous use
  - Not suitable for use in an oxygen rich environment
- IEC 60601-1-2:2014/A1:2020
  - CISPR 11 Class A Emission limits
- 47 CFR Part 15 Subpart B
- ICES-003, issue 7, Information Technology Equipment (including Digital Apparatus)
- IEC 60601-1-6:2010/AMD1:2013/AMD2:2020
- IEC 62366-1:2015/AMD1:2020
- IEC 60601-2-40:2016

11. Data output and cybersecurity controls

The TetraGraph cannot be controlled or otherwise accessed via the external connections. The monitor transmits data over the USB/serial cable, including the TOF ratio, TOF Count, PTC and Single Twitch. The TetraGraph does not contain or transmit Protected Health Information. To avoid unauthorized access to data, ensure that any external devices to which the TetraGraph is connected are on a trusted network.

12. Safety

Warnings and Cautions

International Medical Device Standards require all manufacturers to include appropriate warnings and cautions for their equipment and many of the warnings and cautions shown here also apply to similar devices.

To make sure that all users are well informed, various warnings and cautions are made throughout these instructions.

A **WARNING** is given when hazard with a medium level of risk, which, if not avoided, could result in death or serious injury.

A **CAUTION** is given when hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury.

Summary of Warnings, Cautions and Side-Effects

In common with all medical devices of this nature there are inherent risks and side effects. Whilst every effort has been made to eliminate these risks, care should be taken when using the device. It is important that the user familiarizes himself/herself with all the warnings and cautions contained within this document.

NOTE Any serious incident that has occurred to the user and/or the patient in relation to the device should be reported to Senzime and the competent authority of the Member State (for Europe) or relevant health authority (for other countries) in which the user and/or patient is located.

WARNING!

- In the case equipment that produces strong electromagnetic fields is used, such as high frequency surgical equipment, place the TetraSens electrodes away from the surgical location to reduce the effect of potential interference and risk of burns and inaccurate measurements.
- If it is necessary to use the TetraGraph stacked with other equipment, observe both the TetraGraph and the other equipment to make sure that they are operating normally.
- Patients with an implanted electronic device such as a cardiac pacemaker must not be subjected to electrical stimulation until specialist medical opinion has been obtained.
- Do not use in a flammable atmosphere or in places where flammable anesthetics may concentrate.
- Reuse of TetraSens electrode is prohibited and may lead to inaccurate measurement, cross-contamination and superficial burns.

- The Device should be used only with the leads, spare parts and electrodes recommended for use by the manufacturer.
- Maintenance work including change of battery must be conducted by personnel certified by manufacturer.
- Unauthorized change of battery could lead to fire, electric shock, or injury.
- Tattoo pigments can cause skin burns when subjected to electrical stimulation.
- Only apply electrodes to normal, clean, and dry skin with normal sensation.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should only be applied to hand or foot. Stimulation to other locations may cause injuries.
- Before cleaning, disconnect the power unit from the mains electrical supply. The TetraGraph and its cables must NOT be immersed in water or other liquids during cleaning or disinfection.
- Before use visually inspect the device and the TetraCord cable for any loose or damaged parts. If the performance of the device changes from that specified, required or expected, take the device out of service immediately.
- Twisting the cable or pulling violently when disconnecting from the TetraGraph monitor may cause damage to the TetraCord patient cable.

CAUTION!

- Some patients may experience skin irritation or hypersensitivity due to electrical stimulation or electrically conductive medium, such as clinical adhesive or hydrogel.
- Before use, ensure the battery is fully charged or connected to power supply.
- Do not use abrasive cleaners on the display.
- Caution should be used for patients with suspected or diagnosed heart problems or epilepsy.
- If the electrosurgical grounding fails, skin burns may occur at the site of the electrodes.
- Patients with pre-existing neuromuscular disease (Myasthenia Gravis, Dystrophy etc.) or patients with cerebrovascular accidents (CVAs or Stroke) may have unexpected electromyographic responses that may affect the results of the monitoring. Place the EMG responses in appropriate clinical context.
- Ensure that conductive parts of the sensor or patient cable are in contact with the patient only.

SIDE EFFECTS

The side effects that can occur from use of TetraGraph and its TetraSens Electrodes are the following:

- Allergic reaction to clinical adhesive or hydrogel.
- Localized irritation if stimulation electrodes are not securely fitted or are reused.
- Neurostimulation using maximal currents may induce pain in un-anaesthetized patients.
- Patient may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.

Symbols and Icons

The following symbols are used on the TetraGraph device and on the TetraSens/TetraSens Pediatric/TetraSensitive Electrode.
The following symbols are seen on the labels of the TetraGraph.

Icon	Meaning	Description
CE 2797	CE mark and notified body number	Indicates compliance with European Medical Device regulations. Symbol is associated with a number indicating the Notified Body.
	UL mark	Certified by UL.
	FCC mark	FCC mark is a certification mark employed on electronic products sold in the United States which certifies that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
SN	Serial number	The unique serial number allocated to the device.
REF	Reference number	The catalogue or model number of the device.
	Operating instructions	The device has instructions for use. Consult the instructions for use.
	Refer to instruction manual	You must read the instructions for use.
	General warning sign	Indicate hazard with a medium level of risk, which, if not avoided, could result in death or serious injury.
	Caution sign	Indicate hazard with a low level of risk, which, if not avoided, could result in minor or moderate injury.

Icon	Meaning	Description
	Keep dry	Product should be kept dry.
	Keep away from sunlight	Do not leave in direct sunlight or close to sources of excessive heat.
	Date of manufacture	Date of manufacture, shown as year and month.
	Manufacturer	Name and address of the manufacturer.
	MR unsafe	The instrument is not MRI safe.
	Medical Device	The instrument is a medical device.
	Unique Device Identification	The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain.
	For prescription use only	Federal law in U.S. restricts this device to sale by or on the order of a medical practitioner licensed by the law of the state in which he practices.
	WEEE	Do not dispose of in domestic waste, see chapter 16.
	Humidity	Transport and storage humidity limits.
	Pressure	Transport and storage pressure limits.
	Temperature	Storage or Transport temperature limits
	BF Defibrillation-proof applied part	Protection against the effects of the discharge of a cardiac defibrillator is dependent on the use of the specified cable and electrodes.

The following icons are seen on the TetraGraph:

Icon	Meaning	Description
	Battery	Indication on battery level of charge.
	Battery	Battery charge indication.

	Standby	On/Off Button

The following additional symbols are used on the electrodes:

Icon	Meaning	Description
	CE mark	The CE Mark w/o any numbers indicated the product is a self-certified Class I Medical Device. This symbol applies to TetraSens/TetraSens Pediatric/TetraSensitive Electrode.
	UKCA mark	The UKCA Mark w/o any numbers indicated the product is a self-certified Class I Medical Device. This symbol applies to TetraSens/ TetraSens Pediatric/TetraSensitive Electrode.
	Batch Code	Lot number of the device.
	Do not use if package is damaged	For the TetraSens/TetraSens Pediatric/TetraSensitive Electrode pouch.
	Do not reuse	For the TetraSens/TetraSens Pediatric/TetraSensitive Electrode – single use only.
	Non-sterile	For the TetraSens/TetraSens Pediatric/TetraSensitive Electrode.
	Use by date	For the TetraSens/TetraSens Pediatric/TetraSensitive Electrode.

The following additional symbols are used on the TetraGraph Power Supply:

Icon	Meaning	Description
	IEC 60417-5172	Class II equipment.
	IEC 60417-5032	Alternating current.
	IEC 60417-5031	Direct current.

13. Environment

Environment during transportation

Temperature	-20°C to 60°C (-4°F to 140°F)
Relative humidity	10% to 85% non-condensing
Atmospheric pressure	50 kPa to 106 kPa

Environment during storage

Temperature	5°C to 50°C (41°F to 122°F)
Relative humidity	10% to 85% non-condensing
Atmospheric pressure	50 kPa to 106 kPa

Environment during use

Temperature	5°C to 40°C (41°F to 104°F)
Relative humidity	10% to 85% non-condensing
Atmospheric pressure	70 kPa to 106 kPa
Electromagentic environment	See 14. Electromagnetic Compatibility Information on page 46.

14. Electromagnetic Compatibility Information

The TetraGraph is intended for use in the electromagnetic environment specified below. The customer or the user of the TetraGraph should assure that it is used in such an environment. See Restriction on other Equipment or Network/Data Couplings to be Connected with this Device on page 39.

WARNING The following points should be considered prior to installation and operation of the TetraGraph:

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- If it is necessary to use the TetraGraph stacked with other equipment, observe both the TetraGraph and the other equipment to make sure that they are operating normally.
- Ensure the TetraCord cable is separated from other cables.
- Place the TetraSens electrodes away from the location of high frequency surgical equipment to reduce the effect of potential interference and risk of burns and inaccurate measurements.

WARNING Patients with an implanted electronic device such as a cardiac pacemaker must not be subjected to electrical stimulation until specialist medical opinion has been obtained.

Guidance and declaration - electromagnetic emissions

NOTE This equipment has been tested and found to comply with the CISPR 11 limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. It is not intended for use in a residential environment..

Emissions test	Compliance	Electromagnetic environment - guidance
RF e RF emissions CISPR 11:2024	Group 1	The TetraGraph uses RF energy only internally for its internal function. Therefore, the RF emissions are not likely to cause any interference in nearby electronic equipment.
CIS RF e RF emissions CISPR 11:2024	Class A	The TetraGraph is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.

Guidance and declaration - electromagnetic immunity

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the TetraGraph including cables specified by the manufacturer. Exposing the Tetragraph to an electromagnetic environment outside specification could result in degradation of the performance, e.g. (but not limited to) measurement accuracy.

Immunity test	IEC 60601-1-2:2015+A1:2021 test level — the device is tested to the compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2:2009	±8 kV contact ±2 kV air ±4 kV air ±8 kV air ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4:2015+A1:2021 PR 11:2024	±2 kV for power supply line	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5:2014+A1	±0.5 kV line to line ±1 kV line to line At 0°, 90°, 180°, 270°	Class II power supply. Mains power quality should be that of a typical commercial or hospital environment.

Immunity test	IEC 60601-1-2:2015+A1:2021 test level — the device is tested to the compliance level	Electromagnetic environment - guidance
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11:2020	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source and/or that the battery is fully charged at the start of a procedure.
Power frequency magnetic fields (50/60 Hz) IEC 61000-4-8:2010	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity fields from RF wireless communications equipment IEC 61000-4-3:2020	See table below.	This equipment might not offer adequate protection against all radio frequency communication services. The user may need to take mitigation measures, such as moving or reorienting the equipment.
Proximity magnetic fields 9kHz to 13.56MHz IEC 61000-4-39:2017	134.2 kHz, PM 2.1kHz, 65A/m (unmodulated) 13.56 MHz, PM 50kHz, 7.5A/m (unmodulated)	Only use approved RFID equipment in proximity of the device.
Conducted disturbances induced by RF fields IEC 61000-4-6:2014	3 VRMS 150kHz – 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation
Radiated RF IEC 61000-4-3:2020	6 VRMS in ISM bands between 150kHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz to 2.7 GHz 80 % AM at 1 kHz	Distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined according to an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

Proximity fields from RF wireless communications equipment

The TetraGraph is compliant according to test specification for enclosure port Immunity to RF wireless communication equipment per IEC60601-1-2:2014/AMD1:2020.

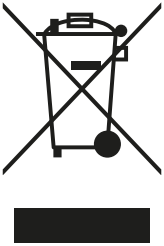
Test Frequency [MHz]	Band [MHz]	Service	Modulation	Immunity Test Level [V/m]
385	380 to 390	Tetra 400	Pulse modulation 18Hz	27
450	430 to 470	GMRS 460, FRS 460	Frequency modulation +5 kHz deviation 1kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217Hz	9
745				
780				
810	800 to 960	GSM 900/900, Tetra 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GDM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	9
5500				
5785				

15. Product Warranty

The product, when new, is guaranteed to be free from defects in materials and workmanship and to perform in accordance with the manufacturer's specification throughout its lifetime (seven (7) years from the date of purchase from the manufacturer or their approved distributor).

The manufacturer will repair or replace, at their discretion, any components found to be defective or at variance with the manufacturer's specification within this time at no cost to the purchaser.
The warranty does not provide cover for breakage or failure due to tampering, misuse, neglect, accidents, modifications, or shipping. The warranty is also void if the product is not used in accordance with the manufacturer's instructions or is repaired during the warranty period by any persons other than the manufacturer or its appointed agent. No other expressed or implied warranty is given.

16. Disposal of Waste Electrical and Electronic Equipment



This symbol means that used electrical and electronic products should not be mixed with general waste.
Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. If you are unsure of your national requirements with respect to disposal, contact your local authority, dealer, or supplier for further information.
Penalties may be applicable for incorrect disposal of this waste, in accordance with national legislation.

Manufacturer:
Senzime AB
Verkstadsgatan 8
753 23 Uppsala
Sweden

CE
2797

MEDICAL - APPLIED CURRENT/ENERGY EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH AAMI ES60601-1:2005/(R)2012 and A1:2012/(R)2012 and A2:2021; IEC 60601-1-6; IEC 60601-2-40; CAN/CSA-C22.2 No. 60601-1:14 (Reaffirmed 2022); CSA-C22.2 No. 60601-1-6; CSA-C22.2 No. 60601-2-40

www.senzime.com
info@senzime.com

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