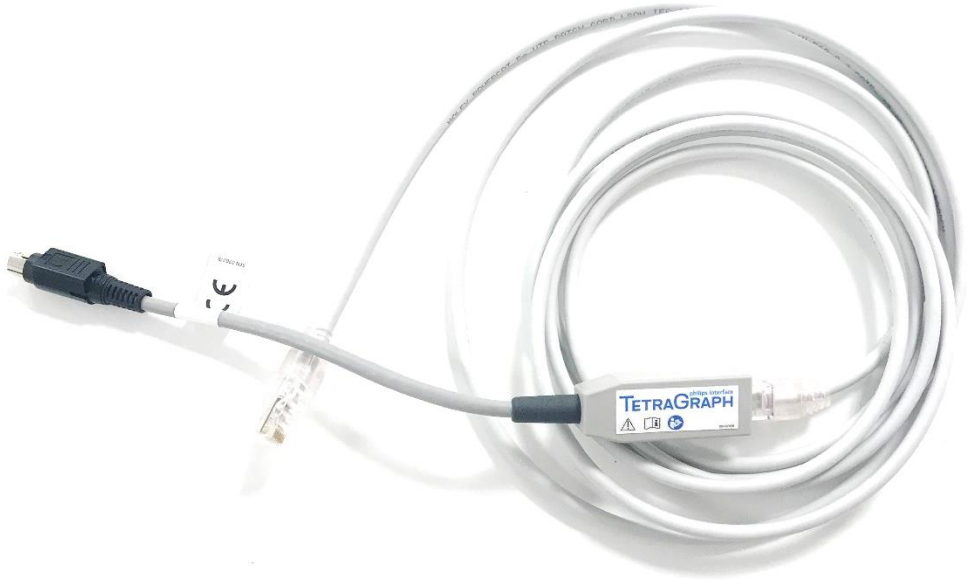
# TetraGraph Philips Interface Operating Instructions

## TetraGraph Philips Interface SEN 2007



# Contents

# 1. Introduction

These instructions are intended to assist with the operation of the TetraGraph Philips Interface and its connection to the TetraGraph Monitor and the Philips IntelliVue Monitors.

It is important that these instructions be read thoroughly and understood before using the equipment.

Always inspect the TetraGraph Philips interface device for any physical damage or missing parts before use. Make sure that the universal CAT5e cable is connected to the TetraGraph Philips Interface module before use.

# 2. Abbreviations

| | |
|---|---|
| CAT5e | Category 5e network cable |
| EMG | Electromyography |
| IVOI | IntelliBridge and VueLink Open Interface |
| NMT | Neuromuscular Transmission |
| PTC | Post Tetanic Count |
| SPI | Standard Parameter Interface |
| ST | Single Twitch |
| TOF | Train of Four |
| TOFcnt | Train of Four Count |
| TOFrat | Train of Four Ratio |

# 3. Warnings and Cautions

The European Medical Device Directive requires all manufacturers to include appropriate warnings and cautions (Figure 1) 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 the personal safety of the patient or user may be affected and when disregarding this information could result in injury.

**A CAUTION** is given when special instructions must be followed. Disregarding this information could cause damage to the device.

**Figure 1**. Description of a warning and a caution.

# 4. Scope of Use and Contraindications

The intended use of the TetraGraph Philips interface device is to connect a TetraGraph Monitor(SEN 2001) to a Philips IVOI compatible monitor so that the Neuromuscular Transmission data; TOF Ratio and TOF Count, PTC and ST measurements monitored by the TetraGraph can be displayed on the IVOI enabled monitor.

Indications for use
To connect the TetraGraph to a Philips IntelliVue (IVOI) Monitors to allow data transfer and the display of TetraGraph data on the Philips monitor.

Contraindications
No contraindications have been identified for the intended use of the TetraGraph Philips Interface.

# 5. Intended Users

The intended user of the TetraGraph Philips Interface product is the same user group as intended for the TetraGraph Monitor and the Philips IntelliVue Monitor.

# 6. Summary 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.

For more information about the TetraGraph and its functionality refer to the Operating instructions for the TetraGraph monitor.

Using the TetraGraph Philips Interface the TetraGraph can be connected to any Philips IntelliVue monitor to provide an external display of numeric presentations of TOF Ratio, TOF Count, PTC, and ST measurements. TOF responses can also be displayed in wave form.

The TetraGraph Philips Interface makes use of nine standard labels, as specified by Philips, and two additional custom labels. The custom labels are **'NMT'** (measurement numeric) and **'TOF'** (wave).

**'NMT'** represents TOF-responses and the label presents either TOFrat, TOFcnt, or PTC depending on the level of neuromuscular block. This numeric is further described with the standardized Philips IntelliVue label parameters: TOFrat or TOFcnt.

**'TOF'** is a waveform representation of the TOF-responses and it is represented as bars identical to the EMG-bars displayed by TetraGraph Monitor.

To find more information about the labels, please read section 17, List of labels.

# 7. Associated Devices

The associated devices for TetraGraph Philips Interface are the TetraGraph Monitor and the Philips IntelliVue Monitor.

Supported software versions
The required software version of the TetraGraph Monitor for the purpose of being connected with any Philips IntelliVue Monitor is: 34b.22b.12a or higher.

The Philips IntelliVue monitor needs to be of software version H.15 or higher and the Philips Patient Information Center PIIC iX (version B.0) and PIC iX (version C.0 or higher).

# 8. Summary of Warnings and cautions

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

| | |
|---|---|
| ⚠ | WARNINGS |

The Philips monitor shows inoperable (INOP) messages to indicate that the TetraGraph device might be inoperable.

The user operates TetraGraph Monitor with TetraGraph User Interface at all times. Consult the IFU of TetraGraph for how to use and handle the TetraGraph Monitor.

| | |
|---|---|
| ⚠ | CAUTIONS |

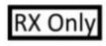
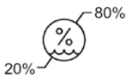
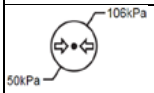
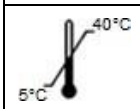
Please ensure that the TetraGraph Philips Interface is used with devices which it is intended to be used.

Please use the CAT5e cable that is supplied together with the TetraGraph Philips Interface. Any other cable may be incompatible with the TetraGraph Philips Interface product.

# 9. Symbols and Icons

The following symbols are used on the TetraGraph Philips Interface.

| | | |
|---|---|---|
| CE | CE mark | Indicates compliance with the European Medical Device Regulations. |
| SN | Serial number | The unique serial number allocated to the device. |
| REF | Reference number | The catalog or model number of the device. |
|  | Operating instructions | The device has instructions for use.<br>Consult the instructions for use. |
|  | Refer to Instruction Manual | You must read the instructions for use. |
|  | General warning sign | Shows important information. |
|  | WEEE | Do not dispose of in domestic waste. |
|  | Manufacturer | Name and address of the manufacturer. |
|  | Date of manufacture | Date of manufacture, shown as year, month, and day. |
| MD | Medical Device | The TetraGraph Philips interface is a Medical Device |
| MR | MR unsafe | The TetraGraph Philips Interface device is not MRI safe. |

| | | |
|---|---|---|
|  | 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. |
|   | For prescription use only | Federal law in the 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 to use or order the use of the device. |
|   | Unique Device Identification | The Unique Device Identification (UDI) is a system used to mark and identify medical devices within the healthcare supply chain. |
|  | Caution | Consult accompanying documents |
|   | Humidity | Transport and storage humidity limits |
|   | Pressure | Transport and storage pressure limits |
|  | Keep away from sunlight | Do not leave in direct sunlight or close to sources of excessive heat. |
|  | Keep dry | Product should be kept dry. |
|   | Temperature | Transport and storage temperature limits |

# 10. Getting Started

List for connecting to IntelliBridge

The following table identifies the equipment involved in the procedure.

| Equipment | Part number |
|---|---|
| TetraGraph Monitor | SEN 2001 |
| TetraGraph Philips Interface | SEN 2007 |
| Operating Instructions | SEN 257 |
| TetraGraph Monitor IFU | SEN 008 |

The TetraGraph monitor and TetraGraph Philips Interface are supplied by Senzime AB, the Philips IntelliBridge EC10 and Philips IntelliVue monitors are supplied by Philips (Figure 2). IntelliBridge EC10 needs to have OpenInterface driver (option 101) version A.6 or higher installed. No EC5 is required from Philips since it is a part of SEN 2007. Philips part numbers for IntelliBridge EC10:

IntelliBridge EC10 - Philips PN 865115 option A01,101

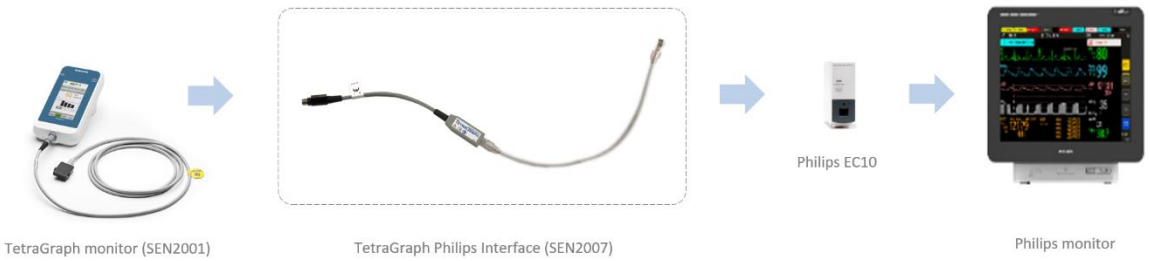



**Figure 2**. Illustrating the products required for connecting the TetraGraph Monitor to Philips IntelliVue.

# 11. Instructions for connecting

Do the following:

Connect the TetraGraph Philips Interface to the RS232 port of the TetraGraph Monitor. The RS232 port is shown to the left in Figure 3.

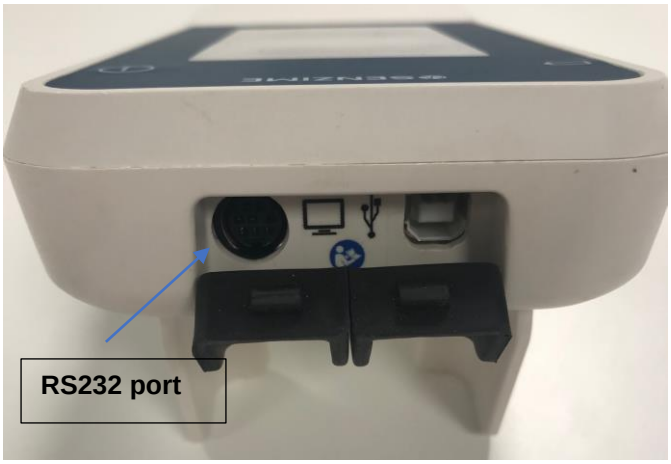



**Figure 3.** The RS232 port of TetraGraph Monitor allows external devices to be connected.

After inserting the TetraGraph Philips Interface to the TetraGraph Monitor, connect the other end of the TetraGraph Philips Interface to the Philips IntelliVue Monitor via an interface module such as EC10 or EC40 *(provided by Philips)*.

Consult the user's manual for the Philips IntelliVue monitor for Philips monitor-specific handling.

Consult the IFU of the TetraGraph Monitor for TetraGraph-specific handling.

The connection of the TetraGraph Monitor to the Philips IntelliVue Monitor via the TetraGraph Philips Interface is recommended to take place before the patient is connected to the system.

When the TetraGraph Monitor is connected to the Philips EC10 module using the TetraGraph Philips Interface, the Philips IntelliVue monitor will automatically display the default labels described below.
The following labels are default SPI:

- TOFcnt (numeric)
- TOFrat (numeric)
- PTC (numeric)
- Twitch (numeric)
- NMT (numeric)
- TOF bars (wave)

Labels that aren't of the default SPI can be displayed by adding them to the display through the Philips monitor's menu system. Similarly, default SPI labels can be removed.

Please see the list of labels in chapter 17 for an elaborate description.

## 12. Operation

When the TetraGraph is turned on and connected to a Philips IntelliVue monitor via the TetraGraph Philips Interface, the default SPI labels will appear on the screen as in the following example from a Philips MX550 monitor (Figure 4):


**Figure 4**. Screenshot from when TetraGraph is connected to a Philips IntelliVue monitor via the TetraGraph Philips Interface, showing the default SPI labels.

Figure 5 shows how the Philips IntelliVue Monitor can display TOF-results generated by the TetraGraph system, for each label as seen in Figure 4.

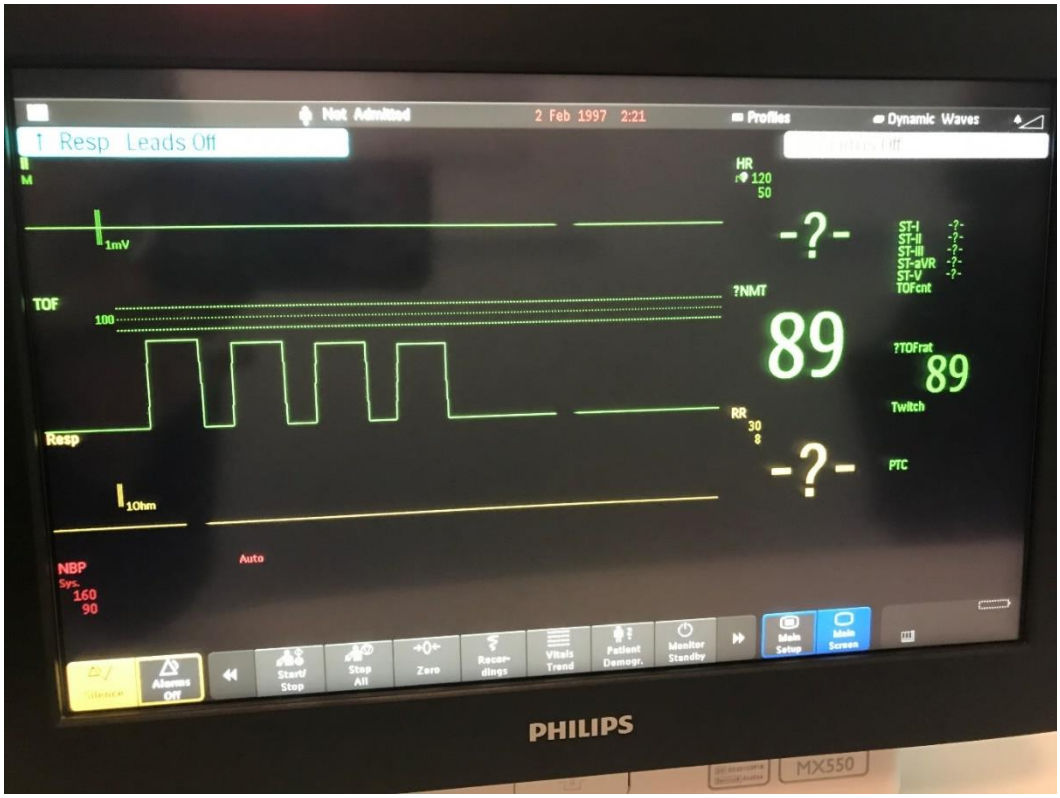



**Figure 5**. Screenshot from when Philips IntelliVue monitor can display TOF-results given by TetraGraph system.

In Figure 5 the TOF bar-wave shows four TOF responses in which the TOF ratio is 89 %. The custom label- NMT displays a numeric value of 89 which is further emphasized by the TOFrat 89.

The purpose of the NMT numeric is to hold TOF Ratio, TOF Count as well as PTC values. This means that if the level of the neuromuscular block would be as deep as TOFc 2 then the NMT would display a numeric value of 2 and be further emphasized with a TOFcnt 2, as seen in Figure 6. When in PTC mode, the result will show both in the NMT number as well as a PTC value on the Philips display.

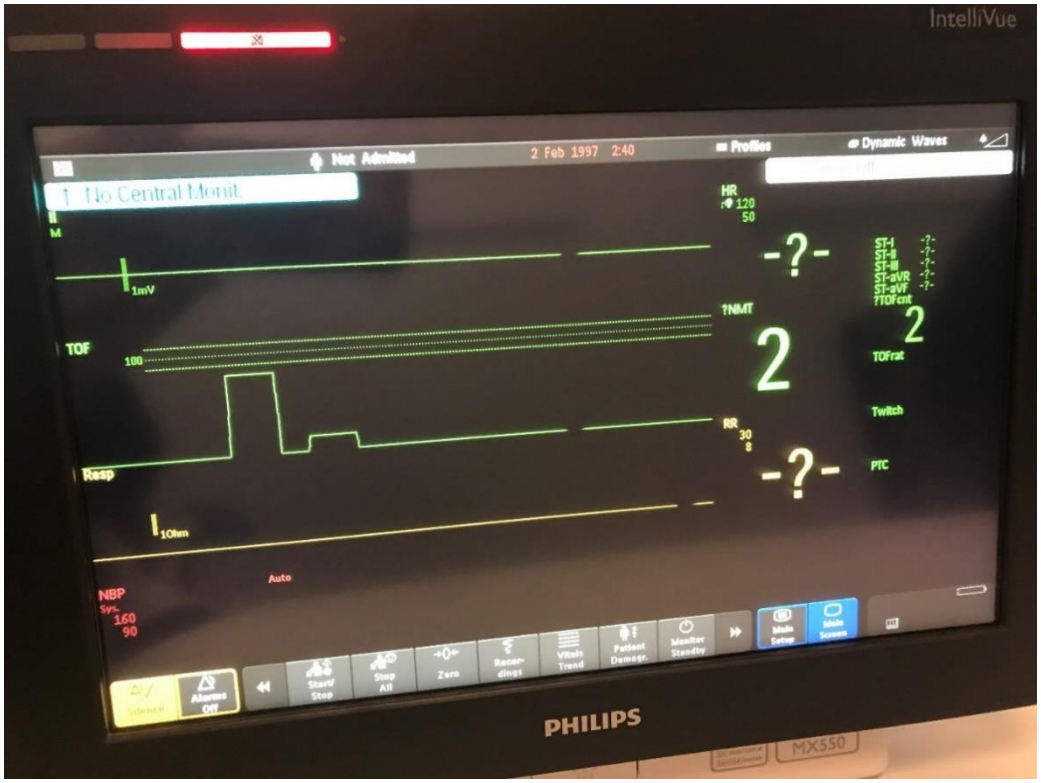



**Figure 6**. Screenshot from when Philips IntelliVue monitor displays NMT-numeric value given by TOFcnt results.

Adding or removing displayed waves or parameters

On the Philips IntelliVue monitors it is possible to change the view settings to display the wave or parameter of your preference. If you would like to add (or remove) any wave representation, then you would have to use the specific menu system of your monitor. In the below example in Figure 7, the Setup Device driver is used to change from the TOF wave to the EMG wave on the MX550 monitor. *Different IntelliVue models might utilize a different set of menu functions to obtain the same result. Please consult your IFU for Philips IntelliVue for more information.*

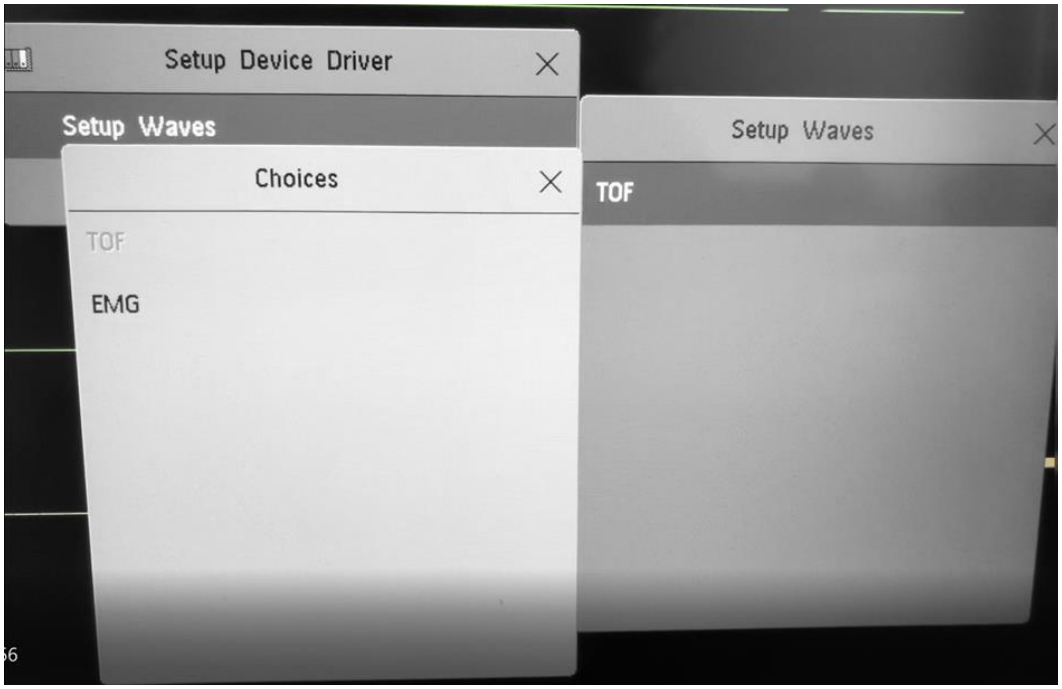



**Figure 7**. Screenshot from Philips IntelliVue monitor displaying ways of obtaining the TOF and EMG waves. The TOF label from 'Choices' is a custom label that can be added when the TetraGraph system is used.

Figure 8 shows the resulting screen after removing the TOF wave and adding the EMG wave.


**Figure 8**. Screenshot from Philips IntelliVue monitor displaying TOF-results with an EMG-wave when the TOFrat numeric is 89%.

Please note that the actual appearance may vary depending on which monitor model you have and which screen mode you use (”Change Screen” menu in the top right corner of the screen). In the above case, we use a screen called ”Dynamic Waves”.

## 13. Finishing Measurement Sessions

Consult the user’s manual for the Philips IntelliVue monitor to shut down the device.

Consult the IFU for the TetraGraph Monitor to shut down the device.

Disconnect the TetraGraph Philips Interface from the Philips IntelliVue Monitor and the TetraGraph Monitor. Proceed with chapter 17 for cleaning.

# 14. Troubleshooting

| Troubleshooting Chart | |
|---|---|
| Use this troubleshooting chart to resolve some of the most common issues identified when using a TetraGraph monitor. | |
| **Symptom** | **Resolution** |
| Nothing is visible on Philips Monitor when the Tetragraph is connected | Please make sure that you have the latest software in your TetraGraph. The required software version is 34b.22b.12a or higher.<br><br>Make sure that all the cables are properly connected. |
| The data presentation on Philips is not representative of results displayed with TetraGraph | Please consult your Senzime distributor |
| The Philips IntelliVue stops displaying TOF-results | Please identify the root cause when the 'INOP' message is displayed on Philips. Troubleshoot TetraGraph.<br>If a '?' appears on TetraGraph display, make sure that the TetraCord cable is properly attached and/or that the TetraSens is properly attached |

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 established;

# 15. Maintenance

When not in use, keep the TetraGraph Philips Interface in its original packaging
The TetraGraph Philips Interface does not have any user-serviceable parts and must not be modified.

# 16. Cleaning and Disinfecting

Before cleaning, disconnect the power unit from the main electrical supply. Disconnect TetraGraph Philips Interface from TetraGraph Monitor and Philips Monitor.

The TetraGraph Philips Interface and its cables must NOT be immersed in water or other liquids during cleaning or disinfection. Do NOT use solvents or abrasive cleaners.

Cleansers and disinfectants must be indicated for use on medical devices and specify compatibility with use on plastics and metal surfaces. Suitable disinfectants include: quaternary ammonium compounds, isopropyl alcohol, chlorine or chlorine dioxide 0.5%, and phenolics.

The TetraGraph Philips Interface may be cleaned with common medical device cleaning and disinfecting agents, excluding solvents and abrasive material. Typically, cleaning will include the use of diluted cleanser or disinfectants on damp cloth wipes which may include the following:

Sodium hypochlorite bleach (diluted)
Hydrogen peroxide (3%)
Ethanol (70%)
Isopropanol (70%)
Glutaral (2%)
Benzalkonium Chloride (0.2%)
Alkyldiaminoethylglycine Hydrochloride (0.5%)

Be careful not to allow moisture into the TetraGraph Philips Interface through the connectors.

# 17. Performance and Technical Specifications

## Compatibility

| | | |
|---|---|---|
| External device information | The IntelliBridge VueLink Open Interface (IVOI) Protocol is unidirectional, i.e. a monitor that adheres to the protocol can display data received from the Tetra Graph but cannot remotely control the device.<br>Note that the user controls the monitoring using the TetraGraph Monitor graphical user interface when interfacing with the Philips monitor.<br>The device transfers 9 measurement numerics and two waves to the monitor, using the Open Interface protocol. The device makes use of the INOP (inoperable) functionality in the Open Interface protocol, to alert the user about a loose connector, low battery, or if somebody has pressed pause on the device. | |
| Supported Devices | This integration supports the TetraGraph only and the minimum version that is supported is 34b.22b.12a. | |
| Supported hosts | Senzime's implementation of the IVOI protocol was carried out using Philips SpecTool (1040), the IntelliBridge, and VueLink Open Interface - Specification Tool (Version B). All hosts that support this version of the IVOI protocol operating at 19200 Baud and open interface driver A.6 and higher will be compatible. | |
| IntelliVue monitor revision | Compatible Philips Monitors (via IntelliBridge EC10) | Tetragraph is compatible with the following Philips Patient Monitors when equipped with integrated or modular IntelliBridge EC10 Interface:<br>• IntelliVue MP series (SW version H.15 or higher)<br>• IntelliVue MX series (all SW versions) |
| | Compatible Philips Information Centers (via IntelliBridge EC40/80) | Tetragraph is compatible with the following Philips Information Centers when connected via EC40/80 hubs<br>• PIIC iX IntelliVue Information Center iX (SW version B.0)<br>• PIC iX Patient Information Center iX (SW version C.0 or higher) |
| | Compatible Driver | OpenInterface version A.6 or higher |
| How to find the software revision of the instrument | To locate the current version of the TetraGraph, please consult the IFU for the TetraGraph.<br>Also, the software version is shown on the display when the OFF button is pressed. | |

## List of labels

In the tables below, all labels are provided with numeric codes from the Medical Device Interface Language (MDIL).

Labels

| MDIL Text ID | Label | Unit of measure | Display range | Definition | Description |
|---|---|---|---|---|---|
| 0002-593c | EMG | % | 0-120 | "EMG" | Electromyography Low EMG |
| 0002-f8ab | TOFcnt | Unitless | 0-4 | "TOFcnt" | Train of Four (TOF) count - Number of TOF responses |
| 0002-f897 | TOFrat | % | 0-120 | "TOFrat" | Train of Four (TOF) ratio. Is the ratio between the first and the fourth TOF response |
| 0002-f88b | PTC | Unitless | 0-20 | "PTC" | Post Tetanic Count stimulation - PTC |
| 0002-f8ac | Twitch | mV | 0-50 | "Twitch" | Twitch height of the 1Hz/0.1Hz stimulation response |
| 0002-f8a7 | TOF1 | mV | 0-50 | "TOF1" | Train of Four (TOF) first response value |
| 0002-f8aa | TOF4 | mV | 0-50 | "TOF4" | Train of Four (TOF) fourth response value |
| 0002-f8a8 | TOF2 | mV | 0-50 | "TOF2" | Train of Four (TOF) second response value |
| 0002-f8a9 | TOF3 | mV | 0-50 | "TOF3" | TrainOf Four (TOF) third response value |

List of custom labels*

| MDIL Text ID | Label | Unit of measure | Display range | Definition | Description |
|---|---|---|---|---|---|
| N/A (custom) | TOF | % | 0-120 | CUSTOM “TOF” | Custom label for the train-of-four response graph (bars). |
| N/A (custom) | NMT | Unitless | 0-120 | CUSTOM “NMT” | Neuro-Muscular Transmission. This is a numeric that displays a value of the response and the value is dependent on the current state of the neuromuscular response. |

* These parameters cannot be trended on Philips IntelliVue monitors and has no steady code assignment in the Philips PIC iX HL7 data output, instead it is embedded as "text" within the HL7 data stream output from Philips PIC iX.

These parameters cannot be used in a pre-configured IntelliVue monitor-screen layout and are not displayed on Philips PIC iX.

## Data mapping

The following table is a mapping of instrument parameters, type (measurement numeric), or waveforms, and alerts to corresponding labels and functions on Philips monitors.

| Vendor’s labels | | | | | Philips’ labels | | | |
|---|---|---|---|---|---|---|---|---|
| Parameter | Type | Label | Unit of measure | Display range | MDIL text ID | Label | Definition | Description |
| EMG | Wave | EMG | % | 0-120 | 0002-593c | EMG | "EMG" | Electromyography Low EMG |
| TOFcnt | Measurement numeric, single/periodic | TOFcnt | Unitless | 0-4 | 0002-f8ab | TOFcnt | "TOFcnt" | Train of Four (TOF) count - Number of TOF responses |
| TOFrat | Measurement numeric, single/periodic | TOFrat | % | 0-120 | 0002-f897 | TOFrat | "TOFrat" | Train of Four (TOF) ratio. Is the ratio between the fourth and the first TOF response |
| PTC | Measurement numeric, single/periodic | PTC | Unitless | 0-20 | 0002-f88b | PTC | "PTC" | Post Tetanic Count stimulation – PTC |
| Twitch | Measurement numeric, single/periodic | Twitch | mV | 0-50 | 0002-f8ac | Twitch | "Twitch" | Twitch height of the 1Hz/0.1Hz stimulation response |
| TOF1 | Measurement numeric, single/periodic | TOF1 | mV | 0-50 | 0002-f8a7 | TOF1 | "TOF1" | Train of Four (TOF) first response value |
| TOF4 | Measurement numeric, single/periodic | TOF4 | mV | 0-50 | 0002-f8aa | TOF4 | "TOF4" | Train of Four (TOF) fourth response value |
| TOF2 | Measurement numeric, single/periodic | TOF2 | mV | 0-50 | 0002-f8a8 | TOF2 | "TOF2" | Train of Four (TOF) second response value |
| TOF3 | Measurement numeric, single/periodic | TOF3 | mV | 0-50 | 0002-f8a9 | TOF3 | "TOF3" | Train of Four (TOF) third response value |
| N/A (custom) | Wave | TOF | % | 0-120 | N/A, CUSTOM “TOF” | N/A (custom) | N/A (custom) | Custom label for the train-of-four response graph. |
| N/A (custom) | Measurement numeric, single/periodic | NMT | Unitless | 0-120 | N/A, CUSTOM “NMT” | N/A (custom) | N/A (custom) | Neuro-Muscular Transmission. This is a numeric that displays a value of the response and the value is |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | dependent on the current state of the neuro-muscular response. |
| General INOP | Hard INOP | Tet Stim Elctr Off | Text | N/A | N/A | N/A | TetraGraph stimulus electrode is off | A general INOP (inoperable indicator) which has the property “Invalid useless”. |
| General INOP | Hard INOP | Tet EMG Electr Off | Text | N/A | N/A | N/A | TetraGraph recording electrode is off | A general INOP (inoperable indicator) which has the property “Invalid useless”. |
| General INOP | Hard INOP | TetraGraph Paused | Text | N/A | N/A | N/A | TetraGraph has been paused | A general INOP (inoperable indicator) which has the property “Invalid useless”. |
| General INOP | Soft INOP | Tetra Battery Low | Text | N/A | N/A | N/A | TetraGraph battery is low | A general INOP (inoperable indicator) which has the property “Invalid questionable”. |

# 18. Environment

| | |
|---|---|
| Environment during initial transportation | |
| Temperature | -30°C to 70°C for periods not exceeding 5 days |
| Relative humidity | 20% to 100% non-condensing |
| Atmospheric pressure | 50 kPa to 106 kPa |
| Altitude | Height above sea level to be 5000 – 0 m (50-100 kPa) |
| Environment during storage and movement between hospital locations | |
| Temperature | 5°C to 40°C |
| Relative humidity | 20% to 80% non-condensing |
| Atmospheric pressure | 50 kPa to 106 kPa |
| Environment during use | |
| Temperature | 15°C to 35°C |
| Relative humidity | 20% to 80% non-condensing |
| Atmospheric pressure | 70 kPa to 106 kPa |

## 19. 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 for a period of one year 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 will take effect from the date of purchase, subject to the purchaser registering the product with the manufacturer to confirm its receipt, installation date, and product details.
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.

## 20. 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
info@senzime.com