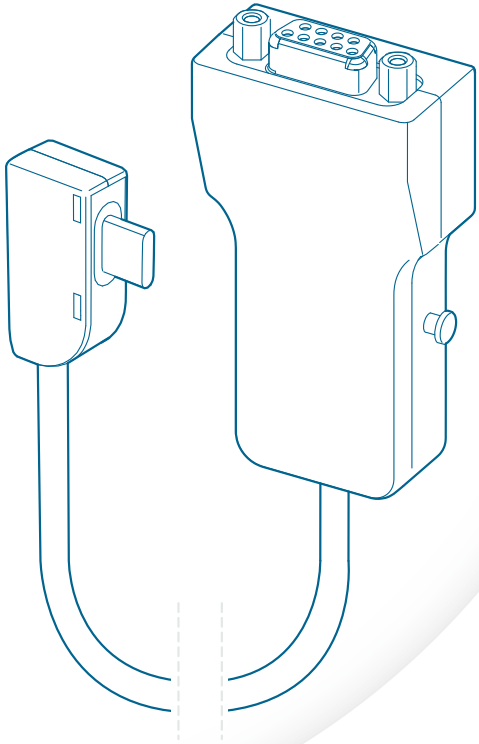
English



TETRA**HUB**

Rx Only

TETRA**GRAPH®** Connectivity Solution

Operating instructions

SENZIME

Contents

1. Introduction

These instructions are intended to assist with the operation of the TetraHub and its connection from the TetraGraph monitor (SEN 2015) to a compatible Electronic Health Record connection hub or an external monitor.
It is important that these instructions be read thoroughly and understood before using the equipment.

Always inspect the TetraHub and the supported external monitor for any physical damage or missing parts before use.

Abbreviations

DB9	D-Subminiatures connector with 9 pins
EMG	Electromyography
NMT	Neuromuscular Transmission
TOF	Train-of-Four
PTC	Post Tetanic Count
ST	Single Twitch
IFU	Instructions for Use

2. Scope of Use and Contraindications

TetraHub can be reused and is an optional accessory of TetraGraph monitor (model no. SEN 2015). It is not intended to be introduced into the human body or applied to any tissues

Intended Users

The intended user of the TetraHub is the same user group as intended for the TetraGraph monitor that has a TetraGraph supported external hub or monitor.

Intended Use

TetraHub is part of the TetraGraph system. For the intended use of the TetraGraph system see TetraGraph User Manual.

Indication for Use

TetraHub is part of the TetraGraph system. For the indication for use of the TetraGraph system see TetraGraph User Manual.

Contraindications

No contraindications have been identified for the intended use of the TetraHub.

Clinical Benefits

TetraHub is part of the TetraGraph system. The clinical benefits of the TetraGraph system see TetraGraph User Manual.

3. Summary of Operation

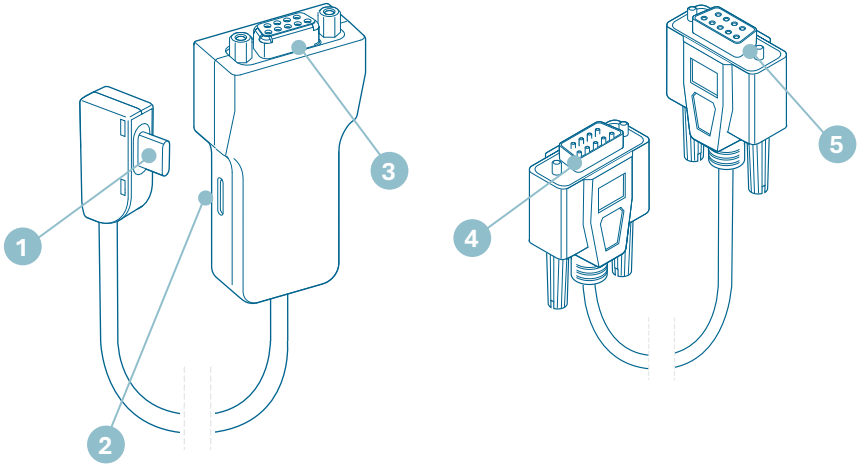
For more information about the TetraGraph and its functionality refer to the Instruction for use for the TetraGraph monitor.

By using the TetraHub, the TetraGraph can be connected to any TetraGraph supported compatible Electronic Health Record connection hub or a TetraGraph supported external hub or monitor to transmit both numeric presentations and wave form display of TOF Ratio, TOF Count, PTC, and ST measurements to the hub or monitor. Stimulus information can also be displayed in the hub or monitor.

To find more information about the labels, please read in section 12 Symbols and Icons on page 12

4. Getting to Know the TetraHub

Device Layout



1. USB-C Cable
2. USB-C Port on TetraHub
3. DB9 Connector
4. DB9 Extension Cable Male Connector
5. DB9 Extension Cable Female Connector

The TetraHub System

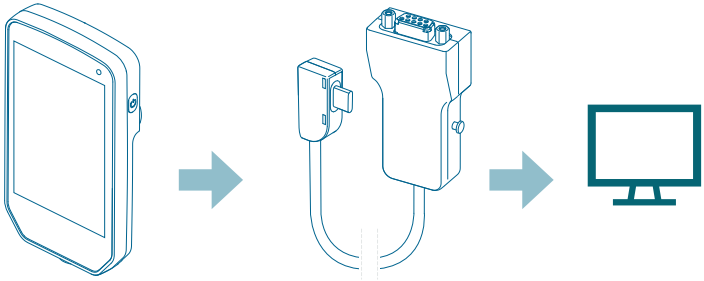
The system as delivered includes the following items:

- SEN 2017 TetraHub
- DB9 Extension cable (RND model no. RND 765-00023)
- INFO0135 Operating Instructions (this document)

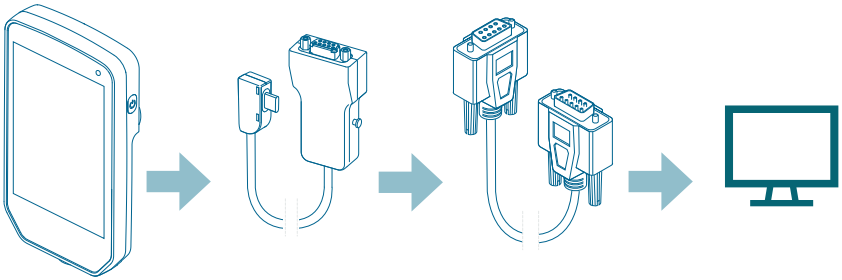
Associated Devices

The associated devices for TetraHub are the TetraGraph monitor and the supported hub or monitor.

Connection Block Diagram without DB9 Extension Cable



Connection Block Diagram Including DB9 Extension Cable



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

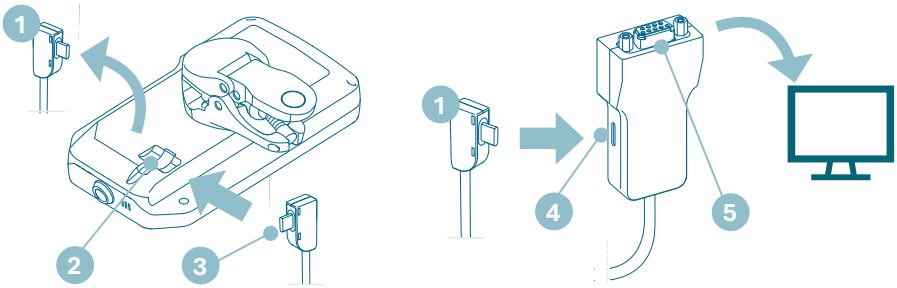
The TetraGraph monitor and TetraHub is supplied by Senzime AB, the supported external hubs or monitors are supplied by the designated manufacturer. The external hub or monitor needs to be updated to the software version that can support the TetraGraph monitor.

CAUTION Before use visually inspect the device and the integrated cable for any loose or damaged parts.

5. Setting Up

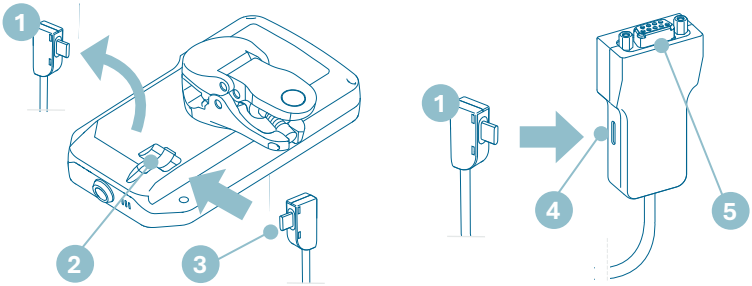
Assembly of TetraHub with TetraGraph and external hub or monitor

1. Disconnect the power supply cable (1) from the USB-C port (2) on the back of the TetraGraph monitor.
2. Connect the TetraHub´s integrated USB-C cable (3) to the USB-C port (2) on the back of the TetraGraph monitor.
3. Connect the TetraGraph power supply cable (1) to the USB-C port on the TetraHub (4).
4. Connect the DB9 connector of the TetraHub (5) to the DB9 port on the external hub or monitor.

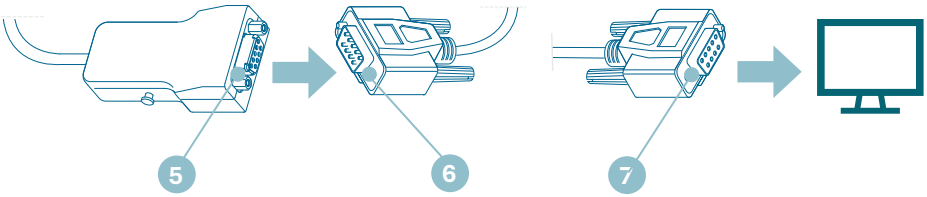


Assembly of TetraHub and DB9 Extension cable with TetraGraph and external hub or monitor

1. Disconnect the power supply cable (1) from the USB-C port (2) on the back of the TetraGraph monitor.
2. Connect the TetraHub´s integrated USB-C cable (3) to the USB-C port (2) on the back of the TetraGraph monitor.
3. Connect the TetraGraph power supply cable (1) to the USB-C port on the TetraHub (4).
4. Connect the DB9 connector of the TetraHub (5) to the male connector on the DB9 Extension cable (6).
5. Connect the female connector of the DB9 Extension cable (7) to the port on the external hub or monitor.



Illustrations continue on next page.



Connect the TetraGraph monitor to the External Hub or Monitor via the TetraHub before the patient is connected to the system.

When the TetraGraph monitor is connected to the external hub or monitor using the TetraHub, the following data is transmitted to the external device:

- TetraGraph monitor Identification (Serial number & software version)
- Pulse Information
- Measurement and status flags
- TOF, PTC, and ST results
- Individual peak-to-peak amplitudes

NOTE Refer to your specific external hub or monitor instructions and descriptions on which information can be displayed by the monitor.

6. Operation

Consult the manual for the external hub or monitor for device-specific handling.
Consult the manual for the TetraGraph monitor for instructions for use.

Starting measurement sessions

1. Turn ON the TetraGraph monitor.
2. Go to Settings > Device > Communication and select and option.
3. Check that the external monitor indication symbol is displayed in the information bar on the TetraGraph.
4. Connect the patient to the system.
5. Start TOF measurements.
6. The external hub or monitor will start displaying information from the TetraGraph monitor.

Finishing measurement sessions

Consult the user's manual for the corresponding external hub or monitor to shut down the device.
Consult the IFU for the TetraGraph monitor to shut down the device.
Disconnect the TetraHub from the power supply, the external hub or monitor, and the TetraGraph monitor. Proceed to clean and disinfect the TetraHub. Further instructions are detailed in chapter 9. Cleaning and Disinfecting on page 9

7. Troubleshooting

Troubleshooting Chart

Use this troubleshooting chart to resolve some of the most common issues identified when using the TetraHub.

Symptom	Resolution
Nothing is visible on external hub or monitor when the TetraGraph is connected	Please make sure that the correct communication protocol is selected (Select under Setting > Device > Communication). Check that the external monitor symbol is displayed on the TetraGraph monitor screen. Make sure that all the cables are properly connected.
The data presentation on the external hub or monitor is not representative of results displayed with TetraGraph	Please consult your Senzime distributor

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

No maintenance or preventive inspection is required.
No modification of this equipment is allowed.

Product Lifetime

The lifetime of the TetraHub is 2 years.

9. Cleaning and Disinfecting

The outer casing shall be manually cleaned and disinfected with surface cleaning agents and disinfectants. Cleansers and disinfectants must be indicated for use on medical devices and specify compatibility with use on plastics and metal surfaces. Suitable disinfectant are defined as 70% alcohol disinfectant such as ethanol or isopropanol, or hydrogen peroxide-based disinfectants.

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 8.

Manual Disinfection

1. Be careful not to allow moisture into the device through connectors.
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

Compatibility

External device information	The communication protocol is unidirectional, i.e. a hub or monitor that adheres to the protocol can display data received from the TetraGraph but cannot remotely control the device. Note that the user controls the monitoring using the TetraGraph monitor graphical user interface when interfacing with the external hub or monitor. The device transfers information regarding the device information, battery status, connection status, wave information and measurement information.
Supported devices	This integration supports the TetraGraph SEN 2015.
Supported hosts	Senzime's implementation of the external communication protocol was carried out using the UART interface operating at 115200 Baud. Contact Senzime AB for more information regarding the communication protocol and the list of the supported hosts.

11. Data output

Restriction on other Equipment

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, 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 qualified technician, or alternatively, a Senzime representative or technical support.
Connect to the equipment or external monitor/hub that is supported by SEN 2015.

The TetraGraph system can only send data to external monitors/hubs via TetraHub.

TetraGraph system should not be connected to the internet or any other networks, see INFO0124 TetraGraph SEN 2015.

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!

- The TetraHub must not be immersed in water or other liquids during cleaning or disinfection.
- Do not use other solvents or abrasive cleaners that are not stated in this operating instruction.

- Before cleaning, disconnect TetraHub from the power supply, TetraGraph monitor, and external hub or monitor.

CAUTION!

- Before use visually inspect the device and the integrated cable for any loose or damaged parts.

Symbols and Icons

The following symbols are seen on the labels of the TetraHub.

Icon	Meaning	Description
CE	CE mark and notified body number	Indicates compliance with European Medical Device regulations. Symbol is associated with a number indicating the Notified Body.
FC	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.
LOT	Batch Code	Lot number of 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.
	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.

Icon	Meaning	Description
	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. Disposal of Waste Electrical and Electronic Equipment on page 14
	Humidity	Transport and storage humidity limits.
	Pressure	Transport and storage pressure limits.
	Temperature	Storage or Transport temperature limits

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 14.

14. Electromagnetic Compatibility Information

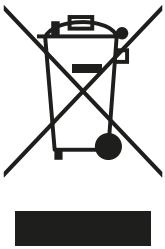
The TetraHub has been tested for electromagnetic compatibility as an accessory in conjunction with the TetraGraph (SEN 2015). See the TetraGraph (SEN 2015) IFU for complete Electromagnetic Compatibility Information.

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 for a period of two (2) 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.

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SENZIME