TETRAGRAPH xcom

Operating Instructions

TetraGraph Xcom Cable SEN 2010

⚔ SENZIME

Contents

1. Introduction

These instructions are intended to assist with the operation of the TetraGraph Xcom cable and its connection from the TetraGraph monitor 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 supported external monitor for any physical damage or missing parts before use. Make sure that there is a DB-9 Female port available on the external monitor before use.

Electronic instruction for use is available, contact your distributor or Senzime AB for more information.

2. Abbreviations

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

3. Warnings and Cautions

The European Medical Device Regulation 2017/745 and 21 CFR Part 801 requires all manufacturers to communicate to the user and/or other person about limitations, contraindications, cautions or warnings 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

TetraGraph Xcom cable can be reused and is an optional accessory of TetraGraph monitor. It is not intended to be introduced into the human body or applied to any tissues.

The intended use of the TetraGraph Xcom cable is to connect a TetraGraph monitor (SEN 2001) to a supported external monitor that is compatible so that the Neuromuscular Transmission data; TOF Ratio and TOF Count, PTC and ST measurements monitored by the TetraGraph can be displayed on the external monitor.

Indication for use

As a connection cable for TetraGraph monitor, TetraGraph Xcom cable share the same indication for use as TetraGraph monitor.

Contraindications

No contraindications have been identified for the intended use of the TetraGraph Xcom cable.

5.   Intended Users

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

6.   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 TetraGraph Xcom cable, 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 section 9 , List of symbols and icons.

7.   Associated Devices

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

Supported software versions

The required software version of the TetraGraph monitor for the purpose of being connected with any supported hub or monitor is: 34e.22f.12d 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 cable. It is important that the user familiarises himself/herself with all the warnings and cautions contained within this document.

⚠ **WARNINGS**

The TetraGraph Xcom cable and its power supply must NOT be immersed in water or other liquids during cleaning or disinfection. DO NOT use other solvents or abresive cleaners that are not stated in this operating instruction. Before cleaning, disconnect the power unit from the main electrical supply. Disconnect TetraGraph Xcom cable from TetraGraph monitor and external hub or monitor.

⚠ **CAUTIONS**

Please use the power supply that is supplied together with the TetraGraph Xcom cable. Any other power supply may be incompatible with the TetraGraph Xcom cable Product.

9. Symbols and Icons

C E	CE mark	Indicates compliance with the European Medical Device Regulations.
LOT	Lot number	Batch code
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	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 Xcom cable is a Medical Device
MR	MR unsafe	The TetraGraph Xcom cable is not MRI safe.

FC	FCC mark	FCC mark is a certification mark employed on electronic products sold in the United States which certify that the electromagnetic interference from the device is under limits approved by the Federal Communications Commission.
Rx Only	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.
UDI	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
☀	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 an storage temperature limits
🔌	Power Supply	Product shall always be connected to a power supply to operate.

10. Getting Started

The following table identifies the equipment involved in the procedure for connecting to a hub or a monitor.

Equipment	Part number
TetraGraph monitor	SEN 2001
TetraGraph Xcom cable	SEN 2010
USB power supply	0302
Primary plug depending on which country:	
- Primary Plug EU	0178
- Primary Plug UK	0179
- Primary Plug US/JP	0180
- Primary Plug AUS	0181
Operating Instructions	INFO0082
TetraGraph monitor IFU	SEN 008

The TetraGraph monitor and TetraGraph Xcom cable 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. The TetraGraph Xcom cable needs to always be connected to a power supply during operation. The connection between the TetraGraph monitor, TetraGraph Xcom and the external hub or monitor can be seen in **Figure 2**.
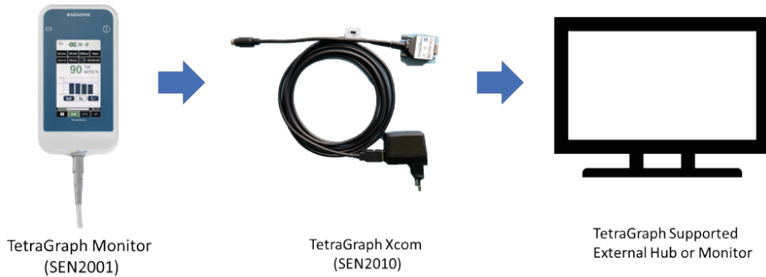

TetraGraph Monitor
(SEN2001)

TetraGraph Xcom
(SEN2010)

TetraGraph Supported
External Hub or Monitor

Figure 2 Connection block diagram

Note: Please contact the distributor or Senzime AB if there are any damages with the packaging/cable upon receiving the package and/or upon starting the monitoring process.

11. Instructions for Connecting

Do the following:
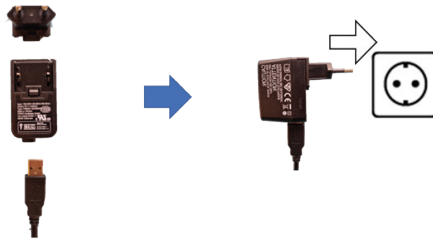
Figure 3 Power supply installation

Assemble the power supply by connecting the primary plug which is used in the country of operation (either 0178, 0179, 0180 or 0181), power supply (0302) and USB port of the TetraGraph Xcom cable (SEN 2010). Connect the assembled power supply to a power source as shown in Figure 3. Power supply should always be connected during operation of the cable.

⚠ Please use the power supply that is supplied together with the TetraGraph Xcom cable. Any other power supply may be incompatible with the TetraGraph Xcom cable Product.

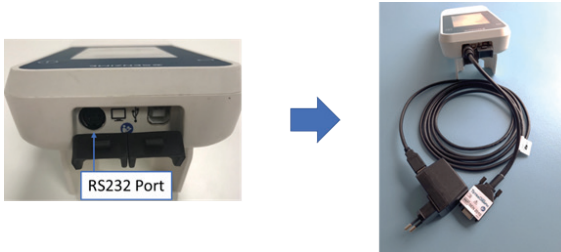*Figure 4* RS232 port of the TetraGraph monitor to be connected to the TetraGraph Xcom cable

Connect the TetraGraph Xcom cable to the RS232 port of the TetraGraph monitor. The RS232 port is shown to the left in Figure 4.
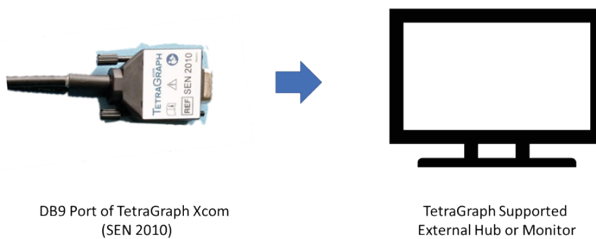

DB9 Port of TetraGraph Xcom
(SEN 2010)

TetraGraph Supported
External Hub or Monitor

Figure 5 DB9 Port of TetraGraph Xcom to be connected with the external hub or monitor

Lastly, connect the DB9 port of the TetraGraph Xcom cable to the external hub or monitor as shown in Figure 5.

After inserting the TetraGraph Xcom cable to the TetraGraph monitor, connect the other end of the TetraGraph Xcom cable to the external hub or monitor via the DB9 port.

Consult the user's manual for the external hub or monitor for the device-specific handling.

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

The connection of the TetraGraph monitor to the External Hub or Monitor via the TetraGraph Xcom cable is recommended to take place before the patient is connected to the system.

When the TetraGraph monitor is connected to the external hub or monitor using the Tetra-Graph Xcom cable, the monitor is able to display the information described below:

• 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.

Please see the list of labels in section 9 for an elaborate description.

12. Operation

After connecting the TetraGraph Xcom cable to the TetraGraph monitor, power supply and the external monitor, turn ON the TetraGraph monitor and perform measurement. The external hub or monitor will start displaying information from the TetraGraph monitor.

Note that each external monitor will support different information to be displayed according to each of the external hub or monitor's specification.

13. 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 TetraGraph Xcom cable Interface from the external hub or monitor and the TetraGraph monitor. Proceed with section 16 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 external hub or monitor when the Tetragraph is connected	Please make sure that you have the latest software in your TetraGraph. The required software version is 34e.22f.12d or higher. Make sure that all the cables are properly connected.
The software version is correct, and everything is properly connected but nothing is visible on the external hub or monitor	Please make sure that the power supply is connected to a functioning power source and the cables are not damaged.
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 established.

15. Maintenance

When not in use, keep the TetraGraph Xcom cable and the power supply in its original packaging. The TetraGraph Xcom cable 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 Tetra-Graph Xcom cable from TetraGraph monitor and external hub or monitor.

The TetraGraph Xcom cable and its power supply 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 Instructions for Use.

Cleansers and disinfectants must be indicated for use on medical devices and specify compatibility with use on plastics and metal surfaces. Suitable disinfectant is defined as 70% alcohol disinfectant such as ethanol or isopropanol.

The TetraGraph Xcom cable 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 consists of 70% alcohol (ethanol or isopropanol).

Be careful not to allow moisture into the TetraGraph Xcom cable or its power supply through the connectors.

17. 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 only and the minimum version that is supported is 34e.22f.12d.
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.
How to find the software revision of the instrument	To locate the current version of the TetraGraph, please consult the IFU for the TetraGraph. The software version is shown on the display when the OFF button is pressed.

Specification

Cable length	280 – 300 cm
Nominal input voltage	100 – 250V AC ±10%
Nominal input frequency	50 – 60 Hz
Nominal output voltage	5V DC ±10%

18. Environment

Environment during transportation/storage

Temperature	-25°C to 70°C
Relative humidity	10% to 95% non-condensing

Note: Please contact your supplier and/or Senzime AB if there are any damages present on the packaging and/or cable due to shipping.

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 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.

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