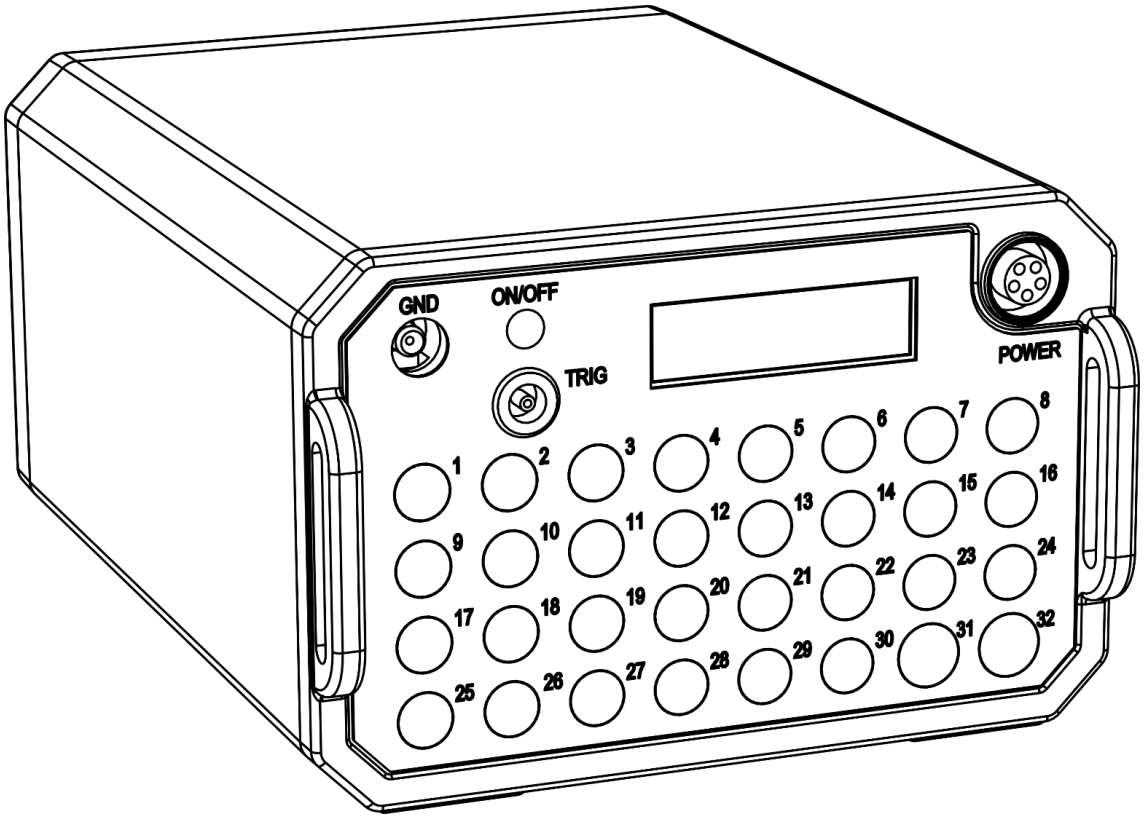
# Porti 7

## User Manual

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CE 0344

# TABLE OF CONTENTS

# 1 SERVICE AND SUPPORT

## 1.1 About this manual

This manual is intended for the user of the Porti7 system – referred to as 'product' throughout this manual. It contains general operating instructions, precautionary measures, maintenance instructions and information for use of the product. Read this manual carefully and familiarize yourself with the various controls and accessories before starting to use the product.

## 1.2 Contact information TMSi

TMSi Support can be reached via email (support@tmsi.com) or by phone during office hours (CET). Please make sure you have read our Troubleshooting section on www.tmsi.com, because this may resolve your problem without the need of external assistance. Always provide as much information on your problem as possible, including serial numbers of the products. This will help us to support you in the best and most efficient way.

### Address

**Twente Medical Systems International B.V.**

Zutphenstraat 57
7575 EJ Oldenzaal
The Netherlands

Phone +31 (0)541 534603
Fax +31 (0)541 534628
Website www.tmsi.com

| | |
|---|---|
| **Important**  | In case of need for repair **ALWAYS** first contact TMSi Support. The support staff will supply you with an RMA number in case a return is required. Never ship products back to TMSi without this authorization and/or RMA number. |

## 1.3 Warranty information

The product, except its cables and accessories, is warranted against failure of materials and workmanship for a period of 2 years from the date of delivery. Cables and accessories have a warranty period of 6 months.

Repairs can only be performed by the manufacturer. Warranty will terminate automatically when the product is opened by any person other than qualified personnel (authorized by TMSi).

The warranty does not cover the following:

- failure resulting from misuse, accident, modification, unsuitable physical or operating environment, or improper maintenance
- failure caused by a product for which TMSi is not responsible
- damage resulting from use of non-approved accessories
- any non-TMSi products

The warranty is voided by removal or alteration of identification labels on the product or its parts. Warranty is also voided in case seals on the enclosure are broken. TMSi does not warrant uninterrupted or error-free operation of wired or wireless data transmission.

Any technical or other support provided for a product under warranty, such as assistance with "how-to" questions and those regarding device set-up and installation, is provided without warranty.

# 2 SAFETY INFORMATION

This section contains general warnings, explanation of markings, limitations of use, safety measures, and precautionary measures that are important for the safe use of the product.

## 2.1 Explanation of markings

This section explains the various markings and symbols used with the product.

Manual contains important safety information

Attention: read important safety information

Important information / guidance for use

Consult instructions for use

Device has type CF applied parts


Ingress protection rating

Keep dry

CE-certified (93/42/EC Annex XII), see declaration of conformity

Identification of the manufacturer


TMSi reference number


TMSi serial number

Contains transmitter module

Contains Bluetooth transmitter

Special EU instructions for disposal are applicable to a product on which this symbol is placed. The Maintenance section of this manual contains information on how to dispose of this equipment.

## 2.2 Limitations of use

| Limitations of use |
| --- |
| • Under federal law (only applicable to the USA) this product may only be sold by or on the order of a physician or licensed practitioner.<br>• The product may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional. |
| The product is NOT intended for:<br>• critical patient monitoring<br>• use in life support systems |
| The product is NOT to be:<br>• used near MRI equipment<br>• exposed to ionizing radiation<br>• used on patients undergoing electro surgery<br>• used in oxygen rich environments (concentration > 25 % at 1 atm) |
| The product is NOT:<br>• suitable for use in an inflammable mixture of anesthetics or agents and air, oxygen or nitrous oxide<br>• defibrillator proof<br>• suitable for sterilization |
| Do not use, store or transport the product outside the specified environmental conditions, this may damage the product. |
| Do not store or use in environments with Magnetic Resonance Imaging (MRI) equipment, or equipment capable of emitting diagnostic levels of ionizing radiation. |

Apart from the above, there are no contra-indications. There are no known side effects from the use of this product.

## 2.3 Safety measures and warnings

| Warnings |
| --- |
|  <br>• IEC60601-1 compliance is the responsibility of the end user. To ensure compliance to IEC60601-1, the system must meet the following conditions:<br>1. The PC and peripherals (e.g. USB hubs) must comply with IEC60950 or equivalent, and must be located outside the patient environment (the patient environment is defined as the area within 1.5 m (6 ft around and 7.5 ft above) of the patient;<br>• AND<br>2. The enclosure leakage current from any device within the patient environment, including any parts of equipment which extend into that environment, is not more than 0.1 mA in normal condition and 0.5 mA in single fault conditions.<br>The required low enclosure leakage current may be achieved by powering the PC and peripherals from an isolation transformer. It is not recommended that the equipment be connected to other non-isolated monitoring equipment or communication networks. In this event it is the end user's responsibility to ensure compliance with IEC60601-1. |
| • Make sure the computer is installed according to local regulations and safety precautions. If the computer is equipped with a safety earth conductor, use it and connect it to a well-earthed wall socket. |
| • The only mains power supply that may be used is the one supplied with the system, a type ‘SUP3’ or power supply approved by TMSi. DO NOT replace it with something else. If any non-TMSi type of supply is used, then patient safety is not guaranteed. |
| • Do not combine the use of the product with any other electronic equipment, except those specified in this manual. Doing so may impair the product’s emissions and immunity regarding EMC. |
| • The product can only be used with the accessories designated by the manufacturer. The use of other accessories may impair the product's emissions and immunity regarding EMC. |
| • The accessories supplied with the device can only be used with TMSi approved devices. |
| • Sensors with their own power are not to be connected to any of the inputs. |
|  <br>• Transmission quality decreases when there are other radio devices in the neighborhood. The wireless transmission may be interfered with by other equipment. |
| • The product should not be used adjacent to or stacked with other equipment. If this is required, then it should be observed if normal operation of the product in that configuration is confirmed. |
| • Before batteries are replaced, disconnect the patient from the device, make sure that the mains power supply is disconnected and the device is switched off (LCD screen is clear). All batteries have to be replaced simultaneously, and all have to be of the same type. Note the orientation of the batteries. |
| • Do not use batteries that contain lithium |
| • Do not use rechargeable batteries |
| • Do not immerse the product in any liquid. |

- The product is to be kept dry. If operated out of office, it must be fitted in a carrying case that provides an ingress protection of at least IP02.
- Do not expose the product to direct sunlight, heat from a source of thermal radiation, excessive amounts of dust, moisture, vibrations, or mechanical shocks.
- Do not incinerate any part of the product.
- If any liquids or moisture penetrate the product or any part thereof, remove the batteries from the device; and remove the plug from the wall socket and have the product checked by the manufacturer.
- Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation.
- The manufacturer cannot guarantee safety and performance of the product when used in conjunction with accessories that are not manufactured or approved by the manufacturer.
- No modification of this product is allowed. The product should not be tampered with.

- Do not touch the electrical connectors that are accessible inside the battery bay if the battery cover is removed.
- Do not touch the connector pins of interface plugs or receptacles.
- Do not open the product using tools.
- The product is not to be used when it is clearly damaged or wet, or suspected to be wet inside.
- The product connectors contain nickel, avoid prolonged skin contact with patients with nickel allergy.
- Disposable electrodes, which are used for electrophysiological measurements, may be a biohazard. Handle, and when applicable dispose of these materials in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
- Reusable electrodes present a potential risk of cross-infection especially when used on abraded skin, unless they are restricted to a single patient.
- To prevent contamination: store electrodes in a separate bag within the packaging.
- Do not attempt to service any part of the product while it is in use or connected to a patient.
- Except for the batteries there are no user serviceable parts within the product. Repairs can only be performed by the manufacturer.
- When connecting the system in an IT-network:
  Simultaneous connection of other equipment to the same optical fiber or Bluetooth network may result in previously unidentified risks to patients, operators or third parties. Such risks must be identified, analyzed, evaluated and controlled. Subsequent changes to the optical fiber or Bluetooth network can introduce new risks that require additional analysis. Changes to the IT-network include: changes to its configuration, connecting additional items, disconnecting items, updates and upgrades of connected equipment.
- Clean the product only according to the cleaning instructions in this manual. Before cleaning, make sure the device is switched off. Never use any aggressive chemicals to clean the product.

## 2.4 Precautionary measures

| Precautionary measures |
| --- |
| • Make sure that the wall socket is well earthed, to reduce 50 or 60Hz disturbances. |
| • Reliability of the signal transmission decreases when the distance between the Bluetooth PC receiver and the device increases or when there are conducting materials in the straight line between the Bluetooth PC receiver and the device. |
| • Do not use an operating cellular phone within 50 cm of the device to avoid excessive noise on the signals. |
| • Sharp bends or winding the cables in a loop smaller than 5 cm diameter may damage the cables. |
| • Do not bend the glass fiber too sharply, as it may break. |
| • Do not use sharp objects such as pencil-points or pen-tips to manipulate the buttons on the control panel, as this can cause damage. |
| • When the product is not in use for a longer time (more than a few days) the batteries have to be removed to prevent damage in case they start leaking. |
| • Dispose of batteries according to local regulations. |

## 2.5 Disclosure of residual risk

The risk analysis process for the product has determined that there are no residual risks which need to be disclosed for the product.

## 2.6 Information for lay operators

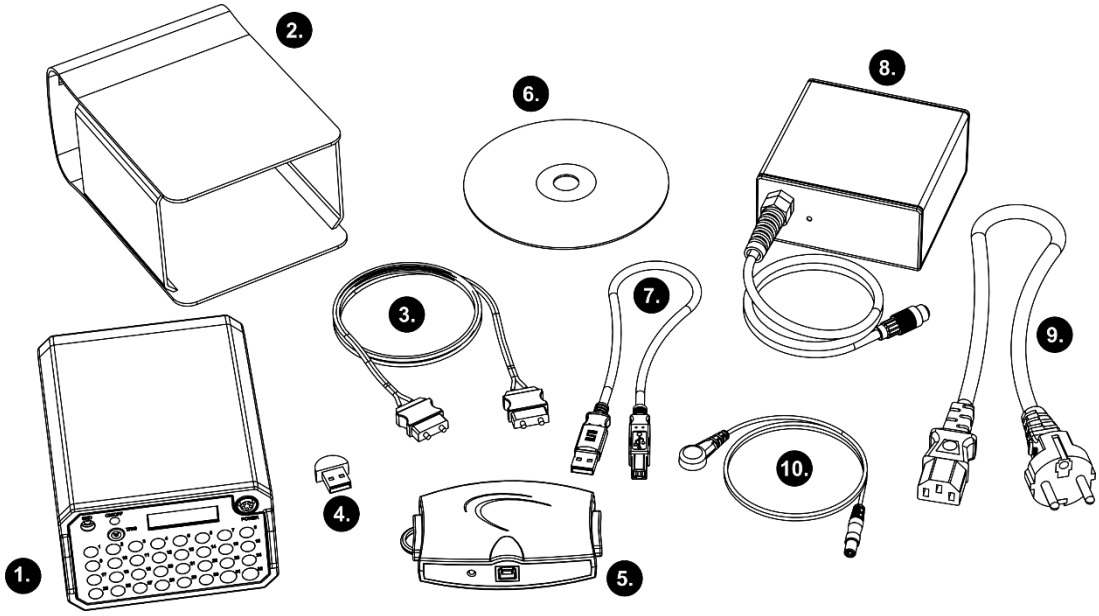
Operators must convey the following information to patients in case they carry the product out of the professional's office:

- Precautions to be taken with respect to environmental temperature and EM fields, ingress of liquid
- That wireless equipment (network, phone, walkie-talkie) should be kept >4 m away from the device
- How to deal with accessories and accessory cables
- How to deal with information provided by indicators and the display
- How to replace batteries

# 3 PRODUCT OVERVIEW

## 3.1 Product components

The product comprises the following functional components:




| # | Item | Description |
|---|---|---|
| **1.** | **Porti device** | The data acquisition device (Porti Amplifier). |
| **2.** | **Carrying bag** | The carrying bag to be used when the system is used in portable measurement configurations. |
| **3.** | **Optical fiber** | Glass fiber used to provide isolation from the PC to the patient. |
| **4.** | **Bluetooth dongle** | Bluetooth interface to be used on the PC side to provide wireless IT network with the device. |
| **5.** | **Fusbi** | Module used as interface between glass fiber and USB cable. |
| **6.** | **Software* (PC Driver)** | Device driver with application programming interface. The device is supplied to you either on CD or via email (download). |
| **7.** | **USB Cable** | USB cable to connect Fusbi to the PC. |
| **8.** | **Power supply** | Power supply to be used when the device is powered via mains. |
| **9.** | **Power cable** | Power cable to be used in combination with power supply. |
| **10.** | **Accessories** | Patient ground lead is depicted. Together with this cable, various other electrodes, sensors and accessories may be delivered with the package. Refer to the list of supported active sensors to see which are supported by the product. |

* Optional: Software may be sent to you as download by email

Not on the picture but also part of the total product are:

- Suitcase for storage of the product when not in use.
- User manual and other Labelling: Accompanying documentation
- Other accessories for electrophysiological measurements, such as headcaps, bipolar leads, unipolar leads etc. Refer to the documents supplied with those sensors for specific instructions for use.
- Active accessories
    - The device supports active sensors that are approved by TMSi. A list of supported sensors can be found on the website: www.tmsi.com

## 3.2 Intended use

The product is intended to be used for acquisition of (electro)-physiological signals by, or under supervision of, a physician. The user must have knowledge of current good practice in physiological measurement in science and clinical application. The product is intended to be used within a clinical or home environment and can be used stationary or ambulatory.

Electrophysiological signals (e.g. EEG, EMG or ECG) are measured via the unipolar or bipolar inputs on the device via electrode leads connected to a patient or subject. Other physiological parameters, such as respiration, body position, body movement and temperature are measured using the auxiliary input channels. These types of signals require additional sensor interface modules.

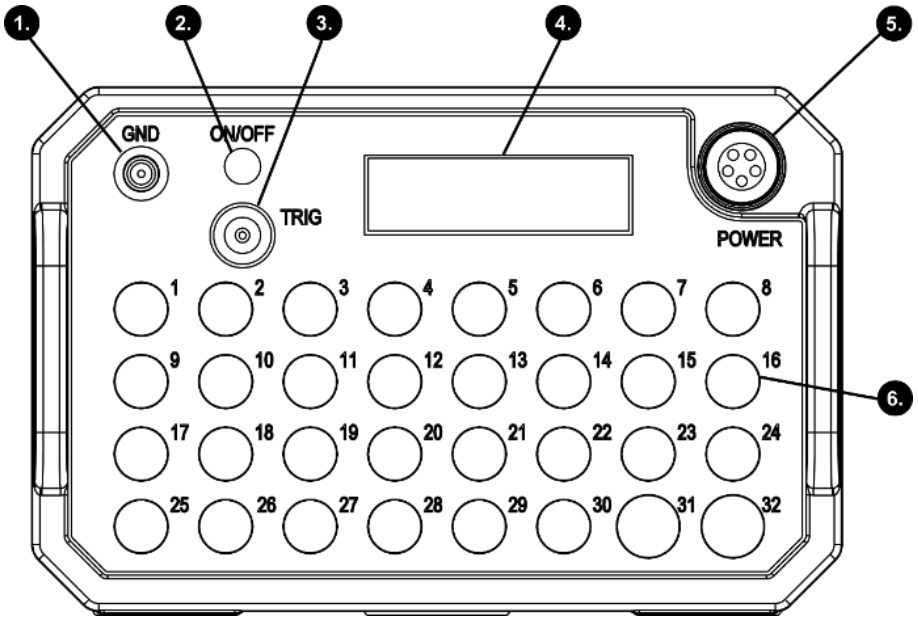
| | |
|---|---|
| **Important**  | The system does **not** perform any signal interpretation or signal analysis. This is left to the researcher/physician.<br>The system is **not** intended for use in a life supporting system. |

For stationary measurements the device transfers the data to the PC by means of a glass fiber or wireless (Bluetooth) connection, where the signals can be viewed or stored for further processing. The device is powered by either a power supply, a set of batteries, or both.

For ambulatory measurements the data can be stored on a Compact Flash disk within the Porti. The card recording functionality is an add-on of the Porti that is to be ordered separately. The PCMCIA Card and Compact Flash Card may therefore not be present in your package. For instructions of use of the card recording option, please download the Card Recording Manual from our website: www.tmsi.com.

## 3.3 Porti views

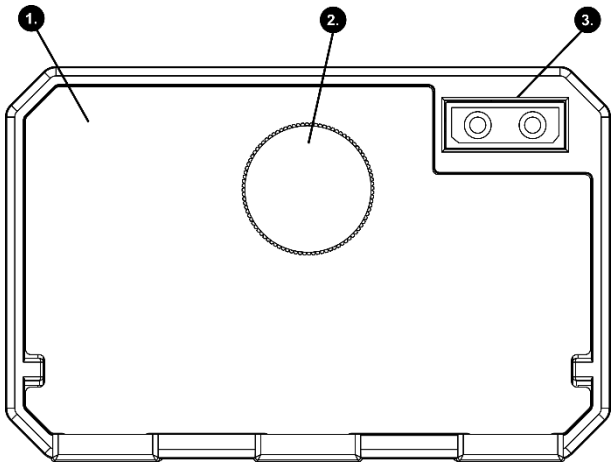
### Front View




| # | | Description |
|---|---|---|
| **1.** | **GND** | Patient Ground input |
| **2.** | **ON/OFF** | On/Off button |
| **3.** | **TRIG** | Trigger Input* |
| **4.** | **LCD** | User Interface |
| **5.** | **POWER** | Power Connector |
| **6.** | **PATIENT CONNECTION(s)** | Input for Patient leads; Unipolar, Bipolar, Auxiliary or Saturation ** |

* The presence of this input depends on the configuration
** Type and number of patient lead inputs depend on the Porti configuration

### Back View




| # | Description |
|---|---|
| **1.** | Battery Cover |
| **2.** | Thumbscrew for battery cover |
| **3.** | Fiber interface |

## 3.4 User interface

### On/Off Button

When the device is solely powered by batteries, the device will switch on when the On/Off button is pressed shortly.

When the device is transmitting data (via optical fiber or Bluetooth), the On/Off button acts as a Marker button. This will result in a signal in the digital channel of the product. In this case, the device will not shut down.

When you press and hold the On/Off button for more than 4 seconds, a card recording will be started or stopped. Please note that this mode requires the PCMCIA card module that is to be ordered separately.

An error message will appear if the card is missing or not configured.

### Messages and indicators on LCD screen

The table below states all possible states of the LCD screen of the device

| Topic | LCD Screen appearance | Description |
|---|---|---|
| **Starting up** | TMSInternational<br>Porti7 SW X.xx<br><br>Date 11 Aug 2015<br>Time 14:56:10 | • LCD screen when device is starting up.<br>• SW X.xx indicates Firmware version<br>• Time is the Real Time Clock of the device |
| **Ready** | Connect 14:56:17 | Device is in stand-by mode and waiting for connection. |
| **Saturation** | SPO2 ---<br>Connect 14:56:17 | In case a saturation input is present, this will be indicated in the top right corner. (Also for other LCD Screen messages) |
| **Shutting down** | System is<br>shutting down | Device is shutting down because:<br>• On/Off button was pressed when running on batteries<br>• Device goes in (battery) power saving mode because it was not used for 5 minutes<br>• Batteries in the device are depleted |
| **Fiber** | Fiber 14:57:08 | Device is transmitting data over the Fiber optic link |
| **Bluetooth** | Serial 14:57:08 | Device is transmitting data via Bluetooth |
| **Battery low** | Batt low | Batteries of the device are running low. |
| **Recording Error** | Rec Err<br>No flashdisk | On/Off button was pressed for more than 4 seconds, but no flash disk was found. |

## 3.5 Patient connections

### Patient Ground

The patient ground should always be connected in order to keep the amplifier in range. The location of the patient ground is ideally away from your measurement electrodes.

### Patient Lead Connectors: Unipolar, Bipolar, Auxiliary, Saturation

The number and type of inputs on your device depend on the configuration you have. Porti devices exist in many different configurations, varying from 8 up to 32 input channels. In general there are three types of patient connection inputs on the device: unipolar, bipolar or auxiliary. Some configurations also include a fourth type, being the digital saturation input.

| Type of input | Connector | Description |
|---|---|---|
| **Unipolar** |  | Used for EEG, EMG, ECG, or in general, E*x*G leads. Signals are measured against the mean of all connected electrodes of this type (average reference). The type of connector is micro coax. |
| **Bipolar** |  | Used for differential measurements. Leads that fit in the bipolar inputs have two cables going to the patient. The bipolar input uses a 4 pin connector. |
| **Auxiliary** |  | Used for sensors that require (5V) power or additional sensor modules. The auxiliary input is a 5 pin connector. |
| **Saturation** |  | Used for saturation input. The connector is a 4 pin metal connector. |

Technical specifications of the inputs of your configuration can be downloaded from www.tmsi.com.

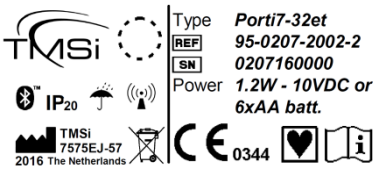
Porti devices exist in many different configurations. Not all types of inputs may be available on your device.

Next to that the number of inputs may vary between devices.

## 3.6 Trigger input

The trigger input can be used to record a TTL trigger signal on the digital channel of the Porti. The trigger input is isolated from all other inputs and the patient within the Porti.

## 3.7 Device Label




The device label can be found at the bottom of the device (example label shown here). It contains the REF code, Serial Number, power requirements and other properties of the device. Use the REF number to look up the channel specifications as listed in the technical specification document that can be downloaded from www.tmsi.com.

# 4 INSTRUCTIONS FOR USE

## 4.1 Software

Software, that is needed to use the product, is supplied to you by email as download or by one or more CDs in the package. It is recommended to download the most up-to-date software via www.tmsi.com. Once installed and activated, this step can be skipped.

### PC requirements

**Hardware**

- Processor: > 1 GHz
- RAM: > 1 GB
- HDD: > 50 GB (> 250 GB recommended)
- Internet connection or CD/DVD Drive

**Operating system**

**Windows**

- Windows 10 (64-bit)
- Windows 8.1 (64-bit)
- Windows 7 (32-bit & 64-bit)

| | |
|---|---|
| **Important**  | Disconnect all TMSi products from the PC before installing any TMSi software.<br>It is recommended to uninstall older versions of the driver before installing new drivers. |

### TMSi PC Driver

Start the installer by clicking *setup.exe*. The TMSi PC-Driver Setup Wizard starts and guides you through the process of installation of the driver. Follow the steps on screen.

### TMSi Polybench (Optional)

The installer of TMSi Polybench software can be found on the CD supplied with your system or was sent to you via email. Click the setup file (tmsi_polybench_setup_*a_b_c_xxxx*.exe) and follow the steps on screen. During the installation a license file (*.PLIC file) will be asked in order to activate the software, which was supplied to you together with the installer.

Please refer to the *Quick Recording Guide* for instructions on using TMSi Polybench. This guide is provided to you by email, with the system or can be downloaded on www.tmsi.com.

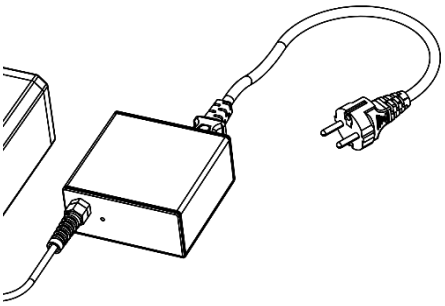
Complete the next steps in the installation instructions before you start using TMSi Polybench.

## 4.2 Powering the Porti

The Porti can be powered using batteries, via the mains power supply, or both.

### Mains power supply

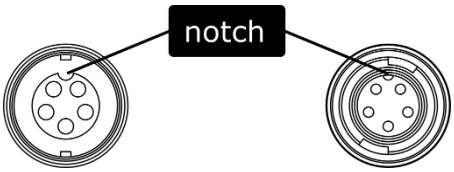
**Mains Power Cable**

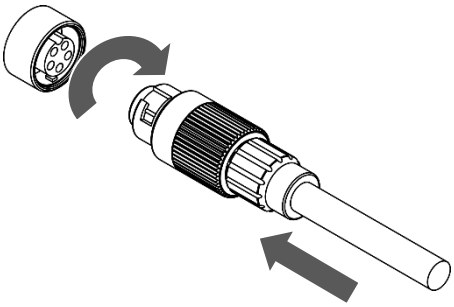


Connect the mains cable to the power supply and the other side into a well-grounded power outlet. The LED on the power supply will light up green.

NOTE: Position the power supply such that it is easy to disconnect the power supply from the mains.

**Connect power cable to Power Connector on the Porti**



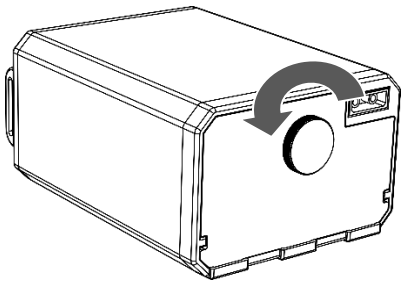
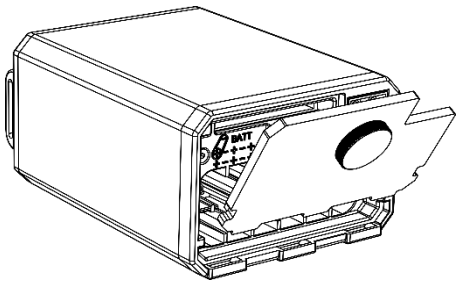
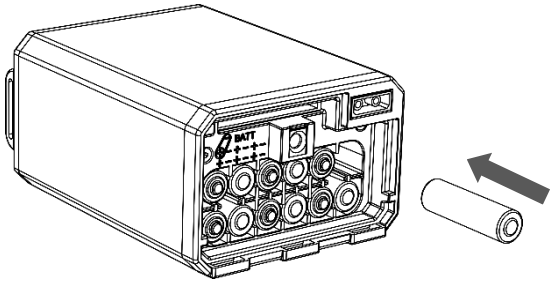
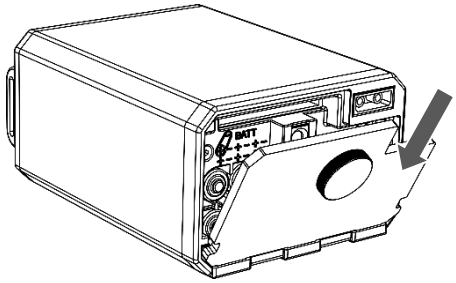
Connect the power supply cable into the power supply socket on the front of the device (POWER).

Make sure the notch of the connector is at the top of the connection, turn the connector part to position the notch correctly.

After inserting of the power connector, the Porti starts up automatically.

### Battery

The batteries should be placed in the battery compartment on the backside of the Porti. Follow the steps below.

| STEP 1: Unscrew battery cover | STEP 2: Remove battery cover |
|---|---|
|  |  |
| **STEP 3: Insert batteries** | **STEP 4: Tighten thumbscrew** |
|  |  |

**Important**

- Do not use rechargeable batteries.
- Do not use batteries that contain lithium.
- TMSi strongly recommends high quality AA batteries (for example Duracell Procell) in order to have optimal performance.

Please note that it is not required to use all free battery slots in order to power the device. Large Porti devices (> 16 channels) also run on 6 AA batteries (in one row) instead of 12.

### Power Saving Mode

When the device is not in use (e.g. there is no active connection with the PC, or running ambulatory recording), the device will switch off after 5 minutes to save its power.

## 4.3 Transfer data to PC

Both USB (via optical fiber) and Bluetooth IT-network connections are supported by the product. The purpose of the IT-network connection is for device control and/or data transfer. The intended information flow is:

- Control from a PC to the device
- Raw data from the device to the PC

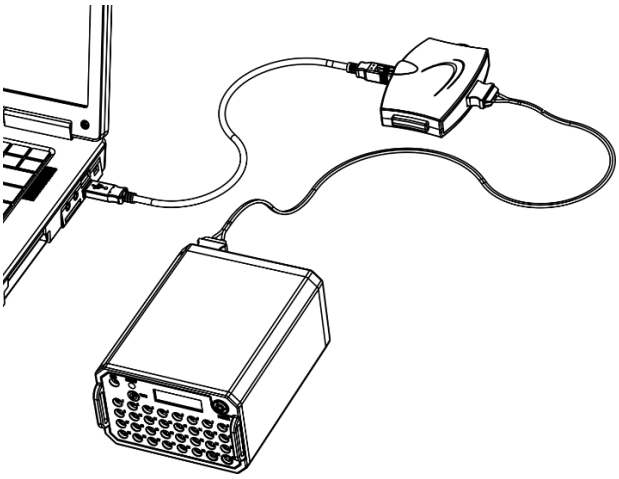
The supported versions of the IT network connections are:

- USB: 2.0 and higher
- Bluetooth: 1.1 and higher

The following two sections describe the installation of the USB (via optical fiber) link and Bluetooth IT-network connections.

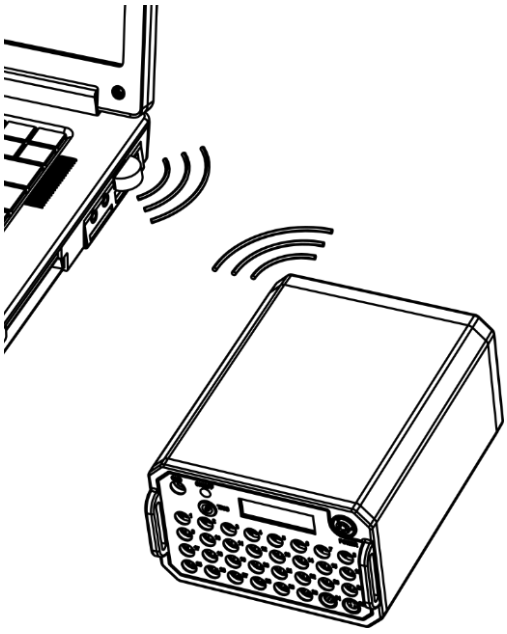
Please note: No hazardous situations have been identified for the product due to loss of the IT-network functionality.

## Wired transmission: Fiber to USB interface (Fusbi)

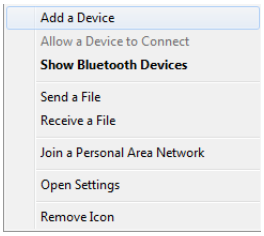


1. Connect the optical fiber to the input of the Fusbi and the other end to the fiber connector on the Porti. It does not make a difference which connector goes where.
2. Connect the USB cable to the Fusbi and to a free USB port on the PC. In case this is the first time you use the system, Windows will report that a driver is being installed.
3. The LED next to the USB input of the Fusbi will light up green to indicate the Fusbi is ready to use.

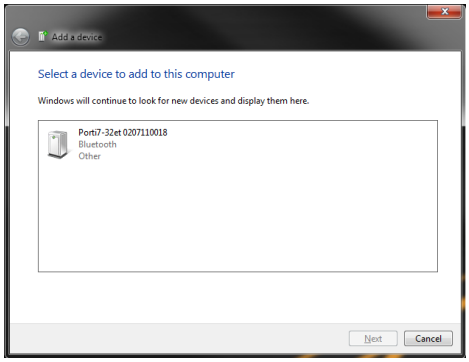
## Wireless transmission: Bluetooth interface



4. Insert the Bluetooth dongle in a USB port. Wait for Windows Update to install the drivers for the Bluetooth dongle.
5. After Windows has finished installing the Bluetooth drivers, click the Bluetooth tray icon in the right bottom corner of the Windows taskbar.
6. Click, *'Add a device'*. If you do not see the Bluetooth tray icon, click *Start > Devices and Printers > Add a device*




7. Windows will start scanning the environment. Make sure the Porti is powered on. The Porti should automatically show up in the list.
8. Select the device and click '*Next*'. Windows will ask for a pairing code. The pairing code consists of the last four digits of the serial number. The serial number can be found on the back of the Porti on the silver label next to 'SN'. In the figure displayed to the right the pairing code is *0018*. Click Next to finish the Bluetooth setup.
9. Windows may report that drivers are being installed. Wait until Windows reports that the '*Device is ready to use*'.

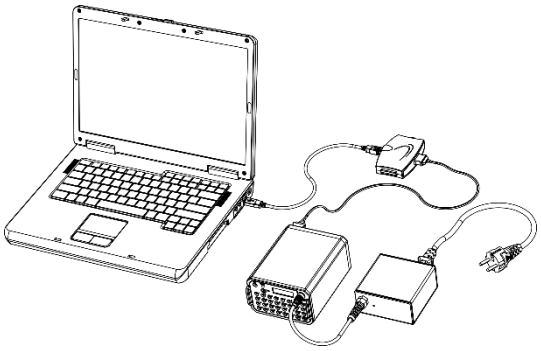
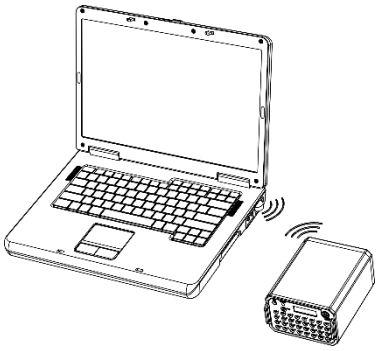
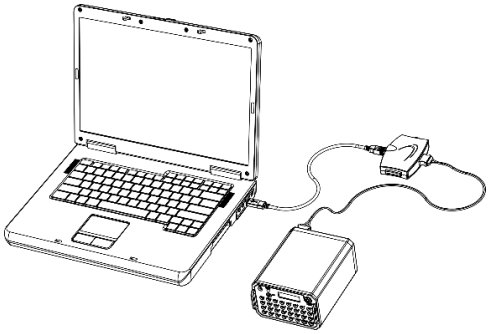
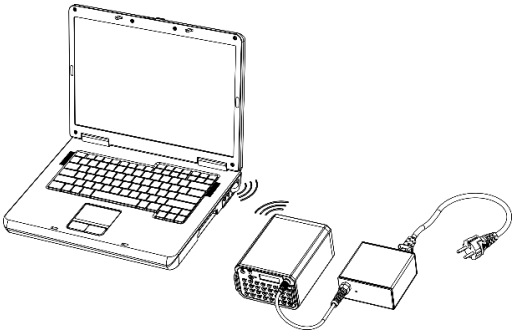



The Bluetooth pairing remains valid until you plug the Bluetooth dongle into a different USB port, delete the link from Windows, or pair the device with another PC.

## 4.4 Perform measurement

### Possible Use Scenarios

The most suitable combination of means of power and data transfer depends on your application. Below we list the four options and considerations for deciding which setup to use.

| OPTION 1: Fusbi and Mains power supply | OPTION 2: Bluetooth and Battery |
|---|---|
|  |  |
| • **ADVANTAGES**<br>○ Maximum sampling rate<br>○ Optimal data transmission reliability<br>○ Virtually unlimited measurement time | • **ADVANTAGES**<br>○ Optimal freedom of movement for patient |
| • **DISADVANTAGES**<br>○ Limited freedom of movement for patient | • **DISADVANTAGES**<br>○ Sampling rate may be limited due to limited bandwidth<br>○ Increasing chance of data loss when distance between Porti and PC increases<br>○ Measurement time limited |
| **OPTION 3: Fusbi and Battery** | **OPTION 4: Bluetooth and Mains power supply** |
|  |  |
| • **ADVANTAGES**<br>○ Maximum sampling rate<br>○ Optimal data transmission reliability<br>○ Increased freedom of movement when using a long optical fiber | • **ADVANTAGES**<br>○ Virtually unlimited measurement time |
| • **DISADVANTAGES**<br>○ Measurement time limited | • **DISADVANTAGES**<br>○ Sampling rate may be limited due to limited bandwidth<br>○ Increasing chance of data loss when distance between Porti and PC increases. |

### Connect Patient Leads

Connect the Patient Ground lead to the GND input of the amplifier and to the patient. Use the TMSi Patient Ground wristband for optimal contact. Wet the band and place it around the wrist.

TMSi recommends using the wet wristband to optimize measurement setup. This will improve the signal quality. (www.tmsi.com)

Connect all patient leads and patient ground. Please refer to instructions for use of the accessories and sensors for more information.

### TMSi Polybench: Quick Recording Application

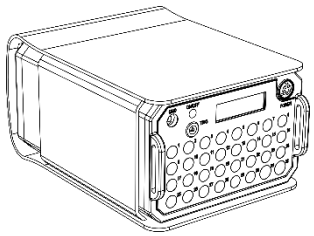
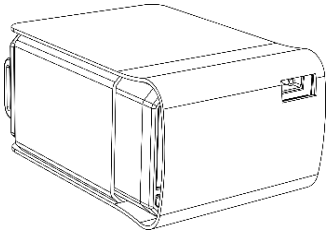
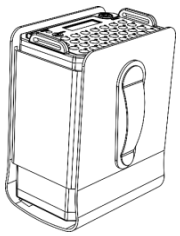
The Quick Recording Application is a TMSi Polybench measurement configuration supplied with your product or downloadable on www.tmsi.com.

In case you are not using TMSi Polybench, but different application software in combination with our products, please refer to the User Manual of that application software.

## 4.5 Mobility

TMSi recommends using the carrying bag in case the patient needs to carry the device during the measurement.

- Slide the device in the carrying bag. This may require some force. The elastic bands hold the device in place.
- Use the clip on the carrying bag to fix it to a belt or waistband.
- There is a rectangular cut-out on the back of the carrying bag. This is where the fiber can be connected.

| Device in Carrying bag | Backside: Rectangular cut-out for optical fiber | Carry device using the clip on your belt or waist band |
|---|---|---|
|  |  |  |

**Important**

For ambulatory measurements it is required to use the TMSi Carrying Bag (REF 95-8020-0001-0) with ingress protection rating IP02 instead of the carrying bag depicted above. This bag is to be ordered separately. Contact sales@tmsi.com for more information and refer to the separate instructions for use for the ambulatory carrying bag.

# 5 OPERATIONAL PRINCIPLES

## 5.1 Unipolar input channels

The input stage for measuring unipolar electrophysiological signals is configured as a so called average reference amplifier. All signals are amplified against the average of all connected unipolar inputs. Inputs that are not connected to an electrode cable are not used in the average reference and automatically switch off. These channels will show a flat line signal on screen. The input impedance of the active channels is very high (100 MΩ). The influence of electrode impedance is therefore very small and no electrode impedance measurement is required.

The patient ground electrode is required, but it is not an active input. It is meant as a way to keep patient potential and amplifier potential at about the same level.

All electrode cables are shielded with the electrode signal itself (active shielding). The active shielding ensures that disturbances such as cable movement artefacts and mains interference (50/60 Hz) are reduced to a minimum.

No high pass or low pass filters that can cause signal phase shifts or filter overflows are present in the device.

## 5.2 Bipolar input channels

The input stage for measuring bipolar electrophysiological signals is configured as an instrumentation amplifier. The difference between a 'plus' and 'minus' signal is amplified. The patient ground electrode is required to keep patient potential and amplifier potential at about the same level.

All electrode cables are shielded with the average of the 'plus' and 'minus' electrode signal (active shielding). The active shielding ensures that disturbances such as cable movement artefacts and mains interference (50/60 Hz) are reduced to a minimum.

After the first amplifier stage (gain = 20) the signals go directly to the ADC. No high pass or low pass filters that can cause signal phase shifts or filter overflows are present.

## 5.3 Auxiliary input channels

Each auxiliary input has a 5-pin connector. Signals on this connector are +5V output, -5V output, GND, +signal input and -signal input. The +5V/-5V/GND pins can be used to power an active sensor. The + and - inputs are connected to an instrumentation amplifier with a gain of 1. The output of the amplifier goes to the ADCs without any filtering.

## 5.4 Filtering

There is a 1st order low pass filter before the ADC with a -3db point at 4,8kHz. The ADC of the Porti has a digital sinc3 filter with a cutoff frequency of 0,27 * sample frequency. Devices have a maximum sampling rate of 2048 Hz or 2000 Hz, depending on the configuration. Device specific technical specifications can be downloaded from www.tmsi.com.

Besides above no other filtering is applied when using the fiber optic link.

An additional averaging filter in the firmware is used for decimating different channels when using Bluetooth.

# 6 MAINTENANCE

The product does not contain user serviceable parts. Maintenance is limited to regular cleaning. Repairs can only be performed by the manufacturer, contact support@tmsi.com in case the product needs to be repaired. TMSi Support staff will determine whether a repair is required and possible.

The product does not require regular servicing or re-calibration during its expected service life of 10 years. If the product is intended to be used after its expected service life, contact TMSi to have the product inspected before continued use.

**Cleaning**

- Before cleaning, make sure the product is switched off and not in contact with a patient.
- Use only tap water, if necessary with a mild detergent, applied through a soft damp cloth.
- Do not spill fluids or submerge product in liquids.
- Never use sharp tools or aggressive chemicals for cleaning or disinfecting.
- Do not sterilize the product.

**Environmental protection**

Special EU instructions for disposal are applicable to a product on which this symbol is placed. These instructions apply to all parts of the equipment.

When the product has reached End of Life, it must not be disposed of with other waste. Instead, it is the user's responsibility to dispose of their waste equipment by handing it over to a designated collection point for the recycling of waste electrical and electronic equipment.

The separate collection and recycling of your waste equipment at the time of disposal will help to conserve natural resources and ensure that it is recycled in a manner that protects human health and the environment.

For more information about where you can dispose of your waste equipment for recycling, please contact your local city office, your household waste disposal service, or TMSi.

# 7 ELECTROMAGNETIC GUIDANCE

Portable and mobile RF communications equipment can affect the system. The system needs special precautions regarding EMC and must be installed and put into service according to the EMC information outlined below.

| Guidance and manufacturer's declaration - electromagnetic emissions | | |
|---|---|---|
| The Porti is intended for use in the electromagnetic environment specified below. The customer or the user of the Porti should assure that it is used in such an environment. | | |
| **Emission test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions CISPR 11 | Group 1 | The Porti uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Class B | The Porti is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions 61000-3-3 | Complies | |

| Guidance and manufacturer's declaration - electromagnetic immunity | | | |
|---|---|---|---|
| The Porti is intended for use in the electromagnetic environment specified below. The customer or the user of the Porti should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ± 6 kV contact<br>± 8 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 | ±2 kV for power supply lines<br>±1 kV for input/output lines | ±2 kV for power supply lines<br>±1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | ±1 kV line(s) to line(s)<br>±2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | <5 % $U_T$ (>95 % dip in $U_T$) for 0,5 cycle<br>40 % $U_T$ (60 % dip in $U_T$) for 5 cycles<br>70 % $U_T$ (30 % dip in $U_T$) for 25 cycles<br><5 % $U_T$ (>95 % dip in $U_T$) for 5 s | Mains power quality should be that of a typical commercial or hospital environment.<br>If the user of the Porti requires continued operation during power mains interruptions, it is recommended that the Porti be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level. | | | |

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The Porti is intended for use in the electromagnetic environment specified below. The customer or the user of the Porti should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Porti, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance:** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 V | $d = 1.2\sqrt{P}$ |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.5 GHz | 3 V/m | $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz<br>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).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]<br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Porti is used exceeds the applicable RF compliance level above, the Porti should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Porti.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the Porti**

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

| Rated maximum output power of transmitter<br>W | Separation distance according to frequency of transmitter<br>m | | |
|---|---|---|---|
| | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 100 | 12 | 12 | 23 |

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

The Porti7 has no essential performance.

# 8 TECHNICAL SPECIFICATIONS

More detailed Technical specifications of your configuration can be downloaded from the website: www.tmsi.com. Use REF number on device label to identify the device configuration.

| General Specifications | |
|---|---|
| **Type** | Porti7 |
| **TMS code / REF** | See device label |
| **Size (device only)** | • 8 / 16 input channels: 112 mm x 155 mm x 53 mm (l x b x h)<br>• 24 / 32 input channels: 112 mm x 155 mm x 73 mm (l x b x h) |
| **Weight** | • 8 / 16 input channels: approximately 560 g (700 g with batteries)<br>• 24 / 32 input channels: approximately 775 g (1070 g with batteries) |
| **Maximum Sampling Rate** | 2000 Hz or 2048 Hz (depends on device configuration) |

| Regulatory Specifications | |
|---|---|
| **MDD class (Annex IX)** | IIa |
| **Power source** | External mains power supply or internal batteries |
| **Mode of operation** | Continuous operation |
| **Electric shock protection** | Mains power supply: Class I<br>Applied parts: Class CF |
| **Applied parts** | • The outside enclosure of the Porti, also after removal of the battery cover including all contacts and receptacles.<br>• The patient accessories. |
| **Accessible parts** | The accessible part of the Porti is its power supply enclosure. |
| **Software class per IEC 62304** | A |
| **Ingress protection** | Main unit: IP20<br>**NOTE**: Refer to the TMSi Carrying bag instructions for use (REF 92-8020-0001-0) for carrying bag with IP02. |

| Mains power supply | |
|---|---|
| **Input voltage** | 100 to 240 V AC, 50 / 60 Hz |
| **Input current** | 0 to 0.2 A |
| **Output voltage** | 10 V DC |
| **Output current** | max. 350 mA |
| **Isolation voltage** | > 4000 V |
| **Leakage current** | < 3 µA |
| **Fuses** | See label or manual of the power supply. |

To disconnect the power supply from the mains, remove the plug from the power outlet.

| Filtering | |
|---|---|
| **High pass** | None |
| **Low pass** | Digital FIR filter in ADC; cutoff frequency = 0.27 * sample frequency |

| Battery | |
|---|---|
| **Batteries** | 12 (or 6) x AA type disposable alkaline 1.5V |
| **Power Saving** | 5 minutes (no connection to PC or running ambulatory recording) |
| **Battery low indication level** | 6.2 V ± 0.1V |
| **Battery empty shut down level** | 5.9 V ± 0.1V |

| Bluetooth Communication | |
|---|---|
| **Bluetooth 1.1 class 2** | Bluetooth™ |
| **Profile** | Serial port profile |
| **Range** | 10 meters (line of sight) |
| **Baud rate** | 230400 bps |

| Fiber Communication | |
|---|---|
| **Required interface** | Bidirectional optical Fiber and Fusbi, USB port on PC |
| **Fiber length** | Up to 70 m |

| Transportation Conditions | |
|---|---|
| **Temperature** | -25°C to +70°C |
| **Humidity** | 15% to 93% |
| **Pressure** | 500 hPa to 1060 hPa |

| Storage Conditions | |
|---|---|
| **Temperature** | 0°C to +40°C |
| **Humidity** | 15% to 93% |
| **Pressure** | 500 hPa to 1060 hPa |

| Usage Conditions | |
|---|---|
| **Temperature** | +5°C to +40°C |
| **Humidity** | 15% to 93% |
| **Pressure** | 700 hPa to 1060 hPa |

www.tmsi.com