Mobi

User Manual

92-0926-0001-0-2 REVISION 2 2016

CE 0344

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1 SERVICE AND SUPPORT

1.1 About this manual

This manual is intended for the user of the Mobi 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 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 product.

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. • 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: • critical patient monitoring • use in life support systems
The product is NOT to be: • used near MRI equipment • exposed to ionizing radiation • used on patients undergoing electro surgery • used in oxygen rich environments (concentration > 25 % at 1 atm)
The product is NOT: • suitable for use in an inflammable mixture of anesthetics or agents and air, oxygen or nitrous oxide • defibrillator proof • 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
• 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.
• 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.

Warnings
• Before batteries are replaced, disconnect the patient from the device, and make sure the device is switched off (Indicator led is off). Both batteries have to be replaced simultaneously, and 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 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.
• Except for the batteries there are no user serviceable parts within the product. Repairs can only be performed by the manufacturer.
• Do not attempt to service any part of the product while it is in use or connected to a patient.

Warnings
 • When connecting the system in an IT-network: Simultaneous connection of other equipment to the same 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 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
• 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 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
- How to replace batteries

3 PRODUCT OVERVIEW

3.1 Product components

The product comprises the following functional components:

#	Item	Description
1.	**Mobi device**	The data acquisition device (Mobi Amplifier).
2.	**Carrying bag**	The carrying bag to be used when the system is used in portable measurement configurations.
3.	**Software* (PC Driver)**	Device driver with application programming interface. The device is supplied to you either on CD or via email (download).
4.	**Accessories**	Patient ground lead and 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.
5.	**Suitcase**	Suitcase is used for storage of the product when not in use.
6.	**Accompanying documentation**	Documentation such as User Manual and certificates.

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

The device supports TMSi approved active sensors. 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 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. The system is **not** intended for use in a life supporting system.

The device transfers the data to the PC by means of a wireless (Bluetooth) connection, where the signals can be viewed or stored for further processing. The sampling frequency of the device is maximum 2048 Hz per channel. Actual sampling rate depends on the device configuration and channel input types. Refer to the Technical Specifications document for sampling rate table, this document can be downloaded from www.tmsi.com. The device is powered by a set of batteries.

For ambulatory measurements the data can be stored on a SD card within the Mobi. For instructions of use of the card recording option, please download the Card Recording Manual from our website: www.tmsi.com.

3.3 Mobi views

Front View

#		Description
1.	**GND**	Patient Ground input
2.	**ON/OFF**	On/Off button; marker button when in use
3.	**LED INDICATOR**	Device status indicator
4.	**PATIENT CONNECTION(s)**	Input for Patient leads; Bipolar, Auxiliary or Saturation *

* Type of inputs depend on the Mobi configuration

Back View

#		Description
1.	**SATURATION**	Oximetry/Marker input
2.	**ON/OFF**	On/Off button; marker button when in use
3.	**BATTERY COVER**	Access to SD Card and batteries via this cover

3.4 User interface

On/Off Button

The device will switch on when the On/Off button is pressed shortly.

When the device is transmitting data, 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.

Important 	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 a SD card that is to be ordered separately. The indicator led will blink an error code if the card is missing or not configured.

Indicator LED

The table below states all possible states of the LED indicator of the device

LED Indicator	Meaning	Description
OFF	System off	The LED indicator does not show LED. The device is off.
ORANGE	Startup	At startup the LED lights up orange for about 2-3 seconds. If LED does not turn green, replace batteries or contact TMSi support, there may be a defect.
GREEN	Idle, running	LED lights up green when it is transmitting data or ready to be used.
ORANGE BLINKING **(Slow blinking; ~1 per second)**	Battery low	Battery voltage is getting low.
ORANGE BLINKING **(Fast blinking; 2 per second)**	Recording error	Possible causes for this are: • No memory card present • Memory card not formatted correctly • Memory card not initialized correctly • Memory card full

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: Bipolar, Auxiliary, Saturation

The type of inputs on your device depends on the configuration you have. Mobi devices exist in several configurations. The configuration can be identified from the label on the back of the device. In general there are two types of patient connection inputs on the device: bipolar or auxiliary. Some configurations also include a third type, being the digital saturation input.

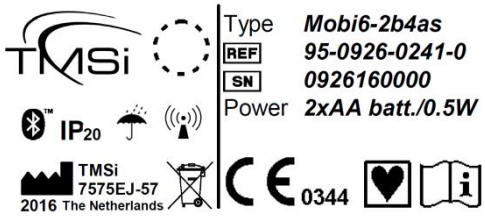
Type of input	Connector	Description
Patient Ground		Patient ground connector The patient ground lead should be connected here in order to keep amplifier in range.
Bipolar		Used for differential measurements. Leads that fit in the bipolar inputs have two cables going to the patient. The bipolar input 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/ Marker		If device type (see device label) ends with an '*s*', this input can be used for a saturation sensor. In devices without the '*s*' in the device type, it can be used as marker input. The connector is a 4 pin metal connector on the back side of the device. Note the red dot for connector alignment.

Device specific technical specifications can be downloaded from the website: www.tmsi.com

3.6 Marker input

When the device is transmitting data to the PC the On/Off button acts as a marker button. This marker appears in the digital channel of the Mobi.

3.7 Device Label



The device label (example depicted here) can be found at the bottom of the device. 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.
	It is recommended to uninstall older versions of the driver before installing new drivers.

TMSi PC Driver

Start the installer by executing *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 Mobi

The Mobi can be powered using batteries. Follow the steps below to insert the batteries.

Steps to in insert batteries.	
Remove the battery cover by sliding it to the right.	
Insert batteries. Note the orientation.	 
Close the battery cover	

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

Power Saving Mode

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

4.3 Transfer data to PC

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 version of the IT network connections is:

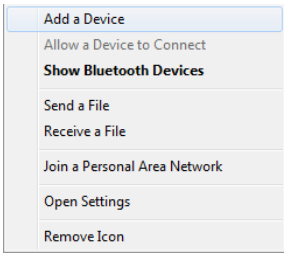
- Bluetooth: 1.1 and higher

The following section describes the installation of the Bluetooth IT-network connection.

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

Wireless transmission: Bluetooth interface

1. Insert the Bluetooth dongle in a USB port. Wait for Windows Update to install the drivers for the Bluetooth dongle.
2. After Windows has finished installing the Bluetooth drivers, click the Bluetooth tray icon in the right bottom corner of the Windows taskbar.
3. Click, '*Add a device*'. If you do not see the Bluetooth tray icon, click *Start > Devices and Printers > Add a device*
4. Windows will start scanning the environment. Make sure the Mobi is powered on. The Mobi should automatically show up in the list.
5. 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 Mobi on the silver label next to 'SN'. Click *Next* to finish the Bluetooth setup.
6. 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

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 your wrist.

TMSi recommends using the wet wristband to optimize measurement setup. This will improve the signal quality. Please read the Application Note on the reference amplifier for more background. (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 other 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. You can attach the carrying bag to a belt or use a shoulder 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 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.

5.2 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.

5.3 Filtering

The analog-to-digital converter (ADC) of the device has a digital sinc5 filter with a cutoff frequency of 0.2 * sample frequency. There is a 1st order lowpass filter before the ADC with a -3dB point at 4.8 kHz. 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 product.

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 Mobi is intended for use in the electromagnetic environment specified below. The customer or the user of the Mobi should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Mobi 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 Mobi 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	Not applicable Battery powered equipment	
Voltage fluctuations/flicker emissions 61000-3-3	Not applicable Battery powered equipment	

Guidance and manufacturer's declaration - electromagnetic immunity			
The Mobi is intended for use in the electromagnetic environment specified below. The customer or the user of the Mobi 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 ±8 kV air	± 6 kV contact ± 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 ±1 kV for input/output lines	Not applicable Battery powered equipment Not applicable cabling shorter than 3m	
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Not applicable Battery powered equipment Not applicable Battery powered equipment	
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 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Not applicable Battery powered equipment Not applicable Battery powered equipment Not applicable Battery powered equipment Not applicable Battery powered equipment	
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 Mobi is intended for use in the electromagnetic environment specified below. The customer or the user of the Mobi 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 Mobi, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, 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.			
[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 Mobi is used exceeds the applicable RF compliance level above, the Mobi should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mobi. [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 Mobi			
The Mobi is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mobi can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mobi as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
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 Mobi has no essential performance.

8 TECHNICAL SPECIFICATIONS

More detailed Technical specifications of your configuration can be downloaded from the website: www.tmsi.com/manuals

General Specifications		
Device	Mobi	
Available Configurations	**Type**	**TMS Code / REF**
	Mobi6-2b4a	95-0926-0240-0
	Mobi6-2b4as	95-0926-0241-0
	Mobi6-4b2a	95-0926-0420-0
	Mobi6-4b2as	95-0926-0421-0
	Mobi6-6b	95-0926-0600-0
	Mobi6-6bs	95-0926-0601-0
Sampling rate	Maximum 2048 Hz (depends on configuration)	
Size (device only)	114 mm x 98 mm x 37 mm (l x b x h)	
Weight (g)	Approximately 190 g (240 g with batteries)	

Regulatory Specifications	
MDD class (Annex IX)	IIa
Power source	Batteries
Electric shock protection	Applied parts: Class CF
Applied parts	• Its enclosure, also after removal of battery cover including all contacts and receptacles • The patient accessories.
Accessible parts	Apart from the applied the Mobi has no accessible parts.
Software class per IEC 62304	A
Ingress protection	• Main unit: IP20 **NOTE**: Refer to the TMSi Carrying bag instructions for use (REF 92-8020-0001-0) for carrying bag with IP02.

Filtering	
High pass	None
Low pass	Digital FIR filter in ADC; cutoff frequency = 0.2 * sample frequency

Battery	
Batteries	2 x AA type disposable alkaline 1.5V
Power Saving	5 minutes without connection to PC
Battery low indication level	2.1 V ± 0.1V
Battery empty shut down level	1.8 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

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