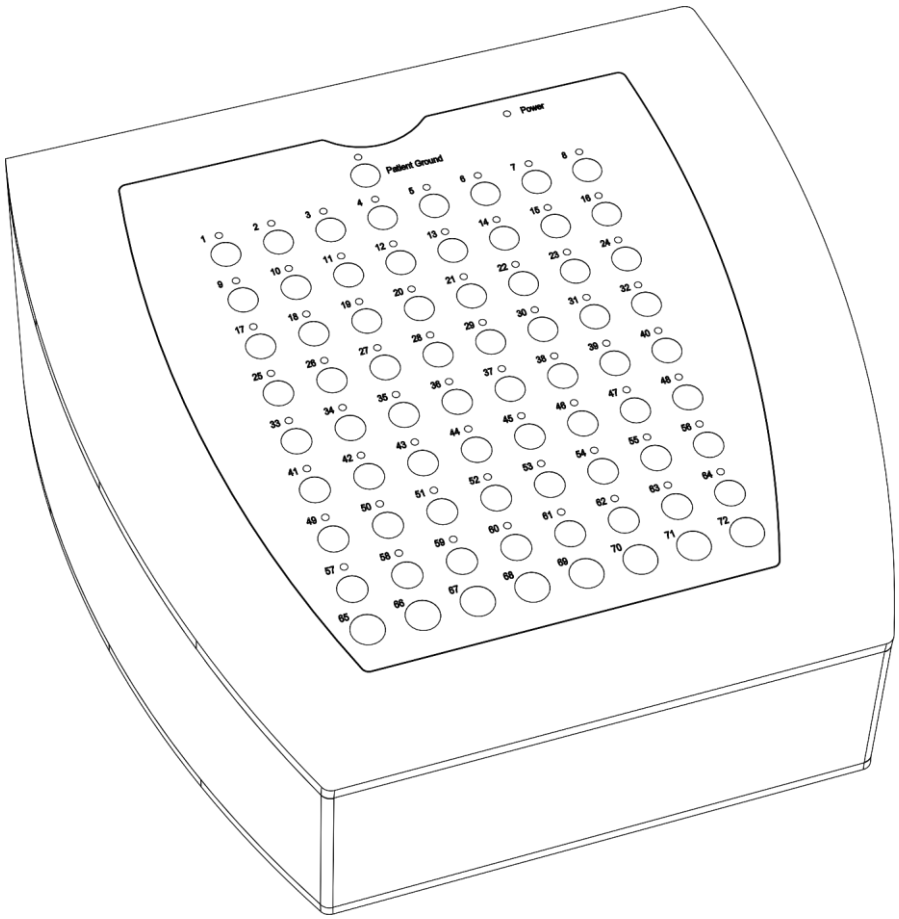
Refa

User Manual



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CE 0344

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1 SERVICE AND SUPPORT

1.1 About this manual

This manual is intended for the user of the Refa 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

Keep dry symbol

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

Identification of the manufacturer

TMSi reference number

TMSi serial number

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.
- 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 equipment 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

- IEC60601-1 compliance is the responsibility of the end user. To ensure compliance to IEC60601-1, the system must meet the following conditions:
  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;

- AND
  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.

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.

Warnings
• 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 original supply, type 'SUP3' or 'CSUPEMCA' that came with the system. 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 system 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.
• 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.
• Do not immerse the product in any liquid.
• The product is to be kept dry.
• 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 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 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.

Warnings
• 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.
• 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 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 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.
• 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.

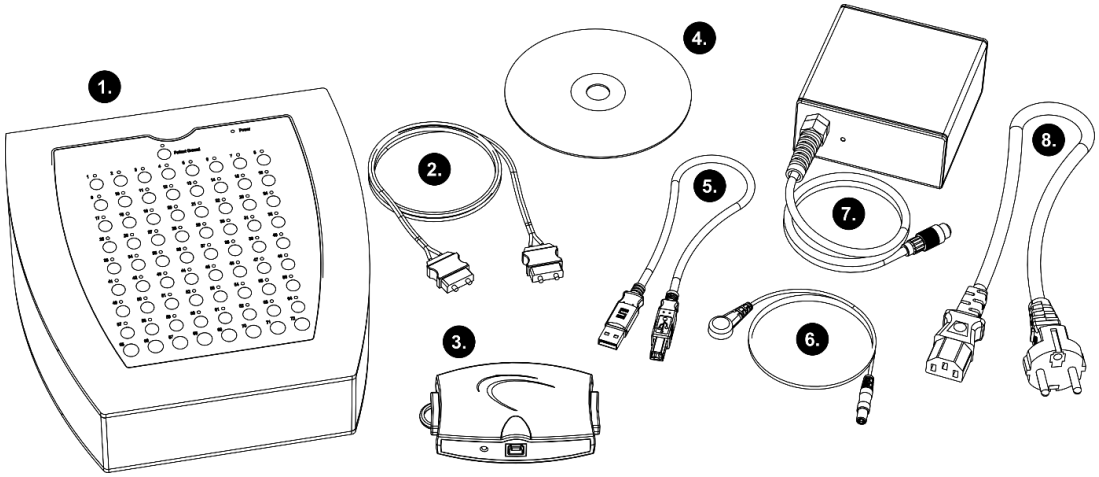
2.5 Disclosure of residual risk

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

3 PRODUCT OVERVIEW

3.1 Product components

The product comprises the following functional components:



#	Item	Description
1.	**Refa device**	The data acquisition device (Refa Amplifier).
2.	**Optical fiber**	Glass fiber used to provide isolation from the PC to the patient.
3.	**Fusbi**	Module used as interface between glass fiber and USB cable.
4.	**Software* (PC Driver)**	Device driver with application programming interface. The device is supplied to you either on CD or via email (download).
5.	**USB Cable**	USB cable to connect Fusbi to the PC.
6.	**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.
7.	**Power supply**	Power supply to be used when the device is powered via mains.
8.	**Power cable**	Power cable to be used in combination with power supply.

* 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.

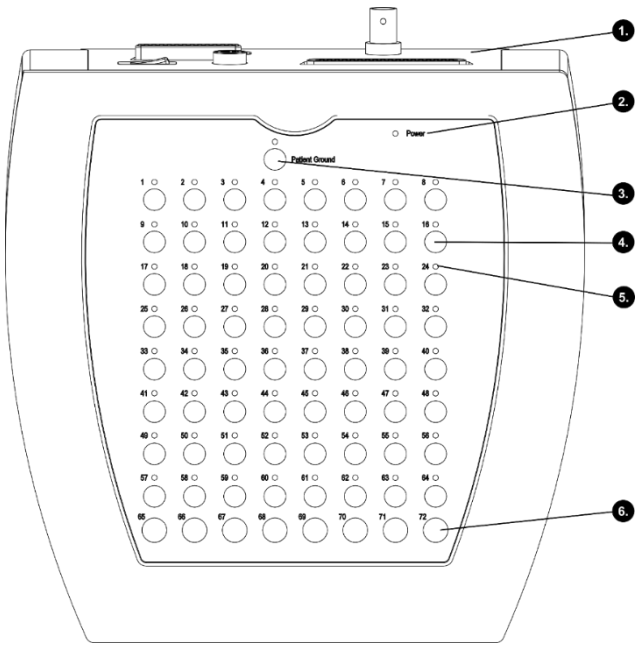
Electrophysiological signals (e.g. EEG, EMG or ECG) are measured via the unipolar or bipolar inputs on the device via electrode leads connected to a patient or subject. Other physiological parameters, such as respiration, body position, body movement and temperature are measured using the auxiliary input 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. The system is **not** intended for use in a life supporting system.

For measurements the device transfers the data to the PC by means of a glass fiber connection, where the signals can be viewed or stored for further processing. The device is powered by a power supply.

3.3 Refa views

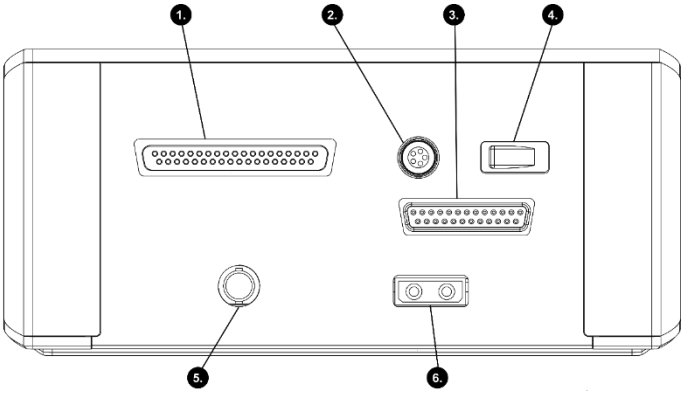
Front View



#		Description
1.	**Back Panel**	See below for description of the back panel components
2.	**Power indicator**	LED indicator for system power
3.	**Patient ground**	Patient ground input
4.	**Unipolar patient connections**	Input for unipolar patient connections
6.	**Impedance LEDs**	When in impedance mode, LED to indicate if impedance is lower than a user defined threshold
6.	**Bipolar and Auxiliary patient connections**	Input for bipolar and auxiliary patient connections

* Type and number of patient lead inputs depend on the Refa configuration

Back View



#		Description
1.	**Patient connection**	Connector for (unshielded) ExG inputs (DB37 connector (1-4x*)
2.	**Power connector**	Connector for external power supply of the system
3.	**8 bit trigger connector**	8 bit trigger input. DB25 trigger connector
4.	**ON/OFF switch**	Switch to power the system.
5.	**BNC input**	1 bit trigger input (BNC). Equals first bit of 8 bit trigger input.
6.	**Optical fiber interface**	In/Output of the optical fiber.

* Number of available connectors depends on Refa configuration

3.4 User interface

On/Off Switch

When the system is connected to the external power supply, the On/Off switch is used to switch the system on or off.

Indicator LEDs

LED		Description
POWER INDICATOR		When the power indicator LED is off, the system has no power, check the switch and power supply. The system is powered when this LED is green.
CHANNEL LEDS	**Startup**	At startup all LEDs light up for about 1 – 2 seconds.
	Impedance Mode	When the system is set in impedance mode, the Impedance LEDs will light up orange if an impedance value drops below a user defined value or when the default value drops below 20 kOhm, or a different threshold set by the application software.
	Impedance error	When the Impedance LEDs blink, the requirements for correct impedance determination are not met. See chapter 4.5 for instructions.
FUSBI Indicator	**On**	System IDLE and connected to USB
	Blinks	Fusbi is transferring data

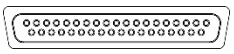
3.5 Patient connections

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, Multiconnector

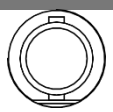
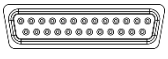
The number and type of inputs on your device depend on the configuration you have. Refa devices exist in many different configurations, varying from 8 up to 136 input channels. In general there are three types of patient connection inputs on the device: unipolar, bipolar or auxiliary.

Type of input	Connector	Description
Unipolar		Used for EEG, EMG, ECG, or in general, ExG 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.
Multiconnector		Used for connecting multiple channels at once (for example head caps). This input is unshielded.

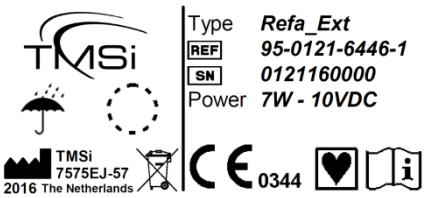
More detailed technical specifications of the inputs of your device configuration can be downloaded from the website (www.tmsi.com).

3.6 Trigger input

The Refa has two trigger inputs. A single bit BNC trigger input and an 8 bit TTL trigger input. The trigger input can be used to record (up to 8) TTL trigger signals on the digital channel of the Refa. The trigger input is isolated from all other inputs and the patient within the Refa. Technical specifications can be found in in the appendix.

Type of input	Connector	Description
BNC		TTL trigger input. The trigger is shown in the digital channel of the Refa. The input corresponds to the first bit of the 8 bit trigger.
DB25 trigger		8 bit trigger input to send trigger codes to the Refa. The first bit is shared with the BNC trigger input.

3.7 Device Label



The device label can be found at the bottom of the device (example depicted here, can be different from actual label). 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 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 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.

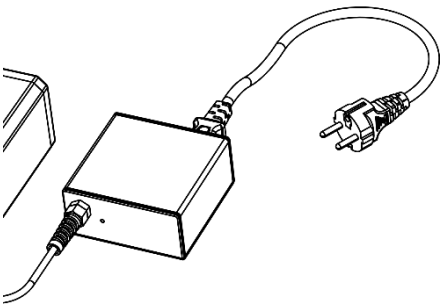
Complete the next steps in the installation instructions before you start using TMSi Polybench.

4.2 Powering the Refa

The Refa is powered using the mains power supply.

Mains power supply

Mains Power Cable



Check that the power supply is labelled as ‘SUP3’ or ‘CSUPEMCA’.

NOTE: a Refa Extended requires a CSUPEMCA power supply.

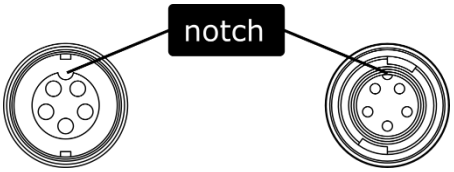
Connect the mains cable to the power supply and the other side into a well-grounded power outlet.

On the SUP3 power supply a green LED on the power supply will light up green.

On the CSUPEMCA power supply you also have to switch on the power supply.

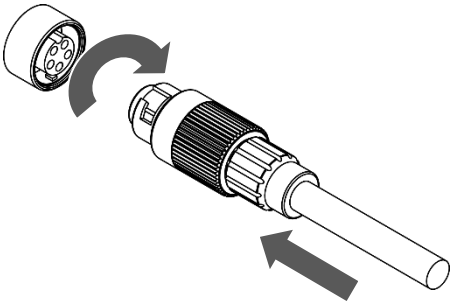
Position the power supply such that it is easy to disconnect the power supply from the mains.

Connect power cable to Power Connector on the Refa

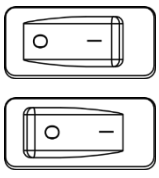


Connect the power supply cable to the power supply socket on the back of the device.

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



Flip the power switch



Switch on the Refa by flipping the switch from ‘O’ to ‘I’. On the front panel all LEDs will light up shortly. The Power LED on the front panel will turn green.

4.3 Transfer data to PC

An USB (via optical fiber) IT-network connection is 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:

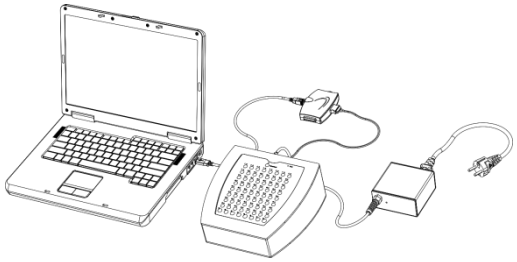
- USB: 2.0 and higher

The following section describes the installation of the USB (via optical fiber) link IT-network connections.

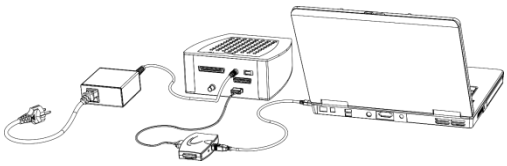
Please note: No hazardous situations have been identified for the product due to loss of the IT-network functionality.

Setup of the Refa system seen from the front and back side.

Front view



Back view



Steps to connect the system as depicted above.

1. Connect the optical fiber to the input of the Fusbi and the other end to the fiber connector on the device. 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.

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 the 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 a different software package in combination with our products, please refer to the User Manual of that software package.

4.5 Using impedance measurement

The impedance measurement of the Refa is controlled by the commands from the application software. Refer to instructions for use of the application software to use impedance mode on the Refa.

The device requires the following to be able to measure the impedance correctly:

- At least one odd and one even channel above channel number 4 to be connected
- Connected Patient Ground electrode.
- The system must be set to impedance mode.

Until all these requirements are fulfilled, impedance LEDs will blink to indicate that impedances cannot be determined properly.

Please follow the instructions for use for the TMSi Polybench Quick Recording application. For other application software, refer to the user manual of that software.

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.

5.4 Filtering

A 1st order low pass filter is placed before the analog-to-digital converter (ADC) with a -3db point at 6.8 kHz. Next to that, the ADC of the device has a digital sinc5 filter with a cutoff frequency of 0.2 * sample frequency. The maximum sampling frequency depends on the Refa configuration. Refer to the technical specifications of your device which can be downloaded from www.tmsi.com.

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 equipment 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 equipment.

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 Refa is intended for use in the electromagnetic environment specified below. The customer or the user of the Refa should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Refa 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 Refa 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 Refa is intended for use in the electromagnetic environment specified below. The customer or the user of the Refa 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	±2 kV for power supply lines ±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) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±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 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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Refa requires continued operation during power mains interruptions, it is recommended that the Refa 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 Refa is intended for use in the electromagnetic environment specified below. The customer or the user of the Refa 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 Refa, 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 Refa is used exceeds the applicable RF compliance level above, the Refa should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Refa. [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 Refa			
The Refa is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Refa can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Refa 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 Refa has no essential performance.

8 TECHNICAL SPECIFICATIONS

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

General Specifications	
Type	Refa or Refa_Ext
TMS code / REF	See device label.
Size (device only) (l x b x h)	• 8 to 72 input channels: 2100 mm x 2100 mm x 73 mm • 136 input channels: 3600 mm x 2100 mm x 73 mm
Weight	• 8 to 72 input channels: approximately 1625 g • 136 input channels: approximately 3000 g

Regulatory Specifications	
MDD class (Annex IX)	IIa
Power source	External mains power supply
Mode of operation	Continuous operation
Electric shock protection	Mains power supply: Class I Applied parts: Class CF
Applied parts	• All front side connectors, and the backside connectors for head-caps, power and fiber-optic link • The patient accessories.
Accessible parts	The accessible part of the Refa is the enclosure.
Software class per IEC 62304	A

Mains power supply (SUP3 and CSUPEMCA)	
Input voltage	100 to 240 V AC, 50 / 60 Hz
Input current	0 to 0.2 A
Output voltage	10 V DC
Output current	**SUP3**: max. 350 mA **CSUPEMCA**: max 700 mA
Isolation voltage	> 4000 V
Leakage current	< 10 µA
Fuses	**SUP3:** See label or manual of the SUP3. 2 x T 0.5AH or 2 x T 1.0AH, 250V, 5x20mm **CSUPEMCA:** 2 x T 1.25AH, 250V, 5x20mm

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 = 0.2 * sample frequency

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

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