企建　生理信號放大器

Nutronic Physiologic Recording Systems

衛署醫器輸字第 022601 號

使用前請務必詳閱原廠之使用說明書並遵照指示使用

型號:

Refa_Ext、Refa8

Porti7

Mobi6

產品敘述及用途 :

在進行神經理學/生理學的研究及測試時,醫生可使用本產品或在醫生的指示下使用本產品記錄並獲取腦波圖(EEG),多功能記錄儀及多頻道睡眠檢查訊號,再將訊號傳送至電腦。

多功能記錄及多頻道睡眠檢查訊號(除了腦波圖之外)包含肌電圖(EMG)、心電圖(ECG)、眼電圖(EOG)、胃電圖(EGG)、酸鹼值(PH)、呼吸、溫度及血氧濃度。

本產品不用於維持生命系統。

本產品不做訊號的解釋或分析。

Mobi6 是一個 4 或 6 通道生理學監測平台,利用藍牙 1.1 第 2 類無線傳輸及快閃記憶體科技。Mobi6 可用於臨床醫療或居家環境,並搭配藍牙或內建快閃記憶體進行測量。

Porti7 可測量單一病患的多頻道(8-32)(電)生理訊號。Porti7 包含固定或移動形式,可用於臨床醫療或居家環境。

固定測量的系統電力是由外部電力供應,把取得的資料經由玻璃纖維或無線(藍牙)連接傳到電腦裡,信號進一步可被觀看或儲存。

移動測量的系統電力由一組電池供應,需要的資料可被儲存於快閃記憶碟,此快閃記憶碟之後可在電腦上閱讀。

Refa8 是一個固定式生理學研究系統,頻道數最高可達 72 頻道。此系統最高為 64 頻道單極生理電氣訊號輸入點('ExG')、4 頻道雙極生理電氣訊號輸入點('BIP')(選配)、4 頻道預備輸入點('AUX')(選配)及一個數位輸入頻道(8 位元)。

預備輸入點('AUX')可以用來測量溫度、酸鹼值、呼吸、血氧飽和等。為了使用主動式感測器或感測器模組,每一個預備輸入點('AUX')頻道有一個+5V 和-5V 輸出。

Refa8 由外部的電源供應器供電。 Refa8 以雙向作用的玻璃纖維連接至電腦。電腦內部一個特殊的介面卡(DSP 數位訊號處理器/纖維介面卡)或 USB 介面來負責玻璃纖維傳遞。Refa8 完全地由電腦控制。

Refa_Ext 是一個固定式生理學研究系統,頻道數最高可達 136 頻道。此系統最高為 128 頻道單極生理電氣訊號輸入點('ExG')、4 頻道雙極生理電氣訊號輸入點('BIP')(選配)、4 頻道預備輸入點('AUX')(選配)及一個數位輸入頻道(8 位元)。

預備輸入點('AUX')可以用來測量溫度、酸鹼值、呼吸、血氧飽和等。為了使用主動式感測器或感測器模組,每一個預備輸入點('AUX')頻道有一個+5V 和-5V 輸出。

Refa_Ext 由外部的電源供應器供電。 Refa_Ext 以雙向作用的玻璃纖維連接至電腦。電腦內部一個特殊的介面卡(DSP 數位訊號處理器/纖維介面卡)或 USB 介面來負責玻璃纖維傳遞。Refa_Ext 完全地由電腦控制。

警告及注意事項 :

- 運送時須使用原廠裝箱。
- 關於電腦規格的部分，詳閱電腦軟體手冊。
- 只能使用原廠指定或手冊內敘述的感測器及電極。
- 勿將本產品與其他電子儀器連結使用，除非手冊中有詳細指明。
- 在更換電池前，須先將病患身上的裝置關閉。必須同時更換所有的電池且為同一種類型。在每次使用前先確認系統操作時間長短，若長時間操作的話建議更換新電池。
- 當使用充電電池時，須根據電池製造商的指示。
- 在易燃的麻醉劑、空氣、氧氣及笑氣混合環境中，不適用此裝置。
- 此裝置不適用於滅菌法。
- 不要用刺激性的化學物品來清潔裝置。
- 勿將此裝置直接曝露於陽光下、熱輻射來源、過量的灰塵、濕氣、震動或機械的撞擊中。
- 確認電腦的安裝是根據當地規範及安全預防措施。
- 勿浸泡入液體中。
- 若任何液體或濕氣滲透入此裝置，移開電池並且由合格的技術人員確認裝置。
- 小心安排病患並且避免感測器電極線糾結或勒傷病患的風險。
- 當電腦的藍牙接收端與本產品之間的距離大過 10 米或當 2 者連線間有阻礙物時，其訊號傳輸的品質不能被保證。
- 當此裝置鄰近有其他無線電裝置時，其傳輸品質不能被保證。
- 在特殊空間或區域內，反射傳輸可能被影響，在此情況下其傳輸品質不能被保證。
- 為避免過度的噪音及雜訊，在此裝置 30 公分內勿使用手機。
- 此裝置不能連接至接受核磁共振造影(MRI) 、電外科手術、去顫的病人上。
- 非為病危的病患監測
- 非防電擊器裝置
- 過度的彎曲或將電極線捲繞成直徑小於 5 公分的圓圈可能損傷電極線。
- 電池的處理是根據當地的規範。
- 本產品包含可回收再利用對環境有害的材質，當裝置拆開，特定的回收公司可以分離這些材質。在裝置處理前，請詢問當地廢棄物管理規範。
- 長時間不使用本產品時(超過幾天的時間)須將電池移開，以防止漏電。
- 除了電池之外，無使用者可自行維修的部分，維修只能由製造商處理。
- 校正是不需要的。
- 外部的電源供應只能使用原廠附帶的供應器，’SUP5’ 或’SUP3’ ，**勿更換成其他的供應器**。若使用任何非原廠的供應器，將不能保證病患的安全。
- 確認牆上插座電源接地是良好的，能夠減少 50 或 60Hz 的干擾。
- 勿使用鋒利的物體如:筆尖去操作控制板按鈕，因為此將造成裝置損壞。
- DB37 頭連接器的腳位 19 及 37 傳送-5V 及+5V 供應，確認這些腳位絕不能連接到病患。

Mobi6

尺寸

外部尺寸	11.4 x 9.8 x 3.7cm(長 x 寬 x 高)
重量	165 克(不含電池)

內部電源供應

電池	電池 2 顆 AA 充電式(1.2V)或拋棄式(1.5V)
低電量指示等級	2.1±0.1V
空電量關機等級	1.8±0.1V

雙極輸入(EMG)

雜訊	<1.0 μVrms(@Fs=128Hz)
增益	19.5x
輸入訊號差	<0.1V
共模輸入範圍	-2V / +2V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	100dB
連接埠	4 腳位 BINDER 719 序列
準確性	±2%

外部輸入

雜訊	<15 μVrms(@Fs=128Hz)
增益	1x
準確性	±2%
輸入訊號差	-2V / +2V
共模輸入範圍	-2V / +2V
輸入阻抗	$>10^{10}\Omega$
共模拒斥比	>80dB
連接埠	5 腳位 BINDER 719 序列
輸出電壓	+5V,-5V,每頻道最大 5mA

取樣

解析度	24bits,雙極每位元 12.2nV,最大每位元 0.238μV
取樣率	128Hz,256Hz,512Hz,1024Hz,2048Hz

藍芽傳輸

藍芽 1.1 第二等級	Bluetooth
使用外觀	序列埠外觀
瞄準範圍	>10 公尺

快閃記憶卡

支援記憶卡類型	SD 卡,32Mb 或更高,最大至 2Gb
群組尺寸	盡可能使用大群組尺寸,至少 2 區段群組

Porti7

尺寸

外觀尺寸	158 x 112 x 73 mm(長 X 寬 X 高)
內部電源供應器	電池 6/12 顆 AA 充電式(1.2V)或拋棄式(1.5V)
低電量指示等級	6.2±0.1V
空電量關機等級	5.9±0.1V

單極 ExG 輸入(腦波圖(EEG)、心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

雜訊	<1 μVrms(@最低取樣率)
增益	20x
輸入訊號差	-150mV / +150mV
共模輸入範圍	-2V / +2V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	>90dB
連接埠	微軸，有效隔離

雙極 ExG 輸入點(腦波圖(EEG)、心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

雜訊	<1 μVrms(@最低取樣率)
增益	20x
輸入訊號差	-150mV / +150mV
共模輸入範圍	-2V ~ +2V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	>90dB
連接埠	4 腳位 BINDER 719 序列

外部輸入

雜訊	<20 μVrms(@最低取樣率)
增益	1x
輸入訊號差	-3V ~ +3V
共模輸入範圍	-4V ~ +4V
輸入阻抗	$>10^{10}$ Ω
共模拒斥比	>70dB
輸出電壓	+5V,-5V,每頻道最大 5mA 或全部頻道一起 40mA
連接埠	5 腳位 BINDER 719 序列

觸發輸入

輸入	啟動電流=2mA @Vin=3.0V , Vin_max=5V
隔離	>4000V
連接埠	塑膠 LEMO 微軸

取樣

解析度	22bits,ExG/BIP 每位元 71.526nV,AUX 每位元 1.4305μV
取樣率	2048Hz,1024Hz,512Hz,256Hz，128Hz

濾波/增益

增益	ExG 20x,固定(=50mV/V)
	BIP 20x,固定(=50mV/V)
	AUX 1x, 固定(=1V/V)
高頻率波	無
低頻率波	數位 FIR 濾波在類比數位轉換，截止頻率=0.27 ＊取樣頻率

藍芽傳輸

藍芽 1.1 第二等級	Bluetooth
使用外觀	序列埠外觀
瞄準範圍	>10 公尺
鮑率	230400 bps

光纖傳輸

位元率	7.340032Mbit/s
最大支援取樣率	2048Hz
光纖長度	最長 70m
介面要求	FUSBI,USB1.1 或 USB2.0 在電腦上

外部電源供應器 SUP5

輸入電壓	100-240VAC，50-60Hz
輸出電壓	10VDC
輸出電流	最大 200mA
隔離電壓	>4000V
漏電流	<3μA
保險絲	2X1.6A slow,250V,5X20mm glass

外部電源供應器 SUP3

輸入電壓	100-240VAC，50-60Hz
輸出電壓	10VDC
輸出電流	最大 350mA
隔離電壓	>4000V
漏電流	<3μA
保險絲	2X1.5A slow,250V,5X20mm glass

Refa8

尺寸

外部尺寸	210 x 207 x 92mm(長 x 寬 x 高)

外部電源供應器

輸入	110-240V AC，50-60Hz
輸出電壓	10V DC
輸出電流	最大 700mA
隔離電壓	>4000V
漏電流	<3μA

單極 ExG 輸入點(腦波圖(EEG)、心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

頻道數	64
噪音	<1.0μVrms(@最低取樣率)
增益	26,55x
輸入訊號差異	<0.15V
共模輸入範圍	-2V-+2V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	>90 dB
連接頭	細微處理，有效隔離//subD37 母頭

雙極 ExG 輸入點(心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

頻道數	4
噪音	<1.0μVrms(@最低取樣率)
增益	26,55x
輸入訊號差異	<0.15V
共模輸入範圍	-2V-+2V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	>90 dB
連接頭	4 腳位連接頭，有效隔離

AUX 輸入點

頻道數	4
噪音	<20μVrms(@最低取樣率)
增益	1x
輸入訊號範圍(差異)	-3V-+3V
共模輸入範圍	-4V-+4V
輸入阻抗	$>10^{12}$ Ω
共模拒斥比	>70 dB
輸出電壓	+5V，-5V，每一頻道最大 5mA，或所有頻道一起 20mA
連接頭	5 腳位連接頭

數位輸入

連接埠	DB25,8 組訊號,1 組接地
輸入	啟動電流=2mA @Vin=3.0V，Vin_max=5V
隔離	>4000V

取樣

頻道數	同步 72 頻道
解析度	24bits，ExG//BIP 每位元 18.39nV，每位元 AUX0.048828μV
取樣率	2000Hz,1000Hz,500Hz,250Hz，125Hz
輸出 74 頻道	1-64=單極 ExG
	65-68=雙極 ExG
	69-72=外部
	73=數位(0-7 位元=數位輸入(反向))
	74=數位(0-14 位元=鋸齒測試信號)

濾波/增益

增益	ExG 26.55x,固定(=37，7mV/V)
	BIP 26.55x,固定(=37，7mV/V)
	AUX 1x,固定(=1 V/V)
高頻率波	無
低頻率波	數位 FIR 濾波

光纖傳輸

位元率	7.68Mbit/s
最大支援取樣率	2000Hz
光纖長度	最長 70m
介面要求	FUSBI,USB2.0 在電腦上

Refa_Ext

尺寸

外部尺寸	210 x 360 x 92mm(長 x 寬 x 高)

外部電源供應器

輸入	110-240V AC，50-60Hz
輸出電壓	10V DC
輸出電流	最大 700mA
隔離電壓	>4000V
漏電流	<3μA

單極 ExG 輸入點(腦波圖(EEG)、心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

頻道數	128
噪音	<1.0μVrms(@最低取樣率)
增益	26,55x

輸入訊號差異	<0.15V
共模輸入範圍	-2V-+2V
輸入阻抗	$>10^{12}\Omega$
共模拒斥比	>90 dB
連接頭	細微處理，有效隔離//subD37 母頭

雙極 ExG 輸入點(心電圖(ECG)、眼電圖(EOG)、肌電圖(EMG)等)

頻道數	4
噪音	<1.0μVrms(@最低取樣率)
增益	26,55x
輸入訊號差異	<0.15V
共模輸入範圍	-2V-+2V
輸入阻抗	$>10^{12}\Omega$
共模拒斥比	>90 dB
連接頭	4 腳位連接頭，有效隔離

AUX 輸入點

頻道數	4
噪音	<20μVrms(@最低取樣率)
增益	1x
輸入訊號範圍(差異)	-3V-+3V
共模輸入範圍	-4V-+4V
輸入阻抗	$>10^{12}\Omega$
共模拒斥比	>70 dB
輸出電壓	+5V，-5V，每一頻道最大 5mA，或所有頻道一起 20mA
連接頭	5 腳位連接頭

取樣率

頻道數	同時 136 頻道
解析度	24 位元，ExG//BIP 每位元 18.39 nV，每位元 AUX 0.48828 μV
取樣頻率	2048Hz，1024Hz，512Hz，256Hz，128Hz
輸出	138 頻道 ： 1-128=單極 ExG 129-132=雙極 ExG 133-136=AUX 5 腳位連接頭 137=數位化 138=數位化(位元 0-14=鋸齒測試訊號)

濾波/增益

增益	ExG 26,55 x，固定(=37,7m V/V)， BIP 26,55 x，固定(=37,7m V/V)， AUX 1 x，固定(=1 V/V)，
高通	無
低通	數位化 FIR 濾波，截止頻率=0.2 * 取樣頻率

纖維傳遞

位元率	6.29Mbit/s
最大支援取樣率	2048Hz
纖維長度	至 70m
要求介面	FUSBI，電腦 USB2.0 埠

貯存和傳送條件

溫度	-10℃-+50℃
濕度	10%-100%
壓力	500hPa-1060hPa

使用條件

溫度	0℃-+40℃
濕度	10%-90%
壓力	500hPa-1060hPa

製造廠名稱 : TMS International B.V.
製造廠地址 : Zutphenstraat 57, 7575 EJ Oldenzaal,THE NETHERLANDS
藥 商 名 稱 : 企建科技股份有限公司
藥 商 地 址 : 臺北市中山區新生北路二段 41 巷 14 號 1 樓

1 Introduction

Product description

The Mobi6 is a 4 or 6 channel physiological monitoring platform that utilizes Bluetooth 1.1 class 2 wireless communication and Flash memory technologies. The Mobi6 offers data acquisition at up to 2048 samples per second. The advanced technology preamps enjoys independent 24 bit A-D converters per channel with DC coupled amplifiers allowing DC to 512 Hz (0dB) recording. Because this system uses carbon cable with active shielding, movement and noise levels are very low by design.

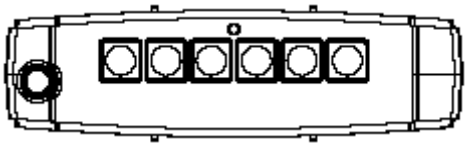

Figure 1 - Mobi6 front view

The bipolar channels operate at a sample frequency of 2048 Hz and are specific for ECG/EEG measurements but a number of other electrophysiological measurements are possible like EMG. The auxiliary channels can be used to connect active sensors for temperature, respiration, movement etc. A special connectors enables the use of SpO2 oximetry and/ or pulse or event synchronization.

A number of different configurations Mobi6 configurations are available. They differ in number of bipolar and auxiliary channels. See the specifications chapter for details about the different types.

Intended use

The Mobi6 is intended to measure electrophysiological signals on the human body for recording.

The Mobi6 is intended to be used within a clinical or home environment for measurements either via Bluetooth connected to a computer or via a flash memory card within the Mobi6. The small design together with the carrying case make it easy to wear and the exclusion of a communication wire to the PC makes for easy movement within the range of the Bluetooth.

The system is NOT intended for use in a life supporting system.

Indications for use

The Mobi Physiological Amplifier family is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of the signals to a PC during recording of neuro-physical/ physiological research and exams.

Polygraphy and Polysomnography may besides EEG, include physiological information such as EMG, ECG, EOG, EGG, PH, Respiration, Temperature and Oxygen Saturation.

Product liability

Many countries have a product liability law. This law stipulates, among other things, that a manufacturer ceases to be liable for any product deficiencies 10 year after the product concerned was first put onto the market.

Limitation of liability

Insofar as is maximally permitted under the applicable prescriptive law, neither TMS International nor its suppliers or dealers are liable under any circumstances for any indirect, exceptional, incidental or consequential damages arising from the use of the product or from the inability to use it, including (but not restricted to) the damage arising from loss of goodwill, work interruption, computer defects or faults or any other damage or losses consequential upon business interruption, even if the possibility of these occurring had been mentioned and irrespective of the legal or impartial theory (agreement, unlawful act or otherwise) on which the losses are based. In any case and pursuant to any of the provisions of the present agreement, the total liability of TMS International is limited in its entirety to the sum of the price that was paid for this product and the fee for the product support granted by TMS International under a (possible) separate support contract, with the exception of death or personal injury arising from negligence by TMS International insofar as the applicable prescriptive law forbids limitation of damages in such cases.
TMS International cannot be held liable for the consequences of any incorrect information furnished by its staff or for any errors in this user guide and/or other accompanying documentation (including trade documentation).

1 About this manual

This manual, which is intended for the user of the Porti7, contains general operating instructions, precautionary measures, maintenance instructions and information about components. To maximize the safety, service life and efficiency of the system, it is important that you read this manual through carefully and familiarize yourself with the various controls and accessories before starting to use the system.

2 Product description / intended use

The Porti7 system is a general purpose signal acquisition device for the fields of neurology, cardiology, sleep analysis, movement sciences, rehabilitation, ergonomics etc.
The system can measure a number (8 - 32) of (electro-)physiological signals on a person.
An operator (researcher or physician) determines the type and source of signals that are measured.

Electrophysiological signals (ExG/unipolar or BIP/bipolar, like ECG, EEG, EMG etc) can be measured by means of electrode leads.
Other physiological signals, like respiration, body position, body movement, temperature etc. can be measured on AUX/auxiliary channels. These type of signals require additional sensor interface modules.

The system is intended to be used within a clinical or home environment, and can be used stationary or ambulatory.

For stationary measurements the system is powered by a specially designed external power supply, and the acquired data is sent to a PC via a glass fiber or wireless (Bluetooth) connection, where the signals can be viewed or stored for further processing.
For ambulatory measurements the system can be powered by a set of batteries, and the acquired data can be stored on a PCcard flash disk within the system. This flash disk can later be read by a PC.

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.

2.1 Indications for use

The Porti7 Physiological Amplifier family is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of the signals to a PC during recording of neuro-physical/ physiological research and exams.

Polygraphy and Polysomnography may besides EEG, include physiological information such as EMG, ECG, EOG, EGG, PH, Respiration, Temperature and Oxygen Saturation.

3 Warnings and precautionary measures

This section contains general warnings and precautionary measures that are important for the safe use of the system.

Explanation of used symbols


Manual contains important safety information


Device is Class II equipment


Device has type CF applied parts

1 Product description / intended use

The Refa8 is a stationary system for physiological research with a maximum of 72 channels.
The system has maximum 64 unipolar electrophysiological ('ExG') inputs, 4 bipolar electrophysiological ('BIP') inputs (optional), 4 so called auxiliary ('AUX') inputs (optional) and one digital input-channel (8 bits).
The unipolar electrophysiological inputs are configured as a reference amplifier: all channels are amplified against the average of all connected inputs. With these channels or the Bipolar channels signals like EEG, EMG, ECG, EOG, EGG etc. can be measured.
The auxiliary inputs can be used for measuring temperature, pH, respiration, oxygen saturation etc. Each AUX channel has a +5V and –5V output in order to use active sensors or sensor modules.

An external power supply, which plugs into the mains socket, powers the Refa8. The Refa8 is connected to a PC by means of bidirectional glass fiber. Inside the PC a special interface board (DSP/fiber card) or a USB interface takes care of the glass fiber communication. The Refa8 is in this situation completely controlled by the PC.

The system does not perform any signal interpretation or signal analysis. This is left to the researcher/Physician.

The system is NOT intended to be used as part of a life supporting system.

indications for use

The Refa8 Physiological Amplifier family is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of the signals to a PC during recording of neuro-physical/ physiological research and exams.

Polygraphy and Polysomnography may besides EEG, include physiological information such as EMG, ECG, EOG, EGG, PH, Respiration, Temperature and Oxygen Saturation.

2 About this manual

This manual, which is intended for the user of the Refa8, contains general operating instructions, precautionary measures, maintenance instructions and information about components. To maximize the safety, service life and efficiency of the system, it is important that you read this manual through carefully and familiarize yourself with the various controls and accessories before starting to use the system.

3 Warnings and precautionary measures

This section contains general warnings and precautionary measures that are important for the safe use of the system.

 : manual contains important safety information

 : class II

 : type CF

Instructions for Disposal of Waste Electrical and Electronic Equipment (WEEE) by Users in the European Union
This symbol is placed on the product, which indicates that this product 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

1 About this manual

This manual, which is intended for the user of the Refa_Ext, contains general operating instructions, precautionary measures, maintenance instructions and information about components. To maximize the safety, service life and efficiency of the system, it is important that you read this manual through carefully and familiarize yourself with the various controls and accessories before starting to use the system.

2 Product description / intended use

The Refa_Ext is a stationary system for physiological research with a maximum of 136 channels.
The system has maximum 128 unipolar electrophysiological ('ExG') inputs, 4 bipolar electrophysiological ('BIP') inputs (optional), 4 so called auxiliary ('AUX') inputs (optional) and one digital input-channel (8 bits).
The unipolar electrophysiological inputs are configured as a reference amplifier: all channels are amplified against the average of all connected inputs. With these channels or the Bipolar channels signals like EEG, EMG, ECG, EOG, EGG etc. can be measured.
The auxiliary inputs can be used for measuring temperature, pH, respiration, oxygen saturation etc. Each AUX channel has a +5V and –5V output in order to use active sensors or sensor modules.

An external power supply, which plugs into the mains socket, powers the Refa_Ext. The Refa_Ext is connected to a PC by means of bidirectional glass fiber. Inside the PC a special interface board (DSP/fiber card) or a USB interface takes care of the glass fiber communication. The Refa_Ext is in this situation completely controlled by the PC.

The system does not perform any signal interpretation or signal analysis. This is left to the researcher/Physician.

The system is NOT intended to be used as part of a life supporting system.

Indications for use

The REFA Physiological Amplifier family is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of the signals to a PC during recording of neuro-physical/ physiological research and exams.

Polygraphy and Polysomnography may besides EEG, include physiological information such as EMG, ECG, EOG, EGG, PH, Respiration and Temperature.

3 Warnings and precautionary measures

This section contains general warnings and precautionary measures that are important for the safe use of the system.

 : manual contains important safety information

 : class II

 : type CF

Instructions for Disposal of Waste Electrical and Electronic Equipment (WEEE) by Users in the European Union

This symbol is placed on the product, which indicates that this product 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 drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service, or TMS International BV.

2 About this manual

This manual, which is intended for the user of the Mobi6, contains general operating instructions, precautionary measures, maintenance instructions and information about components. To maximize the safety, service life and efficiency of the system, it is important that you read this manual through carefully and familiarize yourself with the various controls and accessories before starting to use the system.

3 Warnings and precautionary measures

This section contains general warnings and precautionary measures that are important for the safe use of the system.

 : manual contains important safety information

 : internally powered, type CF

Instructions for Disposal of Waste Electrical and Electronic Equipment (WEEE) by Users in the European Union

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- Under federal law (only applicable to the USA) this apparatus may only be sold by or on the prescription of a physician or an authorized medical professional.
  The apparatus may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional.
- Transport the Mobi6 in original case.
- See manual of the PC software for details about the PC specifications.
- Only use sensors and electrodes as described within this manual and specified by TMSI
- Do not combine the use of the Mobi6 with any other electronic device, except those specified in this manual.
- Before batteries are replaced disconnect the patient from the Mobi6. Make sure that the Mobi6 is switched off, light is off. All batteries have to be replaced simultaneously, and all have to be of the same type. Note the orientation of the batteries. It is advised to place fresh batteries before each use to make sure the system operates long enough.
- When using rechargeable batteries always charge according to instructions of battery manufacturer.
- This system is not suitable for use in an inflammable mixture of anesthetics and air, oxygen or nitrous oxide.
- This system is not suitable for sterilization.
- Do not use aggressive chemicals to clean the system
- Do not expose the system to direct sunlight, heat from a source of thermal radiation, excessive amounts of dust, moisture, vibrations, or mechanical shocks.
- The Mobi6 is totally isolated from the mains due to battery operations but make sure the PC is installed according to local regulations and safety precautions.
- Disposable electrodes which are used for EMG measurement etc 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 or sterilized between patients. When sterilizing electrodes, employ only gas sterilization.
- Store electrodes within separate bag within the packaging to prevent contamination
- Not to be immersed in any liquid
- If any liquids or moisture penetrate the system or any part thereof, remove the batteries from the Mobi6 and have the system checked by an approved technician.
- Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation
- When the distance between the Bluetooth PC receiver and the Mobi6 is more then 10 meters or when there are conducting materials in the straight line between the Bluetooth PC receiver and the Mobi6 signal quality cannot be guaranteed.

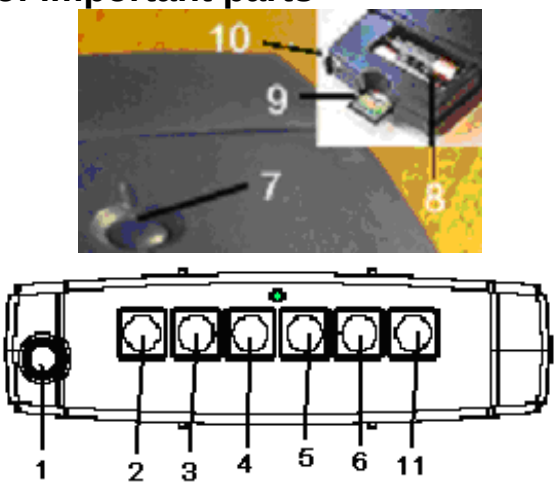
- When there are other radio devices in the neighborhood the transmission quality cannot be guaranteed.
- Due to reflections the transmission can be influenced within specific rooms or areas. In these cases the transmission quality cannot be guaranteed.
- Do not use an operating cellular phone within 30 cm of the Mobi6 to avoid excessive noise on the signals
- Not to be connected to a patient undergoing MRI, Electro surgery or defibrillation.
- Not for critical patient monitoring.
- Not defibrillator proof.
- Sharp bends or winding the cables in a loop smaller than 5 cm may damage the cables
- Dispose of batteries according to local regulations
- The Mobi6 contains recyclable materials that can be harmful for the environment. Specialized companies can separate these materials when the apparatus is disassembled. Before disposing of the apparatus, enquire about the local waste management regulations.
- When the Mobi6 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.
- Except for the batteries there are no user serviceable parts within the Mobi6, repairs can only be performed by the manufacturer.
- Due to design no calibrations are needed.
- There are no known side effects from the use of this equipment.

4 Contents of the packaging

Standard contents Mobi6 package
Mobi6 (see specifications chapter for specific types)
Bluetooth USB module
Suitcase for the Mobi and optional accessories
Carry case Mobi

Optional accessories
Bipolar cables for measurement of EMG, ECG etc
Patient ground cable
Nonin XPOD model 3012 pulseoximeter
NONIN 8000J flexwrap sensor
Nonin fingerclip 8000K2

5 Identification of important parts



1	Patient ground connector
2	Channel 1 EMG / Auxiliary connector
3	Channel 2 EMG / Auxiliary connector
4	Channel 3 EMG / Auxiliary connector
5	Channel 4 EMG / Auxiliary connector
6	Channel 5 EMG / Auxiliary connector (only 6-channel version)
11	Channel 6 EMG / Auxiliary connector (only 6-channel version)

Instructions for Disposal of Waste Electrical and Electronic Equipment (WEEE) by Users in the European Union

This symbol is placed on the product, which indicates that this product 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 drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service, or TMS International BV.

- Under federal law (only applicable to the USA) this apparatus may only be sold by or on the order of a physician or licensed practitioner.
  The apparatus may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional.
- The **only** external power supply that may be used is the original supply, type 'SUP5' or 'SUP3', that came with the Porti. **DO NOT replace it with something else**. If any non-TMSI type of supply is used then patient safety is not guaranteed.
- Make sure that the wall socket is well earthed, to reduce 50 or 60Hz disturbances.
- Do not combine the use of the Porti with any other electronic device, except those specified in this manual.
- Sensors with their own power are not to be connected to any of the inputs.
- Before batteries are replaced disconnect the patient from the Porti, make sure that the external power supply is disconnected and the Porti is switched off (LCD is clear). All batteries have to be replaced simultaneously, and all have to be of the same type. Note the orientation of the batteries.
- This system is not suitable for use in an inflammable mixture of anesthetics and air, oxygen or nitrous oxide.
- Do not expose the system to direct sunlight, heat from a source of thermal radiation, excessive amounts of dust, moisture, vibrations, or mechanical shocks.
- Not to be immersed in any liquid.
- If any liquids or moisture penetrate the system or any part thereof, remove the plug from the wall socket and have the system checked by the manufacturer.
- Not to be connected to a patient undergoing MRI, Electro surgery or defibrillation.
- Not for critical patient monitoring.
- Not defibrillator proof.
- This system is not suitable for sterilization.
- 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 or sterilized between patients. When sterilizing electrodes, employ only gas sterilization.
- Store electrodes within separate bag within the packaging to prevent contamination.
- Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation.
- Make sure the PC is installed according to local regulations and safety precautions.
- When the distance between the Bluetooth PC receiver and the Porti is more than 10 meters or when there are conducting materials in the straight line between the Bluetooth PC receiver the Porti signal transmission quality cannot be guaranteed.
- When there are other radio devices in the neighborhood the transmission quality cannot be guaranteed.
- Due to reflections the transmission can be influenced within specific rooms or areas. In these cases the transmission quality cannot be guaranteed.
- Do not use an operating cellular phone within 30 cm of the Porti to avoid excessive noise on the signals.
- Sharp bends or winding the cables in a loop smaller than 5 cm 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 Porti 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.
- Except for the batteries there are no user serviceable parts within the Porti. Repairs can only be performed by the manufacturer.
- Dispose of batteries according to local regulations.
- Cleaning of the Porti can be done with a slightly damp soft cloth. Before cleaning, make sure the Porti is turned off. Never use any aggressive chemicals to clean the Porti.
- Due to design no calibrations are needed.
- There are no known side effects from the use of this equipment.

4 Contents of the packaging

Each Porti is delivered with certain accessories depending on the model, a full list is included as packaging list. The Porti should only be used with these accessories, if other accessories or spare parts are needed please call TMSI for more information.

5 Installation

Check if the voltage on the available mains supply corresponds with the requirements of the SUP5 or SUP3 external power supply (100-240V, 50-60Hz).
Connect the SUP5 or SUP3 output to the 'POWER' connector of the Porti.
Connect the SUP5 or SUP3 input to the wall socket. The green light on the SUP5 or SUP3 should be lighting up. The LCD on the Porti should show a startup message, followed by the current time and date.

Fiber interface:
Connect the Fiber/USB converter (Fusbi) to a USB port of the notebook or desktop PC. The computer will detect new hardware and asks for a driver. Put the supplied driver CD into the CD-ROM drive, and select the CD-ROM drive after choosing 'Specify a location'. The FUSBI driver will now be installed.

Connect the Porti and the FUSBI by means of the glass fiber. A good fit of the fiber is indicated by a little 'click'. The PC will detect the connected Porti. Use the same driver CD as you did before, and install the driver for 'Porti7, signal acquisition device'.

With the Porti still connected, run the 'PortiSync.exe' program from the driver CD. This will make sure that the internal time and date of the Porti will be the same as the time and date of the connected computer.

Bluetooth interface:
Install the Bluetooth dongle software and hardware according to its accompanying installation instructions.

A so called Bluetooth pairing process between the Porti and the PC is required once.
Make sure that the Porti is powered. Start the Bluetooth software, and start the search for Bluetooth devices. The Porti will show up as 'Porti7-<type> <serial number >', for example: 'Porti7-8b8a 0207050017'. Double-click on the icon of the found Porti. The Bluetooth software will ask for a PIN-code. The code to enter is equal to the last 4 digits of the Porti serial number. In the given example, the PIN-code is '0017'. The Bluetooth services of the Porti will appear. Porti has only one, called 'SPP slave'. Double-click on the SPP slave icon of the Porti. The Bluetooth software will now make a serial connection to the Porti. The Bluetooth software will inform you about the serial port that it uses. Write down this COM-port number and enter it in your application software settings. The pairing process is now complete.

From now on the Bluetooth serial connection between the Porti and the PC can easily be made by just starting your application software, with settings for the COM-port as mentioned above.
Only if you deliberately remove the pairing between the Porti and the PC, or if you move the Bluetooth interface to another USB port or another PC, you will need to repeat this pairing process.

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 drop off your waste equipment for recycling, please contact your local city office, your household waste disposal service, or TMS International BV.

- Under federal law (only applicable to the USA) this apparatus may only be sold by or on the order of a physician or licensed practicioner.
  The apparatus may only be used under the constant supervision of or on the instructions of a physician or other authorized medical professional.

- The **only** external power supply that may be used is the original supply, that came with the Refa. **DO NOT replace it with something else**. If any non-TMSI type of supply is used then patient safety is not guaranteed.
- Make sure that the wall socket is well earthed, to reduce 50 or 60Hz disturbances
- Do not combine the use of the Refa8 with any other electronic device, except those specified in this manual.
- This system is not suitable for use in an inflammable mixture of anesthetics and air, oxygen or nitrous oxide.
- Do not expose the system to direct sunlight, heat from a source of thermal radiation, excessive amounts of dust, moisture, vibrations, or mechanical shocks.
- Not to be immersed in any liquid
- If any liquids or moisture penetrate the system or any part thereof, remove the plug from the wall socket and have the system checked by an approved technician.
- Not to be connected to a patient undergoing MRI or defibrillation.
- The system is intended to allow direct diagnosis or monitoring of vital physiological processes. It is not specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient. (MDD Annex IX, rule 10).
- Not defibrillator proof.
- This system is not suitable for sterilization.
- 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 or sterilized between patients. When sterilizing electrodes, employ only gas sterilization.
- Store electrodes within separate bag within the packaging to prevent contamination
- Take care in arranging patient and sensor cables to avoid risk of patient entanglement or strangulation

- Make sure the PC is installed according to local regulations and safety precautions.
- Do not use an operating cellular phone within 30 cm of the Refa8 to avoid excessive noise on the signals
- Sharp bends or winding the cables in a loop smaller than 5 cm may damage the cables
- Do not bend the glass fiber too sharply, as it may break.

- The Refa8 contains recyclable materials that can be harmful for the environment. Specialized companies can separate these materials when the system is disassembled. Before disposing of the apparatus, enquire about the local waste management regulations.

- Cleaning of the Refa8 can be done with a slightly damp soft cloth. Before cleaning, make sure the Refa8 is turned off. Never use any aggressive chemicals to clean the Refa8.
- Due to design no calibrations are needed.
- There are no known side effects from the use of this equipment.
- Pin 19 and 37 on the DB37 headconnectors delivers –5V and +5V supply. Make sure these pins are never connected to the patient in anyway.

11 Specifications

Type	**Mobi6-4b2a**	TMScode	95-0926-0420-0
Type	**Mobi6-6b**	TMScode	95-0926-0600-0
Type	**Mobi6-4b2as**	TMScode	95-0926-0421-0
Type	**Mobi6-6bs**	TMScode	95-0926-0601-0

Classification

CE 0044 — CE-certified. This device meets all the requirements of the MDD (93/42/EEC)

According to MDD: Class IIa (rule 10)

Applied standards:
* IEC 60601-1:1988 + A1:1991 + A2:1995 : *Medical electrical equipment - Part 1: General requirements for safety*
* IEC 60601-1-2:2001 : *Medical electrical equipment - Part 1-2: Electromagnetic compatibility*

safety according to IEC 60601-1: internally powered, type CF

Dimensions	11.4 x 9.8 x 3.7 cm (l x b x d)
Weight	165 gram (excl. batteries)

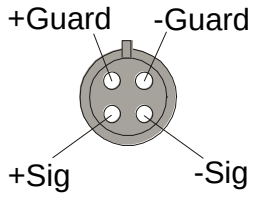
Internal power supply

Batteries	2 x AA type rechargeable NiCd or NiMH 1.2V or disposable alkaline 1.5V
Battery low indication level	2.1 V ± 0.1V
Battery empty shut down level	1.8 V ± 0.1V

Bipolar inputs (EMG)

Noise	< 1.0 µV rms (@ Fs = 128 Hz)
Gain	19.5 x
Input signal difference	< 0.1 V
Input common mode range	-2V / +2V
Input impedance	> 10^{12} Ω
CMRR	100 dB
Connector	Binder 719 series 4 pin
Accuracy	± 2%

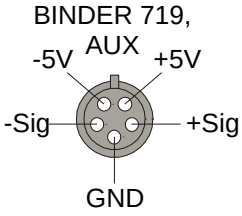
Chassis part, front/outside view



AUX inputs

Noise	< 15 µV rms (@ Fs = 128 Hz)
Gain	1 x
Accuracy	± 2%
Input signal range differential	-2V / +2V
Input common mode range	-2V / +2V
Input impedance	> 10^{10} Ω
CMRR	80 dB
Connector	Binder 719 series 5 pin
Output voltage	+5V, -5V, max. 5mA per channel

Chassis part outside view



pin 1 = +5V
pin 2 = +sig in
pin 3 = GND
pin 4 = -sig in
pin 5 = -5V

Sampling

Resolution	24 bits, Bipolar 12.2 nV per bit, AUX 0.238 µV per bit
Sample frequency (Fs)	128Hz, 256Hz, 512Hz ,1024Hz, 2048Hz

Bluetooth communication

Bluetooth 1.1 class 2	Bluetooth™
Used profile	Serial port profile
Line of sight range	> 10 meter

Flash memory card

Supported card type	* SD card, 32Mb or higher, upto 2 Gb Format FAT16 only
Cluster size	Use as large as possible cluster size, at least 2 sectors/cluster

Appendix 1 Type specific specifications

Type	**Porti7-24e4b3ast**
TMScode	95-0207-4431-2
Manual	92-0207-4431-2-2010

Dimensions

External dimensions	158 x 112 x 73 mm (l x w x h)

Internal power supply

Batteries	6/12 x AA type rechargeable NiCd or NiMH 1.2V or disposable alkaline 1.5V
Battery low indication level	6.2 V ± 0.1V
Battery empty shut down level	5.9 V ± 0.1V

Unipolar ExG inputs (EEG, ECG, EOG, EMG etc.)

Noise	< 1 µVrms (@ lowest sample rate)
Gain	20 x
Input signal difference	-150mV / +150mV
Input common mode range	-2V / +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	micro coax, active shielding

Bipolar ExG inputs (EEG, ECG, EOG, EMG etc.)

Noise	< 1 µVrms (@ lowest sample rate)
Gain	20 x
Input signal difference	-150mV / +150mV
Input common mode range	-2V - +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	4 pin BINDER 719 series, see drawing in chapter 8 for pinout

AUX inputs

Noise	< 20 µVrms (@ lowest sample rate)
Gain	1 x
Input signal range (diff.)	-3V - +3V
Input common mode range	-4V - +4V
Input impedance	> 10^{10} Ω
CMRR	> 70 dB
Output voltage	+5V, -5V, max. 5mA per channel, or 40mA for all channels together
Connector	5 pin BINDER 719 series, see drawing in chapter 8 for pinout

Trigger input:

Input	turn-on current = 2 mA @ Vin = 3.0V, Vin_max = 5V
Isolation	> 4000 V, by means of optocoupler (H11L1)
Connector type	Plastic LEMO micro-coax, center pin is +

Sampling:

Resolution	22 bits, ExG/BIP 71.526 nV per bit, AUX 1.4305 µV per bit
Sample frequency (Fs)	2048 Hz, 1024 Hz, 512 Hz, 256 Hz, 128 Hz

Filtering/gain:

Gain	ExG 20 x, fixed (= 50 mV/V), BIP 20 x, fixed (= 50 mV/V), AUX 1 x, fixed (= 1 V/V)
High pass	none
Low pass	digital FIR filter in ADC, cutoff frequency = 0.27 * sample frequency

Bluetooth communication:

Bluetooth 1.1 class 2	Bluetooth
Used profile	Serial port profile
Line of sight range	> 10 meter
Baud rate	230400 bps

Fiber communication:

Bit rate	7.340032 Mbit/s
Max supported sample rate	2048 Hz
Fiber length	up to 70m
Required interface	FUSBI, requires USB1.1 or USB2.0 port on PC

Channel list:

nr	name	function		resolution	range
1	ExG1	Unipolar input 1		0.0715 µV	-150mV / +150mV
2	ExG2	Unipolar input 2		0.0715 µV	-150mV / +150mV
3	ExG3	Unipolar input 3		0.0715 µV	-150mV / +150mV
4	ExG4	Unipolar input 4		0.0715 µV	-150mV / +150mV
5	ExG5	Unipolar input 5		0.0715 µV	-150mV / +150mV
6	ExG6	Unipolar input 6		0.0715 µV	-150mV / +150mV
7	ExG7	Unipolar input 7		0.0715 µV	-150mV / +150mV
8	ExG8	Unipolar input 8		0.0715 µV	-150mV / +150mV
9	ExG9	Unipolar input 9		0.0715 µV	-150mV / +150mV
10	ExG10	Unipolar input 10		0.0715 µV	-150mV / +150mV
11	ExG11	Unipolar input 11		0.0715 µV	-150mV / +150mV
12	ExG12	Unipolar input 12		0.0715 µV	-150mV / +150mV
13	ExG13	Unipolar input 13		0.0715 µV	-150mV / +150mV
14	ExG14	Unipolar input 14		0.0715 µV	-150mV / +150mV
15	ExG15	Unipolar input 15		0.0715 µV	-150mV / +150mV
16	ExG16	Unipolar input 16		0.0715 µV	-150mV / +150mV
17	ExG17	Unipolar input 17		0.0715 µV	-150mV / +150mV
18	ExG18	Unipolar input 18		0.0715 µV	-150mV / +150mV
19	ExG19	Unipolar input 19		0.0715 µV	-150mV / +150mV
20	ExG20	Unipolar input 20		0.0715 µV	-150mV / +150mV
21	ExG21	Unipolar input 21		0.0715 µV	-150mV / +150mV
22	ExG22	Unipolar input 22		0.0715 µV	-150mV / +150mV
23	ExG23	Unipolar input 23		0.0715 µV	-150mV / +150mV
24	ExG24	Unipolar input 24		0.0715 µV	-150mV / +150mV
25	BIP25	Bipolar input 25		0.0715 µV	-150mV / +150mV
26	BIP26	Bipolar input 26		0.0715 µV	-150mV / +150mV
27	BIP27	Bipolar input 27		0.0715 µV	-150mV / +150mV
28	BIP28	Bipolar input 28		0.0715 µV	-150mV / +150mV
29	AUX29	Auxiliary input 29		1.4305 µV	-3.0V / +3.0V
30	AUX30	Auxiliary input 30		1.4305 µV	-3.0V / +3.0V
31	AUX31	Auxiliary input 31		1.4305 µV	-3.0V / +3.0V
32	AUX32	(Channel occupied by SaO2 connector)		1.4305 µV	-3.0V / +3.0V
33	SaO2	Oxygen saturation		1 %	0 / 100, 127 = invalid
34	Pleth	Plethysmographic waveform		1 (bit)	0 / 255
35	HRate	Pulseoximeter heart rate		1 BPM	0 / 255
36	Status	Pulseoximeter status		1 (bit)	0 / 255
37	Digi	Digital channel (bits)		1 (bit)	0 / 255
		0x01	1 = ON/OFF button pressed		
		0x02	always 1		
		0x04	1 = trigger active		
		0x08	always 0		
		0x10	always 0		
		0x20	always 0		
		0x40	1 = battery low		
		0x80	always 0		

9 General specifications

Type	**Porti7**
TMScode / REF	See Appendix 1 for type specific information

Medical Device Directory (MDD)

Annex IX classification	Class IIa (rule 10)
CE 0044	CE-certified

Applied standards

IEC 60601-1:1988 + A1:1991 + A2:1995	*'Medical electrical equipment - Part 1: General requirements for safety'*
IEC 60601-1-2 :2001	*'Medical electrical equipment - Part 1-2: Electromagnetic compatibility'*

External power supply SUP5

Input voltage	100-240V AC, 50 - 60 Hz
Output voltage	10V DC
Output current	max. 200 mA
Isolation voltage	> 4000V
Leakage current	< 3 µA
Fuses	2 x 1.6A slow, 250V, 5x20mm glass
	safety according to IEC 60601-1: Class II, type CF

External power supply SUP3

Input voltage	100-240V AC, 50 - 60 Hz
Output voltage	10V DC
Output current	max. 350 mA
Isolation voltage	> 4000V
Leakage current	< 3 µA
Fuses	2 x 0.5A slow, 250V, 5x20mm glass
	safety according to IEC 60601-1: Class II, type CF

Storage and transportation conditions:

temperature	-10ºC - +70ºC
humidity	10% - 90%
pressure	500 hPa - 1060 hPa

Usage conditions:

temperature	0ºC - +40ºC
humidity	10% - 90%
pressure	500 hPa - 1060 hPa

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Technical changes reserved

Appendix 1 Specifications

Type	**Refa8-64e4b4a**
TMScode	95-0120-8447-1
Manual	92-0120-8447-1-2204

Classification

according to MDD	Class IIa
CE 0044	CE-certified

Dimensions

External dimensions	210 x 207 x 92 mm (l x w x h)

External power supply:

Input	110-240V AC, 50 - 60 Hz
Output voltage	10V DC
Output current	max. 700 mA
Isolation voltage	> 4000V
Leakage current	< 3 µA
	safety according to IEC 60601-1 class II type CF

Unipolar ExG inputs (EEG, ECG, EOG, EMG etc):

Number	64
Noise	< 1.0 µVrms (@ lowest sample rate)
Gain	26,55 x
Input signal difference	< 0.15 V
Input common mode range	-2V - +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	micro coax, active shielding // subD37 female connector

Bipolar ExG inputs (ECG, EOG, EMG etc):

Number	4
Noise	< 1.0 µVrms (@ lowest sample rate)
Gain	26,55 x
Input signal difference	< 0.15 V
Input common mode range	-2V - +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	4 pin BINDER, active shielding

AUX inputs:

Number	4
Noise	< 20 µVrms (@ lowest sample rate)
Gain	1 x
Input signal range (diff)	-3V -+3V
Input common mode range	-4V - +4V
Input impedance	> 10^{12} Ω
CMRR	> 70 dB
Output voltage	+5V, -5V, max 5mA per channel, or 20mA for all channels together
Connector	5 pin BINDER

Digital input

Connector	DB25, 8 signal, 1 common ground (bit 0 also by BNC)
Input	turn-on current = 2 mA @ Vin = 3.0V, Vin_max = 5V

Isolation	> 4000 V, by means of optocoupler (H11L1)

Sampling:

Number of channels	72 channels simultaneously
Resolution	24 bits, ExG//BIP 18.39 nV per bit, AUX 0.48828 µV per bit
Sample frequency	2000 Hz, 1000 Hz, 500 Hz, 250 Hz, 125 Hz
Output	74 channels: 1-64=Unipolar ExG 65-68 = Bipolar ExG 69-72 = AUX 73=Digital (bit 0-7=digital trigger input (inverted)) 74=Digital (bit 0-14=sawtooth test signal)

Filtering/gain:

Gain	ExG 26.55 x, fixed (= 37,7 mV/V), BIP 26.55 x, fixed (= 37,7 mV/V), AUX 1 x, fixed (= 1 V/V)
Highpass	none
Lowpass	digital FIR filter, cutoff frequency = 0.2 * sample frequency

Fiber communication:

Bit rate	7.68 Mbit/s
Max supported sample rate	2000 Hz
Fiber length	up to 70m
Required interface	FUSBI, USB2.0 port on PC

Storage and transportation conditions:

temperature	-10ºC - +50ºC
humidity	10% - 100%
pressure	500 hPa - 1060 hPa

Usage conditions:

temperature	0ºC - +40ºC
humidity	10% - 90%
pressure	500 hPa - 1060 hPa

Manufactured by:

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Technical changes reserved

Appendix 1 Specifications

Type	**Refa_Ext-128e4b4a**
TMScode	95-0121-6446-2
Manual	92-0121-6446-2-2304

Classification

according to MDD	Class IIa
CE 0044	CE-certified

Dimensions

External dimensions	210 x 360 x 92 mm (l x w x h)

External power supply:

Input	110-240V AC, 50 - 60 Hz
Output voltage	10V DC
Output current	max. 700 mA
Isolation voltage	> 4000V
Leakage current	< 3 µA
	safety according to IEC 60601-1 class II type CF

Unipolar ExG inputs (EEG, ECG, EOG, EMG etc):

Number	128
Noise	< 1.0 µVrms (@ lowest sample rate)
Gain	26,55 x
Input signal difference	< 0.15 V
Input common mode range	-2V - +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	micro coax, active shielding // subD37 female connector

Bipolar ExG inputs (ECG, EOG, EMG etc):

Number	4
Noise	< 1.0 µVrms (@ lowest sample rate)
Gain	26,55 x
Input signal difference	< 0.15 V
Input common mode range	-2V - +2V
Input impedance	> 10^{12} Ω
CMRR	> 90 dB
Connector	4 pin BINDER, active shielding

AUX inputs:

Number	4
Noise	< 20 µVrms (@ lowest sample rate)
Gain	1 x
Input signal range (diff)	-3V -+3V
Input common mode range	-4V - +4V
Input impedance	> 10^{12} Ω
CMRR	> 70 dB
Output voltage	+5V, -5V, max 5mA per channel, or 20mA for all channels together
Connector	5 pin BINDER

Sampling:

Number of channels	136 channels simultaneously
Resolution	24 bits, ExG//BIP 18.39 nV per bit, AUX 0.48828 µV per bit
Sample frequency	2048 Hz, 1024 Hz, 512 Hz, 256 Hz, 128 Hz
Output	138 channels: 1-128=Unipolar ExG 129-132 = Bipolar ExG 133-136 = AUX 5 pin connector 137=Digital 138=Digital (bit 0-14= sawtooth test signal)

Filtering/gain:

Gain	ExG 26,55 x, fixed (= 37,7 mV/V), BIP 26,55 x, fixed (= 37,7 mV/V), AUX 1 x, fixed (= 1 V/V)
Highpass	none
Lowpass	digital FIR filter, cutoff frequency = 0.2 * sample frequency

Fiber communication:

Bit rate	6.29 Mbit/s
Max supported sample rate	2048 Hz
Fiber length	up to 70m
Required interface	FUSBI, USB2.0 port on PC

Storage and transportation conditions:

temperature	-10ºC - +50ºC
humidity	10% - 100%
pressure	500 hPa - 1060 hPa

Usage conditions:

temperature	0ºC - +40ºC
humidity	10% - 90%
pressure	500 hPa - 1060 hPa

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Multi-channel ambulatory system for a wide range of clinical and research applications

Mobi (Mobi6)

- No cable movement artifacts
- No mains interference
- Wireless telemetry
- Compact, lightweight
- True DC signals
- Up to 8 analog channels
- Digital input

TMS INTERNATIONAL

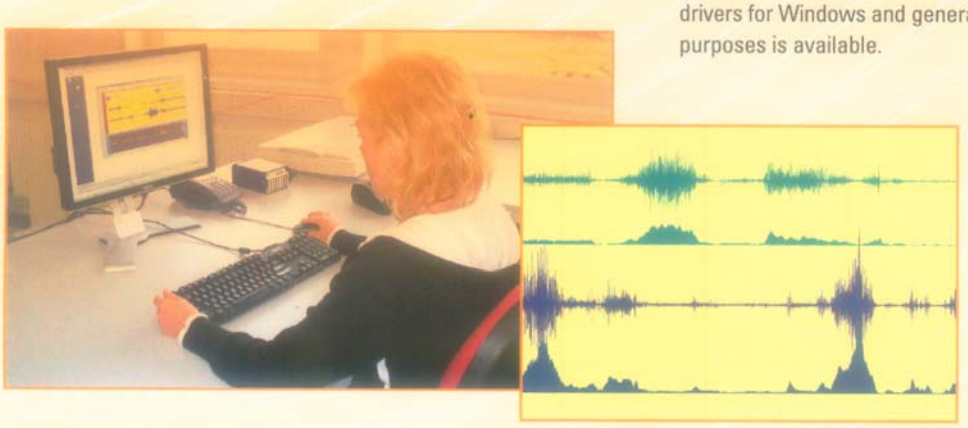
Recording quality signals under tough conditions

Mobi (Mobi6)

General information

The Mobi is a multichannel ambulatory system for measuring a variety of (electro) physiological signals in the field of neurophysiology, human movement sciences, rehabilitation, ergonomics, sports and telemedicine. The Mobi offers a wide range of measurement configurations and user definable measurement parameters. For example EEG, EMG, ECG, force, position, movement, temperature, respiration and saturation can all be measured.

The design of the Mobi comprises a true DC reference amplifier with active shielding. This eliminates mains interference and cable movement artifacts. The Mobi incorporates no hardware filters (other than anti-aliasing) so the raw data is always available and quick recovery ensured. Filtering is consequently done in software on the PC. The Mobi is connected to the PC , PDA or mobile telephone via Bluetooth®. Local data storage is provided by an SD card. The system is further supplied with drivers for Windows and general acquisition software for research purposes is available.



Specification

Sampling

Resolution	:	24 bit, 12.2nV/bit
Sampling rate	:	2048 Hz
Noise	:	< 1 uV rms
CMRR	:	> 100 dB typical
# of channels	:	up to 8 analog, plus digital inputs
Power supply	:	2 AA batteries

Filtering/Gain

Gain	:	Factory pre-set
Filter	:	Configurable in PC software
Connectors	:	Individually shielded inputs
Type	:	Unipolar, bipolar and auxiliary

Dimensions	:	115 * 98 * 37 mm
Weight	:	165 grams

Approvals	:	CE certified (class 2A, type CF)

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Multi-channel ambulatory or stationary system for a wide range of clinical and research applications

Porti (Porti7)

- No cable movement artifacts
- No mains interference
- Wireless telemetry or fiber optic
- No hardware filters
- True DC signals
- From 8 to 32 channels

TMS INTERNATIONAL

Recording quality signals under tough conditions

Porti (Porti7)

General Information

The Porti is a multichannel ambulatory or stationary system for measuring a variety of (electro) physiological signals in the field of neuropsychology, human movement sciences, rehabilitation, ergonomics and sports for. The flexible modular concept of the Porti offers a wide range of measurement configurations and user definable measurement parameters. For example EEG, EMG, ECG, force, position, movement, temperature, respiration and saturation can all be measured.

The design of the Porti comprises a true DC reference amplifier with active shielding. This eliminates mains interference and cable movement artefacts. The Porti incorporates no hardware filters (other than anti-aliasing) so the raw data is always available and quick recovery ensured. Filtering is consequently done in software on the PC. The Porti is connected to the PC via Bluetooth® or optical fiber and USB. Local data storage is provided by an SD card. The system is further supplied with drivers for Windows and general acquisition software for research purposes is available.

Specification

Sampling

Resolution	:	22 bit, 71.5nV/bit
Sampling rate	:	2048 Hz
Noise	:	< 1 uV rms
CMRR	:	> 100 dB typical
# of channels	:	max 32
Power supply	:	Internal 6 or 12 AA batteries
External	:	mains supply

Filtering/Gain

Gain	:	Factory pre-set
Filter	:	Configurable in PC software
Connectors	:	Individually shielded inputs
Type	:	Unipolar, bipolar and auxiliary

Dimensions:

8/16 channel	:	158 * 112 * 54 mm
24/32 channel	:	158 * 112 * 73 mm

Approvals	:	CE certified (class 2A, type CF)

The Porti family of amplifiers is FDA 510 k approved, also for use in the presence of defibrillators

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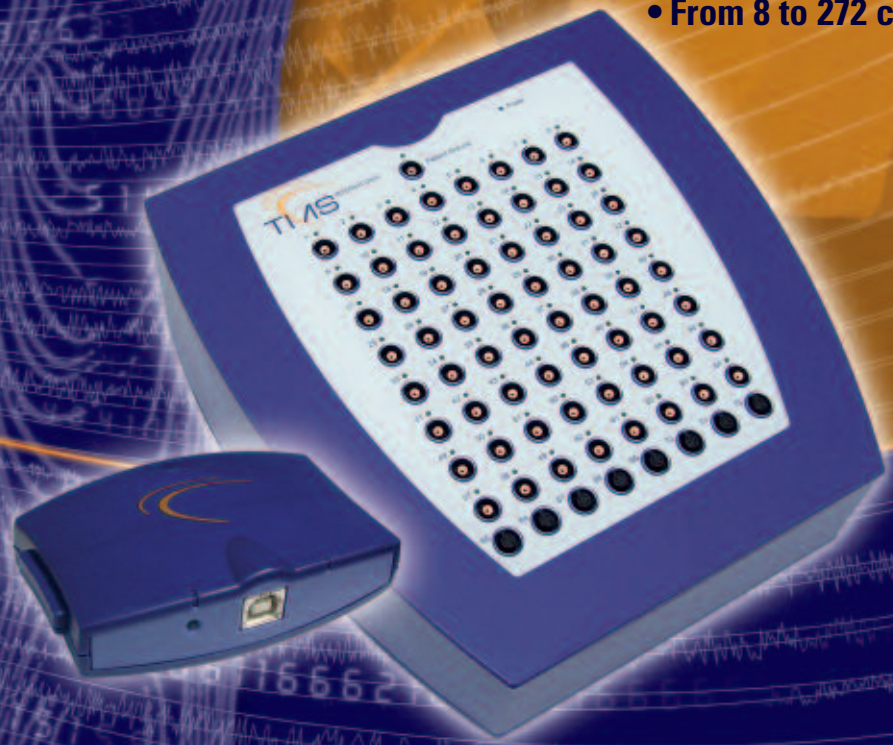
TMS-0049

Compact multi-channel system for neurological and cardiological research

Refa (Refa8/ Refa_Ext)

- No cable movement artifacts
- No mains interference
- Active signal shielding
- No hardware filters
- True DC signals
- From 8 to 272 channels



TMS INTERNATIONAL

Recording quality signals under tough conditions

Refa (Refa8/ Refa_Ext)

General Information

The Refa is a multichannel system for neurological, cardiological and other research with up to 272 input channels. The flexible modular concept of the Refa offers a wide range of measurement configurations and user definable measurement parameters. For example EEG, EMG, ECG, force, position, movement, temperature, respiration and saturation can all be measured. With an optional connection adapter, the Refa is also suited for high density EMG measurements.

The design of the Refa comprises a true DC reference amplifier with active shielding. This eliminates mains interference and cable movement artefacts. The Refa incorporates no hardware filters (other than anti-aliasing) so the raw data is always available and quick recovery ensured. Filtering is consequently done in software on the PC. The Refa is connected to the PC via optical fiber and USB. The system is supplied with drivers for Windows and general acquisition software for research purposes is available.

Specification

Sampling

Resolution	:	22 or 24bit, 71.5 or 18.4 nV/bit
Sampling rate	:	2048 Hz, models up to 20 KHz also available
Noise	:	< 1 uV rms
CMRR	:	> 100 dB typical
# of channels	:	136 in single housing

Filtering/Gain

Gain	:	Factory pre-set
Filter	:	Configurable in PC software
Connectors	:	Individually shielded inputs
Type	:	Unipolar, bipolar and auxiliary

Dimensions:

8/72 channel	:	210 * 207 * 92 mm
136 channel	:	210 * 360 * 92 mm

Approvals : CE certified (class 2A, type CF)
The Refa family of amplifiers is FDA 510 k approved

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