



USER MANUAL



REF 92-1300-0201-EN-7-0 REV 7

Last update: 2023-01-31





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SERVICE AND SUPPORT

1.1 About this manual

This manual is intended for the user of the APEX (electro-)physiological amplifier which is also referred to as 'APEX', 'product' or 'APEX 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 familiarise 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 via the website: www.tmsi.com/support. Please provide as much information as possible, including serial numbers of the used products. This will help to support you in the best way possible.

TMSi Support can be contacted in one of the following languages: Dutch or English.

Manufacturer

Contact Information

Zutphenstraat 57 7575 EJ Oldenzaal The Netherlands

Twente Medical Systems International B.V.



support@tmsi.com



www.tmsi.com

1.3 Warranty information

The product is warranted against failure of materials and workmanship for a period of one year from the date of delivery.

Repairs can only be performed by the manufacturer or by TMSi authorised personnel. Warranty will terminate automatically by removal or alteration of identification labels on the product or its parts. In case seals on the enclosure are broken or removed, warranty is voided and TMSi can no longer guarantee continued safety or correct operation of the product.

The warranty does not cover the following:

- Failure resulting from misuse, accident, modification, unsuitable physical or operating environment, or improper maintenance.
- Wear and tear caused by regular and normal usage and ageing of rechargeable batteries.
- Failure caused by a product for which TMSi is not responsible.
- Damage resulting from use of non-approved accessories.
- Interrupted or erroneous 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.





1.4 Additional accessories

In case you want to order additional accessories such as cables or sensors, please contact sales@tmsi.com for consultation and a detailed quotation. The product is intended to be used with approved headcaps only; the latest version of compatible accessories can be found on the TMSi website www.tmsi.com.

1.5 Abbreviations

Abbreviation		
AC	Alternating Current	
BF	Body Floating	
ВТ	Bluetooth	
CE	Conformité Européenne	
DC	Direct Current	
EEG	Electro-encephalography (Brain activity)	
EM, EMC	Electro-magnetic, Electro-Magnetic Compatibility	
EMG	Electromyography (Muscle activity)	
EOG	Electro-oculography (Standing potential of the eye between front and back)	
EU	European Union	
IT	Information Technology	
ME	Medical Equipment	
PC	Personal Computer	
REF	Reference	
RF	Radio Frequency	
SN	Serial Number	
SAR	Specific Absorption Rate	
TMSi	Twente Medical Systems International B.V.	
UNI	Unipolar	
USB	Universal Serial Bus	





2 SAFETY INFORMATION

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

2.1 Explanation of markings

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

<u> </u>	Warning: read important safety information
Ţ	Caution
Ţ <u>i</u>	Consult instructions for use
	Refer to instructions for use (for USB-C connector function, chapter 4.6)
†	Type BF applied part
CE	CE-certified, see declaration of conformity
***	Identification of the manufacturer
$\overline{\mathbb{A}}$	Date of manufacture (YYYY or YYYY-MM-DD)
IPN ₁ N ₂	Ingress protection rating (where N ₁ and N ₂ are one digit each)
REF	TMSi reference number
SN	TMSi serial number
((<u>`</u>))	Contains transmitter module
R	Contains radio module for which the Technical Regulations Conformity Certification has been granted
X	Special EU instructions for disposal are applicable to a product on which this symbol is placed. The Maintenance section of this manual contains information on how to dispose of this product, see chapter 7.3
((·))	Wireless sensors status indicator; see chapter 3.4
	Cap connection status indicator; see chapter 3.4
	PC connection status indicator; see chapter 3.4
	Recording status indicator; see chapter 3.4
	Power status indicator; see chapter 3.4
(h)	Power button icon; see chapter 3.4
	Marker button icon; see chapter 3.4





● REC Recording button icon; see chapter 3.4

2.2 Limitations of use

There are no known contra-indications to the use of the APEX product. For further information refer to chapters 2.3, 2.4 and 3.2.

The design of this product did explicitly not account for potential applications, uses or environments as listed below and therefore these aspects were excluded from full risk assessment. In order to prevent any associated risks, the following limitations apply to the product:

- This product is not intended for a medical purpose. This includes, but is not limited to, the following:
 - Direct diagnosis.
 - Monitoring of vital physiologic processes.
 - Critical applications.
 - Life-supporting applications.
 - Determination of electro-cerebral inactivity or silence.
- This product is not defibrillator-proof.
- This product is not intended for use in oxygen rich environments.
- This product is not intended for use in environments with flammable mixtures of anesthetics or agents and air, oxygen or nitrous oxide.
- This product is not intended for use in environments with strong magnetic fields.
- This product is not intended for use in environments with ionizing radiation.
- This product is not compatible with HF surgical equipment.
- This product is not intended for use on altitudes higher than 3 000 m above sea level, unless it is used in an environment where the air pressure is maintained within the range (700 to 1060) hPa.
- This product is not to be used in the presence of Magnetic Resonance Imaging (MRI) devices.

NOTE



While the product can be used to measure encephalic (brain) signals, it is NOT intended to be used, alone or in combination with other devices or software, for diagnostic purposes as an electroencephalograph (to produce an electroencephalogram).

2.3 Safety measures and warnings

Some risks associated with the intended use of the product cannot be eliminated in the product design. To avoid consequential residual risks, the following measures and warnings must be followed up for safe usage of the product.

Only use accessories explicitly approved by TMSi to avoid the risk of electric shock.



APEX is intended to receive its power from other electrical equipment in an ME System if not powered from the internal battery. The electrical safety is dependent on this other equipment. Refer to chapter 4.6 for further details.

To avoid the risk of electric shock do not connect APEX to equipment that is not compliant with either IEC 60601, IEC 60950 or IEC 62368.

Do not touch pins of disengaged connector plugs or sockets to avoid the risk of electric shock.





Do not use APEX together with cautery or electro-coagulation equipment on the same subject to avoid damage to the product.

To avoid damage to the product do not use or store it near sources with particle radiation or elevated levels of electrical, magnetic or electro-magnetic fields.

To avoid damage and reciprocal interference, only connect TMSi approved accessories and equipment to APEX.

Do not use APEX together with magnetic resonance imaging equipment on the same subject to avoid reciprocal interference.

Do not tamper with any part of APEX. To maintain safety, no modifications are allowed.

Use of APEX adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, APEX and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of APEX could result in increased electromagnetic emissions or decreased electromagnetic immunity of APEX and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the APEX including its cables. Otherwise, APEX performance degradation could result.

Conductive parts of electrodes and associated connectors should not contact other conductive parts, including earth.

APEX is intended to be operated close to the human body and must comply with the Specific Absorption Rate (SAR) for body worn equipment to ensure compliance with RF exposure requirements set for the USA and Canada. When using APEX while wearing it on the body, maintain a distance of 10mm between APEX and the body. This can for instance be accomplished by using the APEX cradle with a 10 mm thick adhesive foam pad, which must be free of metallic components, mounted to the backside of the cradle. For use in the EU, there is no such requirement.

To further comply with FCC and Industry Canada RF radiation exposure limits for general population, no transmitter or transmitter antenna must be co-located within 20 cm from the APEX.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

2.4 Precautionary measures

Taking the measures listed below should ensure proper operation and result in minimal undesired consequences and optimum benefit of using the product.

Make sure batteries are sufficiently charged before wireless use of APEX. If necessary, connect an external power bank for charging.



To prolong battery life, store APEX with preferably 40 % charged batteries and at a temperature in the range (-20 to 20) °C.

To avoid signal disturbance, keep APEX away from sources of strong electric, magnetic and electromagnetic radiation.

To avoid loss of data, use USB communication for data transport and control.





Route cables for a comfortable wear and freedom of movement for the subject; properly secure any excess cable, for example with some tape or Velcro.

Prevent prolonged physical contact with metal connector parts as they may contain nickel. If necessary, tape them off using for example a bandage.

If any part of APEX appears obviously malfunctioning or damaged, refrain from further using it and contact the manufacturer for repair and check of the device.

When using APEX in combination with a laptop that is connected to external equipment (monitor, ethernet, etc), please ensure that the laptop is grounded in order to avoid possible signal interference.

When using APEX in combination with a laptop/PC or charger, make sure that the product is not positioned in such a way that it is difficult to operate the disconnection device.

2.5 Disclosure of residual risk

The intended and foreseeable use of the APEX product bears an acceptable risk. Residual risks are disclosed in chapter 2.3.

2.6 Information for lays

In case of subject use, the user of the product should instruct the subject on the following topics:

- There are no contra-indications on the use.
- Do's and don'ts regarding use and usage environments. Specifically:
 - a. Keep the product clean and dry.
 - b. Do not enter areas and environments where access is restricted.
 - c. Keep distance from professional and amateur transmission antennas.
 - d. When interacting with children or pets, be careful about pulling at cables.
- Which indicators, if any, must be monitored, how often, and how to react on specific status indications.
- When to press the Event marker button.
- How batteries have to be recharged, if their running out is expected.
- Contact the researcher when an unexpected situation or problem occurs.



3 PRODUCT OVERVIEW

3.1 Product

The APEX product consists of the following components:

- APEX Recorder: Electro-physiological amplifier.
- Accompanying documentation: Quick start guide, User Manual and certificates.
- TMSi APEX Device Driver.
- TMSi BT Dongle.

The product is delivered with the following items to increase the ease of use: a suitcase, USB-C to USB-A cable, the APEX Cradle, some subject cabling and the TMSi Python Interface including a compiled application that provides a Graphical User Interface.

The product is intended to be used with approved headcaps; the latest version of compatible accessories can be found on the TMSi website www.tmsi.com. Please refer to the instructions for use of those accessories, if applicable.

3.2 Intended use

Intended use

The product is intended for acquisition of human electroencephalographic (EEG) signals within the product's technical limitations as specified in chapter 9 Furthermore, the product is designed to log external trigger events.

The product is not intended for a medical purpose (diagnostic, monitoring or treatment).

Subject population

The product is intended to be used by research professionals in a laboratory environment. APEX is also intended to be used for out-of-lab measurements. For this use case, the research professional configures the product, after which it can be handed to the subject. Data can be retrieved afterwards from the onboard memory.

There are no restrictions on the subject population for which the product can be used. The product can be used on subjects regardless of age, gender or other criteria.

Subject interface and operating principle

The product can be worn on the body during wireless measurement setups in which case its enclosure outside is an accessible part. Contact between the subject and product's subject input(s) is made by using accessories such as headcaps, in combination with gel or saline water.

The product amplifies and stores signal data picked up via electrode leads or sensors that are connected to a single subject; no data interpretation is performed.





Applied part

The product has a single Type BF applied part. It consists of the front-side sockets (pins and shield) on the product enclosure that are marked with an applied part symbol, because these parts of the device connect galvanically to the EEG accessories.

User population

The product is intended to be used by, or under supervision of, a physician or research professional. The user/supervisor must have knowledge of current good practice in physiological measurement applications.

User interface

The different user interfaces of the product are:

- The user interface of the APEX.
- The API offers a method to interact with the device from a PC. The application software's user interface provides the various functionalities.

The user interface of the APEX consists of an Event marker button, a Recording button, a Power button and status indicators. All status indicators are explained in chapter 3.4.

The product can be controlled via the user interface of the application software running on a computer. The application software on the PC is used for storage and visualization of the acquired signal data.

Use environment and conditions of use

The product is intended for use on humans in a professional research laboratory environment, within environmental limits as specified in chapter 9. The product can be used as both a stationary device, as well as a portable device. Usage in environments with restricted access due to ionizing radiation and/or strong magnetic fields is excluded, as well as usage in situations referred to in chapter 2.2. The product is not intended for use in a life supporting system. The product is designed for continuous operation and is reusable without requiring any level of sterility or reprocessing. No special handling or pre-treatment is required other than connecting subject accessories between subject and APEX.

APEX is also suitable for out-of-lab usage. Setting up card recordings is explained in chapter 5.3. After being instructed how to deal with the device, the subject can be sent out for a while and during that time the APEX autonomously carries out the measurement as configured. Refer to chapter 2.6 for the instructions for lays.

Only use the product with the supplied parts and accessories. In case other parts or accessories are required, contact TMSi Support (support@tmsi.com) for information.

Expected service life

The expected service life of the device is 5 years. If the product is intended to be used after its expected service life, contact TMSi to have the product inspected before continued use.





The product requires no regular servicing or maintenance and no modification by users is allowed, but it may be cleaned as described in chapter 7. Repairs and modifications can only be performed by the manufacturer. The expected charging cycle life of the internal batteries for \geq 70% remaining capacity, is \geq 500 cycles. Batteries can only be replaced by the manufacturer. Please contact TMSi Support (support@tmsi.com) if the batteries need to be replaced.

Essential performance

Under normal conditions the product ensures:

- All data of a measurement session becomes available.
 - This means that the product makes all data acquired through the product promptly available as digital data, either via streaming or through retrieval of card recording(s).
 - However, disturbances such as mains power glitches and interference in wireless transmission may cause transient loss of streamed signal data.
- Accuracy of amplitude range and sample rate.
- Input dynamic range and differential offset voltage.
- Input noise.
- Frequency response.
- Common mode rejection.

For information regarding performance under abnormal conditions refer to chapter 8. Refer to chapter 9 for the corresponding signal characteristics described above.

3.3 Product views

Top View



#	Description
1.	Physical user interface. See chapter 3.4 for more information on the LED indicators and the button markings.





Front and Side View



#	Description
1.	USB-C connector. Used for charging and communication with the PC.
2.	Trigger connector.

Bottom View



#	Description
1.	Device label. Contains SN of device.



Back and side view



#	Description
1.	PGND connector.
2.	CAP connector.

3.4 User interface

Connections

Туре	Function
USB connector	Gives the possibility to connect a power supply to the product or configure data transmission to be active over USB.
Trigger connector	Enables the user to connect an external device that generates digital trigger events. The connector supports 4 bits.

Subject connections

Туре	Function
Patient Ground (PGND) lead	Lead that can be connected to the subject in combination with a wristband or electrode.
EEG cap (CAP)	Accessory to interface the product with the subject. Typically, a headcap with either 24 or 32 channels.





Buttons

Туре	Function
Power	Switches the device on or off if the device is not sampling. Holding this button for 8 seconds triggers a device reset.
Event marker	Can be pressed by the subject or operator to log an event. Also, serves as a user confirm button to allow the pairing between APEX and the BT Dongle.
● REC Recording	Starts and stops recording on internal memory if the configuration allows a manual start/stop of the card recording. Can only be used when product is not opened in application software.

Status Indicators

(··) <u>\bigsigma</u> <u>\bigsigma</u>		
Indicator	Function and states	
Wireless Bluetooth (BT) Sensors	Reserved for future use th	
	 OFF: No information available on the connection quality of the headcap. GREEN (solid): All headcap channels are within acceptable quality criteria. ORANGE (solid): Reference channel(s) that cross(es) a user- 	
Headcap	 ORANGE (blinking @ 2 Hz): All channels are disconnected, only overflow values are measured. 	
	 OFF: No active connection to the PC. GREEN (solid): Active connection to the PC over USB interface available. 	

- BLUE (blinking @ 1 Hz): Waiting for pairing confirm to Dongle (that can be given by pressing the marker button).
- BLUE (solid): Active connection to the PC over BT interface available.
- ORANGE (blinking @ 2 Hz): Lost connection to the PC over BT interface.

PC Connection



Indicator	Function and states
Recording	 OFF: There is no ongoing recording. BLUE (solid): Impedance mode is active. GREEN (solid): Sampling mode is active. GREEN (blinking @ 4 Hz): Recording button press, to stop sampling mode, is registered (as long as the button is pressed). ORANGE (solid): Card is almost full. In current configuration, less than 120 minutes of data can be stored. Or, more than 80% of the available number of recordings is stored on the device. In sampling mode, the display of this state is alternated every 4 seconds. ORANGE (blinking @ 2 Hz): Card is full.
Power	 OFF: Device is in "Off" state. GREEN (solid): Device is in "On" state. When connected to external power supply, battery is full. GREEN (blinking @ 0.5 Hz): Battery is charging. GREEN (blinking @ 4 Hz): Power button press, to power down device, is registered (as long as the button is pressed). ORANGE (solid): Battery low (< 20% charge left). ORANGE (blinking @ 2 Hz): Battery very low (< 10% charge left).

The various ORANGE LED states indicate possible warnings and error messages. Please take care when encountering one of these messages and act accordingly to troubleshoot:

- "Headcap" warning state: Review signal quality and assess whether this is acceptable. If not, pay attention to preparation of the measurement setup.
- "PC connection" warning state: Ensure device is not positioned too far away from PC with BT Dongle.
- "Recording" warning state: Download data from card and remove files afterwards.
- "Power" warning state: Charge the device.

When APEX' (User Interface) seems unresponsive to user actions, please perform a device reset such as indicated in the "Power button" description.

3.5 Connections

PGND input

The Patient Ground must be connected to keep the amplifier in range. The Patient Ground connection can be made using a separate lead connected to the PGND input. For various accessories, the Patient Ground connection is also available in the CAP multi-connector. Consult the instructions for use of your accessories to check the presence of the PGND lead in the multi-connector.





CAP inputs

The CAP multi-connector includes 24 or 32 unipolar channels to connect an EEG accessory.

Wireless sensors (future use)

In the future, wireless BT sensors can be integrated in the APEX measurement setup.





3.6 Triggering

The trigger interface is accessible via the Trigger connector on the top-left side of APEX. It allows to acquire up to 4 digital input signals on the TRIGGER channel of APEX. Aside from logging events in the data stream, it is also possible to receive synchronisation events from external hardware.

The trigger input is low-voltage TTL compatible and electrically isolated from the subject. Refer to chapter 9 for detailed information regarding input signals. The trigger channel employs negative logic for digital inputs, meaning that a high-voltage trigger input signal is registered as a low trigger value. Passive button presses are registered on the data stream as a high trigger value. Hence, when using a digital trigger generated, it is recommended to use a high-voltage TTL pulse as 'base condition', whilst using a low-voltage TTL pulse as 'trigger event condition'.

Contact support@tmsi.com for details concerning the Trigger connector.

3.7 Device labels

Recorder



The device label can be found on the bottom of APEX. It contains general product information, in light text on black background and device specific information, black text on light background, such as Serial Number (next to SN), Reference number (next to REF) and device model. Please note that the depicted device specific information is an impression of the actual information that is found on the

label.

The device label also contains general product information. Please refer to chapter 2.1 for information about the meaning of all mentioned symbols.

BT Dongle

The BT Dongle's device label consists of two parts. A black part that is imprinted on the housing, containing general product information, and a grey part that contains the device specific



information, such as Serial Number (SN), Reference Number (REF) and Device Model.





4 INSTRUCTIONS FOR USE

4.1 Power Apex

APEX can be powered by holding the Power button for a short time (1 s) or by connecting APEX via USB to a PC. APEX contains rechargeable batteries that cannot be removed from the device. When the product has been idle for more than ten minutes, it will automatically power off. The user also has the possibility to power off the product manually, by holding the power button for 1.5 s. Both conditions are only applicable when APEX is not connected via USB.

Battery low indication

When the battery charge is lower than a certain level (20% charge left), the Power indicator in the status indicator window becomes orange. When the battery charge is below 10%, the status indicator blinks orange to indicate that it is time to charge the product. The batteries of APEX are charged via the USB-C port.

During data acquisition, APEX is not to be charged by using a charger connected to a mains power outlet. If you do wish to charge APEX during data acquisition, please use a portable power supply, such as a commercially available, certified power bank.

Battery life

A fully charged APEX has a battery life of approximately 2 hours.

4.2 Connect accessories

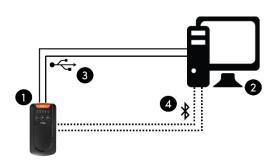
There are three connectors for accessories: the PGND connector, the CAP connector and the Trigger connector. The CAP multi-connector uses a 'Push-Pull' mechanism to prevent it from getting detached inadvertently. To make a connection, observe the alignment symbols (red dot) and gently push the plug into the socket of the APEX device. To disconnect, take hold of the plug at its moving sleeve, the part closest to the socket, and gently pull the plug out. Do NOT pull at the accessory wire or at the wire end of the plug. The trigger connector fits only in one orientation, which can be seen by checking both connectors.





4.3 Data connections

Refer to chapter 9 for used protocols, requirements and settings as applicable.



#	Description
1.	APEX
2.	Data acquisition PC
3.	Wired interface (USB) to send commands and receive data.
4.	Wireless interface (BT) to send commands and receive data using the BT Dongle.

The APEX product (1) can be connected to a PC (2) via a USB cable (3) and via a wireless BT interface, together with a Dongle (4). Both connections are used for control of the device and transfer of data to the PC where it can be stored for further processing. It is also used for sending commands from application software to APEX to control the device (start/stop, configuration updates etc.).

4.4 Software

System requirements

Computer requirements				
Supported Operating systems	•	Windows 10 (64 bit, x64-based)		
Available ports	•	USB-A port (2.0 or higher)		

Driver installation

Windows:

The latest version of the device driver can be downloaded from https://www.tmsi.com/support/. Follow the installer's instructions accordingly.



Application Software

Different types of application software are provided with APEX.

APEX User Application

The APEX User Application provides a Graphical User Interface to configure and control APEX in an intuitive manner. All device-related functionality is embedded in this application. Refer to the documentation provided with the application software for more information.

TMSi Python Interface (Windows)

TMSi has developed an interface to the Python programming language (www.python.org) that supports APEX. The interface can be downloaded free of charge on the TMSi website (www.tmsi.com/support) or directly from GitLab (https://gitlab.com/tmsi/tmsi-python-interface/).

The TMSi Python Interface can be used to configure APEX and stream data to your PC or process the data online in Python. The set of supported features may grow over time. Refer to the documentation provided with the Python interface for more information.

4.5 Wearability

Secure APEX to the subject

APEX can be worn by a subject by placing APEX in a dedicated cradle, that supports APEX to be worn close to the body. The backside of the cradle allows for the positioning of one or two straps, so that APEX can be worn on multiple places on the body. See the figure below for the positioning of APEX in the cradle.







4.6 APEX in an ME system

In case APEX is connected to other electrical equipment such as a charger or a personal computer, APEX is considered to be part of a ME system. The electrical safety depends on this other equipment as stated in the IEC 60601-1 requirements for basic safety and essential performance. Please note the following aspects when using APEX in a ME system:

- If APEX is connected to a computer, the computer and the monitor should be powered from an IEC 60601-1 certified separating transformer. A network cable, connected to the PC, should also be connected with a separating/isolator device. This is especially true if the computer is to be placed inside the patient environment. When the computer is placed outside the patient environment, IEC 60601-1 separating devices should be used in order to prevent an excessive leakage current originating from the USB connector shield.
- Do not connect an additional multiple socket-outlet or an extension cable to the separating transformer.
- If the computer is a laptop, an IEC 60601-1 certified power adapter for powering the laptop can be used as an alternative to the separating transformer.
- The internal batteries of APEX can be charged from the USB port of a computer. For fast charging, it is advised to connect APEX to a charging USB port. APEX regulates the charging current according to the available USB bus power.
- Although it is possible to charge APEX with a dedicated IEC 60601-1 certified USB charger adapter, this should not be done while doing a (wireless data) measurement because of the possibility of increased mains signal interference.





5 PERFORM A MEASUREMENT

APEX supports a variety of usage scenarios:

- Streaming data in stationary use (chapter 5.1).
- Previewing data in portable setting via wireless connection (chapter 5.2).
- Card recording without data streaming (chapter 5.3).

5.1 Perform Stationary Measurement

In a stationary measurement the data acquisition PC and measurement device are at a fixed place and do not move throughout the session. APEX rests on its rubber feet

Advantages

- Maximum data throughput.
- Most reliable data transmission.
- Simultaneous charging during use.

Disadvantages

Limited freedom of movement for subject.

When a USB cable is connected, a connection to the device can always be opened over the USB interface if no BT connection is active.

5.2 Perform Portable Measurement using Bluetooth

In the portable measurement setup, APEX is not connected to a PC. The portable setup uses Bluetooth for wireless data transmission to the BT Dongle, that is inserted into the PC. The wireless setup is optimal for usage scenarios where freedom of movement is an important requirement, whilst the researcher may still monitor the incoming data.

Please note that successful wireless data transmission can never be guaranteed. The amount of transmitted data is reduced by downsampling the data to half the selected sampling frequency. After completing a measurement, the full recordings (at the original sampling rate) can be retrieved from the on-board memory.

Factors that influence wireless transmission are:

- Other wireless networks (or RF devices such as smartphones, tablets).
- Electrical equipment (especially consider microwave ovens) in the vicinity of the APEX.
- The line of sight between APEX and BT Dongle. Metals and human beings tend to reflect or absorb some of the wireless signals.





Pairing of BT Dongle and APEX

The BT Dongle acts as an access point for APEX. The Dongle and APEX need to be paired by exchanging Bluetooth addresses. Application software provides the method to do so, together with a pairing confirm using the Event marker button. To do so, APEX' BT interface needs to be enabled. After that, the BT Dongle can be used to search for available APEX devices and may start a pairing procedure when it finds an unpaired device.

Data logging

Data is always logged on APEX's on-board memory in wireless recordings, making it available for download after a recording.

5.3 Perform Card recordings

In card recording setups, APEX is used as a data logger without the function of data streaming. Typically, this is a use scenario where it is not necessary to process or monitor the incoming data during a recording. The data is logged and can be downloaded from the on-board memory afterwards.

Measurement Configuration

A card recording can be tailored to your needs via the application software interface. The latest used device configuration is used for the recording.

Start/stop using the Recording button

The button on APEX marked with a Recording icon can be used to start and stop a card recording. Press and hold the button for 0.1 seconds to start recording. Press and hold for 1.5 seconds again to stop the recording. After powering the device, the Recording button can be used after approximately 5 seconds. The Recording button can't be used when there is an active connection between APEX and a PC.

Start/stop using recording time

In some use scenarios, the recording should start and stop at a specific moment in time. The start and stop recording times can be configured via the application software interface. The time of APEX can be synchronised to the time of the PC when APEX is connected to a PC. The device will start automatically when the start recording time is reached, even when it was powered down.

You can always access, retrieve and, when necessary, modify the configuration when you connect APEX via USB to the PC. A recording can be forced to stop by holding the Recording button for eight seconds.

Downloading measurement data from APEX

After the card recording is finished, the data can be retrieved via application software. The recordings can be downloaded and stored on the PC for further analysis. Depending on the configuration and length of the card recording, downloading all data may take a few minutes. In the meantime, the product cannot be used for other





measurements. APEX should be connected to a PC via a USB cable. Up to 50 card recordings can be present on the internal memory.

5.4 Impedance Measurement

APEX can be switched to impedance mode. In impedance mode the user can measure the electrode contact quality of all channels, including that of the Patient Ground electrode.

The impedance mode is activated via the application software interface. The impedance value ranges from 0 k Ω to 1000 k Ω and is an indication of electrode contact quality, where lower values indicate better electrode contact. If the impedance measurement indicates 1000 k Ω as value, there is no contact between skin and the electrode or the impedance is larger than 1000 k Ω . When the PGND electrode is not connected, all channels display a value of 1000 k Ω . Please note that if you're using a custom reference (other than all channels), that you prepare at least one of the reference channels before continuing with other channels.

APEX can also perform an impedance measurement in parallel to an active data measurement (live impedance). It does so at the same sampling frequency as the data is sampled with. Furthermore, the Cap status indicator allows for checking the real-time impedance value against a user-configurable threshold so that a warning can also be seen when APEX is not used in combination with application software. The impedance limit may be set between 10 and 100 k Ω . This limit is only checked for channels in the reference set, as poor connection quality in these channels may result in decreased signal quality in all other channels. Please note that the live impedance values are indicative for the quality during a measurement; the values are recorded at a different frequency than the conventional impedance measurement, resulting in lower values for the live impedance measurement.

If electrodes do not make good contact, effects that may appear are increase of noise, mains interference (50/60 Hz) or impedance values that toggle around the edge of connection/disconnection.

5.5 Status Events

There are three status channels, two cycling status channels that display relevant device information, and one more general-purpose status channel that contains less frequent changing device information. The metadata of the cycling status channel (CYCL_IDX) shows which information is available at the checked sample.

The channel 'STATUS' can record several events. These events may be user triggered or triggered by the device itself. The events are used to provide information about what happened with the device during recordings. The trigger input data is also stored in this channel. The following status events are available.

Status Event	Origin	Bit #	Meaning
Marker event	User	0	0 = No marker event1 = Event marker button pressed





Status Event	Origin	Bit #	Meaning
Trigger event (#1)	Trigger	1	0 = Trigger event registered on bit 1.1 = No trigger event registered on bit 1.
Trigger event (#2)	Trigger	2	0 = Trigger event registered on bit 2.1 = No trigger event registered on bit 2.
Trigger event (#3)	Trigger	3	0 = Trigger event registered on bit 3.1 = No trigger event registered on bit 3.
Trigger event (#4)	Trigger	4	0 = Trigger event registered on bit 4.1 = No trigger event registered on bit 4.
Average Reference removal	User	5	0 = Reference removal is not enabled.1 = Reference removal is enabled.
		6 14	Reserved for future use.
Battery low	Device	15	0 = Battery not low.1 = Battery low (needs charging).

The bits in column Bit # are numbered 0 to 15, for the least to most significant bits respectively. Depending on the application software used, they may show to be numbered 1 to 16 respectively.

Event marker Button

The Event marker button on the device can be used to set a Marker event in the Trigger channel. This Marker event is sampled synchronously to the other data.

Typical use of this button is to mark a specific event during a card recording, so that this event can be detected afterwards.

Trigger input

APEX' four trigger bits information are stored on the device's STATUS channel. The trigger inputs are binary inputs that are stored sample synchronous to the recorded EEG data, using negative logic as described in chapter 3.6 and outlined in the table above.

Battery low

APEX runs on internal batteries. When the battery charge is low, APEX logs an event. At this point, APEX should be connected to an external power supply. When the batteries run empty, APEX will close any running data acquisition session and power down.





6 OPERATIONAL PRINCIPLES

6.1 APEX

APEX is an amplifier for EEG measurements designed for optimal signal quality. The APEX amplifier is characterised by low input noise, high input impedance and high common mode rejection. It is a true DC reference amplifier with high resolution. It uses active signal shielding to minimise electrode cable capacitance and thereby minimises cable movement artefacts and sensitivity to mains interference (50/60 Hz).

APEX is an amplifier specifically developed with EEG applications in mind; it offers both wireless and wired setups, at a sampling frequency of 1000 or 1024 Hz. Furthermore, a 4-bits trigger interface is available, so that events can be logged and studies on event-related potentials can be performed with ease. For a full list of (technical) specifications, please refer to chapter 9.

The unipolar channels of APEX are configured as an Average Reference amplifier, where all channels are included in the reference. The user is allowed to configure which channels are used as reference channels.

Application software installed on the computer controls the APEX measurement functions.

6.2 Unipolar input channels

The input stage for measuring unipolar electrophysiological signals is configured as an Average Reference amplifier. All signals are amplified against the average of all connected unipolar inputs. Inputs that are not connected to an electrode are automatically switched off. These channels will show an overflow value.

Reference

The device is always configured as an average reference amplifier. However, when only a single channel is selected to make up the reference, the configuration is essentially a common reference amplifier. Another advantage of selecting your own reference channels is that you may decide to exclude channels that are prone to introduce artefacts, such as eye blinks on pre-frontal electrodes, from your reference signal. This allows for a versatile measurement setup.

Active signal shielding

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. There are no notch filters built into the device.





6.3 Tips for obtaining optimal quality data

Placement of device

Mains interference (50/60 Hz) is coming from external sources. This can be many things. It is a common mistake to state that battery powered devices are not susceptible to mains interference and devices powered from mains are. Mains interference can get into your measurement system via multiple ways, for example from other electrical equipment close by. Optimal placement of systems will increase the quality of the acquired data.

Patient Ground connection

TMSi recommends to use a saline wetted wristband, or to clean/prepare the skin as good as possible for optimal skin contact when using electrode patches as Patient Ground electrode. Preferably, the Patient Ground electrode is not too close (within ~5cm) to the measurement electrodes. Higher Patient Ground electrode impedance may cause more mains interference in all measurement electrodes.

Electrode materials

APEX is a DC-coupled amplifier with a high input range of +/-150 mV. This is more than sufficient for common measurement setups. The skin-electrode interface acts as a battery which causes a DC-shift in the signal of several millivolts up to a few hundred. If all electrodes, including Patient Ground, are made of the same material, this will not be a problem at all. If materials are mixed (for example gold electrodes or platinum electrodes are used in combination with Ag/AgCl electrodes), the DC shift can cause out-of-range channels.

Different electrode materials have different DC characteristics. Some materials may drift a lot, whereas others are fairly stable over time. TMSi recommends Ag/AgCl, as it is known to be a very DC-stable material and is used in most of the commercially available electrodes for contacting intact skin.

Electrode movement artefacts

When cables pull on the electrode, this is visible in the data as a DC-shift, because of the change in skin-electrode interface. This can be prevented by making a strain relief loop in the cabling. If for some reason the cable is pulled, the strain relief prevents that the cable also pulls on the electrode, causing artefacts. Cable movement in itself is not a problem thanks to APEX's active shielding technology.

Re-referencing/Artefacts

If during a measurement an electrode is causing artefacts in the data it may be necessary to exclude this electrode from the measurement data. In Average Reference mode APEX measures its signals against the average of all configured electrodes. This means that if an electrode becomes disconnected, this electrode is immediately taken out of the average calculation. Re-referencing is needed when a channel needs to be removed from the measurement set completely.





7 MAINTENANCE

7.1 Servicing and Updates

The product does not contain user serviceable parts. Maintenance is limited to cleaning at user discretion. 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.

Bug fixes or improvements to the firmware may become available for download from the website (www.tmsi.com). Such updates can be performed by the user. Follow the instructions accompanied with the update package carefully. Not complying with these instructions may cause the device to become unusable.

7.2 Cleaning instructions

- Before cleaning, make sure the product is switched off and not in contact with a subject.
- Use only tap water, with a mild detergent if necessary, applied through a soft damp cloth.
- Do not spill fluids or submerge the product in liquids.
- Do not use sharp tools or aggressive chemicals for cleaning or disinfecting.
- The product surface can be disinfected with disinfection wipes based on 70% isopropyl alcohol. Other disinfectants may damage the product. Never use chlorine-based disinfection products.
- Do not sterilise the product.

7.3 Disposal instructions

Environmental protection

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



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

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

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





8 ELECTROMAGNETIC GUIDANCE

8.1 Degradation of performance

Electromagnetic disturbances, such as electrostatic discharge, mains supply overvoltage spikes and mains interruptions may cause the following types of degradation of performance:

- Noticeable artefacts on signals. These should be discarded because they are clearly non-physiological signal traits.
- Transient interruptions of signal data communication; in extreme cases, cessation of data communication. Data does not appear on screen, but signal acquisition continues and signal data is recorded on the device's onboard memory.
- As a result, the APEX product may need to be reset (recycle power).

Basic safety is not affected by these phenomena.

To prevent electrostatic discharges, relocate the measurement to an environment with anti-static floor and furniture and/or do not unnecessarily touch product parts. Further guidance can be found in the tables on the following pages.

Portable and mobile RF communications equipment can affect the performance of the APEX product by:

- Disturbing data communication within the product. This may cause loss of measurement data for real-time processing or display on the PC. The data can be retrieved from the on-board memory.
- Increasing noise level on signals, large offset shifts or causing signal distortion in extreme cases.

Basic safety is not affected by these phenomena.

To minimize their interference, keep portable and mobile RF communications equipment at sufficient distance from the product.

The product needs special precautions regarding EMC and must be installed and put into service according to the EMC information outlined on the next pages.

8.2 Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Emission test	Compliance	Electromagnetic environment – guidance
RF emissions EN 55011	Group 1	The product 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 EN 55011	Class B	APEX is suitable for use in all establishments, including domestic establishments and those directly





Harmonic emissions IEC 61000-3-2	Class B	connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

8.3 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Complian ce level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV ±15 kV	Degradation of performance may occur: Electrostatic discharges may result in air sparks at connectors coincident with signal loss. Sometimes a measurement restart is required. For further information refer to chapter 8.1. Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Radiated RF EM fields IEC 61000-4-3	10 V/m (80 to 2 700) MHz 80 % AM at 1 kHz	10 V/m	Degradation of performance may occur: Electromagnetic radiation may distort and disturb acquired signals. At some frequencies the live communication link may be interrupted and sometimes a measurement restart is required. For further information refer to chapter 8.1.





Guidance and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Complian ce level	Electromagnetic environment – guidance
Proximity fields from RF wireless	27 V/m At 385 MHz, 1.8 W, 18 Hz pulse modulation	27 V/m	Degradation of performance may occur: Electromagnetic radiation may distort and disturb acquired signals. At some frequencies the live
communication s equipment IEC 61000-4-3	28 V/m At 450 MHz, 2 W, 1 kHz sine FM modulation with ±5 kHz deviation	28 V/m 9 V/m	communication link may be interrupted. For further information refer to chapter 8.1. Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than 0.3 m.
	9 V/m At 710 MHz, 745 MHz and 780 MHz, 0.2 W, 217 Hz pulse modulation	28 V/m	
	28 V/m At 810 MHz, 870 MHz and 930 MHz, 2 W, 18 Hz pulse modulation	28 V/m	
	28 V/m At 1720 MHz, 1845 MHz and 1970 MHz, 2 W, 217 Hz pulse modulation	28 V/m	
	28 V/m At 2450 MHz, 2 W, 217 Hz pulse modulation	9 V/m	
	9 V/m At 5240 MHz, 5500 MHz and 5785 MHz, 0.2 W, 217 Hz pulse modulation	o viiii	
Electrical fast transients / burst IEC 61000-4-4	±2 kV 100 kHz repetition frequency for power supply lines±1 kV for input/output lines	±2 kV NA	Degradation of performance may occur: Electrical transient pulses on AC mains may distort and disturb acquired signals. For further information refer to chapter 8.1. Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	±1 kV Line-to-line ±2 kV Line-to-ground	±1 kV NA	Degradation of performance may occur: During surges transient signal interruptions may occur. For further information refer to chapter 8.1. Mains power quality should be that of a typical commercial or hospital environment.



Guidance and manufacturer's declaration - electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The customer or the user of the product should assure that it is used in such an environment.

Immunity test	IEC 60601-1-2 test level	Complian ce level	Electromagnetic environment – guidance
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V ¹ (0.15 to 80) MHz 80 % AM at 1 kHz 6 V ¹ in ISM and amateur radio bands within (0.15 to 80) MHz 80 % AM at 1 kHz	3 V 6 V	Degradation of performance may occur: High level conducted disturbances on AC mains may cause data communication loss, on other connections including subject connections they may cause transient signal interruptions. For further information refer to chapter 8.1.
Rated power frequency magnetic fields IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	N.A. ⁴	The product is not intended for environments with restricted access due to strong magnetic fields.
Voltage dips IEC 61000-4-11	$0\% \ U_{T}^{2}; \frac{1}{2} \ \text{cycle}$ At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° $0\% \ U_{T}^{2}; 1 \ \text{cycle}$ and $70\% \ U_{T}^{2}; 25/30^{3} \ \text{cycles}$ Single phase: at 0°	0 % U _T	Mains power quality should be that of a typical commercial or hospital environment.
Voltage interruptions IEC 61000-4-11	0 % U _T ² ; 250/300 ³ cycles	0 % U _T	The operation of the device is not interrupted because it is powered from the internal battery in case of a power interruption.
Electrical transient conduction along supply lines ISO 7637-2	As specified in ISO 7637- 2	N.A. ⁵	

Notes:

- This is the R.M.S. level, before modulation is applied.
- 1. 2. 3.
- 4.
- U_T is the A.C. mains voltage prior to application of the test level. E.g. 10/12 means 10 periods at 50 Hz or 12 periods at 60 Hz. Applies only to devices with magnetically sensitive components or circuitry. Applies only to devices intended to be powered from 12/24 V road vehicle power systems. 5.



8.4 Compliance Information

This device complies with part 15 of the FCC Rules and to RSS of Industry Canada.

Operation is subject to the following two conditions:

- (1) this device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Canada ICES-003 compliance statement:

This Class B digital apparatus complies with Canadian ICES-003. Cet appareil numerique de la classe B est conforme a la norme NMB-003 du Canada.

FCC class B Device Notice

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- · Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio / TV technician for help.



9 TECHNICAL SPECIFICATIONS

Use the REF number on the device label to identify the device configuration.

General S	General Specifications				
Model	REF: 95-1300-0200	APEX	Amplifier		
	REF: 95-1305-0200	BT Dongle	Dongle		
REF		See device label			
Size (device	e only)	Recorder: 150 x 75 x 30 mm			
		Dongle:	70 x 25 x 10 mm		
Weight		Recorder:	240g		
		Dongle:	16g		
Power consumption		Recorder:	<2 W on battery power <10 W when charging		
On-board s	On-board storage		able		
Regulator	y Specifications				
Power sour	Power source		r power supplied by PC or by using a ger.		
Mode of op	eration	Continuous operation			
Electric sho	ock protection	Applied parts: Type BF			
Applied par	Applied parts		Refer to chapter 3.2.		
Accessible	Accessible parts		2.		
Ingress pro	Ingress protection		IP22 (APEX)		
		• •	ticulate matter with ≥12.5 mm diameter and ping water when 15° tilted		





Battery	
Battery	Lithium Polymer, 3.7V, 1320 mAh, non-removable
Power Saving	10 minutes (idle, no connection to PC)

Communication Recorder to PC				
Bluetooth	Band	2.4 GHz		
	Range	10 m		
	Power	8 dBm		
	Bandwidth	Maximum 1 Mbit/s under ideal circumstances		
	Modulation	GFSK		
	Standard	5.2		
USB	Bandwidth	Maximum 480 Mbit/s		
	Standard	2.0		
	Cable	Type C to Type A connector (default option) or Type C to Type C connector. Length < 3 m		

BT Dongle		
Bluetooth	Band	2.4 GHz
	Range	10 m
	Power	8 dBm
	Bandwidth	Maximum 1 Mbit/s under ideal circumstances
	Modulation	GFSK
	Standard	5.2

Transportation Conditions		
Temperature	-20 °C to +60 °C	
Humidity	15 % to 85 %, non-condensing	
Pressure	600 hPa to 1 100 hPa	

Storage Condition	ns	
Temperature	0 °C to +40 °C	
Humidity	15 % to 85 %, non-condensing	
Pressure	600 hPa to 1100 hPa	





Usage Conditions	3
Temperature	+5 °C to +40 °C
Humidity	15 % to 85 %, non-condensing
Pressure	700 hPa to 1 060 hPa

CAP Channel Spe	ecifications		
Number of channels	32 or 24 (depending on firmware version)		
RMS noise (0.1 to 100) Hz	<1 µVrms		
Input Range (Differential Mode)	-150 mV to +150 mV (@ 0 V common)		
Input Range (Common Mode)	-2 V to +2 V (@ 0 V differential)		
Resolution (bits)	24 bits		
Resolution (voltage)	<20 nV		
Accuracy	2 %		
Input impedance	>2 GΩ, <1 pF		
Common Mode Rejection Ratio	>90 dB (@ 50/60 Hz), inputs referred to PGND		
Amplifier concept	Average Reference amplifier, with selectable channels to set reference		
Shielding	Individual signal shielding		
Supported Sampling Rates	1024 / 1000 Hz		
Analogue bandwidth	DC to 350 Hz		
Impedance Mode	Separate mode, including Patient Ground impedance measurement		
	Range	0 kΩ to 999 kΩ, special values are: 1000 kΩ overflow, or the channel impedance is ≥1000 kΩ	
	Accuracy	10 % of reading + 1 kΩ	
	Resolution	1 kΩ	
		. 102	



Synchronisation Specifications			
Number of inputs 4 on F		4 on Recorder (TRIGGER input),	
Electrical		Trigger input	
Voltage range	[V]	0 to 3.3	
Low level	[V]	≥2.0	
High level	[V]	≤0.8	
Current @ High	[mA]	-0.1 to 0.1 ^(a)	
Current @ Low	[mA]	-0.1 to 0.1 ^(a)	
		Notes:	
		(a) The input current will typically be close to 0 mA.	
Synchronicity		Trigger input	
Wired [sa	mples]	1	

Channel Overview		
Name	Connection	Remarks
CAP 01 to	CAP	CAP 01 to CAP 24 for 24-channel variant.
CAP 32		
PGND	PGND and CAP	Channel output only available in impedance mode
TRIGGER	TRIGGER	See chapter 5.5
CYCL_IDX	Internal	See chapter 5.5
CYCL_ST1	Internal	See chapter 5.5
CYCL_ST2	Internal	See chapter 5.5
STATUS	Internal	See chapter 5.5
COUNTER	Internal	



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