Instructions for Use

TOF 3D

Neuromuscular Transmission Monitor

MIPM Mammendorfer Institut für Physik und Medizin GmbH, herein after called MIPM.

Printed in Germany

Subject to change without prior notice. For further information contact MIPM.

MIPM assume no responsibility for damages, which can result from using the monitor.
The monitor is intended for use by qualified medical personnel only.

Before using the monitor, read all the manuals that are provided with your device carefully. Patient monitoring equipment, however sophisticated, should never be used as a substitute for the human care, attention, and critical judgment that only specialists, anesthetists and nurses with specialization in anesthesia care can provide.

➤ **NOTE:** A note presents information that helps you operate the equipment or connected devices.

! ***CAUTION:*** *A caution provides information or instructions that must be followed to ensure proper operation and performance of the equipment.*

WARNING: A warning contains important information regarding possible danger to the user or the patient that is present during normal operation of the equipment.

TOF^{3D} operating system software version: v3.1

List of contents

1. Introduction

1.1 Intended use

The TOF^{3D} is used to objectively monitor the level of neuromuscular transmission by measuring muscle contraction following stimulation. The TOF^{3D} can also be used as a peripheral nerve stimulator (without the objective measuring function) for subjective monitoring.

The TOF^{3D} is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care.

Patients:

The device is intended for use for adolescents greater than 18 through 21 years of age, and adults.

Excluded operating environment:

The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable environment or environment with sources of intense electromagnetic disturbances (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short wave therapy equipment is used).

Contraindications:

There are no known contraindications to the use of the device.

Prescription:

In the USA, federal law restricts this device to sale by or on the order of a physician.

Clinical benefits of neuromuscular transmission monitoring:

Avoiding complications for the patient caused by residual paralysis. These complications could be for example:

- pharyngeal dysfunction
- increased risk for aspiration and pneumonia
- acute respiratory events
- residual paralysis increases patients discomfort in general.

The monitoring of neuromuscular transmission helps managing the targeted and effective dosage of NMBAs.

1.2 General

Monitoring the effect of neuromuscular blocking agents (NMBAs) can be accomplished in several ways.

Accurate and objective information on the degree of neuromuscular paralysis can be obtained by measuring the force of contraction of a certain muscle (mechanomyography).

A good alternative for mechanomyography is the measurement of muscle acceleration (acceleromyography). According to the second law of Newton: Force equals Mass times Acceleration (F = M * a). **Thus, the acceleration can be used to obtain the muscle force.**

It has been shown that there is a good correlation between the results of acceleromyography and mechanomyography.

1.2.1 Abbreviations

IEC - International Electrotechnical Commission

s - Seconds

mA - Milliampere

µC - Microcoulomb

°C - Degree Celsius

NMB - Neuromuscular Block

NMBA - Neuromuscular Blocking Agent

NMT - Neuromuscular Transmission

NMTM - Neuromuscular Transmission Monitor

LCD - Liquid Crystal Display

TOF - Train of Four

IFU - Instructions for use

AMG – Acceleromyography

MMG - Mechanomyography

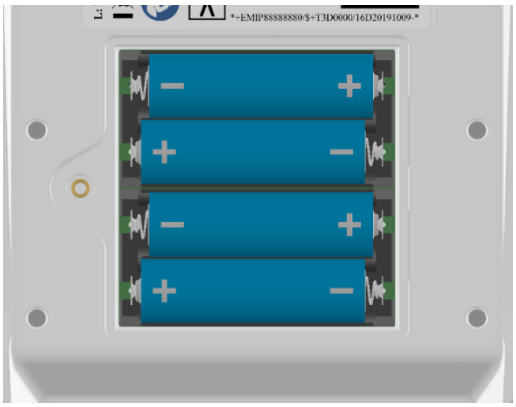
1.3 Actions upon delivery

Upon delivery of TOF^{3D}, please check package contents for completeness and any possible transportation damage.

TOF^{3D} storage conditions are given in chapter 6.1 “Technical Specifications”.

To power the device, 4x 1,5V AA Alkaline or NiCd/NiMH Batteries are required. Insert batteries as shown in battery compartment.

Batteries should only be changed by technically qualified personal. Rechargeable batteries can be used with external recharging.



CAUTION: *Pay attention to battery polarity!*
In case battery fluids are being leaked, the device must be taken out of operation.

1.4 Safety Information

1.4.1 General Safety

CAUTION: *Read all operating instructions carefully before using the device. Specific warnings and cautions are found throughout this IFU where they apply.*

WARNING: The TOF^{3D} must only be used by qualified and trained medical staff. In order to be trained, please contact MIPM or an authorized representative.

- Maintenance, repairs and modifications shall only be carried out by authorized personnel.
- Replace components with MIPM approved spare parts only.
- The device has to be used in accordance with MIPM Operating Instructions. A full technical description is available upon request from your local MIPM representative.

1.4.2 Electrical Safety

WARNING*:* Danger of electric shock

- Do not immerse TOF^{3D} in liquid. This may lead to electrocution.
- Do not open device.
- Maintenance, repairs and modifications are only carried out by authorized personnel.
- The product only fulfils the requirements written in the documentation if the use, handling as well as all maintenance, repair and service works are in accordance with the instructions in this IFU.
- MIPM recommends performing a function test and electrical safety test every 12 months. Please refer to your national regulatory requirements.
- Always perform functional check before using device.
- A damaged device may not be used! Missing parts or parts that are broken, worn out or contaminated must be replaced. If repair of the device or its accessories/components are necessary, please contact your technical service, your local dealer or MIPM directly.
- This device and its internal components shall only be repaired or changed after MIPMs written approval.
- User is solely responsible for malfunctions that arise due to faulty handling or maintenance as well as inadequate repair works or changes to device performed by unauthorized personnel.

1.4.3 Safety for sequence of operation

- Device allows changing of certain stimulation parameters - also while stimulating.
- Device blocks repeated and unnecessary potentially unpleasant electrical stimulations from reaching patient.

WARNING: In case of malfunction, do not continue the operation. Remove all applied parts from the patient and take the device out of operation.

In case of a serious incident please contact MIPM or your local distributor, a service technician or a competent authority of the member state in which the user or the patient are established to report the incident.

CAUTION: Pay attention to ESD safety conditions

- Electronic components and semiconductors can be destroyed by electrostatic discharge (ESD). In particular, MOS components can be damaged from direct or indirect discharges. Damage caused by ESD is sometimes not immediately identifiable and malfunctions can even occur after a longer period of operation.
- All panel connectors and communication ports are sensitive to electrostatic discharges; it is necessary to take precautions before touching connectors (pins or shield), connecting or disconnecting associated cables.
- Touching communication ports without taking ESD precautions may result in potentially fatal error and ESD protection failure.
- Points (e.g. screws) and surfaces that are only accessible for maintenance also require precautions.
- Points (e.g. battery contacts for battery replacement) and surfaces that are accessible for intervention service users also require precautions.

1.4.4 Maintenance

WARNING: Due to the danger of electric shock, never remove the cover of any device during operation.

In interest of patient safety, regular equipment inspection and maintenance are required. Once a year (every 12 month), check all cables, device, batteries and accessories for damage, chassis and patient leakage currents and all monitor functions. Also ensure that all safety labels are legible. Maintain a record of these safety checks. For additional information, refer to Service Manual.

- A function test must be performed before each application of this device. Do not utilize this device if known damage exists. Missing, broken, worn out or soiled parts must be replaced before application. In the event that a repair or part replacement is necessary, please contact your local distributor, or MIPM**.**
- This device, its components and optional accessories may only be repaired or changed by authorized and qualified service personnel. The user of this device is solely responsible for any failure of the device to perform properly due to unauthorized and incorrect maintenance, incomplete repair, or damage and changes made by unauthorized personnel.

NOTE: The service life of the TOF^{3D} is 10 years from the year of manufacturing indicated on the device label. Do not operate the device for longer than 10 years.

1.5 Reducing the EMI

To reduce possible problems caused by **e**lectro**m**agnetic **i**nterference, we recommend following:

➤ **NOTE:** Use of accessories and cables other than those recommended by MIPM, could result in increased electromagnetic emissions and / or decreased electromagnetic immunity of TOF^{3D} system and result in improper operation.

- Use only MIPM-approved accessories.
- Ensure that other products used in areas where patient monitoring and/or life-support are used comply with legal emissions standards.
- Strictly limit exposure and access to portable radio-frequency sources (e.g., cellular phones and radio transmitters). Be aware that portable phones may periodically transmit even when in standby mode**.**
- All portable RF equipment, including peripheral and external antennas, should not be used closer than in a 30cm radius of the device.
- Maintain good cable management. Do not route cables over electrical equipment. Do not intertwine cables.
- Ensure all electrical maintenance is performed by qualified personnel.
- The operating environment of the TOF^{3D} is hospital operating rooms and intensive care units, meaning professional healthcare facility environment. This environment does not include areas of the hospital where there is sensitive equipment or sources of intense electromagnetic disturbances, such as the Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories, shielded rooms, or areas where short- wave therapy equipment is used.
- The medical electrical equipment needs special precautions regarding EMC and needs to be used according to EMC information**.**

WARNING: Do not stack the TOF^{3D} directly on top of other electronic equipment. If stacking is necessary, observe the TOF^{3D} to verify normal operation before applying it to the patient.

WARNING: Exceeding and / or repeating the test level attained in guidance and manufacturer's declaration on EMC may permanently damage device and / or cause serious malfunctions as loss of communication and system reboot.

➤ **NOTE:** The TOF^{3D} has been tested to retain safety and performance in the presence of strong electromagnetic disturbance signals. Strong electromagnetic disturbance signals may cause small fluctuations in display readings within the allowed specifications. Strong electromagnetic disturbance signals may potentially suspend an ongoing stimulation as the disturbance signal may bring the stimulation outside the acceptable tolerance. This is detected by the TOF^{3D} and the TOF^{3D} stops stimulation and signals an alert.

1.5.1 Guidance and manufacturer's declaration on EMC

Emission (Radio Frequency)

Compliance with standards/tests – electromagnetic emission		
The TOF^{3D} is suitable for use in the Professional healthcare facility environment. The user of the TOF^{3D} should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Further information**
RF emissions CISPR 11	Group 1 Class A*	The TOF^{3D} 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.
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in hospitals (CISPR 11 class A).		

Immunity (Electrostatic discharge / magnetic fields)

Compliance with standards/tests – electromagnetic immunity	
The TOF^{3D} is suitable for use in the Professional healthcare facility environment. The user of the TOF^{3D} should assure that it is used in such an environment.	
IMMUNITY test	**IEC 60601 test level: Compliance level**
Electrostatic discharge (ESD): IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Power frequency magnetic field: IEC 61000-4-8	30 A/m - 50 Hz 30 A/m - 60 Hz

Immunity (Radio Frequency)

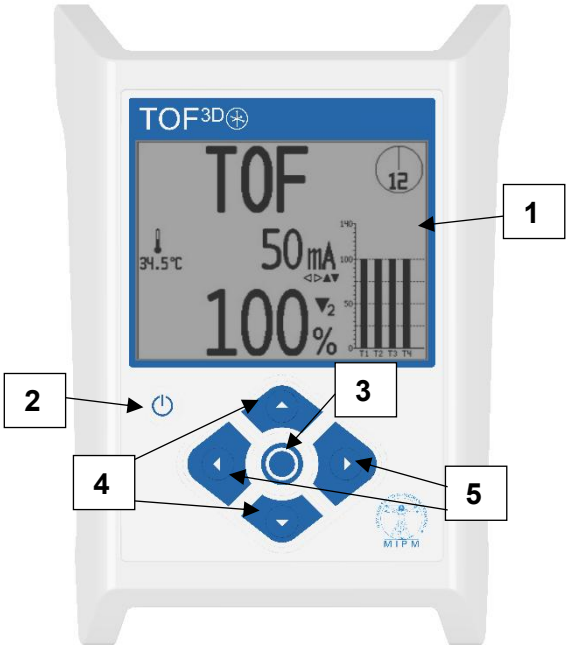
Compliance with standards/tests – electromagnetic immunity			
The TOF^{3D} is suitable for use in the Professional healthcare facility environment. The user of the TOF^{3D} should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level: Compliance level**		
Conducted RF: IEC 61000-4-6	150kHz - 80MHz	3Vrms	80 % AM at 1kHz
	150KHz - 80MHz ISM bands & amateur radio bands	6Vrms	80 % AM at 1kHz
Radiated RF: IEC 61000-4-3	80MHz - 2.7GHz	3 V/m	80 % AM at 1kHz
Proximity fields from RF Wireless communications Equipment: IEC 61000-4-3	385MHz	27V/m	Pulse modulation, 18Hz
	450MHz	28V/m	Pulse modulation, 18Hz
	710; 745; 780MHz	9V/m	Pulse modulation, 217Hz
	810; 870; 930MHz	28V/m	Pulse modulation, 18Hz
	1720; 1845; 1970MHz	28V/m	Pulse modulation, 217Hz
	2450MHz	28V/m	Pulse modulation, 217Hz
	5240; 5500; 5785MHz	9V/m	Pulse modulation, 217Hz
Proximity RI-magnetic fields: IEC 61000-4-39	30kHz	8A/m	Pulse modulation, CW
	134,2 kHz	65A/m	Pulse modulation, 2,1 kHz
	13,56MHz	7,5A/m	Pulse modulation, 50 kHz

2. Device and symbol description

2.1 Device description

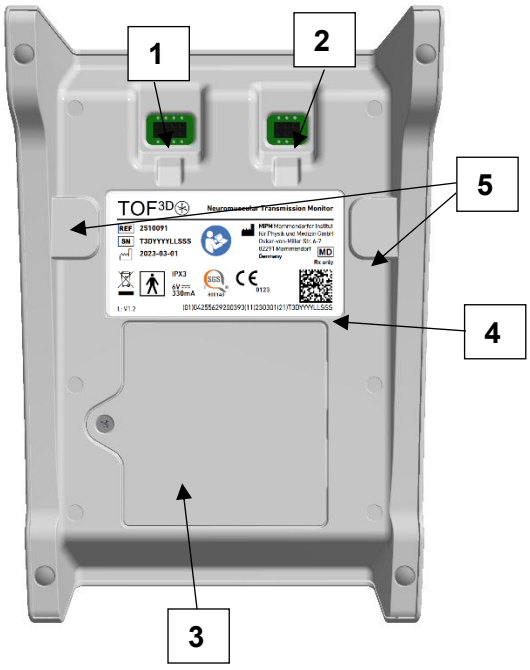
The TOF^{3D} is a neuromuscular transmission monitor used during surgery or intensive care unit. The quantitatively monitor of the level of neuromuscular transmission by means of acceleromyography or with mechanomyography.

2.1.1 Front



1. Display
2. On / Off key
3. Center Key
4. Up / Down keys
5. Right / Left keys

2.1.2 Back



1. Socket for Patient cable
2. Socket for USB Interface cable
3. Battery Compartment
4. Device Labeling
5. Adapter for IV-pole-holder

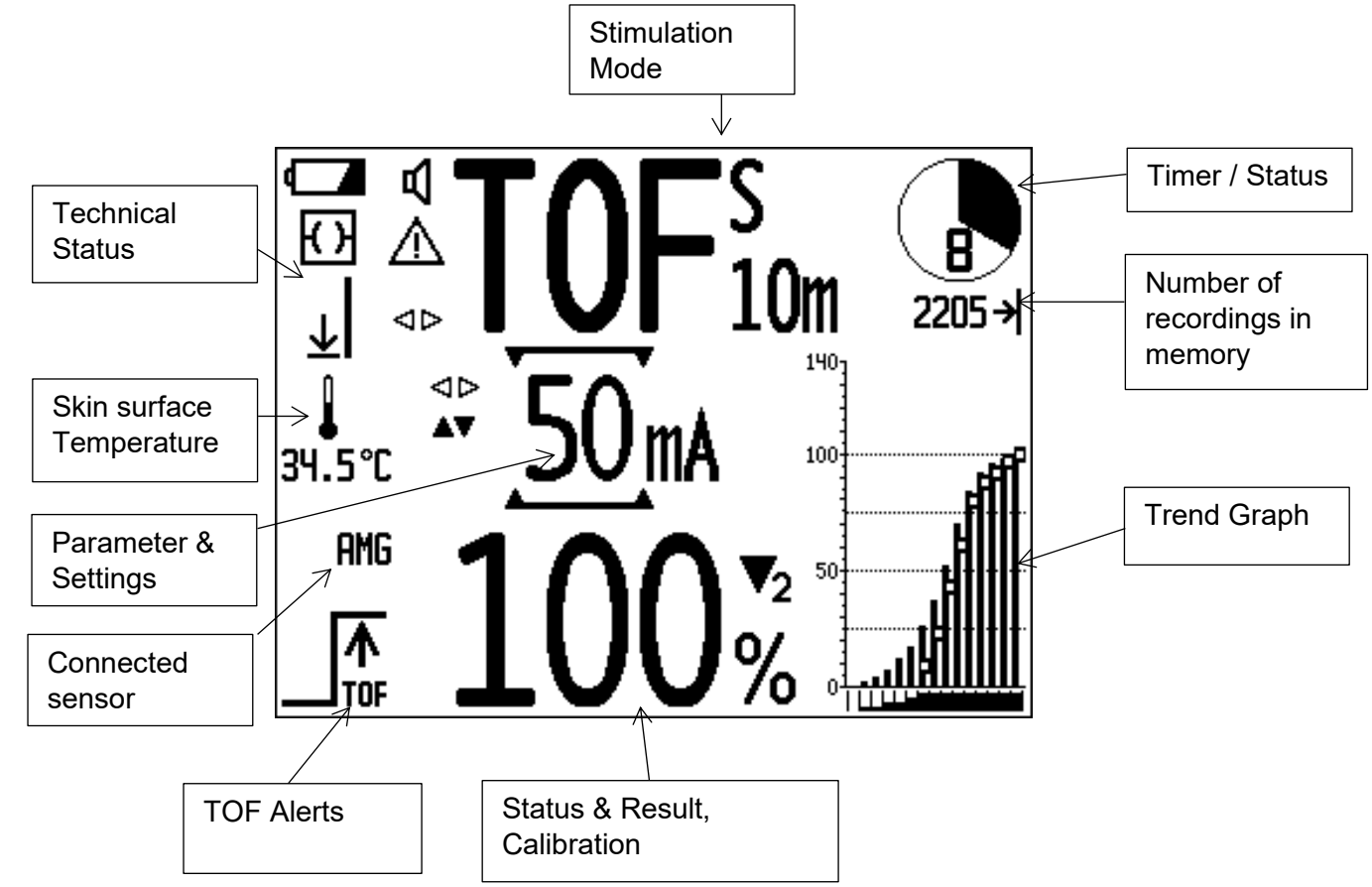
2.1.3 Explanation of Symbols/Labeling

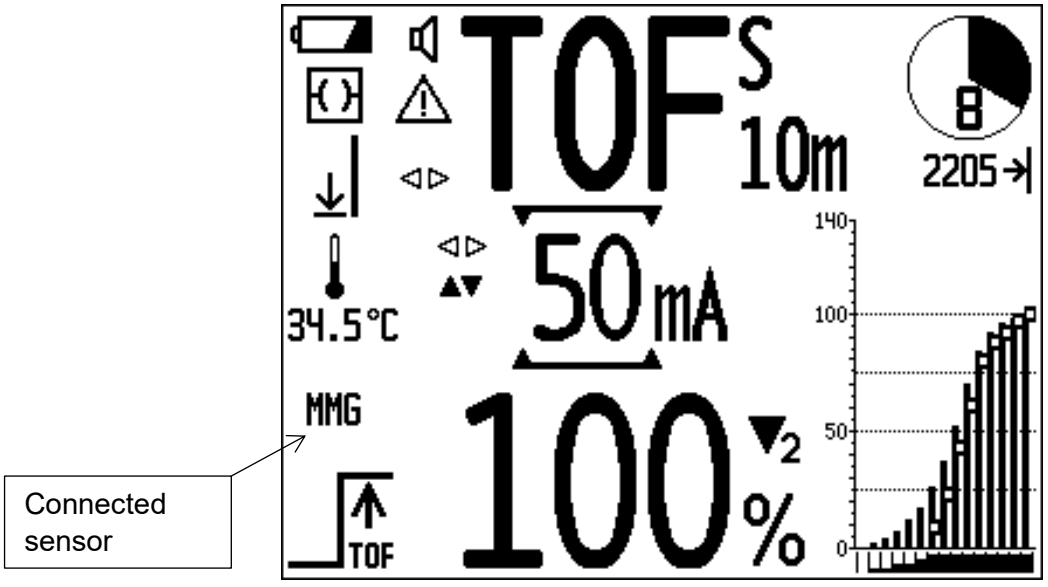
The symbols in the following table may appear on the labeling of TOF^{3D} Neuromuscular Transmission Monitor, the accessories/components, spare parts or the packaging material.

Symbol	Description
TOF^{3D}	Brandname
	"ON"/"OFF" (push-push)
QTY:	String/symbol on label for quantity
REF	Product reference / part number
SN	Product serial number
LOT	Batch/LOT code
Country of origin: Denmark	String/symbol on label for "Country of origin: [country]"
	Date of manufacture YYYY-MM-DD
	Manufacturer
MD	Medical Device
	Obligation for the user to refer to the Instructions for Use (User Manual)
	Parts included in a recovery / recycling process
	A BF (Body Floating) application part is connected to the patient's body to transmit electrical energy or an electrophysiological signal to or from the body (not defibrillation protected).
IPX3	Protection against water spray at an angle of up to 60°
	Direct current (DC)
Rx only	Caution: Federal Law in the United States restricts the device to sale by, or on the order of a physician.
CE **0123**	CE Marking
	Indicate the pressure conditions allowed for transport
	Temperature conditions allowed for transport and specifying the temperature range within which the package must be stored. (Indicate in °C and °F)
	Indicate the humidity conditions allowed for transport
	Fragile, handle with care
	Keep dry

Symbol	Description
	Does not contain or presence of natural rubber latex
	Do not reuse
L:Vx.x	Label Version: Vx.x **x.x**: corresponds to label version
	SGS Safety Certification for US and Canada (NRTL)
	Format GS-1 DataMatrix Barcode - AI 01 = GTIN (fix 14-digits numeric) - AI 11 = Date of manufacture YYMMDD (fix 6-digits, numeric) - AI 10 = LOT Number (variable 1…20-digits, alphanumeric) - AI 17 = Expiration date (fix 6-digits, numeric) - AI 21 = Serial Number (variable 1…20-digits, alphanumeric)
	INMETRO Seal (for Brazil)

2.1.4 Survey of display





2.1.5 Parts of TOF^{3D}

Medical Device

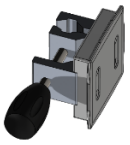
For usage of the TOF^{3D} following components are mandatory:

Product	MIPM REF	Remark
TOF^{3D} – Neuromuscular Transmission Monitor (NMTM)	2510091	Medical Device

Consists of the following necessary components:

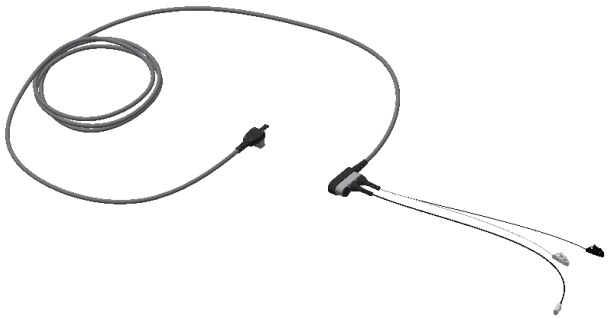
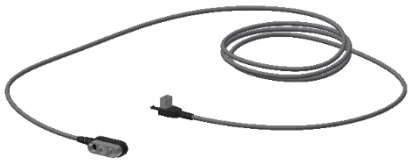
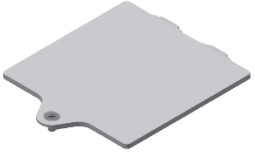
Product	MIPM REF	Remark
TOF^{3D} Unit (multi use)	5750118	 Base Component
Main Cable TOF^{3D} (multi use)	5750108	 Cable from device to split connector
Split connector sealing plug TOF^{3D} (multi use)	5750116	 Cover to seal an open port on split connector
Stimulation cable TOF^{3D} (multi use)	5750107	 Cable with two electrode clamps to connect the stimulation electrodes with main cable
Acceleration sensor (AMG) TOF^{3D} (multi use)	5750105	 Cable with acceleration sensor for measurement of patient response
Battery (single use)	6450044	4x 1,5V AA Alkaline or NiCd/NiMH; Power supply
Interface sealing plug TOF^{3D} (multi use)	5750109	 Cover to seal the open interface port on TOF^{3D}

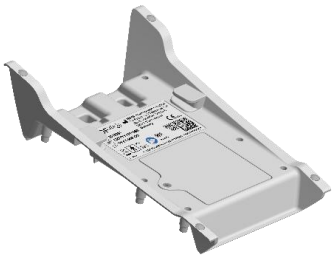
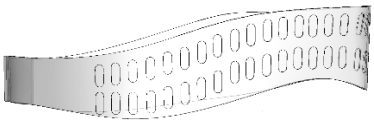
Accessories

Product (mulit/single use)	MIPM REF	Remark
Temperature sensor TOF^{3D} (multi use)	5750106	 Sensor incl. Cable for peripheral skin surface temperature measurement
Eye Adapter TOF^{3D} (single use)	5750102	 Adapter to place the acceleration sensor on the eyebrow. (facial nerve and Musculus Orbicularis Oculi)
Hand adapter TOF^{3D} (multi use)	5750100	 Adapter for fixation of the hand (Nervus Ulnaris and Abductor Pollicis)
Thumb adapter TOF^{3D} (single use)	5750101	 Adapter for fixation of the acceleration sensor on thumb
IV-pole holder TOF^{3D} (multi use)	5750110 Variant A	 Adapter to mount the device to an IV-pole
IV-pole holder TOF^{3D} (multi use)	5750110 Variant B	 Adapter to mount the device to an IV-pole
Mechanomyography sensor (MMG) TOF^{3D} (multi use)	5750126	 Cable with force sensor for measurement of patient response and integrated temperature sensor
USB Interface cable TOF^{3D} (multi use)	5750103	 USB Cable for Data Transmission

With the USB Interface cable TOF^{3D} operation/trend data (no patient data) can be transferred to a suitable 3rd party medical device. For more information about medical devices that have already integrated the TOF^{3D}, please contact MIPM GmbH or local distributor.

Spare Parts

Product	MIPM REF	Remark
Complete Patient Cable TOF^{3D} Including: - Main cable TOF^{3D}, - Stimulation cable TOF^{3D}, - Acceleration sensor (AMG) TOF^{3D} - Split connector sealing plug TOF^{3D} (all parts multi use)	5750104 incl. - 5750108 - 5750107 - 5750105 - 5750116	 Ready to use patient cable consisting of four parts
Main cable TOF^{3D} (multi use)	5750108	 Cable from device to split connector
Stimulation cable TOF^{3D} (multi use)	5750107	 Cable with two electrode clamps to connect the stimulation electrodes with the main cable
Acceleration sensor (AMG) TOF^{3D} (multi use)	5750105	 Cable with acceleration sensor for measurement of the patient response
Battery (single use)	6450044	4x 1,5V AA Alkaline or NiCd/NiMH; Power supply
Split connector sealing plug TOF^{3D} (multi use)	5750116	 Cover to seal an open port on the split connector
Interface sealing plug TOF^{3D} (multi use)	5750109	 Cover to seal an open interface port on TOF^{3D}
Battery Lid TOF^{3D} (multi use)	5750111	 Cover to seal the battery compartment of TOF^{3D} (incl.: 1x srew and 1x o-ring)

Product	MIPM REF	Remark
Housing top shell TOF^{3D} (multi use)	5750114	 Upper half of the housing incl. membrane keyboard and display protection window
Housing lower shell TOF^{3D} including: - Battery Lid TOF^{3D} (multi use)	5750115 - 5750111	 Lower half of housing incl. battery lid, 6x screws, 4x bumpers
Strap for Hand adapter (multi use)	5750122	
Strap for MMG-Sensor (multi use)	5750127	

2.2 Symbol description

2.2.1 General Symbols on display

Adjust baseline gain

 (IEC TR60878; 5652)	Indicator for baseline gain for response signal. Values above 300 means that signal is above normal. Values below 300 means that signal is below normal.

Calibration successful

	Indicator for successful calibration. Indication in stimulation screen if a successful calibration is set and active. 1: Calibration done by CAL1 2: Calibration done by CAL2

Stimulation current units

	Indicator for stimulation strength in milli-ampere.

Stimulation charge units

	Indicator for stimulation strength in micro-coulomb.

Stimulation pulse width units

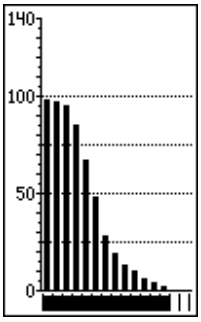
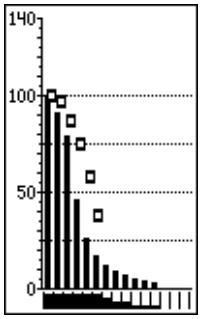
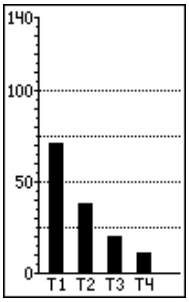
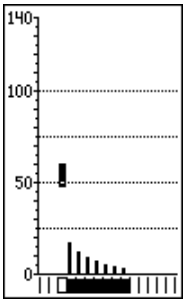
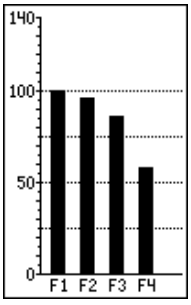
	Indicator for stimulation pulse width in micro-seconds.

Frequency units

	Indicator for repetition frequency – 1Hz, 0.1Hz or for tetanic stimulation frequency – 50Hz, 100Hz.

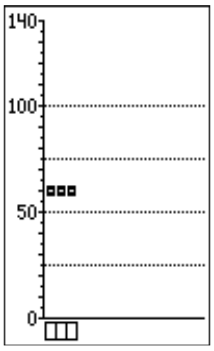
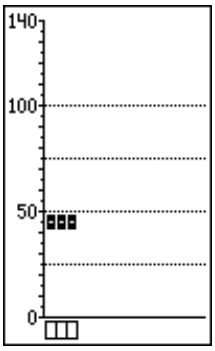
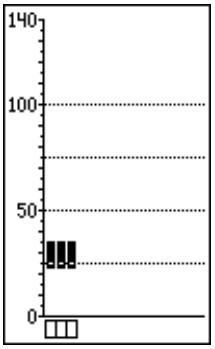
Trending graph (objective)

If valid sensor responses are recorded the trend graph will show these results as follows:

	**Single Twitch Trending graph** Shows the last 15 consecutive single twitch heights for 1Hz, 0.1Hz, PTC. • Graph will be filled up with results from left to right • The oldest results will be deleted The trending graph will be erased if "New Patient" is selected in the Set-up menu (see chapter 5.1.2 "Data Storage management").
	**TOF Trending graph** Shows the last 15 consecutive TOF results (T1 & Ratio/Count) for TOF and TOF**s** together. The horizontal indication shows the detected number of twitches (1-4). • Graph will be filled up with results from left to right • The oldest results will be deleted The trending graph will be erased if a "New Patient" is selected in the Set-up menu (see chapter 5.1.2 "Data Storage management").
	**TOF twitch result graph** TOF responses (T1-T4) are shown for a period of 6 seconds after every TOF stimulation. Hereafter automatically substituted with the *TOF trending graph*.
	**PTC result graph** The whole twitch decay can be observed for at least 15s when the automatic TOF results appear. The graph is a combination of TET and Twitch trend symbols.
	**TET MMG force graph (MMG only)** Shows four forces $F1_{max}$, F2, F3, $F4_{end}$ representing the force measured during tetanic stimulation. $F1_{max}$ is always shown as 100% and F2-F4 is always shown in % of $F1_{max}$. Hereafter automatically substituted with the *trending graph*.

Trending graph (non-objective)

If No valid sensor responses present the trend graph will show these results as follows:

	**Single Twitch Stimulation graph** Shows the last 15 consecutive single twitch stimulations for 1Hz, 0.1Hz, PTC. Elevation of box (white dot) relates to stimulation strength in mA.
	**TOF/DBS stimulation graph** Shows the last 15 consecutive TOF/DBS stimulations. Elevation of box (white dot) relates to stimulation strength in mA.
	**TET stimulation graph** Shows the last 15 consecutive Tetanic stimulations. Elevation of box (white dot) relates to stimulation strength in mA. A single TET stimulation box is also a part of the *PTC result graph* mentioned above.

A small twitch detection silo is located below every measurement in the trend mode. For every objective TOF measurement this twitch detection silo shows the number of detected twitches (T1-T4) - see below:

- Closed box: No valid sensor response or subjective stimulation type (DBS, TET).
- 0/4 silo (empty): Valid response, 0 twitches detected in TOF mode or single twitch mode.
- 1/4 silo: Valid response, 1 twitch detected in TOF mode.
- 1/2 silo: Valid response, 2 twitches detected in TOF mode.
- 3/4 silo: Valid response, 3 twitches detected in TOF mode.
- 4/4 silo (full): Valid response, 4 twitches detected in TOF mode or - 1 twitch detected in single twitch mode.

Temperature units

℃	Indicator for peripheral skin surface body temperature in degree Celsius.

Software version

	Indicator for software version.

Date / Time

 2018-03-05 11:43:27	Shown during power-on sequence and in setup mode. Time format is always 24 hour format (HH:MM:SS) Year: Valid range is from 2018 to 2100 Month: Valid range is from 1 to 12 Day: Valid range is from 1 to 31 (Automatic leap-year calculation)

Stimulation beep

 (IEC TR60878; 5080 / 5436)	Indicator for stimulation beep is turned on/off. Only in Setup mode symbol is used to indicate that stimulation beep is turned off.

Remote Interface connection

 (IEC TR60878; 5424)	Remote connection established and active. If no interface symbol is shown→no remote connection has been detected
 (IEC TR60878; 5424)	Remote connection lost. Device functioning normally. If no interface symbol is shown→no remote connection has been detected

Stimulation/Calibration not possible

	Shown temporarily if the operator tries to initiate a stimulation mode or an action that is not possible. Illegal actions are normally accompanied by audible annunciations (error beeps).

Data management

 (IEC TR60878; 5663)	Prepare for New patient. In setup operator can choose to erase existing data and load default setting for new patient.
 (IEC TR60878; 5390)	Append data for existing patient. In setup operator can choose to append new data to existing data and retain earlier settings.

Clear memory

	Data will be erased. Shown in *Setup*|*New patient* to indicate that existing data will be cleared if *New patient* is selected.

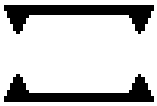
Ready to record

 (IEC TR60878; 5163)	Shown in *Setup*|*New patient* to indicate that data will be recorded and existing data will be kept Shown in stimulation screen when recorded data exists→indicates number of recordings in memory

No data will be recorded

 (IEC TR60878; 5165)	Shown in *Setup*|*New patient* to indicate that no data will be recorded and existing data will be deleted. Shown in stimulation screen to indicate that the memory is full and no data will be recorded

Adjustable items

	Indicates parameter or setting that can be adjusted by pressing keys.

Active keys

	Indicates that parameter or a setting can be selected or adjusted by pressing relevant displayed combination of keys.

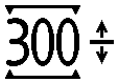
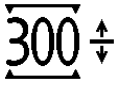
2.2.2 Parameter Symbols

Currently selected parameters are displayed in mode section of LCD and can be directly selected by ◀▶ in active mode or from stop mode by first entering parameter change mode (chapter 5.1.8) by means of ▲▼.

Display stimulation strength

	Indicate selected stimulation strength in µC or mA.
	▲▼ keys will change stimulation strength in µC or mA (indicated). Change mode ends after 2.5s of inactivity.

Baseline gain

 (IEC TR60878; 5652)	Indicate current sensor response baseline. Baseline value of 300 is considered normal→ higher baseline value allows larger patient response signal to be scaled down to show 100% before NMB administration and vice versa.
 (IEC TR60878; 5652)	▲▼ keys will change patient response baseline. Change mode ends after 2.5s of inactivity.

2.2.3 Timer Symbols

 (IEC TR60878; 1140)	Stop mode (ready for operation) Indicates that device is in stop mode (ready for operation). No stimulation will take place. Mode can be selected by means of ◀▶ and parameter mode can be activated by means of ▲▼.
	*Active mode*: Stimulation in progress.
	*Active mode*: Indicates remaining time to next stimulation when time is above 13.5s. Center dot segment will flash on/off every second.
	*Active mode*: Indicates remaining time to next stimulation when time is between 13.5s and 0s (TOF → TOF)

2.2.4 Setup Mode Symbols

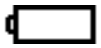
 (IEC TR60878; 5663)	Indicates setup and control of measurement recording log.
 (IEC TR60878)	Indicates setup settings of default Parameters.
 (IEC TR60878; 5130)	Indicates setup settings for stimulation pulses. - Defaults (strength, units and pulse width) - Stimulation beep
 (IEC TR60878; 5184)	Indicates setup of time & date.
 (IEC TR60878; 5307, 5649)	Indicates setup setting for TOF Monitor. - Lower and Higher level - On/Off

2.2.5 Alert Symbols

Internal Error (Medium) - shown in mode

 (IEC TR60878; 0717)	Steady – in halt mode: Operation halted due to internal error no 08. Service will be required if internal error happens on frequent basis. This alert will last until device is powered off, either manually or automatically by detection of [battery empty]. Device cannot stimulate when error is present.

Battery empty (Medium)

 (IEC TR60878; 5546)	Steady – in halt mode: Indicates that device has stopped working due to empty battery situation. Batteries should only be changed by technically qualified personal. 4x 1,5V AA Alkaline or NiCd/NiMH batteries required. Rechargeable batteries can be used with external recharging. Error will last until error does not exist or until device is powered off, either manually or because of empty battery.

Data too old (Medium)

 (IEC TR60878; 5663; 2607)	Data in memory is more than 2 hours old - new data cannot be appended. If more than 2 hours have elapsed since last data recording - data is considered too old (invalid for current patient) and new data cannot be appended. User is forced to clear data before new data can be recorded in memory.

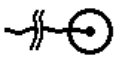
No MAIN cable (Medium)

 (Custom split connector silhouette)	Flashing – in stop mode: Alert will trigger if no main cable is connected to device. Alert is only cleared when a main cable is connected.

No AMG/MMG Sensor (Medium)

 (Custom - TOF^{3D})	Flashing – in stop mode: Alert will trigger if no AMG/MMG sensor is connected. Alert is cleared after 15 seconds or by mode selection.

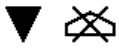
Electrode Error (Medium)

 (Custom - TOF^{3D})	Flashing – in stop mode: Unable to deliver required stimulation strength due to a high skin resistance or a loose/bad electrode connection. Stimulation is stopped but can be re-initiated. Alert is cleared after 15 seconds or by mode selection.

Communication Interrupted (Medium)

 (IEC TR60878; 5424)	Flashing – in stop mode: Device has detected interruption in external communication. Stimulation is stopped but can be re-initiated. Alert is cleared after 15 seconds or by mode selection.

Calibration error (Medium)

 (IEC TR60878;0160 + 5027)	Calibration signal unstable - Active calibration is stopped stop but can be resumed. - Flashing for up to 15 seconds.
 (IEC TR60878;0160 + 5025)	Calibration signal too low - Active calibration is stopped but can be resumed. - Flashing for up to 15 seconds.
 (IEC TR60878;0160 + 5025)	Calibration signal too high - Active calibration is stopped but can be resumed. - Flashing for up to 15 seconds.
 (IEC TR60878;0160 + 5147)	Cannot detect Supra-maximal stimulation in CAL2. - Active calibration is stopped but can be resumed. - Flashing for up to 15 seconds.

Temperature sensor error (Low)

	Steady - in modes: stop, active, parameter change: Warning that temperature error has occurred. If device is switched on without temperature sensor → No alerts are generated, since this is considered deliberate action.
 (IEC TR60878; 0034)	Temperature sensor has been removed: Indicated by “blanking” temperature digits together with crossed temperature symbol.
 (IEC TR60878; 0034)	Temperature above measurement range: Indicated by up-pointing arrow and with “blanked” temperature digits.
 (IEC TR60878; 0034)	Temperature below measurement range: Indicated by down-pointing arrow and with “blanked” temperature digits.

TOF Monitor (Low)

 (IEC TR60878; 5650)	Higher TOF Monitor level detected. - Active TOF Stimulation continues. - Shown until TOF result is no longer considered valid.
 (IEC TR60878; 5651)	Lower TOF Monitor level detected. - Active TOF Stimulation continues. - Shown until TOF result is no longer considered valid.

Skin temperature low (Low)

 (IEC 60878 Ed.1; 0034)	Steady - in modes: stop, active, parameter change: Warning that peripheral skin surface temperature has dropped from >= 32°C to < 32°C – measurement of thumb responses may be unreliable. Alert will exist as long as temperature has dropped below 32°C and will only be cleared upon detection of temperature above 32.0°C (0.2°C hysteresis).

Memory full (Low)

 (IEC TR60878; 5165)	Steadily indicated on stimulation screen - in modes: stop, active, parameter change: Used to indicate that device cannot record more data in memory as memory is full. Alert will exist as long as memory is not cleared by operator or via interface.

Bad response signal (Attention)

	Steady – in modes: stop, active, parameter change: If single twitch or a burst of several single twitches contains a bad response signal → symbol will be shown accompanied by a single beep and blanked result value. Alert is cleared/updated by new data or when result is no longer valid – normally after 15 seconds.

Bad TOF ratio (No audible attention)

	Steady – in modes: stop, active, parameter change: If for some reason single twitch values of TOF burst yields TOF ratio > 199% or otherwise invalid result blank (-II) TOF result is displayed. Alert is cleared/updated by new data or when result is no longer valid – normally after 15 seconds.

Memory low (Attention)

 (Based on IEC TR60878; 5165)	Steady - in modes: stop, active, parameter change: Used during normal operation to indicate that remaining free memory capacity is less than 3.33% (1536 records). Alert will exist as long as memory is not cleared by operator or via external interface or until *Memory full*.

Battery low (Attention)

 (IEC TR60878; 5546)	Steady - in modes: stop, active, parameter change: Used to warn about an almost empty main battery. Alert will be shown until detection of higher input voltage or until *Battery empty*. Batteries should only be changed by technically qualified personal. 4x 1,5V AA Alkaline or NiCd/NiMH Batteries required.

3. Quick Guide

3.1 Electrodes and adapter positioning

Always use TOF^{3D} with round surface electrodes including snap connection during monitoring of neuromuscular transmission. Small (pediatric) electrodes with an active area equal or greater than 1cm² shall be used. An active area of 1cm² is recommended.

Use of electrodes with an active area smaller than 1cm^2 may lead to current densities exceeding 2mA/cm^2 and require special attention of the operator.

➤ **NOTE:** Any electrodes that have current densities exceeding 2mA/cm² may require special attention of the operator.

WARNING: **Application of electrodes near the thorax may increase the risk of cardiac fibrillation. The stimulation must not be applied through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the chest and upper back or crossing over the heart.**

Do only apply the electrodes to the positions indicated below.

Acceleromyography (AMG) and mechanomyography (MMG) can be performed by stimulating the following nerves or muscles:

- adductor pollicis (AMG/MMG)
- facial nerve (AMG)
- posterior tibial nerve (AMG)
- flexor hallucis brevis muscle (AMG)
- orbicularis oculi muscle or corrugator supercilii muscle (AMG)

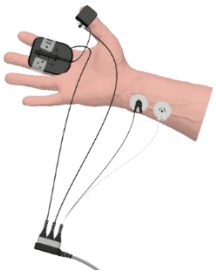
Positioning of electrodes on Adductor pollicis:

- Where proximal bending line crosses radial side of flexor carpi ulnaris muscle.
- Placement of proximal electrode either 2 to 3 cm proximal of distal electrode or over ulnar nerve at elbow.
- Small displacements may result in considerable changes in stimulation current requirements.
- Electrodes must be positioned in a way to avoid direct muscle stimulation.
- Place electrodes on each side of expected position of ulnar nerve→Minimizes effect of any minor misjudgment of actual nerve position.
- Slight pressure on electrodes may improve stimulation considerably. Therefore, taping the electrodes to skin may be advisable.
- Check clamps for proper fixation to avoid unwanted disengagement.

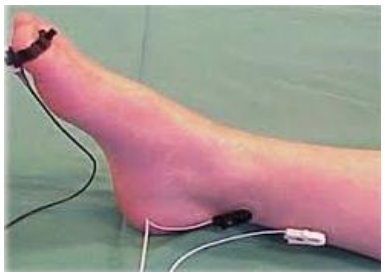
3.1.1 Acceleration sensor position:

- Place acceleration sensor with largest flat side against last segment of thumb.
- Fix acceleration sensor cable so that no traction is applied to acceleration sensor and that thumb-movement is not obstructed in any way.

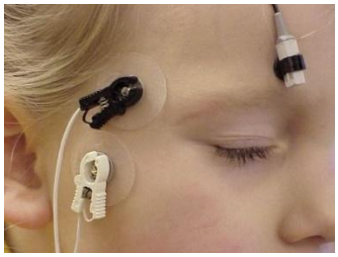
For easier positioning it is recommended to use the hand-adapter.



Electrode and AMG sensor positioning on adductor pollicis / nervus ulnaris



Electrode and AMG sensor positioning on posterior tibial nerve / flexor hallucis brevis muscle



Electrode and AMG sensor positioning on orbicularis oculi muscle

➤ **NOTE:** In case of an emergency (for example unwanted stimulation due to system-failure→can´t be stopped) the clamps can be removed easily.

3.1.2 Temperature sensor position

Changes in temperature at the neuromuscular monitoring site may affect the response to nerve stimulation. It is therefore recommended to monitor the peripheral skin temperature which should be kept ≥ 32 ºC.

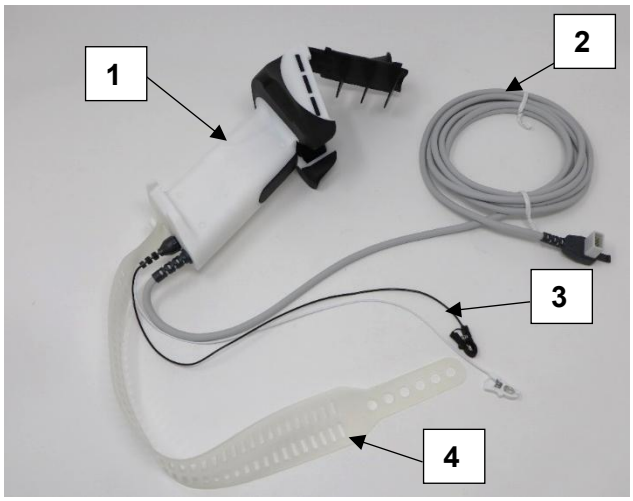
➤ **NOTE:** The peripheral skin temperature sensor of the TOF^{3D} is not intended for and shall not be used as a temperature sensor for monitoring the patient's "core temperature" (physiological parameter/diagnostic parameter/vital sign). No correlation between measured skin temperature and core temperature is being made by the TOF^{3D} temperature sensor (eg. Direct mode only).

If the temperature sensor is used:

- Place the temperature sensor at the neuromuscular monitoring site.
- Use medical tape to place the temperature sensor with the measuring side on the skin.
- Make sure that the temperature sensor is always placed directly on the skin (no air between the sensor and the skin), as this is the only way to obtain an accurate measurement result.

- When you use the Hand adapter TOF^{3D}, place the temperature sensor in the provided recess.

3.1.3 Mechanomyography sensor (MMG) position

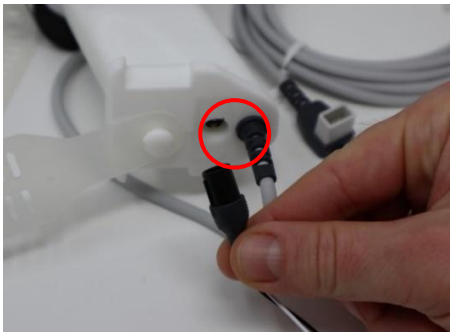


1. MMG sensor handpiece
2. Patient cable
3. Stimulation cables
4. Silicone hand wrap

Replacing the stimulation cable:

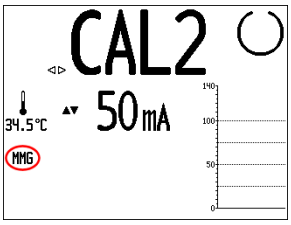
If the stimulation cables are damaged and need to be replaced remove the stimulation cables connector from the socket on the bottom of the hand piece.

Insert the stimulation cables connector to the socket on the bottom of the hand piece. The connector is mechanically coded and will only fit in one way.



➤ **NOTE:** A temperature sensor is integrated in the Mechanomyography sensor (MMG) TOF^{3D} and measures the surface temperature of the thumb muscles (no physiological parameter/diagnostic parameter/vital sign). No correlation between measured skin temperature and core temperature is being made by the temperature sensor (eg. Direct mode only).

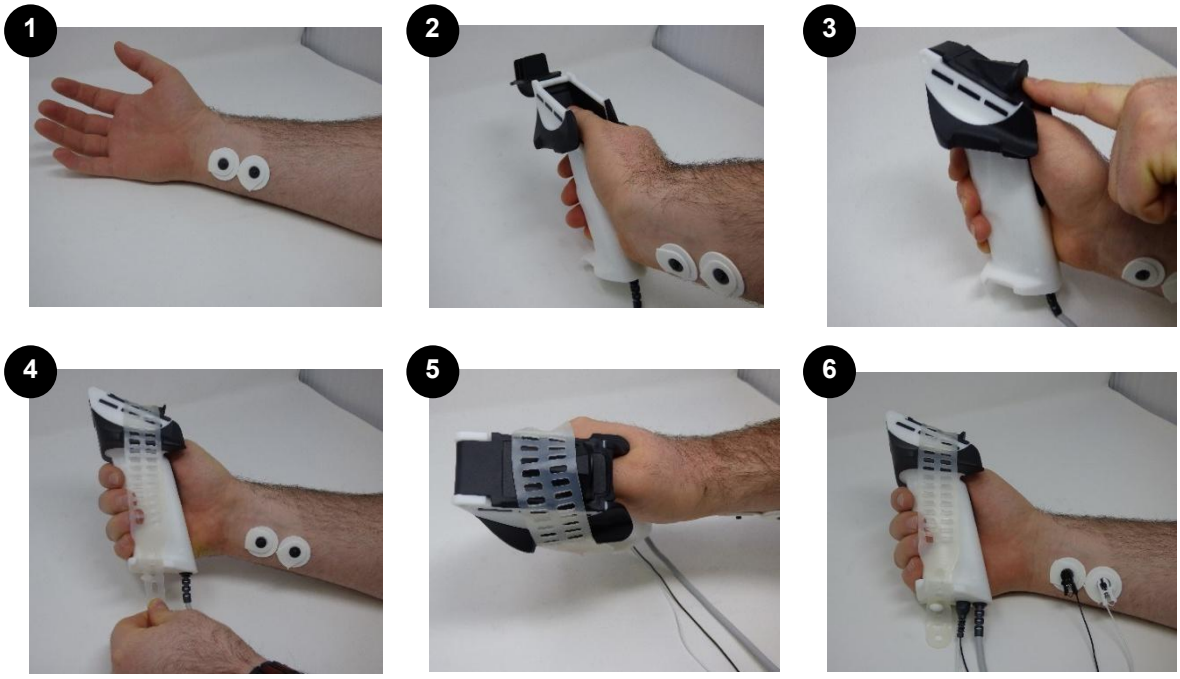
How to use the MMG sensor:



Connect the patient cable to the socket for the patient cable on the back side of the monitor (see chapter 2.1.2).

Once the MMG sensor is connected you will see the MMG symbol on the main screen.

1. Place the stimulation electrodes on the patients forearm over Nervus Ulnaris as described above (see figure 1)
2. Open the flap of the MMG sensor, place the hand piece in the patient's hand and insert the thump in the measurement compartment (see figure 2)
3. Close the flap (see figure 3)
4. Pull the silicon hand wrap around the hand piece and fix it on the knob on the bottom of the hand piece (see figure 4 and 5)
5. Connect the stimulation cables to the stimulation electrodes (see figure 6):
   White: Proximal - Black: Distal
6. The MMG sensor is now ready to use (see figure 6). Follow the instructions in chapter 3.5 TOF Measurement (typical session).



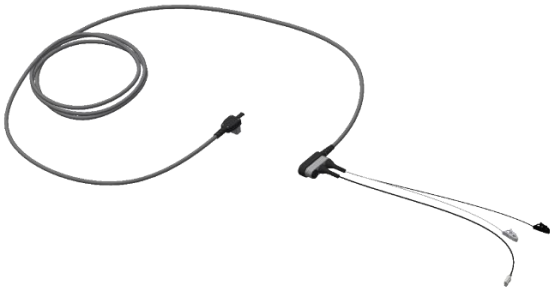
➤ **NOTE:** In case of an emergency (for example unwanted stimulation due to system-failure→can´t be stopped) the clamps can be removed easily.

3.2 Arm position

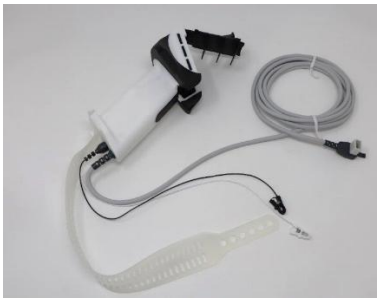
Keep arm (used for acceleration measurement) immobile during whole procedure.

- Arm movement to another position may change twitch height considerably. Train-of-four ratio will not be affected, no matter if twitch height may still differ from original value.
- Hand movements at later recovery stages may disturb measurements and recordings. (Avoidance by use of hand adapter)

3.3 Cable connection



AMG: Patient cable including stimulation cable and acceleration sensor



MMG: Patient cable including stimulation cable and MMG sensor

3.3.1 Subjective monitoring

No connection of acceleration sensor to TOF^{3D} → Device can be used as peripheral nerve stimulator. Instead of patient response, TOF^{3D} shows only stimulation strength in mA (µC) and stimulation mode (default stimulation strength set at 50 mA).

- Connect negative stimulation cable and positive stimulation cable to surface electrodes.
- Connect all cables to designated color-coded outlets on the main cable (reversal of the cables not possible due to mechanical barrier)
- Connect main cable to TOF^{3D}
- By using surface electrodes, automatic stimulation pulses of 200 µs (300 µs) with 0 - 60 mA (0 - 12/18 µC) are generated.

3.3.2 Objective Monitoring

The TOF^{3D} can be used for objective monitoring by using following parts:

a. TOF^{3D}
b. Mechanomyography sensor (refer to chapter 3.1.3)
c. Or Acceleration sensor
d. Main cable
e. Stimulation cable

Thumb adapter / Hand adapter

- Connect black stimulation clamp to the distal electrode at the ulnar nerve.
- Connect white stimulation clamp to the proximal electrode at the ulnar nerve.
- Attach acceleration sensor with its largest flat side to thumb by using of thumb adapter or hand adapter.
- Connect all cables to designated color-coded outlets on main cable (reversal of cables not possible due to mechanical barrier)
- Connect main cable to TOF^{3D}

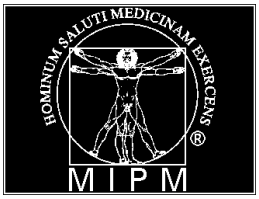
3.4 Connection to stimulator

Before touching electrodes, always check if TOF^{3D} is switched off or stop symbol is displayed.

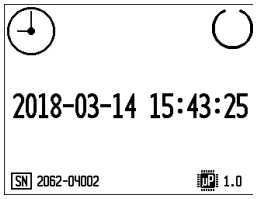
- Proximal electrode is connected to white (Positive) clamp on stimulation cable. Distal electrode is connected to black (Negative) clamp.
- If both electrodes are near wrist, polarity is less critical. Exchanging electrode polarity may sometimes increase stimulation considerably.

3.5 TOF-Measurement (typical session)

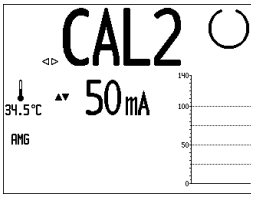
1. Press and hold the ⏻ button to turn on the device



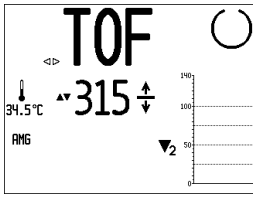
2. After a short time the picture changes to dark



3. System Self Check - Verify Date & Clock

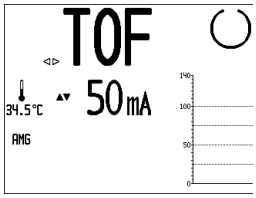


4. To start Initial calibration press and hold key before NMBA BOLUS is administered

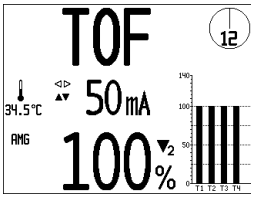


5. Calibration OK - New Baseline and Triangle with index 1 or 2 are shown.

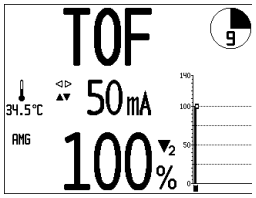
(Index depends on selected Calibration Mode)



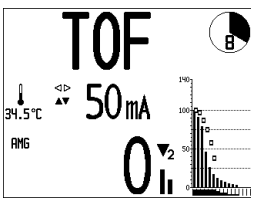
6. After a few seconds Stimulation strength is displayed



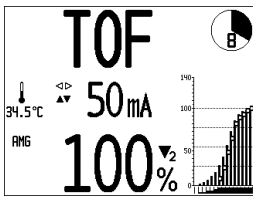
7. Start continuous TOF measurement by pressing the ◯ key for at least 1 second.



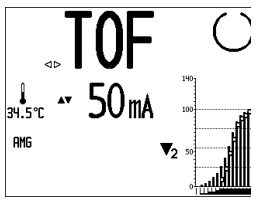
8. Administer NMBA BOLUS dose



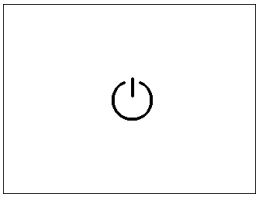
9. Observe effects of NMBA BOLUS dose



10. Await 100% response during recovery



11. Stop TOF Measurement by pressing the ◯ key. Device enters Stop Mode



12. Power Off device by pressing and holding the ⏻ key.

4. Operation

Device is a stand-alone neuromuscular transmission monitor.

The patient cable is the connection platform for negative stimulation cable, positive stimulation cable, acceleration sensor and temperature sensor.

The mechanomyography main cable is the connection platform for negative stimulation cable, positive stimulation cable, MMG sensor including integrated temperature sensor.

4.1 Power-up mode

Battery powered device with separate ON/OFF button ⏻

Power OFF only possible in stop mode

4.2 Stimulation modes

4.2.1 Calibration (CAL1 / CAL2)

1. Select CAL1/2 using ◀ ▶ key in stop mode.
2. Long activation of ◉ key will start calibration.
3. Switching between CAL1/2 refer to chapter 5.1.7 “Parameter set menu”

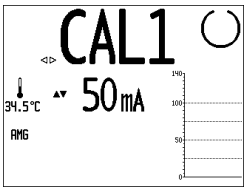
- Device incorporates two calibration sequences compatible with common medical practices.
- Calibration sequences calibrates device and creates base (reference) for subsequent twitch response measurements.
- If calibration procedure finds that sensor signal is too low, too high or too unstable to guarantee reliable calibration, then calibration error is annunciated and stop mode is entered.
- If the symbol for “calibration successful” is lit, this means that device is calibrated - number states type of calibration.

Several factors will clear the calibration status:

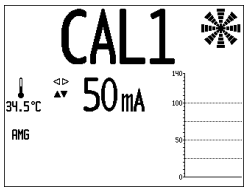
- Manual change of stimulation strength (current or pulse width)
- Manual change of baseline gain
- Dismounting main cable/sensor
- Powering off device with data logging mode in-active (see chapter 5.1.6 Log Mode)
- Long activation of ◉ key in calibration mode

CAL1

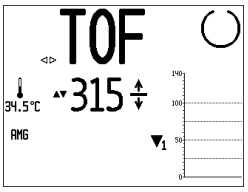
- Calibration sequence calibrates device for measurements at given stimulation current, without finding supra-maximal stimulation current.
- CAL1 sequence uses actual set stimulation strength and performs 100% calibration setting for set current.
- CAL1 calibration is based on a number of averaged single twitches done at rate of 2Hz.



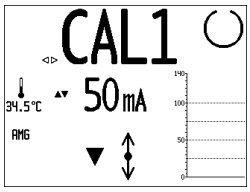
CAL1 mode selected



CAL1 in progress



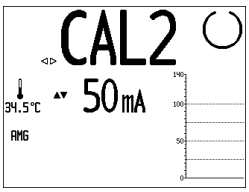
CAL1 OK; TOF mode selected.
New Baseline shown for 3.5s



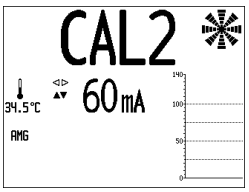
CAL1 error – signal unsteady.
Error flashing up to 15s.

CAL2

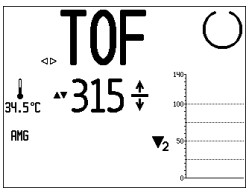
- CAL2 sequence finds supra-maximal stimulation current before performing 100% calibration at “supra-maximal stimulation current +10%”.
- Finding supra-maximal stimulation current is done by first measuring response at 60mA (average of 5 measurements) and then decreasing stimulation current in 5mA steps until a single twitch response is found to be ≤ 90% of the original 60mA response.
- Stimulation current is then increased by 5mA and further increased by 10% and then a final response average (5 stimulations) is used to adjust baseline so that the response will show 100% at the established supra-maximal stimulation current.



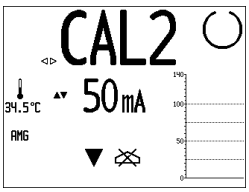
CAL2 mode selected



CAL2 in progress



CAL2 OK; TOF mode selected.
New Baseline shown for 3.5s



CAL2 error – supra-maximal stimulation current could not be established.
Error flashing up to 15s.

4.2.2 TOF/TOF^{s}

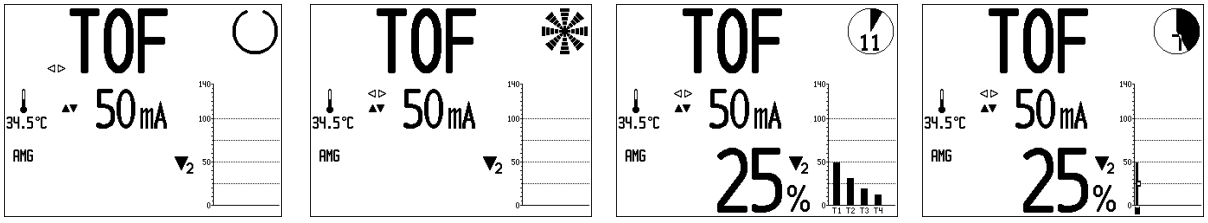
1 Select TOF stimulation by using ◀ ▶ keys in Stop mode.

2. Short activation of ◉ key for single TOF stimulation, long activation (at least 1 second) for continuous TOF stimulation (every 15 seconds).

3. For TOF stimulation with individual stimulation interval select TOF^{s} stimulation in Stop mode.

4. Stimulation interval can be adjusted in setup mode between 30s and 60 minutes. To initiate TOF^{s} stimulation press and hold ◉ key.

5. To stop continuous TOF stimulation press ◉ key.



Train of four (TOF) consists of four single twitch recordings.

- Size of twitch number one (T1) and four (T4) are used to calculate and display the TOF ratio T4/T1.
- TOF ratio is only calculated if T1 is above 20% and T2, T3 and T4 are above 3%. Otherwise number of consecutive twitches above 3% (0-4) will be displayed.
- Good practice seeks to avoid that TOF stimulation response is influenced by prior TOF stimulation. If continuous TOF stimulation is started within log-out period, then stimulation will be delayed and stop-watch will indicate remaining time to next stimulation.
- Repetition rate of continuous TOF measurements is fixed at a rate of 15 seconds. Special slow TOF variant (TOF^{s}): Stimulation interval can be adjusted in setup mode between 30s and 60 minutes.
- In continuous TOF/TOF^{s} mode stop-watch in upper right corner will indicate time to the next stimulation.

4.2.3 PTC

1. Select PTC stimulation mode using ◀ ▶ key in Stop mode.
2. Long activation of ◉ key starts PTC sequence. If less than 2 minutes have passed since last tetanic stimulation→PTC sequence won´t be allowed
   - Warning symbol ⚠ will appear together with error beep.
3. Short activation of ◉ key won´t start PTC sequence.
   - Warning symbol ⚠ will appear together with error beep.

Post tetanic count (PTC) stimulation sequence consists of three segments followed by automatic entry into TOF mode.

PrePTC(1Hz)

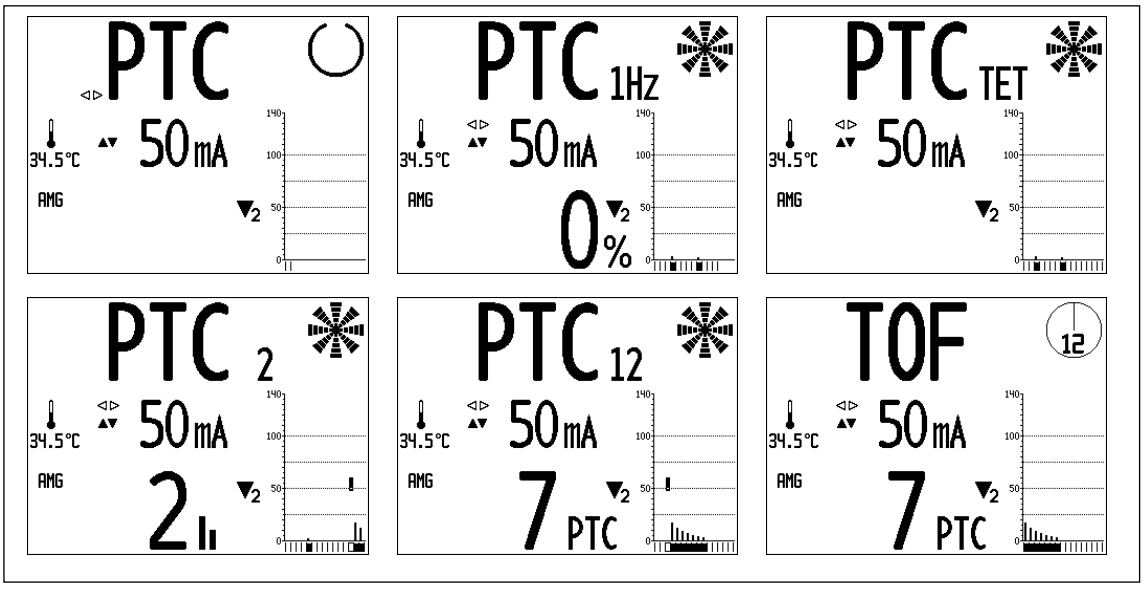
- First segment (PrePTC) ensures that relaxation degree of patient is sufficient for PTC to be useful→consists of 15 single twitch pulses (1Hz).
- If more than five consecutive responses above 3% are detected in PrePTC→ Complete PTC sequence is abandoned and TOF mode is automatically entered.

PTC tetanic stimulation

- 1 second after successfully passing PrePTC→50Hz tetanic burst initiated with duration of 5s followed by 3s pause before next segment is entered.

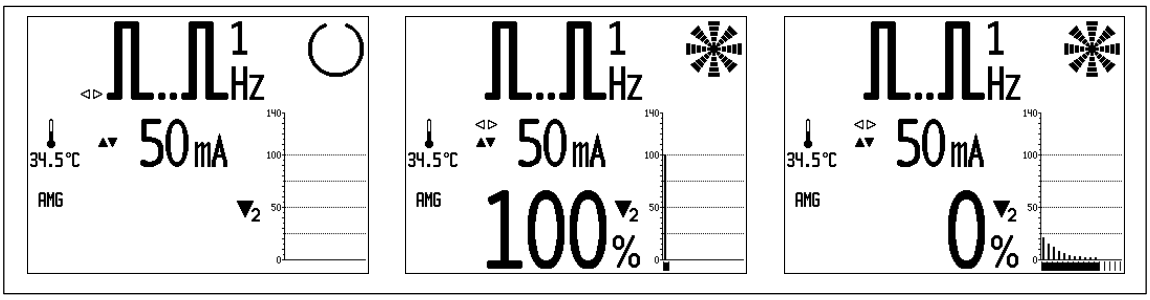
PTC (count)

- Consists of 15 single twitch stimulations (1Hz) where number of consecutive twitch responses ≥ 3% is counted.
- Any responses occurring after first “missing response” (i.e. response < 3%) are not counted.
- All 15 single twitches are always carried out and 15 seconds after last twitch TOF mode is automatically entered.



4.2.4 Single Twitch stimulation

1. Select single twitch stimulation mode using ◀ ▶ keys in Stop mode.
2. Short activation of ◉ key will generate single twitch measurement
3. Long activation of ◉ key will start continuous twitch measurements at rate of 1Hz or 0,1Hz.
4. Stop continuous single twitch stimulation using ◉ key.

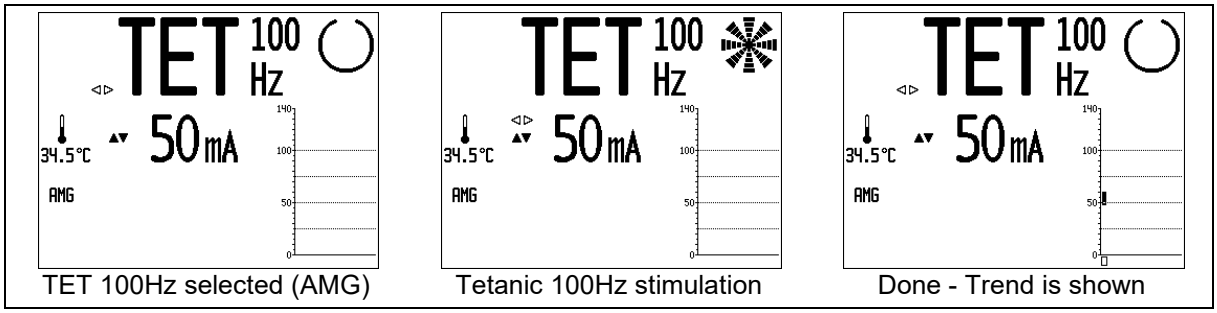


4.2.5 TET (Tetanic stimulation)

1. Select TET 50/100Hz measurement mode using ◀ ▶ keys in Stop mode.
2. Activation by pressing ◉ key → 50/100 Hz tetanic stimulation will be initiated.
3. Stimulation can be prematurely stopped by means of ◉ key.

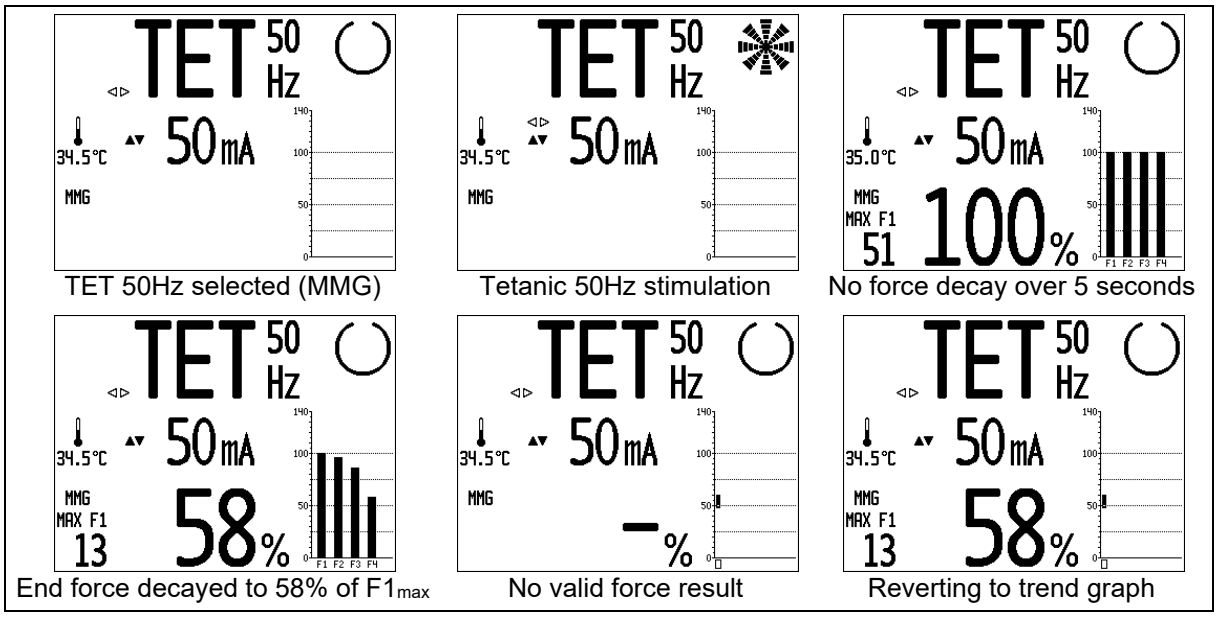
- Stimulation frequency can be adjusted in Setup mode (chapter 5.1.8 “Stimulation setup”).
- Tetanic stimulation cannot be repeated within a period of two minutes from beginning of last TET. If operator tries to start TET within restricted period, warning symbol ⚠ occurs and error beep is emitted.

AMG sensor / no sensor:
In TET mode no acceleration signal can be recorded, but a 5 second tetanic burst consisting of fast repeating single twitches at user programmed rate of 50 Hz or 100 Hz is provided.



TET 100Hz selected (AMG) | Tetanic 100Hz stimulation | Done - Trend is shown

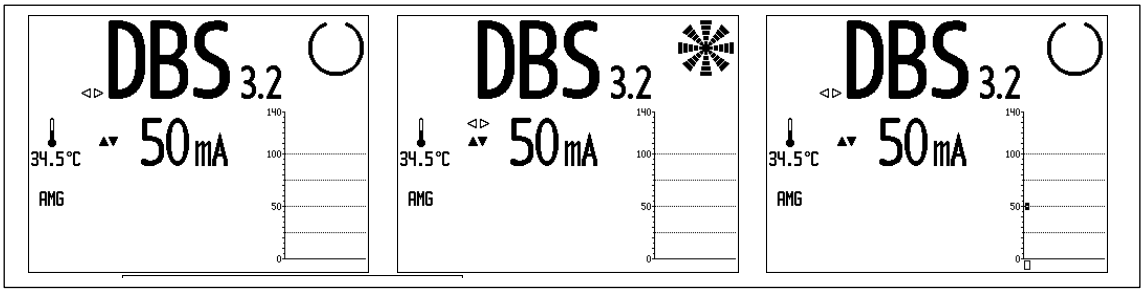
MMG sensor:
In TET mode the force response will be recorded during the 5 seconds of tetanic stimulation. If four valid force values are detected the display will show the force ratio ($F4_{end}$:$F1_{max}$). The absolute size of $F1_{max}$ is shown in the bottom left corner. Also the four blocks (F1-F4) will be shown for 6 seconds after which the display will revert to normal trend graph. When no valid force responses are recorded no force results (-%) will be shown together with the normal trend graph.



4.2.6 Double Burst

1. Select Double Burst (DBS) stimulation using ◀ ▶ key in stop mode.
2. Short activation of ● key will generate single DBS stimulation 3.2 according to setup.

DBS 3.2 (same procedure for starting DBS 3.3)

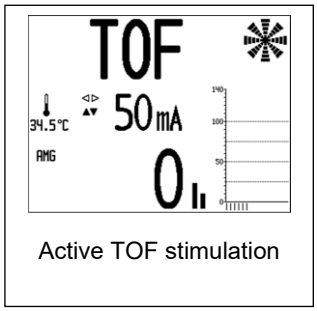


Double Burst Stimulation mode consists of two 750ms spaced pulse bursts:

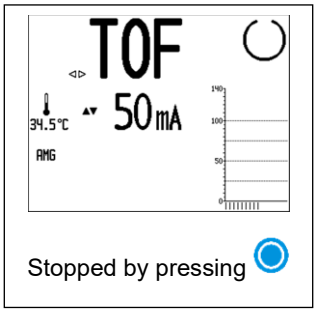
- The first always contains 3 stimulations with 20ms intervals and last burst contains 2(DBS3.2) or 3(DBS3.3) stimulations with 20ms intervals.
- It allows the anesthesiologist to perform a subjective evaluation of the relaxation degree.→ No objective response signal is recorded.
- The Stimulation cannot be repeated at a rate faster than 20s.
- The DBS stimulation pattern can be programmed in the setup mode to either DBS 3.2 or DBS 3.3.

4.2.7 Stop Stimulation

Any active stimulation can always be stopped by pressing ◉.



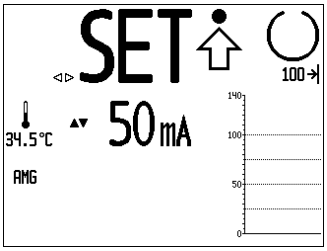
Active TOF stimulation



Stopped by pressing ◉

5. Setup

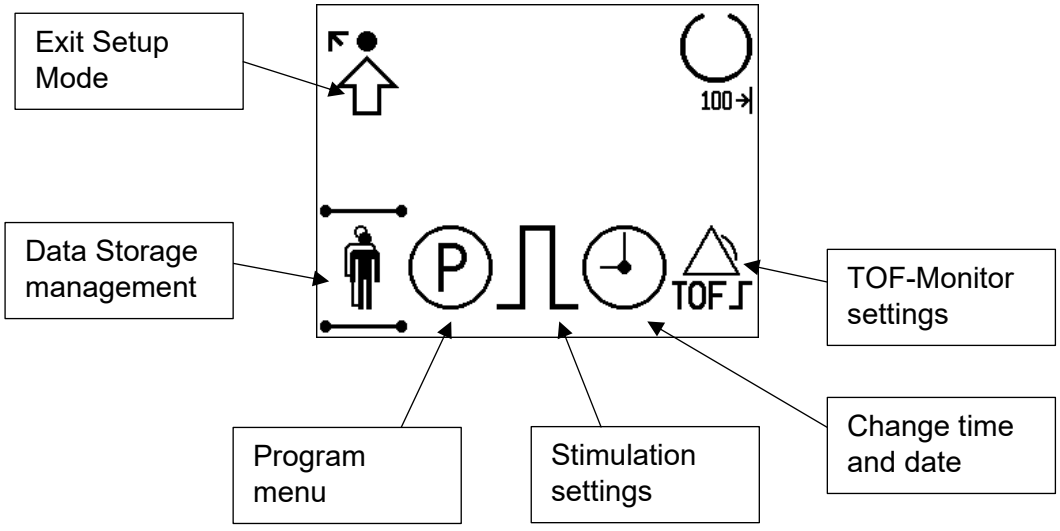
5.1 Quick Guide



Use ◀▶ to select Setup mode and press ◉ key to enter.

Setup Mode is automatically exited after 30 seconds of inactivity.

5.1.1 Select and change setup items



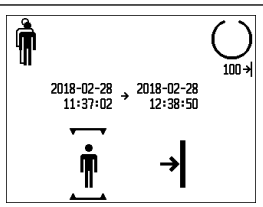
Selection of sub-sections as well as items in sub-sections is done by pressing ◀▶.

Select the wanted menu by pressing ◉ key.

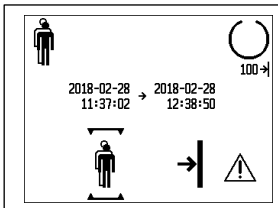
5.1.2 Data Storage management

New Patient:

- Press ◀▶ to select if old data should be kept or not.
- Press ◉ to accept selection and exit to main screen.



Keep data in buffer – append new data to existing data



Memory ready to be cleared when exiting sub menu

⚠ **indicates that data is about to be erased!**

Symbol description see chapter 2.2.2 Data management

If new patient selected, then exiting menu will erase calibration and load default stimulation/base line values:

- All recordings cleared
- Default stimulation strength
- Default baseline gain
- Default pulse width
- Default calibration (not calibrated, default baseline gain)

Data selection:

After completion of power up sequence device checks if old data is present in the non-volatile memory. If present→amount of used memory is displayed and device waits for user to decide what to do with existing data.

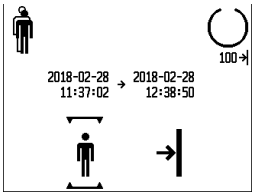
CAUTION: *If more than 2 hours have elapsed since last data recording→operator is required to erase data before new measurements are possible (◀▶ and ◉).*

At this stage all existing data can still be transferred to an external device via the interface and if an external device chooses to clear the existing data from remote hold, then the device will automatically enter stop mode.

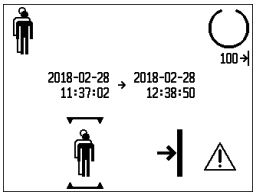
- Press ◀▶ to toggle between appending or erasing data
- Press ◉ to accept selection.

NOTE: Old data being more than 2 hours old is considered to be too old. The device does not allow appending additional data to data being too old (measured from last data entry). Therefore, it is only possible to accept to clear the obsolete data. Old obsolete data can still be transferred to an external device before proceeding with clearing of data in device memory.

If last recorded data is less than 2 hours old, new data may be appended to existing data.



Data will be appended to existing data



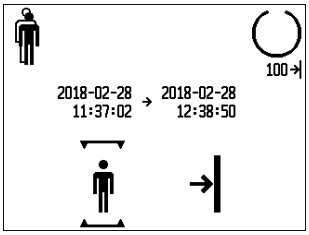
Existing data will be cleared - new patient.

To accept selection press ◉ key and device will continue in stop mode (TOF or CAL).

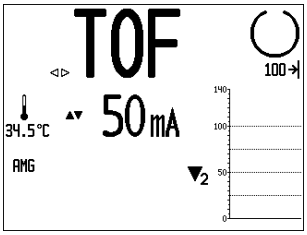
Keep old data:

***CAUTION*:** If user selects to append new data to existing patient data, then by pressing ◉ all recorded data in buffer will be preserved and parameters will be set to values present for last recording done just before device was powered off. These parameters are:

- All recordings
- Stimulation strength and pulse width
- Calibration type and baseline



Data will be appended after exiting Setup by pressing ◉.



Data has been preserved and new data will be appended.

To accept selection press ◉ key and device will continue in stop mode (TOF or CAL).

➤ **NOTE:** This functionality allows user to change device batteries without loss and without losing calibration settings.

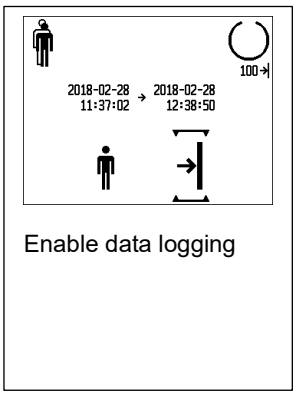
No existing data:

If no existing valid data is present during power-up or LOG is disabled, then no data selection screen will appear and device will load all parameters with default values and select calibration mode (CAL1/CAL2).

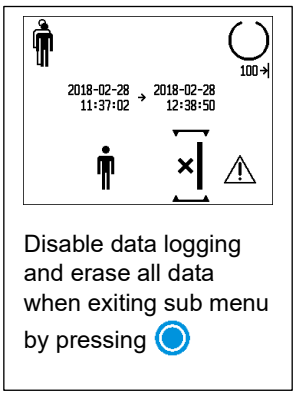
➤ **NOTE:** It is also possible to manually clear all recorded data in setup mode. This should be done for every new patient –if device is not switched off/on between patients.

Log Mode:

- Press ◆◆ to select to enable or disable patient logging.
- Press ◉ to accept selection and exit to main screen.



Enable data logging



Disable data logging and erase all data when exiting sub menu by pressing ◉

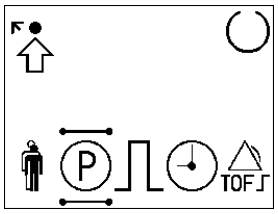
⚠ indicates that data is about to be erased upon exit of sub-menu!

If having selected not to log data then exiting the sub-menu will also erase any previously recorded logging data, but will leave other settings unchanged.

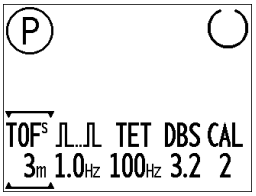
5.1.3 Parameter set menu

Select Ⓟ in setup mode and press ◉ key to enter.

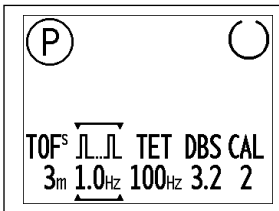
This menu controls additional pre-settings for various stimulation modes: [TOF^{S}, Single Twitch, TET, DBS, CAL].



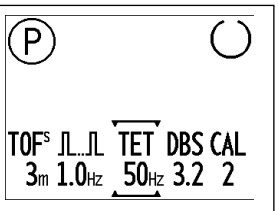
- Selection of a stimulation type is done by pressing ◂ or ▸ and change of a pre-defined stimulation mode parameter is done by pressing ▴ or ▾.
- Exit to main screen is done by pressing ◉.



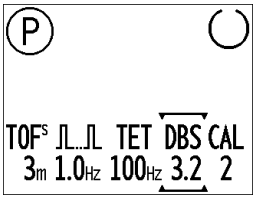
Slow TOF select individual stimulation interval [30s-60min] using the ▴▾ keys.



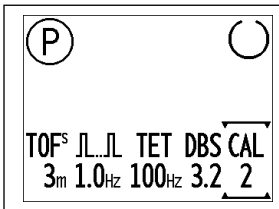
Single twitch – Choose between 1 or 0,1HZ using the ▴▾ keys



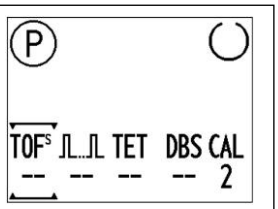
Tetanic stimulation Set rate for tetanic stimulation using the ▴▾ keys



Double Burst Select DBS 3.2 or 3.3 using the ▴▾ keys

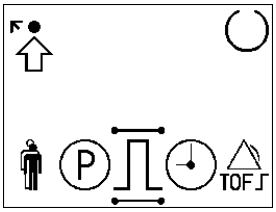


Calibration Select CAL1 or CAL2 using the ▴▾ keys



Deactivation of stimulation modes.

5.1.4 Stimulation setup

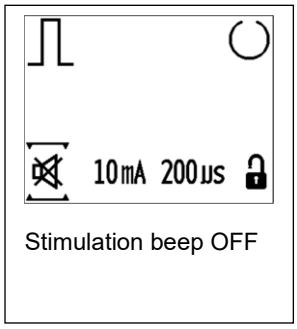


This menu controls stimulation related parameters. Select Stim Setup in setup mode and press ◉ key.

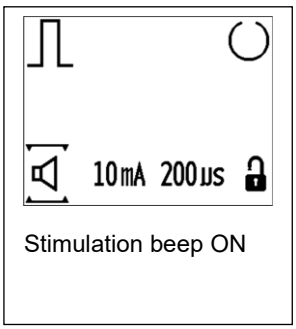
- Selection of a stimulation parameter is done by pressing ◀ or ▶ and change of selected parameter is done by pressing ▲ or ▼ .
- Exit to main screen is done by pressing ◉.

Stimulation Beep

Device can be set to emit a small beep every time a stimulation is initiated.
▼▲ toggles stimulation beep ON/OFF (no auto-repeat is active).



Stimulation beep OFF

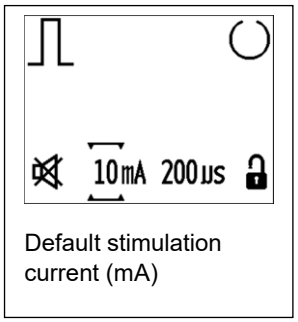


Stimulation beep ON

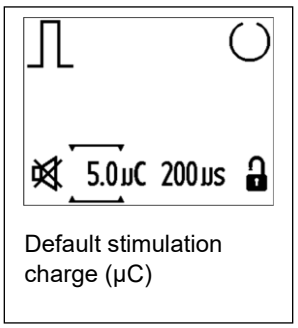
Default stimulation strength

Default stimulation strength can be adjusted between 0 and 60mA or if unit is set to display µC, then between 0 and 12µC/18µC depending on the selected stimulation pulse width (200µs/300µs).

- Default stimulation strength is the initial value right after *power up*/*new patient*.
- ▼▲ controls default stimulation strength setting and auto-repeats if held down for more than 0.5s



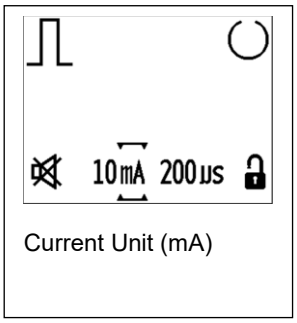
Default stimulation current (mA)



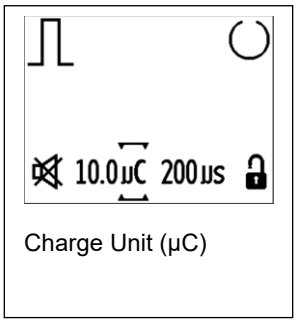
Default stimulation charge (µC)

Stimulation strength unit

Stimulation strength unit can be toggled between mA and µC by means of ◆◆ (no auto-repeat).



Current Unit (mA)

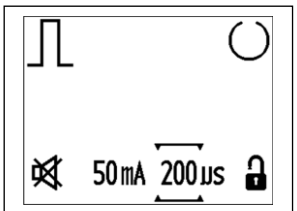


Charge Unit (µC)

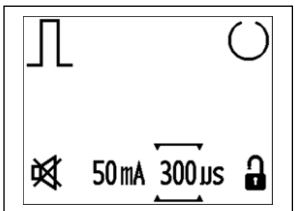
Default stimulation pulse width

Each single twitch consists of either a 200µs or a 300µs electrical pulse.

- Default pulse width can be controlled in setup mode and will be set right after *power up*/*new patient*.
- Changing pulse width will set device into an uncalibrated state.
  ◆◆ toggles the stimulation pulse width and no auto-repeat is active.



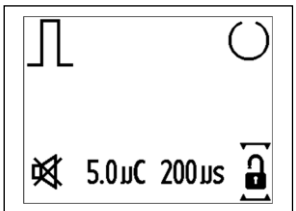
200µs electrical pulse



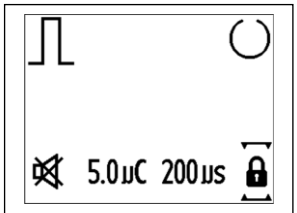
300µs electrical pulse

Lock/unlock stimulation settings

Changing of the parameter settings in the main screen can be locked or unlocked if necessary.



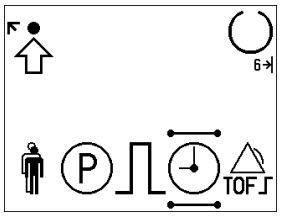
Unlock parameter settings



Lock parameter settings

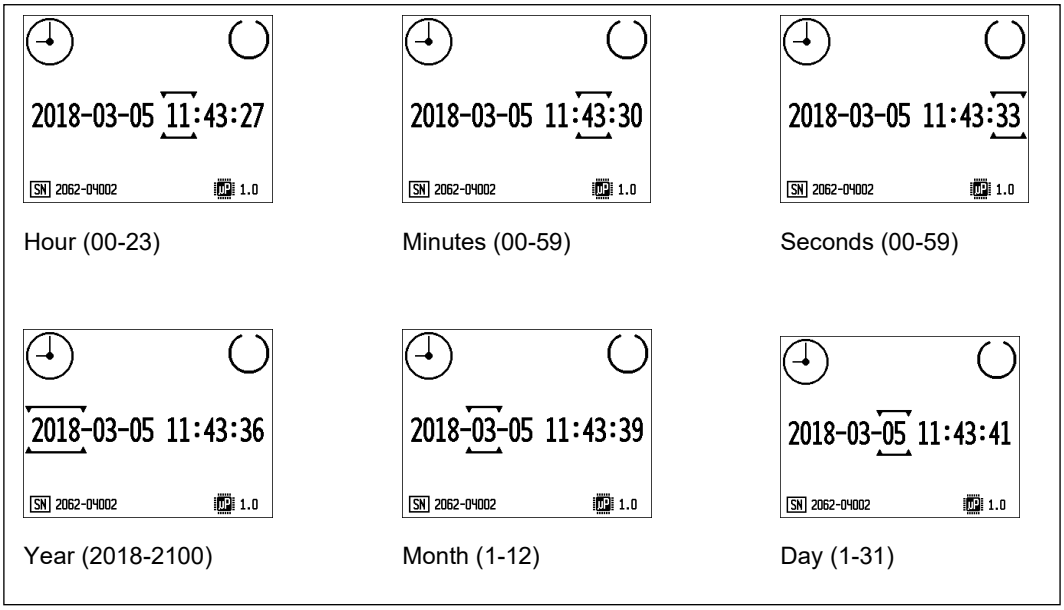
5.1.5 Set time and date

Select Clock in setup mode



Device contains a real-time 24-hour clock calendar.

Cursor will indicate [hours, minutes, seconds, year, month or day] to be adjusted by pressing ◀▶ (auto-repeats if held down for more than 0.5s)



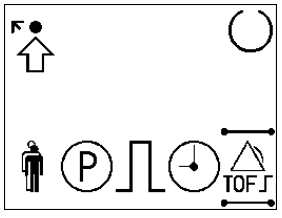
➤ **NOTE:** In case previous recordings are present in memory, change time and date is blocked (indicated by warning symbol ⚠). This is to ensure valid and un-manipulated timestamps in the recordings.

Exit to main screen by pressing ◉.

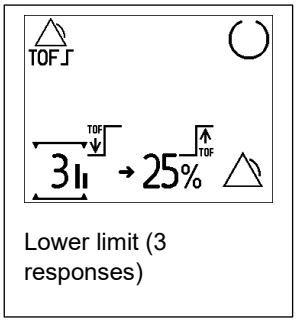
5.1.6 Set TOF Monitor

Select TOF limit section in setup mode and press the ◉ key.

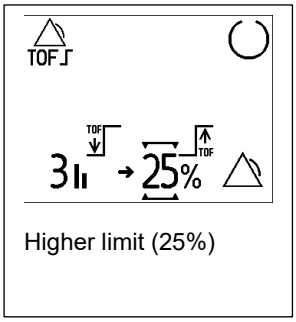
You may define a target range for TOF results.



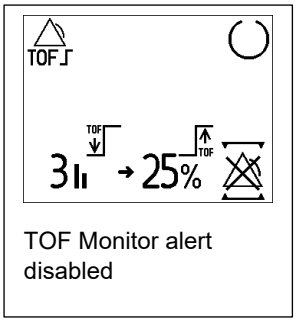
- If TOF results are outside of adjusted range, visual and audio alert will appear. Adjust limits by using ◀▶ (auto-repeats if held down for more than 0.5 seconds).
- Exit to main screen by pressing ◉.
- If one limit-value comes too close to opposite limit, this limit will be corrected in order to maintain valid min./max range.
- It is possible to disable TOF Monitor alert, but every change of Lower/Higher limits will automatically enable TOF Monitor alert signal.
- Provided that a valid TOF Monitor range exists→TOF Monitor alert signal can be muted/unmuted and reenabled in *Parameter change mode* (see 5.1.7).



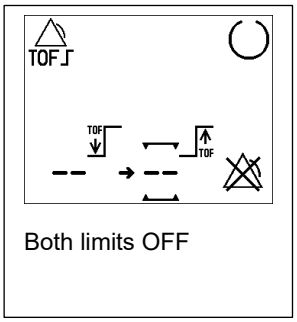
Lower limit (3 responses)



Higher limit (25%)



TOF Monitor alert disabled

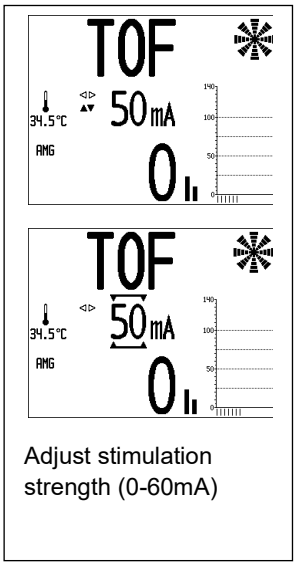


Both limits OFF

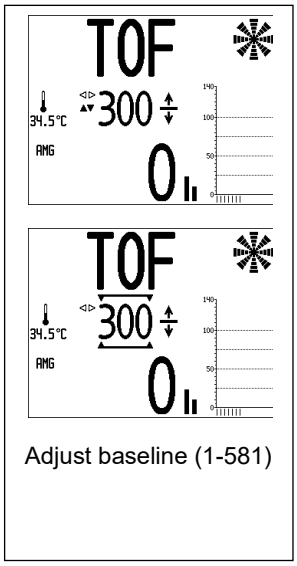
5.1.7 Parameter change mode

Pressing or in active mode will activate *Parameter change mode*, indicated by a cursor symbol around changeable parameter.

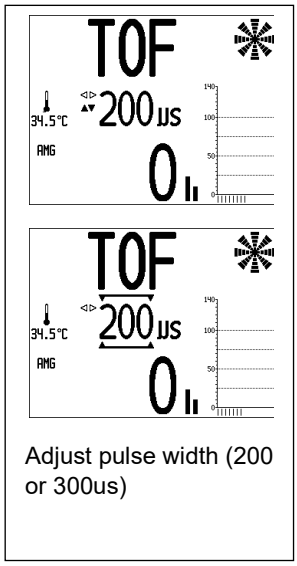
- Change selected parameter by using .
- When in *Parameter change mode,* it is also possible to use to select between four different parameters.



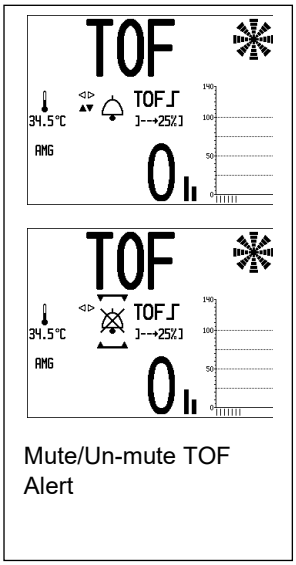
Adjust stimulation strength (0-60mA)



Adjust baseline (1-581)



Adjust pulse width (200 or 300us)



Mute/Un-mute TOF Alert

Note: * Baseline and TOF Monitor alert will only be shown when an AMG or MMG sensor is present.

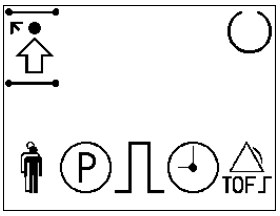
Note: After 2.5 seconds of inactivity the device will exit Parameter change mode and after further 7.5 seconds of inactivity the device will revert to stimulation strength display.

Note: The results from old or new measurements will still be shown/updated during the Parameter change mode. This makes it possible to judge the influence of changing a parameter.

Note: The stimulation strength and the baseline can automatically be set by using one of the automatic calibration sequences. Any manual adjustment of either stimulation strength, baseline or pulse width will set the device back into un-calibrated state!

5.1.8 Exit Setup Mode

Select exit symbol in main Setup mode and press key or exit Setup mode at any time by long pressing key.



The setup mode is automatically exited after 30 seconds of inactivity.

5.2 Alerts

5.2.1 Alerts during setup

Check for these alerts before using device:

- Internal error – during use
- Battery empty – during use
- Battery low – during use
- Clock OK – during use
- Data in memory outdated – during use

5.2.2 Medium alerts during use

Following situations will lead to alert, which stops ongoing stimulations.

- Internal error
- Battery empty
- No MAIN cable
- No AMG/MMG sensor
- Bad electrode connection
- Calibration error

5.2.3 Lower priority alerts during use

Following situations will lead to alert, which maintains ongoing stimulations.

- No Temperature sensor (only if sensor previously detected)
- Temperature out of valid range [20 - 45°C]
- Peripheral skin temperature low (<32°C)
- TOF Monitor alert - if enabled by operator
- Memory full
- External communication lost

5.2.4 Attentions during use

Following situations will lead to attention signal:

- Bad AMG/MMG response (audible annunciation)
- Memory low
- Battery low

5.2.5 Audible and visual signaling of alerts

No.	Description	Priority Level	Origin	Resulting System status	Displayed in section
1	Battery empty	Medium	O/T	Halt	1. Technical status [Bat] + <Halt Full screen>
2	Clock Reset	Medium	T	Halt	
3	Internal error	Medium	T	Halt	
4	LOG Data too Old	Medium	O/T	Halt	
5	No MAIN cable	Medium	O	Stop	8. Results & Alert [Result]
6	No AMG/MMG sensor	Medium	O	Stop	
7	Stimulation error	Medium	O	Stop	
8	Stimulation stopped due to lost communication	Medium	O/T	Stop	
9	Calibration signal unstable	Low	P/O	Stop	
10	Calibration signal too low	Low	P/O	Stop	
11	Calibration signal too high	Low	P/O	Stop	
12	Calibration cannot detect supra max. stimulation in CAL2	Low	P/O	Stop	
13	TOF monitor (high)	Low	P	Active	8. Results & Alert [TOFmon]
14	TOF monitor (low)	Low	P	Active	
15	No temperature sensor	Attention	O	Active	5. Peripheral skin temperature
16	Temperature out of range (low)	Attention	O	Active	
17	Temperature out of range (high)	Attention	O	Active	
18	Skin temperature low (<32 °C)	Attention	P	Active	
19	Memory full	Attention	T	Active	1. Technical status [Mem]
20	Memory low	Attention	T	Active	
21	External communication lost	Attention	T	Active	1. Technical status [Com]
22	Battery low	Attention	T	Active	1. Technical status [Bat]
23	Bad AMG/MMG response	Info	P/O	Active	8. Results & Alert [Result]
	Abbreviations in table: O: Operator P: Physiological T: Technical	Audio annunciations: Medium: 3 long beeps - 1100Hz Low: 2 long beeps - 1100Hz Attention: 2 short beeps - 1100Hz Info: 1 short beep - 1100Hz Long Key: 1 long beep - 2730Hz StimBeep: 1 short beep - 2730Hz				Note: Some of the above display sections have separate exclusive status indication areas stated in brackets [ ].

6. Technical Data

6.1 Technical Specification

6.1.1 Environmental Conditions

Operating Conditions:	
Temperature:	10C to 40 °C
Relative Humidity:	10 % to 90 %; (non-condensing)
Ambient Pressure:	70 kPa to 106 kPa
Altitude:	Max. 3000 m (9842.52 feet)
Use during HF surgery	The device will remain at the patient during electro cautery. The device will not be damaged during electro cautery. Strong electromagnetic disturbance signals may potentially suspend an ongoing stimulation as the disturbance signal may bring the stimulation outside the acceptable tolerance. This is detected by the TOF^{3D} device and the TOF^{3D} stops stimulation and signals an error.
Storage and Transport Conditions:	
Temperature:	-40 °C to 70 °C
Relative Humidity:	10 % to 90 %; non-condensing
Ambient Pressure:	70 kPa to 106 kPa

6.1.2 Device specifications

Physical characteristics

Height	62,5 mm
Width	141 mm
Depth	202 mm
Weight	390 gram
Colours	Housing: RAL 9016 (traffic white) Keyboard: RAL 9003 (signal white) and RAL 5017 (traffic blue)

Display

Type	LCD
Colour	Monochrome
Size	active area ≈ 89.6 mm × 67.2 mm
Resolution	240 x 320 dots

Battery Operation

Technology	Alkaline or NiCd/NiMH
Type	4x 1,5V AA
Battery Operating Time	≈ 1500 hours of constant TOF stimulation (Assumes 2000 mAh capacity in batteries).
Battery capacity monitoring	Indication of battery status (low/empty).
Low Battery condition	The device must be able to detect Low Battery condition and subsequently indicate a warning.
Removal	Battery connection allows removing the battery from the housing without special knowledge. For removing the battery compartment lid a screwdriver (PH2) is needed.
Recommended Types	Energizer & Duracell

Electrical Specifications

Classification	Internally powered (IEC 60601-1).
Classification of applied parts	Type BF (IEC 60601-1)
Equipment type	Handheld (IEC 60601-1)
AP/APG proof category	Not AP/APG rated (IEC 60601-1)
Mode of operation	Continuous
Classification according to the degree of protection against harmful ingress of water or particulate matter	IPX3
Operating Voltage Range	4 – 6 Volts; typical ≈5 Volts; absolute max. 7 Volts
Max. current	330mA$_{rms}$ [rms value measured over 1s]
Power consumption	Max 2,5 Watt

Stimulation specifications

Stimulation pulse	
Stimulation waveform	Monophasic rectangular wave.
Pulse width (duration)	200 or 300 µs [pulse width (duration) is measured at 50 % of the "pulse amplitude level"]. [Allowed measurement uncertainty: +/- 10 µs].
Pulse width accuracy:	+/- 10 %.
Stimulation current range	
Constant current	0 – 60 mA
Load range	100 Ohm to 5 kOhm
Current accuracy:	
6-60 mA setting	+/- 5 % of set current
0-5 mA setting	+/- 0.25 mA of set current
	[current is measured as "pulse amplitude level"]. [Allowed measurement uncertainty: 0-10 mA: +/-0.1 mA 11-60 mA: +/-0.25 mA]
Stimulation current increment	
Increment size	1 mA

Acceleration sensor (AMG)

Read-out range	3-254 % (valid data)
Read-out resolution within range	1 %
Accuracy of reading	±5 % of calibrated setting [100 % full scale]

Mechanomyography sensor (MMG) with Integrated Temperature sensor

Read-out range	3-254 % (valid data)
Read-out resolution within range	1 %
Accuracy of reading	±5 % of calibrated setting [100 % full scale]
Read-out range of Integrated Temperature sensor	20.0 - 45.0 °C
Read-out resolution within measurement range of Integrated Temperature sensor	0.1 °C
Accuracy of Integrated Temperature sensor	±0.5 °C

Temperature measurement requirements – Peripheral skin surface temperature sensor

Read-out range	20.0 - 45.0 °C
Read-out resolution within measurement range	0.1 °C
Accuracy	±0.5 °C

6.2 Cleaning and disinfection

CAUTION: *The Eye adapter TOF^{3D} and the Thumb adapter TOF^{3D} are for single use and shall not be cleaned or disinfected. Re-use of single use accessory can cause cross-infection of patients and/or incorrect monitoring.*

The TOF^{3D} and all of its multi-use components and accessories must be cleaned and disinfected in between each patient. Low-level disinfection is generally sufficient.

The TOF^{3D} and its components and accessories are non-sterile devices and shall under no circumstances be sterilized.

The surfaces of the TOF^{3D}, its multi-use components and its accessories have to be cleaned with a lint-free cloth moistened with one of the recommended cleaning and disinfection agents approved by the manufacturer.

Following cleaning / disinfection agents have been validated with the TOF^{3D}. Please check with your local distributor or with the manufacturer which products are available and approved in your country.

- Oxivir® Tb Wipes from Diversey Inc
- mikrozid® sensitive liquid from Schülke & Mayr GmbH
- mikrozid® sensitive wipes from Schülke & Mayr GmbH
- Descogen® Liquid rfu from ANTISEPTICA
- Mikrobac® Tissues from Hartmann/Bode
- Bacillol® AF from Hartmann/Bode
- Dismozon® plus from Harmann
- AHK Spiritus from Walter & Schmidt
- DISINFECTANT WIPES from Medipal
- Sani-Cloth Active Wipes from PDI
- Sporicidal Wipes from clinell
- Universal Wipes rom clinell

For the display of the TOF^{3D} use only Descogen® or mikrozid® from the list above.

It is recommended due to clinical practice to use all cleaning and disinfection agents according to their application instructions. Other chemical cleaners may damage the device and are not recommended. Do not use abrasive cleaners as these will damage the surface. Do not allow liquid to enter the case.

Cleaning Substances for Mechanomyography sensor (MMG) TOF^{3D}

The substances listed below can generally be used for cleaning and disinfection of the Mechanomyography sensor (MMG) TOF^{3D} according to the recommendations of manufacturer of the respective EPA registered products:

Group	Active substances
Alcohol	1-propanol; 2-propanol (isopropanol); ethanol
QAC (Quaternary ammonium compounds)	DDAC (didecyl dimethyl ammonium chloride); BAC (benzalkonium chloride)
Acids	Citric acid; lactic acid; acetic acid
Phenols	o-phenylphenol; p-chloro-m-cresol
Peroxides	Hydrogen peroxide; peracetic acid
Aldehydes	Glutaraldehyde; glyoxal; formaldehyde
Alkylamines	N-(3-aminopropyl)-Ndodecylpropane-1,3-diamin; coco propylene diamine

7. WARNINGS

- Be aware that federal law restricts this device to use by or on the order of a physician. (US only)
- The duration of the TOF^{3D} and its accessory should not exceed 24 hours.
- Do not use the TOF^{3D} on patients with implanted metallic or electrical devices e.g. cardiac pacemakers unless specialist medical opinion has first been obtained.
- Always make sure that no other equipment can touch the stimulation electrodes.
- Do not apply stimulation through the head, directly on the eyes, covering the mouth, on the front of the neck (especially the carotid sinus), or from electrodes placed on the chest and upper back or crossing over the heart.
- Cover the stimulation electrodes with insulating material so that, e.g., catheters can never be exposed to stimulation.
- Check each time before use that the material insulating the acceleration sensor and the stimulation cable is intact and does not show signs of wear and tear.
- Never touch the electrodes unless the stimulation has been stopped. When the display shows the stop symbol ◯ there is no stimulation. If this is not the case, press the button ◉ key.
- Do not use the TOF^{3D} in the presence of flammable anaesthetics.
- Patients with nerve damage, Bell's palsy, Myasthenia gravis or other neuromuscular problems may not respond properly to stimulation. The TOF^{3D} may show unusual patterns when monitoring relaxation in these patients.
- Do not apply electrodes to patients in areas where inflammation or injury is evident.
- The TOF^{3D} provides additional information on the patient's condition as far as relaxation is concerned. It does not replace any clinical judgment performed hitherto, or any test made when no TOF^{3D} was available.
- Monitoring of neuromuscular transmission or neuromuscular block can only be performed by using surface electrodes.
- Be sure only to use CE marked electrodes.
- Use of accessories, components, sensors, and cables other than the ones supplied with TOF^{3D} may result in degrade the electromagnetic compatibility and the performance of the device.

8. Disposal

Before disposal, remove batteries from the device. Batteries and devices with this label must not be disposed of with the general waste. They must be collected separately and disposed of according to local regulation.

CAUTION: *In the event that the TOF^{3D} is damaged and cannot be repaired or has reached the end of the product life dispose of the TOF^{3D} and all its components through an approved hazardous materials disposal facility in accordance with local regulations or return it to MIPM or an authorized distributor.*

CAUTION: *Accessories/Components that are damaged, worn out or contaminated with infectious substances of human origin must be disposed through an approved hazardous materials disposal facility in accordance with local regulations. Hereby it must be paid attention to physical hazards that arise from sharps.*

Area for company stamp or business card of the MIPM partner

Manufacturer:

MIPM Mammendorfer **I**nstitut für **P**hysik und **M**edizin GmbH

Oskar-von-Miller Str. 6-7

82291 Mammendorf (Germany)

Tel.: +49 (0) 8145 92090
www.mipm.com

Part Number: 5500121