Instructions for Use

TOF 3D

Neuromuscular Transmission Monitor

CE 0123

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.

TOF3D operating system software version: v1

List of contents

1. Introduction

1.1. Intended use

The TOF3D is intended to be used to quantitatively monitor the level of neuromuscular transmission during surgery or in the intensive care unit by means of acceleromyography. The device will be operated by medical staff and will aid qualified medical staff to maintain the proper level of neuromuscular block and to determine the level of recovery from neuromuscular block.

The TOF3D is intended for use by specialists, anesthetists and nurses with specialization in anesthesia care.

Patients:

The device is intended for use for adults (age > 18 years)

Prescription:

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

Excluded operating environment:

The device is not designed to be used outdoors, in homecare, ambulances, helicopters, aircraft, submarines, boats, hyperbaric chambers, explosive, flammable and oxygen rich 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 or micro wave therapy equipment is used)

Contraindications:

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

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

SPL - Sound Pressure Level

NMB - Neuromuscular Block

NMBA - Neuromuscular Blocking Agent

NMT - Neuromuscular Transmission

NMTM - Neuromuscular Transmission Monitor

OP - Operating theatre

LCD - Liquid Crystal Display

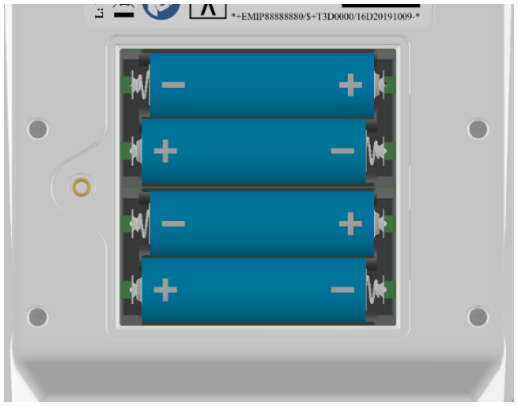
TOF - Train of Four

IFU - Instructions for use

1.3. Actions upon delivery

Upon delivery of TOF3D, please check package contents for completeness and any possible transportation damage.
TOF3D storage conditions are given in chapter 6.1 “Technical Specifications”.

To power the device, 4 x AA 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 TOF3D 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 TOF3D 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 installation, 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.

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 TOF3D 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 TOF3D 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 installed according to EMC information**.**

WARNING*:* Do not stack the TOF3D directly on top of other electronic equipment. If stacking is necessary, observe the TOF3D 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 TOF3D 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 TOF3D and the TOF3D 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 TOF3D is suitable for use in the Professional healthcare facility environment. The user of the TOF3D should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Further information**
RF emissions CISPR 11	Group 1 Class A*	The TOF3D 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 TOF3D is suitable for use in the Professional healthcare facility environment. The user of the TOF3D 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)

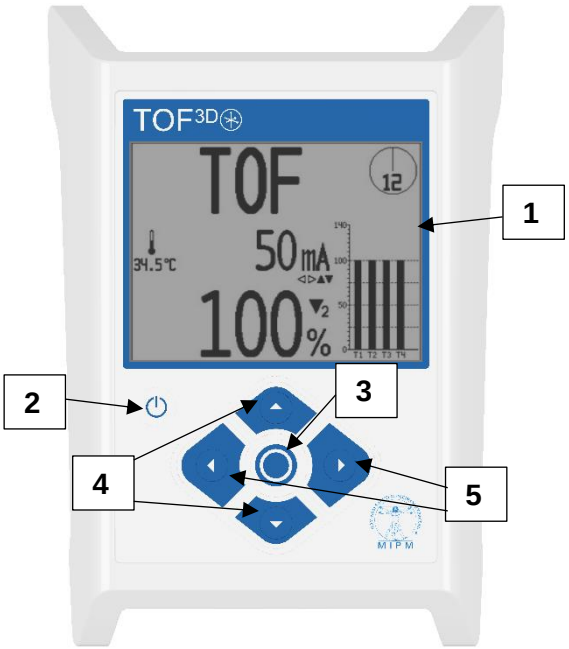
Compliance with standards/tests – electromagnetic immunity			
The TOF3D is suitable for use in the Professional healthcare facility environment. The user of the TOF3D should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level Compliance level**		
Conducted RF IEC 61000-4-6	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

2. Device and symbol description

2.1. Device description

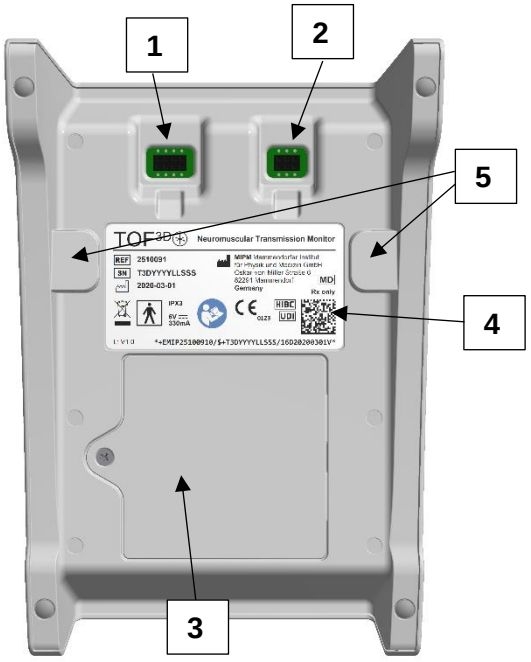
The TOF3D is a neuromuscular transmission monitor used during surgery or intensive care unit. The quantitatively monitor of the level of neuromuscular transmission by means of acceleromyography.

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/Labelling

The symbols in the following table may appear on the labelling of TOF3D Neuromuscular Transmission Monitor, the accessories/components, spare parts or the packaging material.

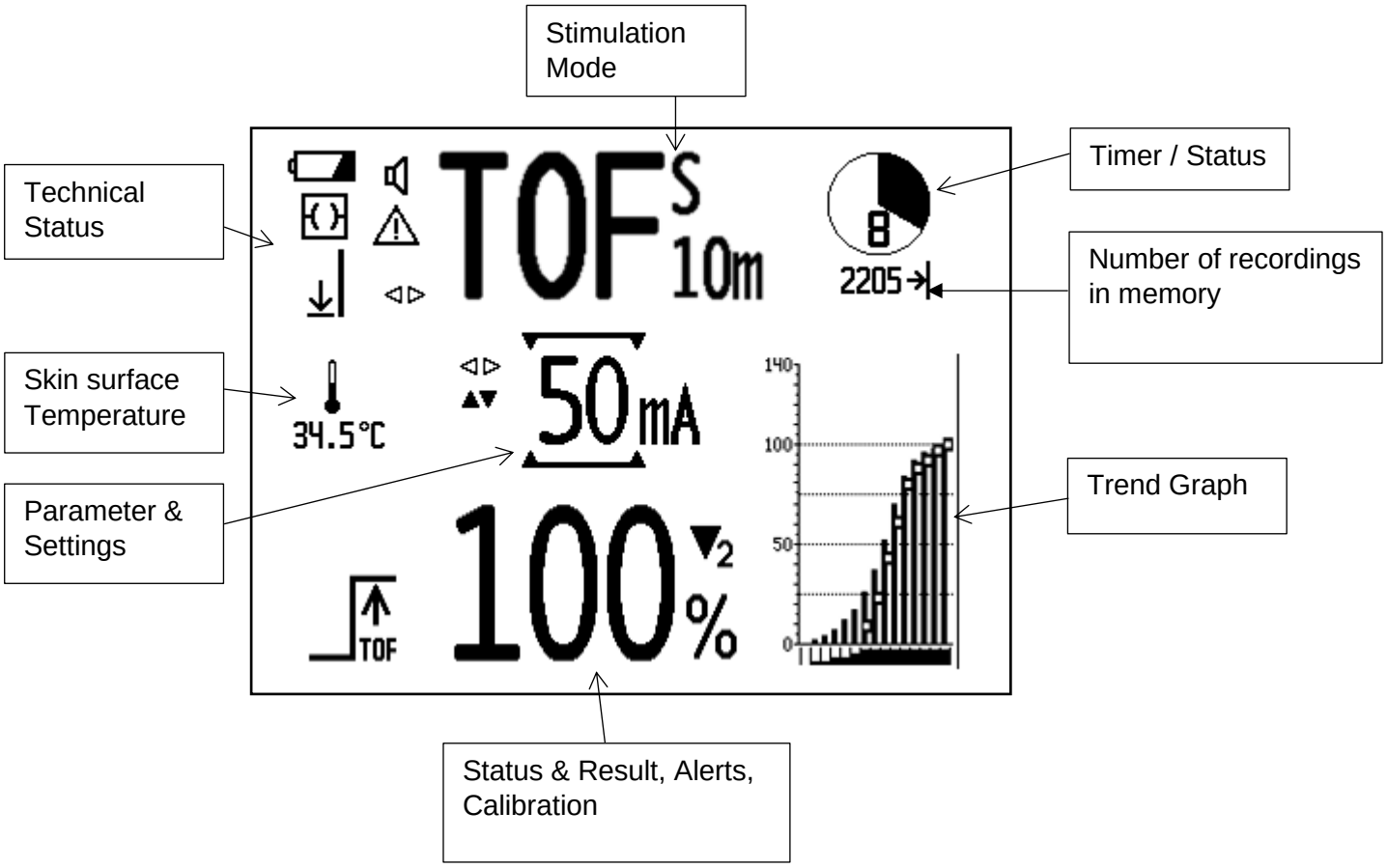
Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
TOF3D	Brandname	MIPM
´Keep packaging for reference`	Keep packaging for reference	MIPM
QTY:	String/symbol on label for quantity	MIPM
REF	Product reference / part number	ISO 15223-1 (ISO 7000-2493)
SN	Product serial number: T3DYYYYLLSSS Structure: - "T3D" (fix 3-digits): device ID - "YYYY" (variable 4-digits, numeric): year of manufacturing - "LL" (variable 2-digits, numeric): production LOT no./Batch no. of that particular year (of manufacturing) - "SSS" (variable 3-digits, numeric): serial no. of the unit in the actual LOT no./Batch no.	ISO 15223-1(ISO 7000-2498)
LOT	Batch code: T3DYYYYLL Structure: - "T3D" (fix 3-digits): device ID - "YYYY" (variable 4-digits, numeric): year of manufacturing - "LL" (variable 2-digits, numeric): production LOT no./Batch no. of that particular year (of manufacturing)	ISO 15223-1 (ISO 7000-2492)
Country of origin: Denmark	String/symbol on label for "Country of origin: [country]"	MIPM
	Date of manufacture YYYY-MM-DD	ISO 15223-1 (ISO 7000-2497)
	Manufacturer	ISO 15223-1 (ISO 7000-3082)
MD	Medical Device	ISO 15223-1:2020 (Proposal)

Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
	Obligation for the user to refer to the Instructions for Use (User Manual)	IEC 60601-1 (ISO 7010-M002)
	Parts included in a recovery / recycling process	WEEE (EN 50419)
	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).	IEC 60601-1 (IEC 60417-5334)
IPX3	Protection against water spray at an angle of up to 60°	IEC 60529
	Direct current (DC)	IEC 60601-1 (IEC 60417-5031)
Rx only	Caution: Federal Law in the United States restricts the device to sale by, or on the order of a physician.	21 CFR Part 801 Subpart D
CE 0123 CE	CE Marking	Directive 93/42/EEC (MDD); Regulation (EU) 2017/745 (EU-MDR)
	Indicate the pressure conditions allowed for transport	ISO 15223-1 (ISO 7000-2621)
	Temperature conditions allowed for transport and specifying the temperature range within which the package must be stored. (Indicate in °C and °F)	ISO 15223-1 (ISO 7000-0534)
	Indicate the humidity conditions allowed for transport	ISO 15223-1 (ISO 7000-2620)
	Fragile, handle with care	ISO 15223-1 (ISO 7000-0621)
	Keep dry	ISO 15223-1 (ISO 7000-0626)
	Does not contain or presence of natural rubber latex	ISO 15223-1:2012 5.4.5, Annex B, B2.

Symbol	Description		Source of Symbol: Referenced standard (basic standard and no. of Symbol)
	Do not reuse		ISO 15223-1 (ISO 7000-1051)
L:Vx.x	Label Version: Vx.x **x.x**: corresponds to label version		MIPM
	Unique Device Identification		ISO 15223-1:2020 (Proposal)
	Health Industry Bar Code		Health Industry Business Communications Council

	**UDI (Unique Device Identifier) is represented in AIDC (Automatic Identification Data Capture) acc. HIBCC with HIBC Data Matrix**
	Content varies depending on which Production Identifiers (SN; LOT or Manufacturing date) are used.
	(variable characters are highlighted)
	
	- Start Code after (not part in the Data Matrix):
	- HIBC Supplier Labeling Flag Character (fix 1-digit):
	- Labeler Identification Code (LIC) (fix 4-digits, alphanumeric):
	- Labelers Product/Catalog Number (fix 7-digits, numeric):
	- Unit of Measure ID (fix 1-digit, numeric):
	- Data Delimiter (fix 1-digit):
	
	if SN used:
	- Serial Number Reference Identifier (fix 2-digits):
	- Serial Number (Structure of SN explained above):
	
	if Lot used:
	- Lot Number Reference Identifier (fix 1-digit):
	- Lot Number (Structure of LOT explained above):
	
	if Code ends:
	- Check Character by Modulo 43 (variable, 1-digit):
	- End Code before (not part in the Data Matrix):
	
	if Manufacturing date is added continue Code:
	- Secondary Supplemental Data Delimiter (fix 1-digit):
	- Date of Manufacture Data Identifier (fix 3-digits):
	- Date of Manufacture (variable 8-digits, numeric):
	- Check Character by Modulo 43 (variable, 1-digit):
	- End Code before (not part in the Data Matrix):
		Readable text:
		
		“*”
		“+”
		
		“EMIP”
		
		“XXXXXXX”
		“Q”
		„/“
		
		“$+”
		“T3DYYYYLLSSS”
		
		“$”
		“T3DYYYYLL”
		
		“C“
		“*”
		
		“/”
		“16D”
		“YYYYMMDD”
		“C“
		“*”
			ANSI/HIBC 2.6

2.1.4. Survey of display



2.1.5. Parts of TOF3D

Medical Device

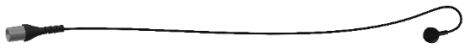
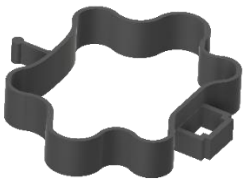
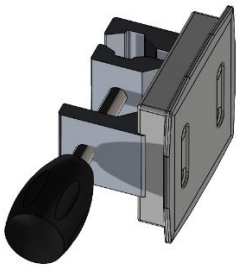
For usage of the TOF3D following components are mandatory:

Product	MIPM REF	Remark
TOF3D – Neuromuscular Transmission Monitor (NTM)	2510091	Medical Device

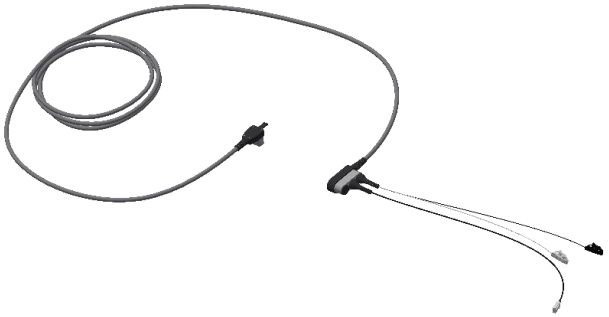
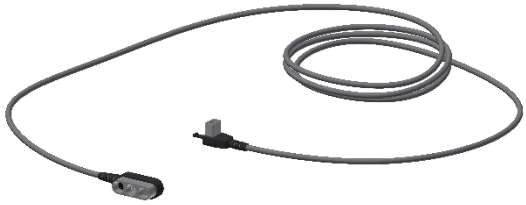
Consists of the following necessary components:

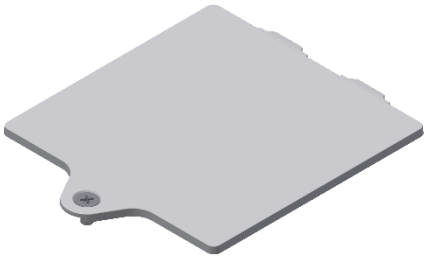
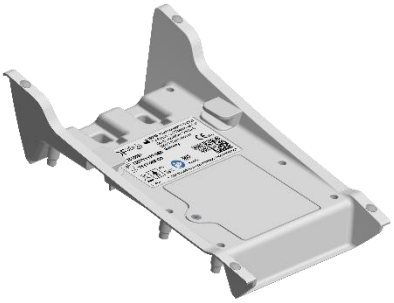
Product	MIPM REF	Remark
TOF3D Unit (multi use)	5750118	 Base Component
Main Cable TOF3D (multi use)	5750108	 Cable from device to split connector
Split connector sealing plug TOF3D (multi use)	5750116	 Cover to seal an open port on split connector
Stimulation cable TOF3D (multi use)	5750107	 Cable with two electrode clamps to connect the stimulation electrodes with main cable
Acceleration sensor (AMG) TOF3D (multi use)	5750105	 Cable with acceleration sensor for measurement of patient response
Battery (single use)	6450044	4xAA, Power supply
Interface sealing plug TOF3D (multi use)	5750109	 Cover to seal the open interface port on TOF3D

Accessories

Product (mulit/single use)	MIPM REF	Remark
Temperature sensor TOF3D (multi use)	5750106	 Sensor incl. Cable for skin surface temperature measurement
Eye Adapter TOF3D (single use)	5750102	 Adapter to place the acceleration sensor on the eyebrow (facial-nerve and Musculus Orbicularis Oculi)
Hand adapter TOF3D (multi use)	5750100	 Adapter for fixation of the hand (Nervus Ulnaris and Abduktor Pollicis)
Thumb adapter TOF3D (single use)	5750101	 Adapter for fixation of the acceleration sensor on thumb
IV-pole holder TOF3D (multi use)	5750110 Variant A	 Adapter to mount the device to an IV-pole
IV-pole holder TOF3D (multi use)	5750110 Variant B	 Adapter to mount the device to an IV-pole

Spare Parts

Product	MIPM REF	Remark
Complete Patient Cable TOF3D Including: - Main cable TOF3D, - Stimulation cable TOF3D, - Acceleration sensor (AMG) TOF3D - Split connector sealing plug TOF3D (all parts multi use)	5750104 incl. - 5750108 - 5750107 - 5750105 - 5750116	 Ready to use patient cable consisting of four parts
Main cable TOF3D (multi use)	5750108	 Cable from device to split connector
Stimulation cable TOF3D (multi use)	5750107	 Cable with two electrode clamps to connect the stimulation electrodes with the main cable
Acceleration sensor (AMG) TOF3D (multi use)	5750105	 Cable with acceleration sensor for measurement of the patient response
Battery (single use)	6450044	4xAA, Power supply
Split connector sealing plug TOF3D (multi use)	5750116	 Cover to seal an open port on the split connector
Interface sealing plug TOF3D (multi use)	5750109	 Cover to seal an open interface port on TOF3D

Battery Lid TOF3D (multi use)	5750111	 Cover to seal the battery compartment of TOF3D (incl.: 1x srew and 1x o-ring)
Housing top shell TOF3D (multi use)	5750114	 Upper half of the housing incl. membrane keyboard and display protection window
Housing lower shell TOF3D including: - Battery Lid TOF3D (multi use)	5750115 - 5750111	 Lower half of housing incl. battery lid, 6x srews, 4x bumpers

Service Parts

Product	MIPM REF	Remark
USB Interface cable TOF3D (multi use)	5750103	 USB Cable for Data Transmission

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 100 means that signal is above normal. Values below 100 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

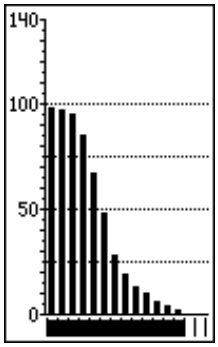
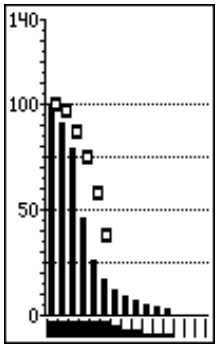
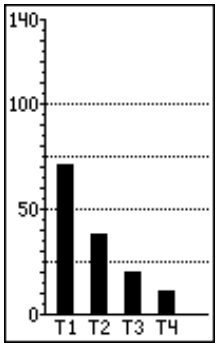
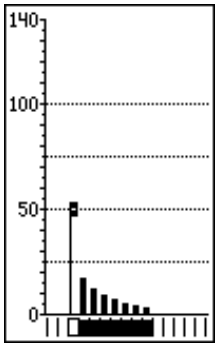
	Indicator for stimulation pulse width in micro-seconds.

Frequency units

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

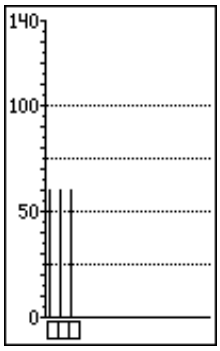
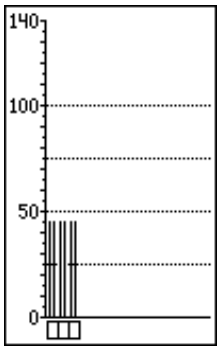
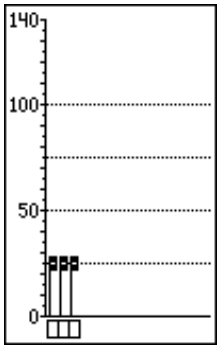
Trending graph (objective)

If valid acceleration 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 TOFs 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.

Trending graph (non-objective)

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

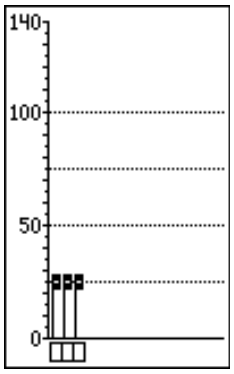
	**Single Twitch Stimulation graph** Shows the last 15 consecutive single twitch stimulations for 1Hz, 0.1Hz, PTC. Height of bars relates to stimulation strength in mA.
	**TOF/DBS stimulation graph** Shows the last 15 consecutive TOF/DBS stimulations. Height of bars relates to stimulation strength in mA.
	**TET stimulation graph** Shows the last 15 consecutive Tetanic stimulations. Height of bars (box center) relates to stimulation strength in mA. A single TET stimulation bar 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:

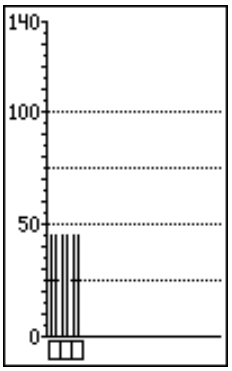
Closed box:	No valid acceleration response or subjective stimulation type (DBS, TET).
0/4 silo (empty):	Valid response, 0 twitches detected in TOF mode or single twitch mode.
1/4 silo:	Valid response, 1 twitch detected in TOF mode.
1/2 silo:	Valid response, 2 twitches detected in TOF mode.
3/4 silo: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

Trending mode with-out valid objective acceleration responses

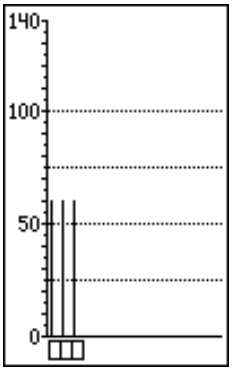
If for some reason no valid acceleration response can be recorded (DBS/TET/no sensor/bad response) then the height of the related trend bar indicates the actual stimulation strength in mA (thin lines).



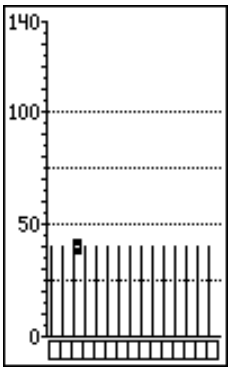
Tetanic stim. (25mA)



TOF/DBS stim. (45mA)



Single twitch stim. (60mA)



PTC stim. (40mA)

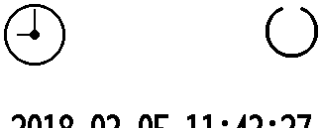
Temperature units

℃	Indicator for 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 in stimulation screen if calibration or stimulation is not possible

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.

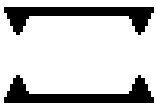
Ready to record

 (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.

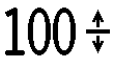
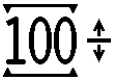
2.2.2. Parameter Symbols

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 acceleration response baseline. Baseline value of 100 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.

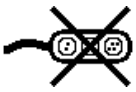
Battery empty (Medium)

 (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. 4 x AA 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.

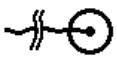
No MAIN cable (Medium)

 (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 Sensor (Medium)

 (Custom - TOF3D)	Flashing – in stop mode: Alert will trigger if no AMG sensor is connected. Alert is cleared after 15 seconds or by mode selection.

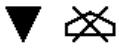
Electrode Error (Medium)

 (Custom - TOF3D)	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 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 32.2°C (0.3°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. 4 x AA Batteries required

3. Quick Guide

3.1. Electrodes and adapter positioning

Always use TOF3D 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 1cm² may lead to current densities exceeding 2mA/cm² and require special attention of the operator.

➤ **NOTE:** Any electrodes that have current densities exceeding 2 mA/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 can be conducted by stimulating following nerves or muscles:

- adductor pollicis / facial nerve
- posterior tibial nerve
- flexor hallucis brevis muscle
- orbicularis oculi muscle

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.

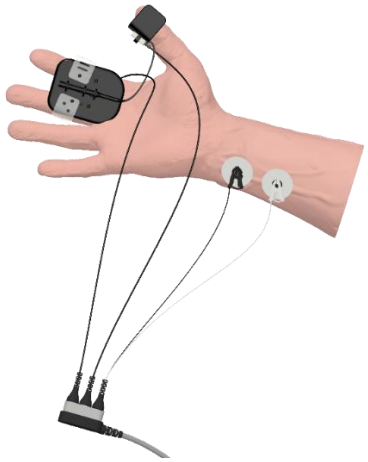
  For easier positioning it is recommended to use the hand-adapter.

3.2. Arm position

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

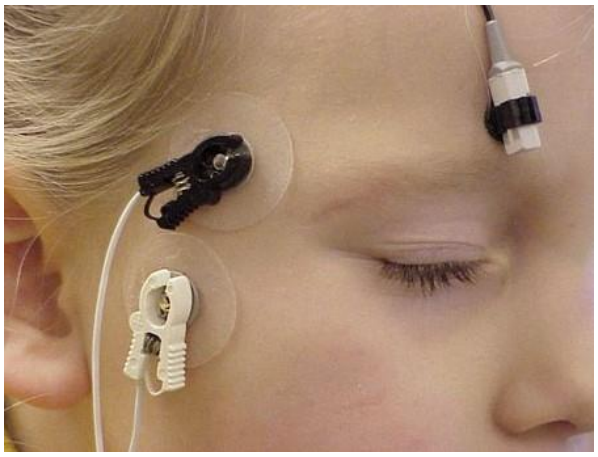
- Arm movement to another position may change twitch height considerably. train-of-four ratio will not be affected, no matter if twitch height may still differ from original value.
- Hand movements at later recovery stages may disturb measurements and recordings. (Avoidance by use of hand adapter)

<u>Electrode and sensor positioning on adductor pollicis / nervus ulnaris:</u>



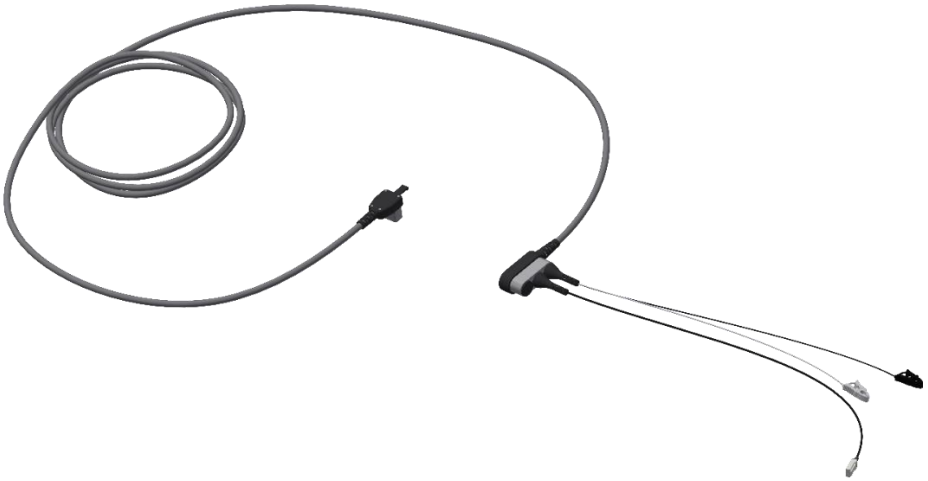
<u>Electrode and sensor positioning on posterior tibial nerve / flexor hallucis brevis muscle:</u>

Electrode and 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.

3.3. Cable connection



3.3.1. Subjective monitoring

No connection of acceleration sensor to TOF3D → Device can be used as peripheral nerve stimulator. Instead of patient response, TOF3D shows only stimulation strength in mA (µC) and stimulation mode (default stimulation strength set at 50 mA).

- Connect stimulation cable negative and stimulation cable positive 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 TOF3D
- 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 TOF3D can be used for objective monitoring by using following parts:

a. TOF3D
b. Acceleration sensor
c. Main cable
d. Stimulation cable
e. Thumb adapter / Hand adapter

- Connect stimulation cable negative and stimulation cable positive to surface electrodes placed on 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 TOF3D

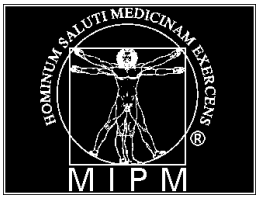
3.4. Connection to stimulator

Before touching electrodes, always check if TOF3D is switched off or stop symbol is displayed.

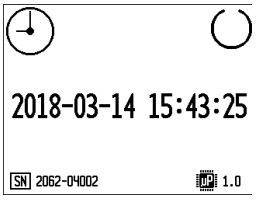
- Proximal electrode is connected to white (Positive) clamp on stimulation cable. Distal electrode is connected to black (Negative) clamp.
- If both electrodes are near wrist, polarity is less critical. Exchanging electrode polarity may sometimes increase stimulation considerably.

3.5. TOF-Measurement (typical session)

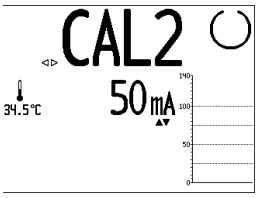
1. Press and hold the ⏻ button to turn on the device



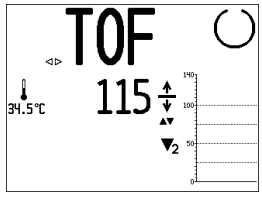
2. After a short time the picture changes to dark



3. System Self Check - Verify Date & Clock

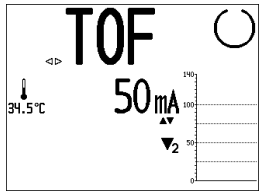


4. To start Initial calibration press and hold ◉ key before NMBA BOLUS is administered

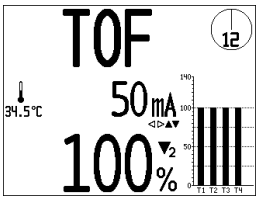


5. Calibration OK - New Baseline and Triangle with index 1 or 2 are shown.

(Index depends on selected Calibration Mode)

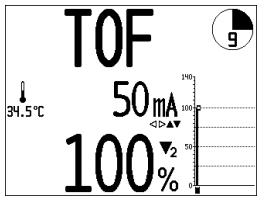


6. After a few seconds Stimulation strength is displayed

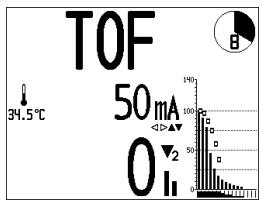


7. Start continuous TOF measurement by pressing

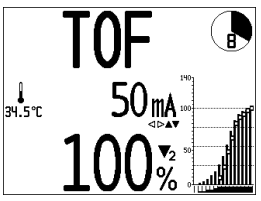
the key for at least 1 second.



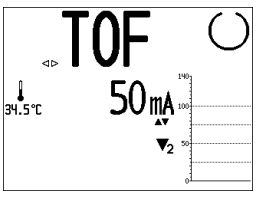
8. Administer NMBA BOLUS dose



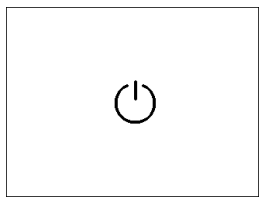
9. Observe effects of NMBA BOLUS dose



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 stimulation cable negative, stimulation cable positive, acceleration sensor and 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”

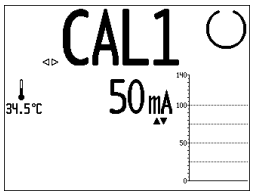
- Device incorporates two calibration sequences compatible with common medical practices.
- Calibration sequences calibrates device and creates base (reference) for subsequent twitch response measurements.
- If calibration procedure finds that acceleration signal is too low, too high or too unstable 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:

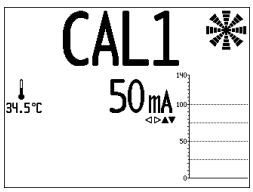
- Manual change of stimulation strength (current or pulse width)
- Manual change of baseline gain
- Dismounting cables/ acceleration sensor
- Powering off device with data logging mode in-active (see chapter 5.1.6 Log Mode)
- Long activation of key in calibration mode

CAL1

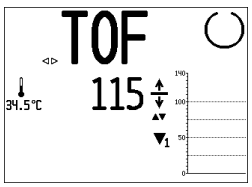
- Calibration sequence calibrates device for measurements at given stimulation current, without finding supra-maximal stimulation current.
- CAL1 sequence uses actual set stimulation strength and performs 100% calibration setting for set current.
- CAL1 calibration is based on number of averaged single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



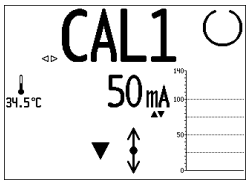
CAL1 mode selected



CAL1 in progress



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

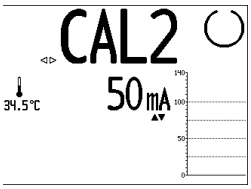


CAL1 error – signal unsteady

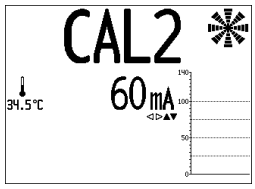
New Baseline shown for 3.5s

CAL2

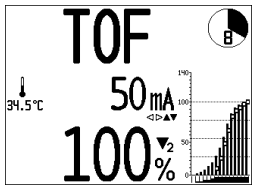
- CAL2 sequence finds supra-maximal stimulation current before performing 100% calibration at “supra-maximal stimulation current + 10%”.
- Finding supra-maximal stimulation current is done by first measuring response at 60mA (average of 5 measurements) and then decreasing stimulation current in 5mA steps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



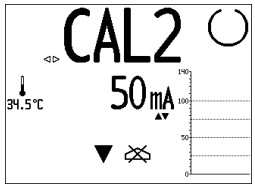
CAL2 mode selected



CAL2 in progress



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



CAL2 error – supra-maximal stimulation current could not be established

4.2.2. TOF/TOFs

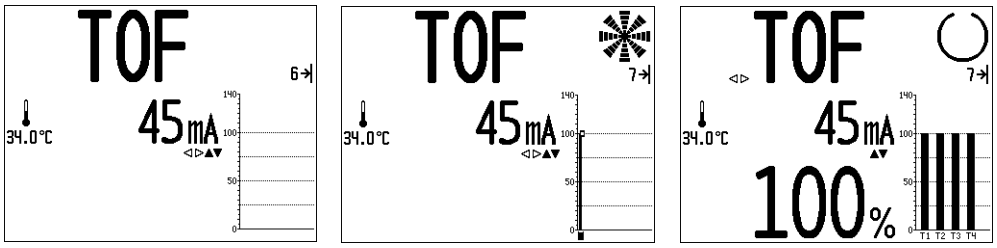
1 Select TOF stimulation by using keys in Stop mode.

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 TOFs stimulation in Stop mode.

4. Stimulation interval can be adjusted in setup mode between 1min and 60min. To initiate TOFs 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) used to calculate and display 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 rate of 15 seconds. Special slow TOF variant (TOFs): Stimulation interval can be adjusted in setup mode between 1min and 60min.
- In continuous TOF/TOFs 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)

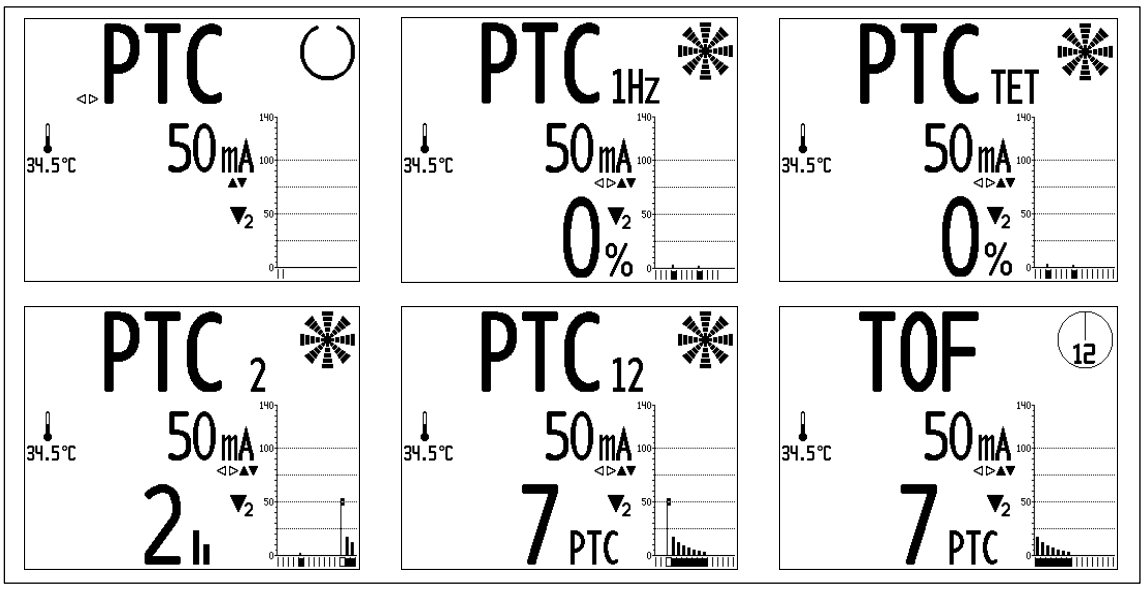
- First segment (PrePTC) ensures that relaxation degree of patient is sufficient for PTC to be useful→consists of 15 single twitch pulses (1Hz).
- If more than five consecutive responses above 3% are detected in PrePTC→ Complete PTC sequence is abandoned and TOF mode is automatically entered.

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.

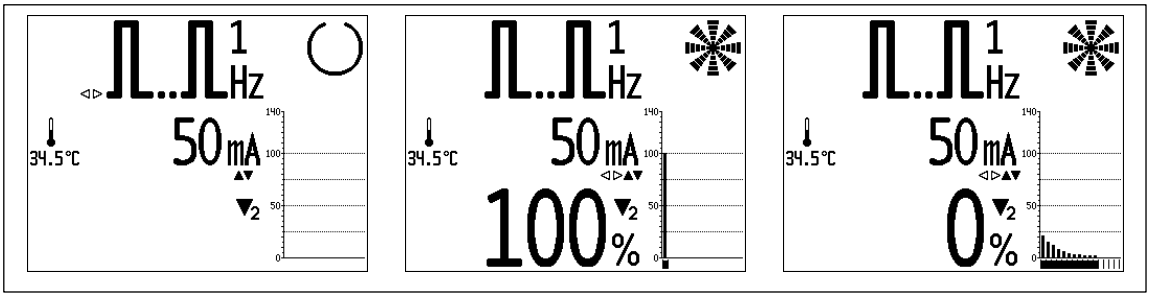
PTC (count)

- 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

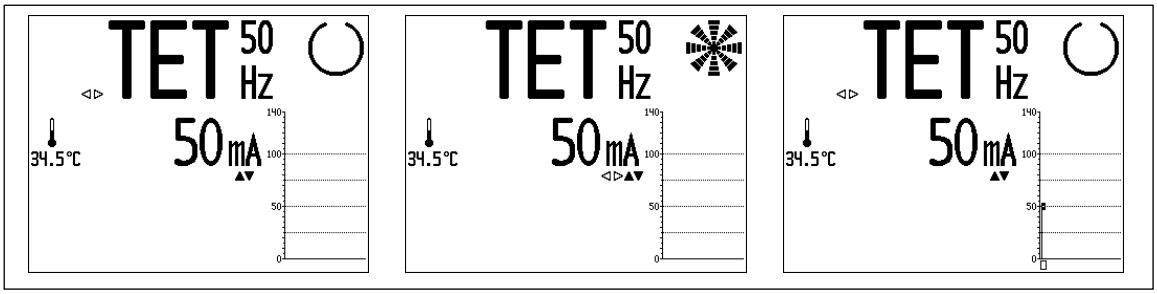
1. Select single twitch stimulation mode using keys in Stop mode.
2. Short activation of key will generate single twitch measurement
3. Long activation of key will start continuous twitch measurements at rate of 1Hz or 0,1Hz.
4. Stop continuous single twitch stimulation using key.



4.2.5. TET

1. Select single twitch stimulation mode using keys in Stop mode.
2. Activation by pressing key → 50 Hz tetanic stimulation will be initiated.
3. Stimulation can be prematurely stopped by means of key.

TET 50 Hz (same procedure for starting TET 100Hz)

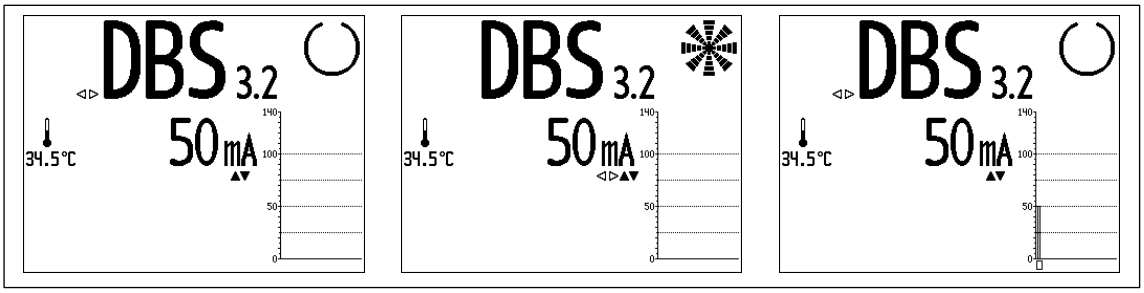


- In TET mode no acceleration signal can be recorded, but 5 second tetanic burst consisting of fast repeating single twitches at user programmed rate of 50 Hz or 100 Hz is performed.
- Stimulation frequency can be adjusted in Setup mode (chapter 5.1.8 “Stimulation setup”).
- Tetanic stimulation cannot be repeated within 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.

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)

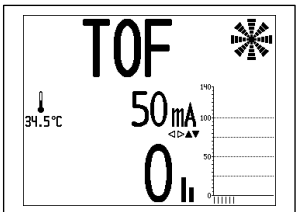


Double Burst Stimulation mode consists of two 750mS spaced pulse bursts:

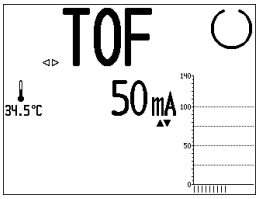
- The first always contains 3 stimulations with 20ms intervals and last burst contains 2(DBS3.2) or 3(DBS3.3) stimulations with 20ms intervals.
- It allows the anesthesiologist to perform a subjective evaluation of the relaxation degree.→ No objective response signal is recorded.
- The Stimulation cannot 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 ◉.



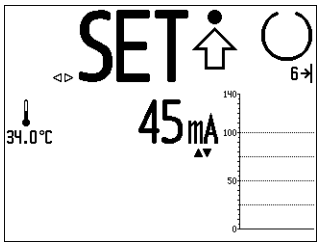
Active TOF stimulation



Stopped by pressing ◉

5. Setup

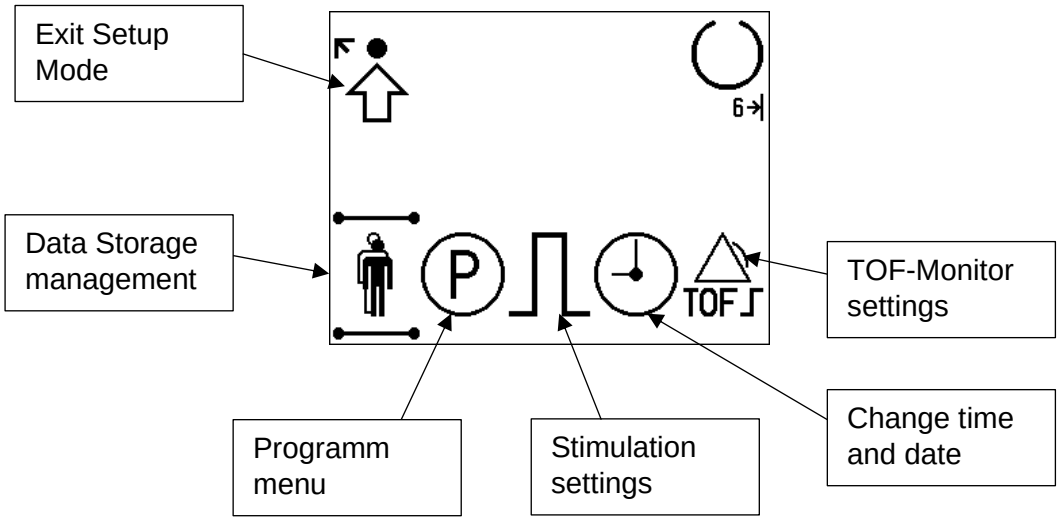
5.1. Quick Guide



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



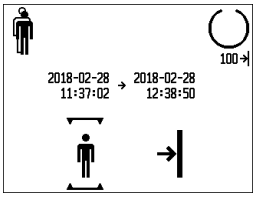
Selection of sub-sections as well as items in sub-sections is done by pressing ◀▶

Select the wanted menu by pressing ● key.

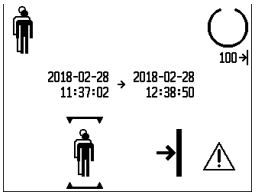
5.1.2. Data Storage management

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 present in non-volatile memory. If present→amount of used memory is displayed and device waits for user to decide what to do with existing data.

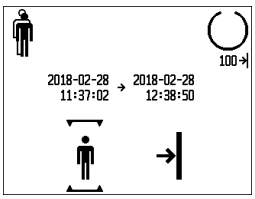
CAUTION: If more than 2 hours have elapsed since last data recording→operator is required to erase data before new measurements are possible (and).

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.

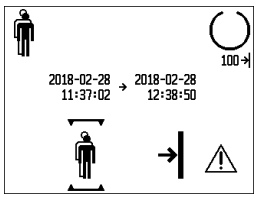
- Press to toggle between appending or erasing data
- Press to accept selection.

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



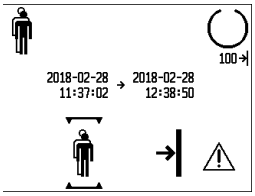
Existing data will be cleared - new patient.

To accept selection press key and device will continue in stop mode (TOF selected)

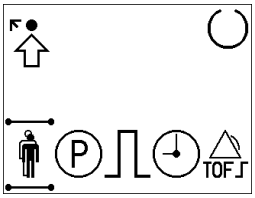
Keep old data:

***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:

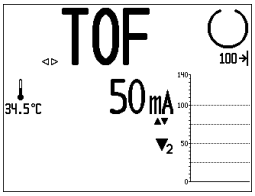
- All recordings
- Stimulation strength and pulse width
- Calibration type and baseline



Data will be cleared



:Exit to Setup mode



Press (Long): exit directly to TOF

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

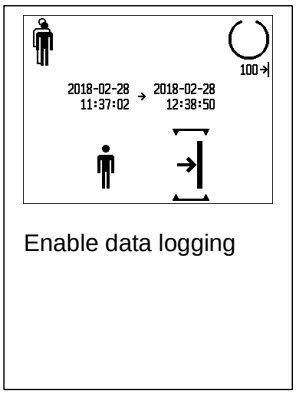
No existing data:

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 enter default stimulation type (TOF).

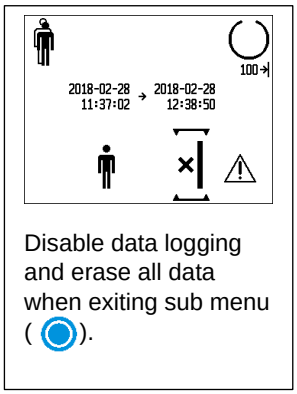
➤ **NOTE:** It is also possible to manually clear all recorded data in setup mode. This should be done for every new patient –if device is not switched off/on between patients.

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 ( ).

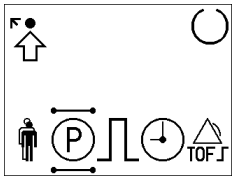
⚠ indicates that data is about to be erased upon exit of sub-menu!

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.

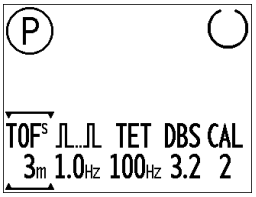
5.1.3. Parameter set menu

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

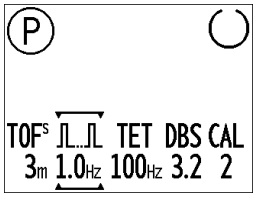
This menu controls additional pre-settings for various stimulation modes: [TOFs, Single Twitch, TET, DBS, CAL].



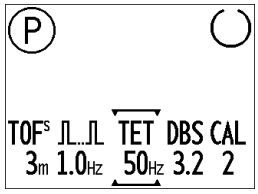
- Selection of a stimulation type is done by pressing ◂ or ▸ and change of a pre-defined stimulation mode parameter is done by pressing ▴ or ▾ .
- Exit to main screen is done by pressing ◉.



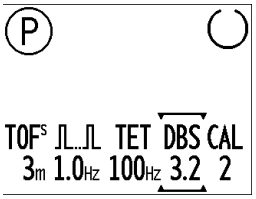
Slow TOF select individual stimulation interval using the ▾▴ keys - [1-60min]



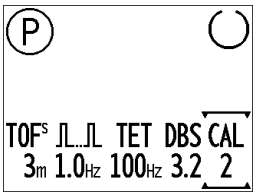
Single twitch – Choose between 1 or 0,1HZ using the ▾▴ keys



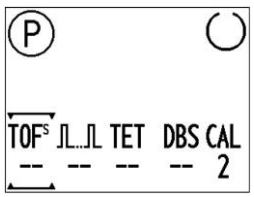
Tetanic stimulation Set rate for tetanic stimulation using the ▾▴ keys



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

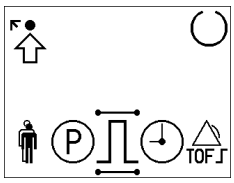


Calibration Select CAL1 or CAL2 using the ▾▴ keys



Deactivation of stimulation modes.

5.1.4. Stimulation setup

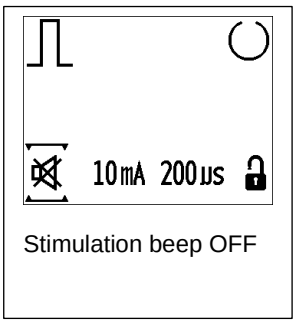


This menu controls stimulation related parameters. Select Stim Setup in setup mode and press key.

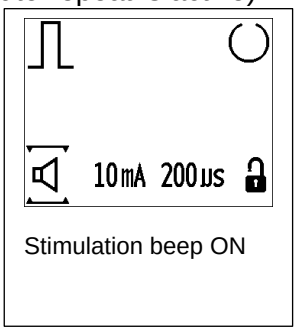
- Selection of a stimulation parameter is done by pressing or and change of selected parameter is done by pressing or .
- Exit to main screen is done by pressing .

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

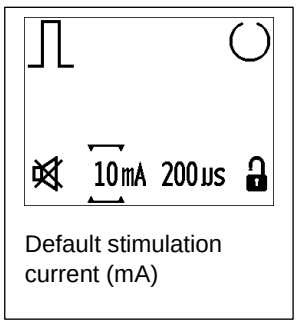


Stimulation beep ON

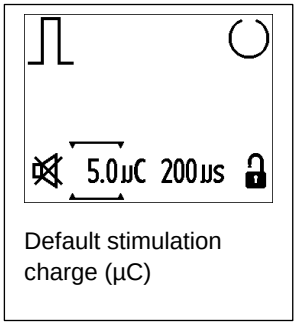
Default stimulation strength

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 3D stimulation pulse width (200µS/300µS).

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



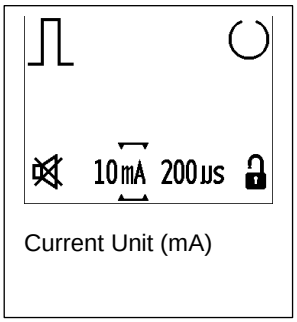
Default stimulation current (mA)



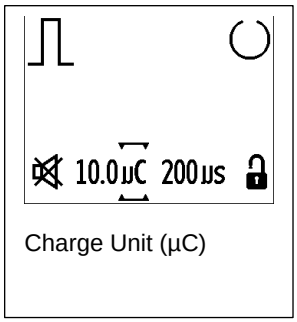
Default stimulation charge (µC)

Stimulation strength unit

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



Current Unit (mA)

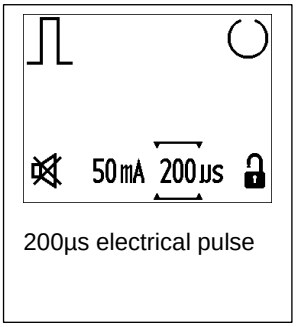


Charge Unit (µC)

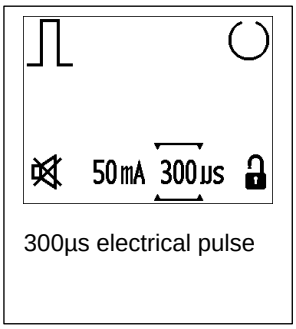
Default stimulation pulse width

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.



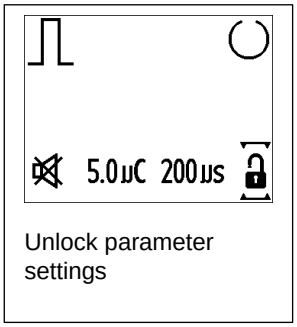
200µs electrical pulse



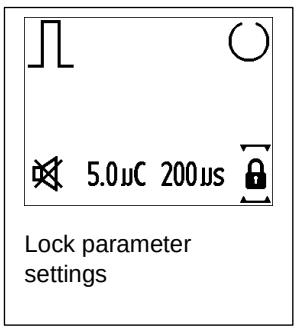
300µs electrical pulse

Lock/unlock stimulation settings

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

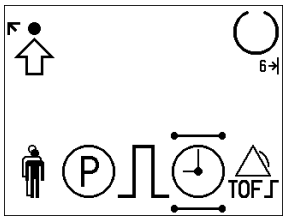


Unlock parameter settings



Lock parameter settings

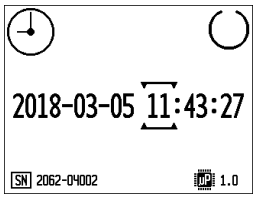
5.1.5. Set time and date



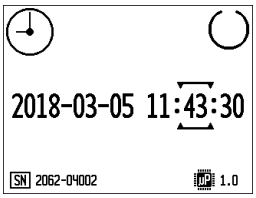
Select Clock in setup mode

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

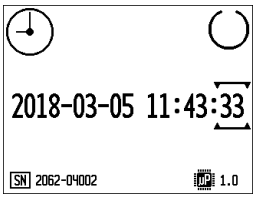
Cursor will indicate [hours, minutes, seconds, year, month or day] to be adjusted by pressing (auto-repeats if held down for more than 0.5s)



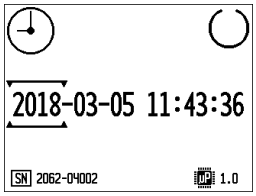
Hour (00-23)



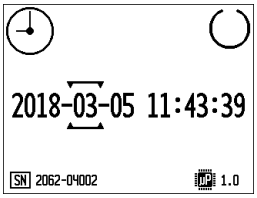
Minutes (00-59)



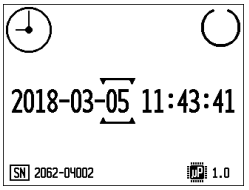
Seconds (00-59)



Year (2018-2100)



Month (1-12)



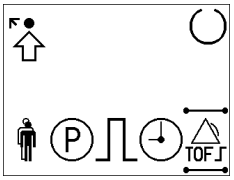
Day (1-31)

NOTE: In case previous recordings are present in memory, then changing time and date will generate a special recording event→Allows an external data processing unit to correctly interpret data where some time stamps are not true in real time.

Exit to main screen by pressing .

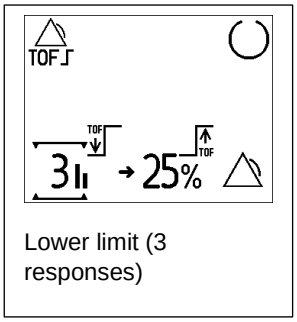
5.1.6. Set TOF Monitor

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

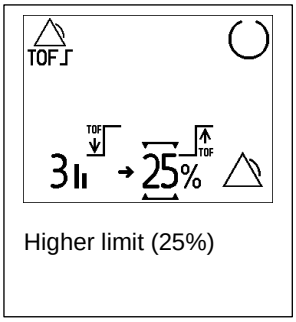


You may define a valid range for TOF results.

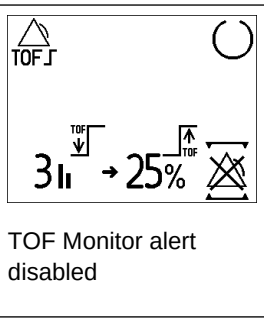
- If TOF results are outside of adjusted range, visual and audio alert will appear. Adjust limits by using (auto-repeats if held down for more than 0.5 seconds).
- Exit to main screen by pressing .
- If one limit-value comes to close to opposite limit, this limit will be corrected in order to maintain 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).



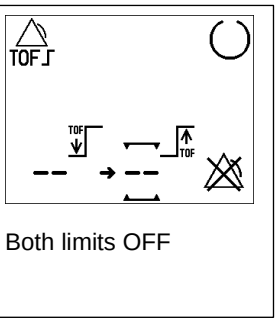
Lower limit (3 responses)



Higher limit (25%)



TOF Monitor alert disabled

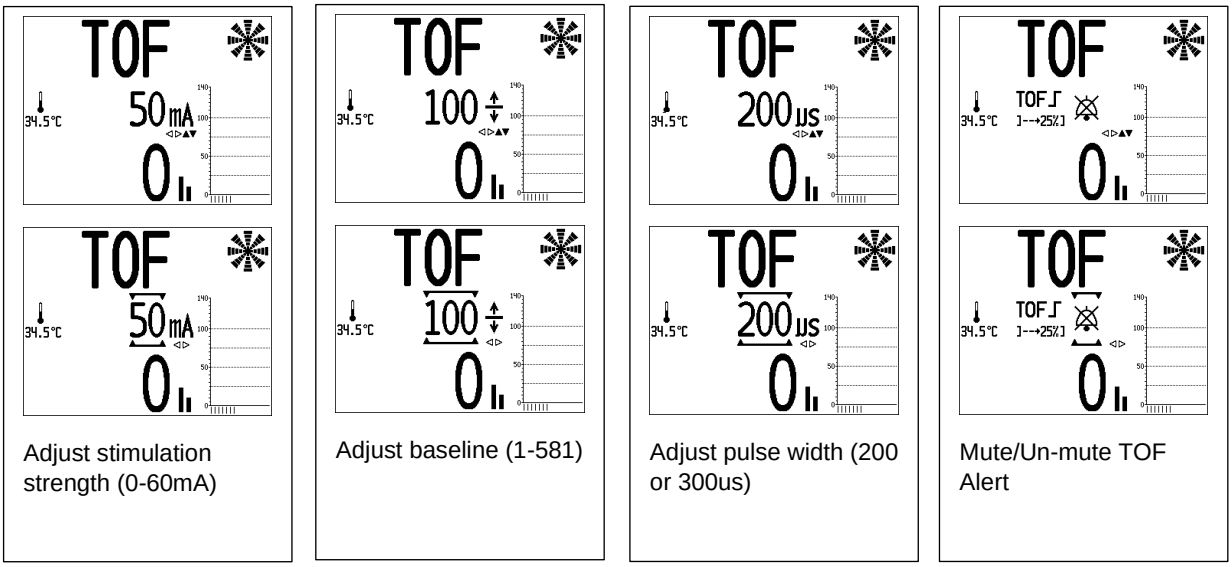


Both limits OFF

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 acceleration 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.

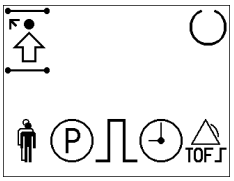
Note: The results from old or new measurements will still be shown/updated during the *Parameter change mode*. This makes it possible to judge the influence of changing a parameter.

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 reset 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 NMT cable
- No AMG 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]
- 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 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 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. 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 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:	15 °C to 40 °C
Relative Humidity:	20 % to 60 %; (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 TOF3D device and the TOF3D stops stimulation and signals an error.
Storage and Transport Conditions:	
Temperature:	-10 °C to 50 °C
Relative Humidity:	10 % to 95 %; non-condensing
Ambient Pressure:	70 Pa 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	4 x 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.

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

Temperature measurement requirements - 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

➤ **NOTE:** It is recommended due to clinical practice to disinfect the device and all of its components and accessories before each application on the patient.

It is recommended due to clinical practice to use all cleaning agents according to their application instruction.

Explanation of the Recommended application

The corresponding articles (multi use) are listed under the following terms.

Recommended application	Included parts of TOF3D
Housing	- Housing top shell - Membrane keyboard - Housing lower shell - Battery lid
Display	- Protection window
Accessories	- Temperature sensor - Hand adapter - IV pole holder
Spare Parts	- Main cable - Stimulation cable - Acceleration sensor - Split connector - Interface sealing plug

Cleaning agents

Manufacturer	Name	Form	Recommended application	Content / Ingredient (basic/major)
Antiseptica	Descogen-Liquid	Liquid	Housing, Display, Accessories, Spare Parts	Pentakalium-bis (peroxymonosulfat)
Hartmann/Bode	Microbac Tissues	Tissues	Housing, Accessories, Spare Parts	Benzyl-C12-18-alkyldimethylammoniumchlride, Didecyldimethylammoniumchlorid
Hartmann	Bacillol_AF	Liquid, Tissue, Foam	Housing, Accessories, Spare Parts	Propan, Ethanol
Hartmann	Bacillol_Plus	Liquid	Housing, Accessories, Spare Parts	Propan, Glutaral
Hartmann	Dismozon plus	Granules	Housing, Accessories, Spare Parts	Magnesium monoperoxyphthalat Hexahydrat
Schülke & Mayr	Mikrozid-sensitive liquid, wipes	Liquid, Spray, Tissues	Housing, Display, Accessories, Spare Parts	Benzyl-C12-16-Alkyl, methyl, dimethyl-, Chloride
Walter & Schmidt	AHK Spiritus	Liquid	Housing, Accessories, Spare Parts	Ethylalkohol
Pharmacy	Isopropyl	Liquid	Housing, Accessories, Spare Parts	Isopropyl Alcohol
Diversey Inc	Oxivir TB	Tissues	Housing, Accessories, Spare Parts	Hydrogen Peroxide

7. WARNINGS:

- Be aware that federal law restricts this device to use by or on the order of a physician. (US only)
- Do not use the TOF3D 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 TOF3D 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 TOF3D 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 TOF3D 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 TOF3D 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 TOF3D may result in degrade the electromagnetic compatibility and the performance of the device.

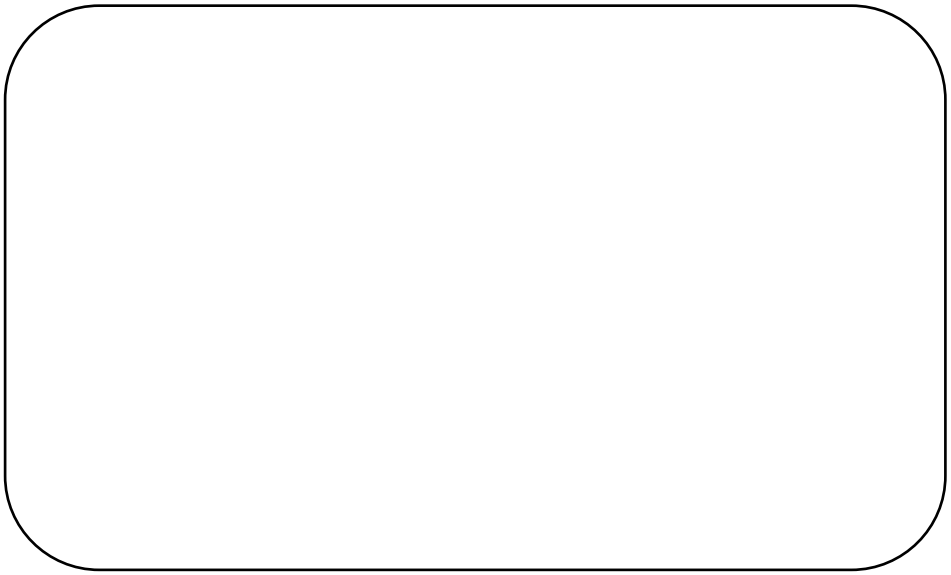
8. Disposal

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.

In the event that the TOF3D is damaged and cannot be repaired or has reached the end of the product life dispose of the TOF3D 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.

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 payed attention to physical hazards that arise from sharps.

Area for company stamp or business card of the MIPM partner



Manufacturer:
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