

Service Manual

TOF3D Neuromuscular Transmission Monitor



	<p align="center">Project/Product: TOF3D</p>	<p align="center">Service Manual</p>
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Table of Content

1.	Introduction	3
1.1	Purpose and Scope.....	3
1.2	Related Documents.....	3
1.3	Symbols/Definitions.....	3
1.4	Safety and Essential Performance	4
2.	Definition of Abbreviations and Terms.....	4
3.	Intended Use.....	5
4.	Device Description.....	5
4.1	Medical Device.....	5
5.	Troubleshooting.....	6
5.1	Troubleshooting:	6
5.2	Audible and visual signalling alerts:	7
6.	Repair procedures.....	8
6.1	Open Housing.....	8
6.2	Replacing Enclosure upper part.....	10
7.	TSC Procedures.....	11
7.1	Visual Inspection.....	11
7.2	Functional Check.....	11
8.	Accessories/ Spare Parts.....	12
8.1	Accessories.....	12
8.2	Spare Parts.....	14



Project/Product: TOF3D

Service Manual

1. Introduction

1.1 Purpose and Scope

This manual provides the technically qualified service person with troubleshooting information, repair procedures, and calibration and performance verification instructions. This manual is written for qualified technical service personnel familiar with the operation and design of the TOF3D and who have been authorized and trained by MIPM to service the system.

1.2 Related Documents

Instruction for Use TOF3D Master

1.3 Symbols/Definitions



NOTE: A note presents important information and set it off from the rest of the text.




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 danger that may result in equipment damage or personal and patient injury.



The indicator refers to a possible action that can be performed by the technician.

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

1.4 Safety and Essential Performance

The TOF3D has to be evaluated to the applicable general, collateral and particular requirements (standards) for safety and essential performance of Medical Electrical Equipment (IEC 60601-x).

There are no essential performances specified in the relevant particular standards (IEC60601-2-10 and IEC60601-2-40). Therefore, the essential performances are specified in the table below:

Requirement
The device has to operate according its intended use even during exposure to strong EM fields*
The information indicated on display has to be clearly readable
The electrical pulse height and length on surface stimulation electrodes have to be within the specified values, limits and tolerances**
The response signal of the acceleration sensor has to be within the specified values, limits / tolerances
The response signal of the temperature sensor has to be within the specified values, limits / tolerances
* Stopping of active stimulation during the exposure to strong EM fields is allowed, as long stimulation and measurement can be (re)started after stop of the exposure. (maintain Essential Performance)
** The device has to detect if stimulation parameters are outside the acceptable tolerance due to external influences (EM fields), stop the stimulation and signal an alert.

2. Definition of Abbreviations and Terms

Abbreviation	Term – Definition, Description
TOF	Train of Four
TOFR	Train of Four ratio
TOFC	Train of Four count
PTC	Post tetanic count
TET	Tetanic stimulation
DBS	Double Burst Stimulation
ST	Single Twitch
AMG	Acceleromyography
MMG	Mechanomyography
NMT	Neuromuscular Transmission
SRS	Software Requirement Specification
PRS	Product Requirement Specification
TBD	To be defined
OR	Operating Room environment
LCD	Liquid Crystal Display
NMB	Neuromuscular Block
NMBA	Neuromuscular Blocking Agent
TSC	Technical Safety Check

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

3. 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 environment or environment with sources of intense electromagnetic disturbances (e.g. Radio Frequency (RF) shielded room of magnetic resonance imaging equipment, electrophysiology laboratories or areas where short wave therapy equipment is used).

Contraindication:

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

4. Device Description

4.1 Medical Device

Description	MIPM REF	Remark
TOF3D - Neuromuscular Transmission Monitor (NTM)	2510091	Medical Device


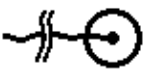


Consists of following necessary components:

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

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

5. Troubleshooting

5.1 Troubleshooting:

Problem	Potential cause	Potential involved parts and suggested actions
Device does not switch on	<ul style="list-style-type: none"> - Batteries empty - Defective PCB 	<ul style="list-style-type: none"> - Replace batteries - If the problem persists, contact MIPM
Internal alert symbol appears: 	<ul style="list-style-type: none"> - Defective PCB - Software problem 	<ul style="list-style-type: none"> - Replace batteries and restart the device - If the problem persist, contact MIPM
Electrode alert appears: 	<ul style="list-style-type: none"> - Wrong placement of electrodes - Bad electrodes - Defective stimulation cable 	<ul style="list-style-type: none"> - Place electrodes as described in IFU - Replace electrodes - Replace stimulation cable
Main cable alert appears: 	<ul style="list-style-type: none"> - Main cable defective - Connector on PCB defective 	<ul style="list-style-type: none"> - Replace cable - If the problem persists, contact MIPM
AMG sensor alert appears: 	<ul style="list-style-type: none"> - Crystal inside housing damaged - AMG cable damaged - Main cable damaged 	<ul style="list-style-type: none"> - Replace AMG sensor cable - Replace Main cable
System alert No. XX	Refer to Table 1	<ul style="list-style-type: none"> - Contact MIPM



Project/Product: TOF3D

Service Manual

5.2 Audible and visual signalling alerts:

No.	Description	Priority Level	Origin	Resulting System status	Displyed 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: <u>Medium:</u> 3 long beeps - 1100Hz <u>Low:</u> 2 long beeps - 1100Hz <u>Attention:</u> 2 short beeps - 1100Hz <u>Info:</u> 1 short beep - 1100Hz <u>Long Key:</u> 1 long beep - 2730Hz <u>StimBeep:</u> 1 short beep - 2730Hz			Note: Some of the above display sections have separate exclusive status indication areas stated in brackets [].

Table 1

6. Repair procedures



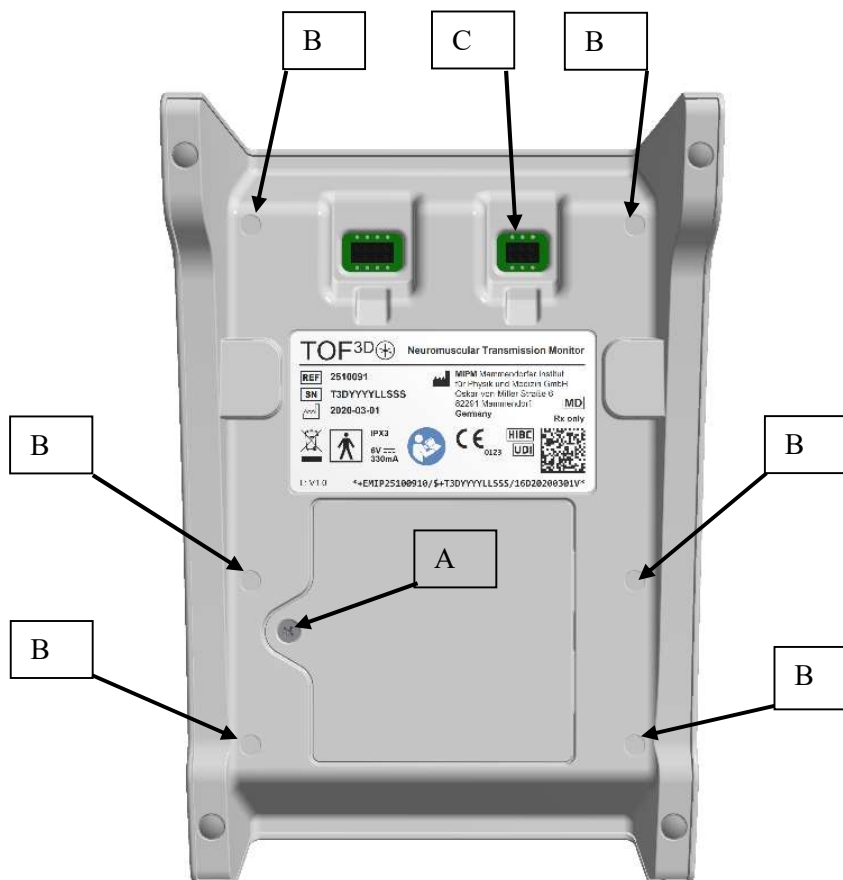
It is advisable to clean and disinfect the device's external surfaces before any maintenance operation in order to protect the operator.



The TOF3D contains electrostatic sensitive components. You must wear a wrist grounding strap when handling components and place on an anti-static pad. Failure to comply may result in damage to equipment due to electrostatic discharge.

6.1 Open Housing

- Remove the battery lid by removing screw (PHI no. 1) (marker A)
- Remove the 4 batteries within battery compartment (if present)
- Remove the Interface sealing plug (marker C)
- Remove the six silicone plugs and the six screws below (Torx X6) (marker B)

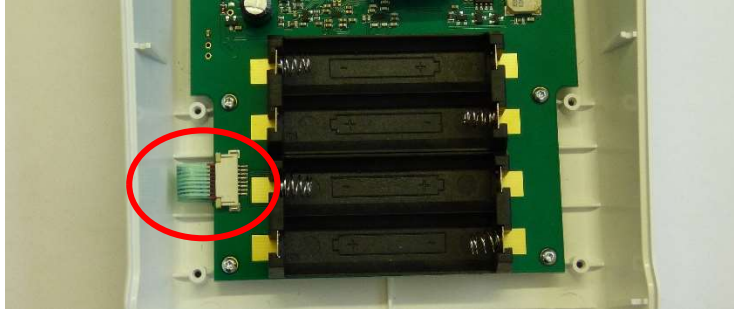


- Slide out the lower housing shell

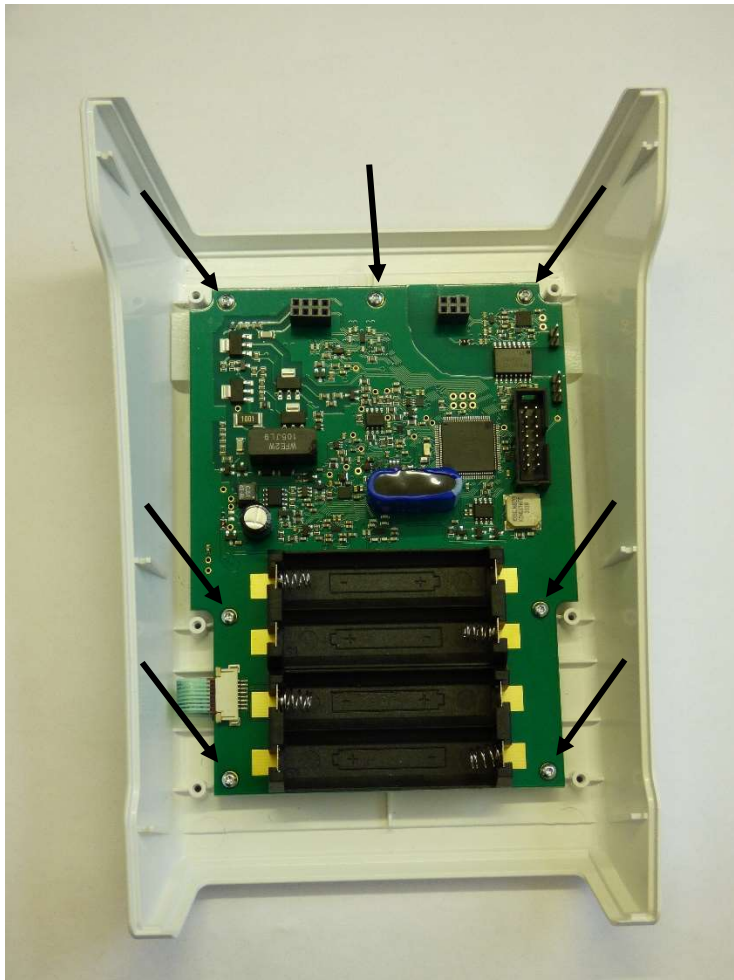


6.2 Replacing Enclosure upper part

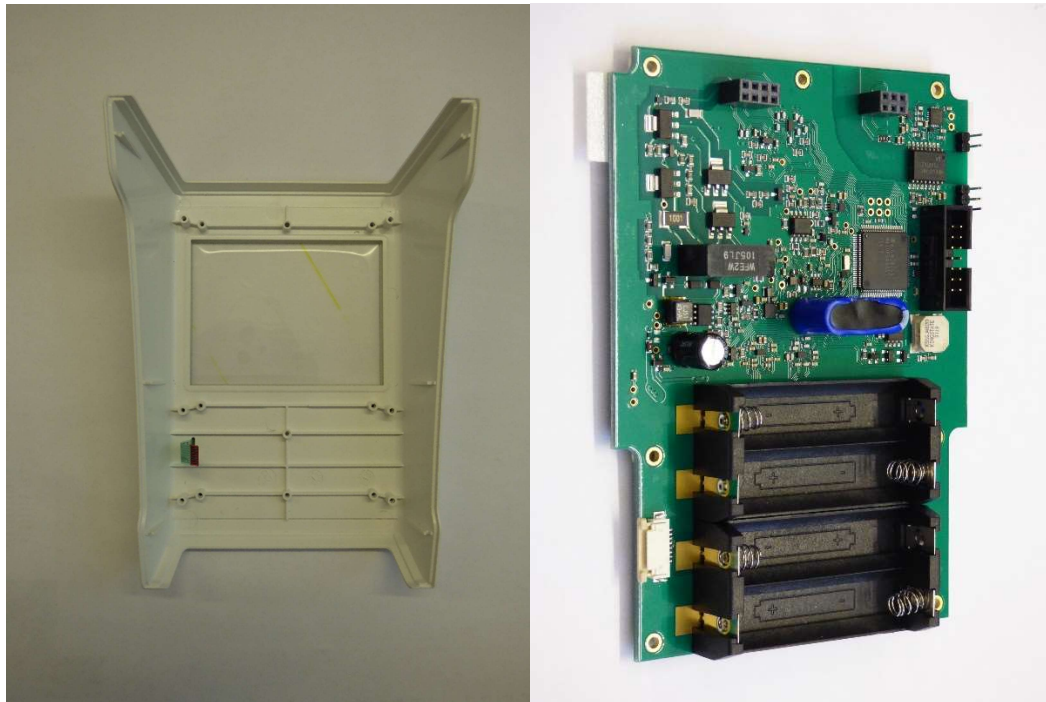
- Unplug flat ribbon cable from PCB



- Remove all screws
-



- Carefully slide out PCB/Display assembly



7. TSC Procedures

7.1 Visual Inspection

- Check the overall condition of the instrument for mechanical defects which might influence the performance and safety of the device.
- Check the overall condition of the accessories for mechanical defects which might influence the performance and safety of the device.




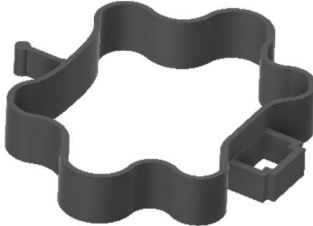

7.2 Functional Check

- Check voltage of the used batteries are sufficient to carry out normal operation of the device.
- Connect testbox with resistor to the surface electrode stimulation cable and connect an oscilloscope across the two terminals of the resistor. Connect the surface electrode stimulation cable and the AMG sensor cable to the TOF3D
- Switch the device ON and check that all functions and associated display information are functional and as described in the user manual. Check functionality of all switches.
- Adjust the current and the pulse width settings to the values on the protocol and start a “1 Hz” stimulation. Check by means of the connected oscilloscope that the peak to peak voltage across the resistor is correct. Check that the pulse width of the stimulation pulse is correct.
- Decrease the stimulation current gradually and see that the amplitude of the stimulation voltage also decreases gradually. Check that there are no read-out of AMG sensor signals when the AMG sensor is kept complete still during stimulation and that a reading is present if the AMG sensor is shaken during a stimulation.

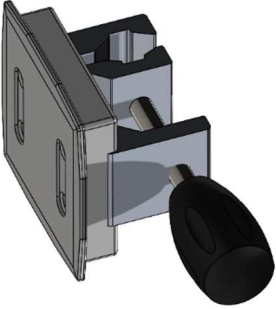

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

8. Accessories/ Spare Parts

8.1 Accessories

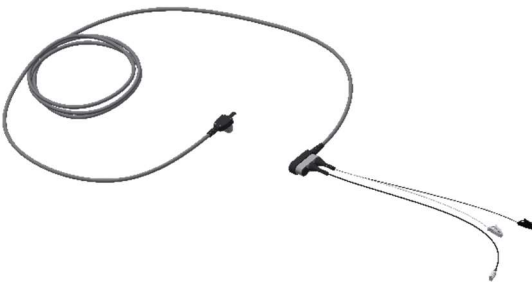



Product	MIPM REF	Remark
TOF3D Temperature sensor (multi use)	5750106	 <p>Sensor incl. Cable for skin surface temperature measurement</p>
TOF3D Eye Adapter x50 (single use)	5750102	 <p>Adapter to place the acceleration sensor on the eyebrow (facial-nerve and Musculus Orbicularis Oculi)</p>
TOF3D Hand adapter (multi use)	5750100	 <p>Adapter for fixation of the hand (Nervus Ulnaris and Abductor Pollicis)</p>
TOF3D Thumb adapter x50 (single use)	5750101	 <p>Adapter for fixation of the acceleration sensor on thumb</p>
TOF3D USB Interface cable (multi use)	5750103	 <p>USB Cable for Data Transmission</p>

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

Product	MIPM REF	Remark
IV-pole holder TOF3D (multi use)	5750110 (Variant A)	 <p>Adapter to mount the device to an IV-pole</p>
Adapter for IV Pole (multi use)	5750110 (Variant B)	 <p>Adapter to mount the device to an IV-pole</p>


	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

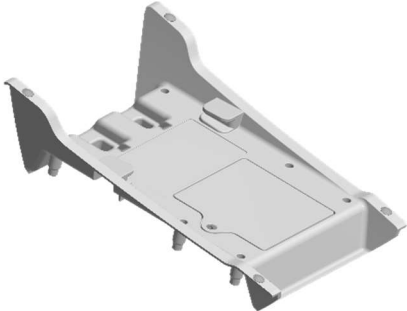
8.2 Spare Parts

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

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

Product	MIPM REF	Remark
TOF3D Split connector sealing plug (multi use)	5750116	 Cover to seal an open port on the split connector
TOF3D Interface sealing plug (multi use)	5750109	 Cover to seal an open interface port on TOF3D
TOF3D Battery Lid (multi use)	5750111	 Cover to seal the battery compartment of TOF3D (incl.: 1x screw and 1x o-ring)
TOF3D Housing top shell (multi use)	5750114	 Upper half of the housing incl. membrane keyboard and display protection window

	Project/Product: TOF3D	Service Manual
-----------------------------------------------------------------------------------	-----------------------------------------	-----------------------

Product	MIPM REF	Remark
TOF3D Housing lower shell including: - TOF3D Battery Lid	5750115	 <p>Lower half of housing incl. battery lid, 6x screws, 6x sealing plugs and 4x bumpers</p>