

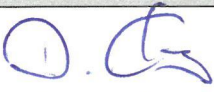

| | | |
|--|---|---|
|  | Project/Product: TOF3D | Field Change Notice (FCN) – Update / Upgrade |
|--|---|---|

| Revision History | | | |
|--------------------|---------------|----------------------|----------------------------|
| (Doc.-) Version | Author | Date (YYYY-MM-DD) | Revision, Changes, Remarks |
| V1.0 | Daniel Contag | 2025-06-24 | First final version |

Field Change Notice (FCN) – Update / Upgrade for TOF3D FCN_TOF3D_Update-PV3.0_V1.0

Manufacturer – Contact Information:


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| Name and Function | Date (YYYY-MM-DD) | Signature |
|--|----------------------|---|
| Created by (MIPM): Daniel Contag Technical Sales, Service and Vigilance Manager | 2025-06-24 |  |
| Reviewed and Approved by (MIPM): Marco Wieser Project Manager, Product Development, Regulatory Affairs | 2025-06-24 |  |

Transmission of this Field Change Notice:

Please transfer this notice to other organizations on which this action has an impact.

In cases where you as customer choose not to proceed with completion of the change requirements described, MIPM cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to act according to this Field Change Notice.

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|--|---|---|
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|--|---|---|

1. Information on Affected Devices

| Product | Device Model / Catalogue / part number(s) | Unique Device Identifier(s) (UDI-DI) | Affected serial number or lot number range | Period affected devices were distributed | Software version |
|------------|---|--------------------------------------|--|--|------------------|
| TOF3D-Unit | 2510091 | EMIP25100910 | T3D202002001-T3D202303221 | 2021-02-12 – 2025-06-16 | V1.0; V1.1 |

Priority:

| Priority of Action(s) | Field Retrofit Required? | Description to Priority of Action(s) |
|--|---|---|
| <input type="checkbox"/> Urgent | Yes | Field Safety Corrective Action / Recall (FSN) has to be performed immediately (consider Field Safety Notice!) |
| <input type="checkbox"/> Priority | Yes | Important, but implementation for the schedule should be open and defined for each Upgrade/Update separately |
| <input type="checkbox"/> Next Service | <input type="checkbox"/> Yes <input type="checkbox"/> No | Shall / Should be performed next time the unit is serviced (routine servicing) |
| <input type="checkbox"/> Incidental / Occurrence | No | Should be performed upon a failure of the area/component if service is required |
| <input checked="" type="checkbox"/> Convenience | No | May be performed on a convenience basis |

2. Description of change

MIPM has developed a new sensor for use with the TOF3D, the “Mechanomyography sensor (MMG)” which serves as an additional/alternative to the approved AMG sensor to measure the neuromuscular transmission at the ulnar nerve/adductor pollicis muscle. The basic functionality is for both sensors the same: They quantitatively measure the neuromuscular transmission by measuring muscle contraction following stimulation. The stimulation is identical in both sensors, as it uses the same muscles (ulnar nerve/adductor pollicis muscle) and stimulation cable. The TOF3D receives the same signal from both sensors.

This FCN describes the procedure for upgrading the TOF3D to software version V3.0

The update is required in order to be able to use the new MMG sensor. There are no other changes to the TOF3D and its functionality. The AMG sensor can still be used.

3. Reason for change

Additional variant for measuring the patient's relaxation. The new sensor offers alternative application and supports the clinical work flow.

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4. Necessary parts for change

| Quantity* | Part Number MIPM | Description |
|-----------|------------------|-------------|
| N/A | N/A | N/A |

5. Special equipment / tools required to perform the change

| Quantity | Part Number MIPM | Description |
|----------|------------------|--|
| 1 | 5750123 | Updater Cable TOF3D incl. TOF3D Updater V3.1 |

5.1 Control of replaced parts

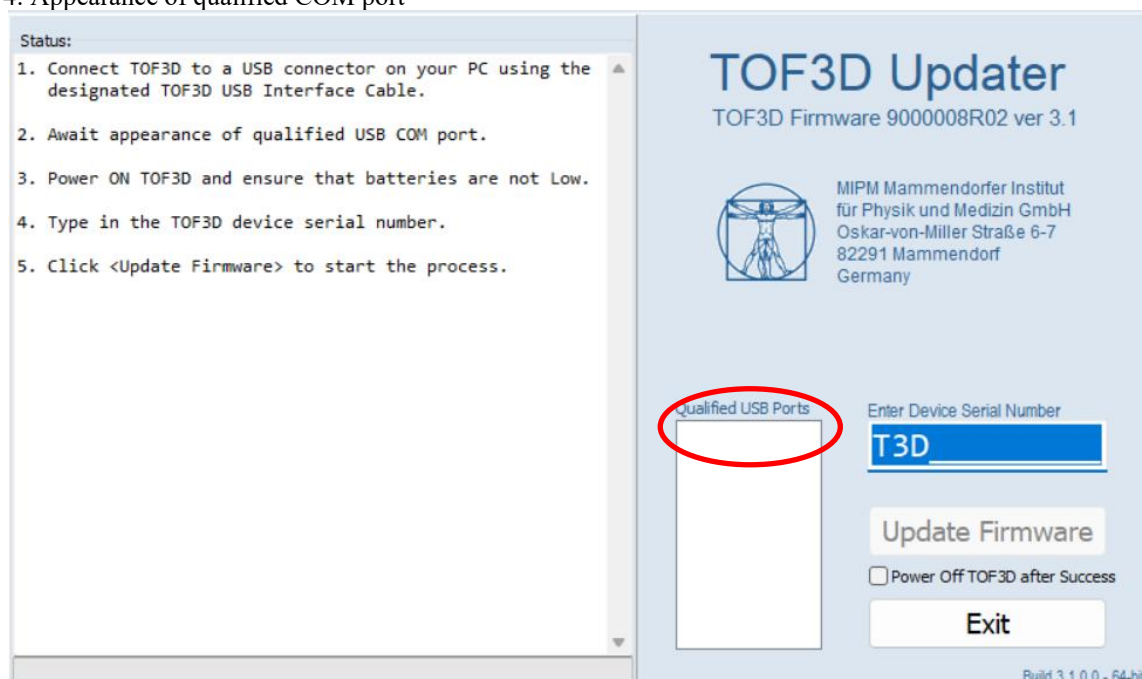
- ☒ Not Applicable
 ☐ Return to MIPM
 ☐ Destroy / Destruction / Scrap / Disposal of Parts
 ☐ OTHER (please specify)

6. Actions to be taken and detailed instruction for Change

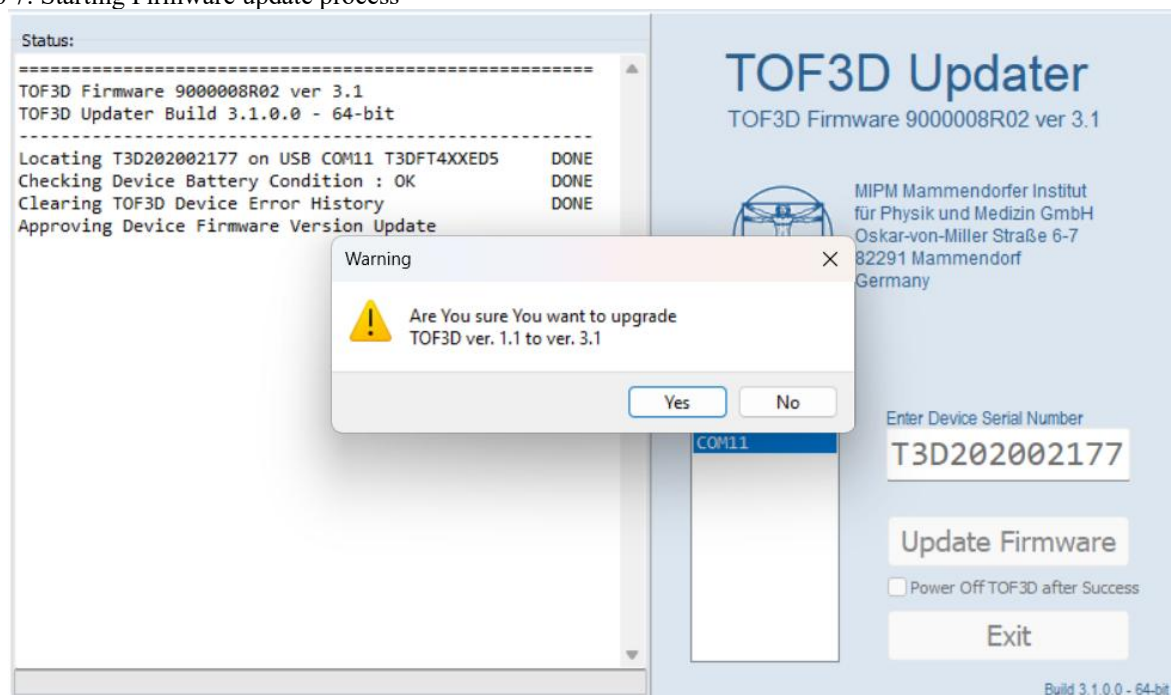
6.1 Serviceinstruction

1. Install TOF3D Updater V3.1 incl. necessary drivers on your Windows computer
2. Open TOF3D Updater V3.1
3. Connect the Updater Cable to your computer and the TOF3D
4. Await appearance of qualified USB COM port
5. Power on TOF3D
 - o Note: If battery low alarm appears, the update cannot be performed
6. Type in the TOF3D serial number
 - o Note: If serial number is not correctly entered, the update cannot be performed
7. Click Update Firmware to start the process
 - o Note: Do **never disconnect** the cable from TOF3D or computer before the Update is successfully finished. Otherwise, this can lead to unrepairable damage to the PCB!
8. Once the update is successfully completed, turn off the TOF3D and disconnect the cable
9. Perform a technical safety check

Step 4: Appearance of qualified COM port



Step 7: Starting Firmware update process



Step 8: Update successfully completed

