



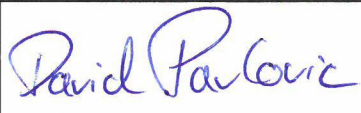
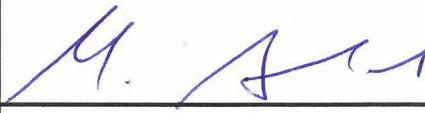
Project/Product:
TOF3D

Device
Labeling

Revision History

(Doc.-) Version	Author	Date (YYYY-MM-DD)	Revision, Changes, Remarks
V1.0	David Pavlovic	2020-03-19	First final version

Device Labeling TOF3D

Name	Date (YYYY-MM-DD)	Signature
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	Project/Product: TOF3D	Device Labeling
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Table of Content

1.	Introduction	3
1.1	Purpose	3
1.2	References	3
1.2.1	Referenced standards for symbol definitions	3
1.2.2	Referenced documents	3
2.	Device Labeling.....	4
2.1	TOF3D.....	4
2.1.1	Device identification label / Regulatory Marking	4
2.1.1.1	Symbols with description	4
2.1.1.2	Indicative Layout and General Specifications	5
2.1.2	Product Marking	6
2.1.2.1	Symbols with description	6
2.1.2.2	Indicative Layout and General Specifications	6

	Project/Product: TOF3D	Device Labeling
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1. Introduction

1.1 Purpose

This document defines the general specifications of the device labels (stickers) and markings of the TOF3D – Neuromuscular Transmission Monitor (NMT)

1.2 References

1.2.1 Referenced standards for symbol definitions

Standard	Title of the referenced standard
ISO 15223-1:2016 (ed3.0)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
ISO 15223-1:2020 (Proposal)	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements
IEC/TR 60878: 2015 (ed3.0)	Graphical symbols for electrical equipment in medical practice
IEC 60601-1:2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1:2012-08 (ed3.1) or IEC 60601-1:2005+A1:2012-08 (ed3.1) Consolidated with AM1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Edition: 3.1)
IEC 60601-1-2:2007 (ed. 3.0); IEC 60601-1-2:2014-02 (ed4.0)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (2007) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (2014)
IEC 60529:2013-08 (ed2.2) Consol. with AM1 (1999) & AM2 (2013)	Degrees of protection provided by enclosures (IP Code)
Directive 93/42/EEC	EU: COUNCIL DIRECTIVE 93/42/EEC concerning medical devices (MDD)
Regulation (EU) 2017/745	EU: Regulation (EU) 2017/745 on medical devices (EU-MDR)
Regulation (EU) 2017/745 Annex 1/Chapter 3	EU: Regulation (EU) 2017/745 on medical devices (EU-MDR) Annex 1 - General safety and performance requirements Chapter 3 - Requirements regarding the information supplied with the device
Directive 2012/19/EU	EU: DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on waste electrical and electronic equipment (WEEE)
21 CFR Part 800 - 898	USA: Code of Federal Regulation Title 21 – Food and Drugs, Parts 800 to 898 – Medical Devices
21 CFR Part 801	USA: Code of Federal Regulation Title 21 – Food and Drugs, Parts 801 - Labeling
21 CFR Part 830	USA: Code of Federal Regulation Title 21 – Food and Drugs, Part 830 – Unique Device Identification
ANSI/HIBC 2.6	THE HEALTH INDUSTRY SUPPLIER LABELING STANDARD FOR PATIENT SAFETY & UNIQUE DEVICE IDENTIFICATION (UDI)

1.2.2 Referenced documents

- Instructions for Use (IFU) of TOF3D

	Project/Product: TOF3D	Device Labeling
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2. Device Labeling

2.1 TOF3D



2.1.1 Device identification label / Regulatory Marking

2.1.1.1 Symbols with description

Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
TOF ^{3D} ⊕	Brandname	MIPM
REF	Product reference / part number	ISO 15223-1 (ISO 7000-2493)
SN	Product serial number: T3DYYYYYLLSSS <u>Structure:</u> - “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)
	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)
	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)

	Project/Product: TOF3D	Device Labeling
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Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
	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 Marking	Directive 93/42/EEC (MDD); Regulation (EU) 2017/745 (EU-MDR)
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 acc. HIBCC in format HIBC Data Matrix (variable characters are highlighted) - Start Code after: - 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): - Serial Number Reference Identifier (fix 2-digits): - Serial Number (Structure of SN explained above): - 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:	“⌘” “+” “EMIP” “2510091” “()” “/” “\$+” “T3DYYYYLLSSS” “/” “16D” “YYYYMMDD” “C” “⌘”
		ANSI/HIBC 2.6

2.1.1.2 Indicative Layout and General Specifications

Position: On the back of the device

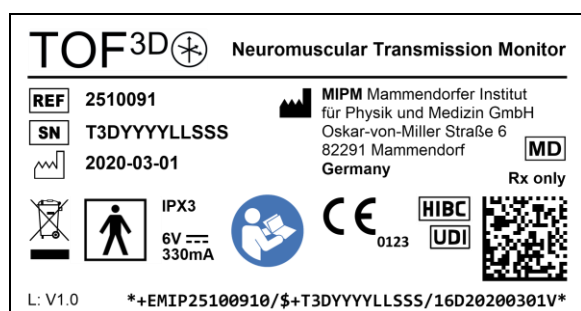
Dimensions (Length x Height): 76x40 mm

Corner Radius: 2 mm

Color of Label: White

Color of Print: Black, Blue

Label Version: V1.0



	Project/Product: TOF3D	Device Labeling
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2.1.2 Product Marking

2.1.2.1 Symbols with description

Symbol	Description	Source of Symbol: Referenced standard (basic standard and no. of Symbol)
	Company Logo of MIPM	MIPM
	Brandname	MIPM
	“ON”/“OFF” (push-push)	IEC 60601-1 (IEC 60417-5009)

2.1.2.2 Indicative Layout and General Specifications

Position: Foil keyboard on front of TOF3D

Dimensions (Length x Height): 99,3x145,5 mm

Colors: RAL 5017; RAL 9003

Version of print: V1.0

