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1. Introduction

This document contains additional technical information that is not included in the user manual (IFU). Information on storage, transport, cleaning and use is available in the Mallya^{®D} IFU. Read the IFU before using the device.

2. Mallya^D compatibilities

Mallya^D allows you to:

- Record the increment injected by the pen injector,
- Record the date and time of each injection,
- Transmit the dose, time and date of each injection to a mobile application on a smartphone, when connected to the device, using Bluetooth[®] technology.

Mallya^D is designed for the Novo Nordisk[®] pen injectors for diabetes treatment.

The molecules and associated concentrations compatible with Mallya^D at the date of this document are listed in the table below:

Molecule	Concentration	Drug name in France	Dose value for 1 increment	Pen dose selector: <i>Min Dose to Max Dose</i> OR dose
Degludec	100 IU/mL	Tresiba® 100 FlexTouch®	1 IU	1 IU - 80 IU
	200 IU/mL	Tresiba® 200 FlexTouch®	2 IU	2 IU - 160 IU
Detemir	100 IU/mL	Levemir® FlexTouch®	1 IU	1 IU - 80 IU
Aspart	100 IU/mL	Novorapid® FlexTouch®	1 IU	1 IU - 80 IU
	100 IU/mL	Fiasp® FlexTouch®	1 IU	1 IU - 80 IU
Degludec + Aspart	100 IU/mL	Ryzodeg® FlexTouch®	1 IU	1 IU - 80 IU
Degludec + Liraglutide	100 IU/mL + 3,6 mg/mL	Xultophy®	1 IU	1 IU - 50 IU
Semaglutide	1,34 mg/mL	Ozempic® 0,25 mg	0,01316 IU	0,25 mg
	1,34 mg/mL	Ozempic® 0,5 mg	0,01316 IU	0,50 mg
	1,34 mg/mL	Ozempic® 1 mg	0,01351 IU	1 mg
Icodec	700 IU/mL	Awikli® FlexTouch®	10 IU	10 IU - 700 IU

Table 1 – Mallya^P compatibilities with Novo Nordisk® pen injectors for diabetes treatment – Molecules and concentrations

3. Radio and EMC specifications

3.1 Loss of connection

Mallya^P uses a Bluetooth® Low Energy (BLE) connection to communicate with your smartphone. The BLE link between Mallya^P and the smartphone can break for various reasons. As soon as the smartphone reconnects to the medical device, the application will be able to request the injections it has missed.

Mallya^P has a storage capacity of 100 injections; in case more than 100 injections are performed during a disconnection, the oldest injection is overwritten by the most recent one.

3.2 Quality of wireless service

Bluetooth® communication limits:

The connectable application may inform you that Bluetooth communication has been interrupted. If the connectable application and Mallya^P are used in a noisy environment (in terms of electromagnetic signal close to 2.4 Ghz), or are too far apart, communication will no longer be possible between them and the connection will be broken. However, Mallya^P will continue to track and record the history of all your injections. As soon as the smartphone reconnects to Mallya^P, the application will be able to integrate the unrecorded injections (up to 100 injections).

Bluetooth® LE type	BLE v4.2
Frequency band	[2400-2483.5] MHz
Spacing channel	2 MHz
Channel bandwidth	1 MHz
Antenna type	Integral
Max EIRP (Equivalent isotopically radiated power)	< -8 dBm

Table 2 – Wireless service

3.3 Wireless coexistence

A key factor that may affect the performance of the Mallya^P wireless medical device is the limited amount of RF spectrum available, which may result in potential competition between wireless technologies for simultaneous access to the same spectrum. In order to avoid communication disruptions due to wireless coexistence, BIOCORP PRODUCTION recommends the following separation distances between the device and its intended companion:

During pairing phase:

Recommended separation distance	Less than 12 inches (30 cm)
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During use:

Recommended separation distance	Less than 7 feet (2,15 m)
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Attention

In the event of wireless coexistence issues, Mallya^P coupled will not be able to communicate with its dedicated app, but injections will still be tracked and recorded and can be retrieved at a later date by the app.

3.4 Wireless transmission and cybersecurity

BIOCORP PRODUCTION recommends that the user perform the pairing process in a private environment, for example at home, to avoid eavesdropping or potential attacks on the process. Once this is done, Mallya^P does not have any particular security requirements.

3.5 Electromagnetic compatibility

3.5.1 General precautions and warnings

Attention

- The use of this equipment alongside (or stacked with) other equipment should be avoided as this may result in malfunction. If such use is necessary, this equipment and other equipment should be observed to ensure that they are operating normally.
- The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of this equipment may result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and may result in malfunction.

Mallya^P does not have any essential performance or safety requirements.

The Mallya^P CND1 device has been tested in accordance with the recommendations of IEC TR 60601-4-2: Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

3.5.2 Electromagnetic emissions

Emissions	
RF emissions	CISPR 11 / Group 1 Class B
Harmonic Distortions IEC 61000-3-2	Not applicable
Voltage fluctuations and Flicker IEC 61000-3-3	Not applicable

Table 3 – Emissions

3.5.3 Electromagnetic immunity

Immunity				
Test	Requirement		Conformity level	
Electrostatic discharges IEC 61000-4-2	± 8 kV at contact ± 2/4/8/15 kV in the air		± 8 kV at contact ± 2/4/8/15 kV in the air	
Radiated RF electromagnetic fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz		10V/m 80MHz-2.7GHz 80% AM at 1kHz	
Proximity fields emitted by wireless RF communication devices IEC 61000-4-3	Frequency (MHz)	Modulation	Level required (V/m)	Conformity level (V/m)
	385	Pulsed modulation: 18 Hz	27	27
	450	Pulsed modulation: 18 Hz	28	28
	710 – 745 – 780	Pulsed modulation: 217 Hz	9	9
	810 – 870 – 930	Pulsed modulation: 18 Hz	28	28
	1720 – 1845 – 1970	Pulsed modulation: 217 Hz	28	28
	2450	Pulsed modulation: 217 Hz	28	28
	5240 – 5500 – 5785	Pulsed modulation: 217 Hz	9	9
Fast/burst electrical transients IEC 61000-4-4	Power supply: ± 2 kV Input/Output lines: ± 1 kV Repetition frequency: 100 kHz		Not applicable (USB cable < 3 m)	
Shock waves IEC 61000-4-5	Between phases: ± 0,5 kV, ± 1 kV Between phases and ground: ± 0,5 kV, ± 1 kV, ± 2 kV		Not applicable	
Conducted disturbances, induced by RF fields IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz		3 V 0,15 MHz – 80 MHz 6 V in ISM and radio-amateur band between 0,15 MHz and 80 MHz	
Magnetic fields at mains frequency IEC 61000-4-8	30 A/m		30 A/m	
Voltage dips and interruptions IEC 61000-4-11	0 % UT; 0.5 cycle A 0°, 45°, 90°, 135°, 180°, 225°, 270 and 315° 0 % UT; 1 cycle at 0° 70 % UT; 25/30 cycles at 0° 0 % UT; 250/300 cycles		Not applicable	
Proximity magnetic fields IEC 61000-4-39	134,2 kHz / Pulse modulation 2,1 kHz / 65 A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5 A/m 30 kHz / CW / 8 A/m		134,2 kHz / Pulse modulation 2,1 kHz / 65 A/m 13,56 MHz / Pulse modulation 50 kHz / 7,5 A/m 30 kHz / CW / 8 A/m	

Table 4 – Immunity

4. Materials

Mallya[®]

PC, ABS, SEBS, PP
Polycarbonate, Acrylonitrile butadiene
styrene, Polystyrene polyethylene butylene,
Polypropylene

5. General information



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