

CONNECTDROP® device

used with the EASYGRIP® ophthalmic pump dispenser



Package contents

CONNECTDROP® (X1) INSTRUCTIONS LEAFLET (X1)

Take the **CONNECTDROP®** out of its pack and read these instructions carefully before using the device.

1 FUNCTIONALITIES

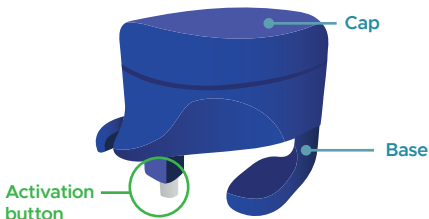
CONNECTDROP® is a reusable, connected device with a smart sensor that clips onto the **EASYGRIP®** ophthalmic pump dispenser, used with the **LABORATOIRES THEA** eye drops bottle. It is used to:

- Record the date / time / angle of the eye drops bottle for each instillation,
- Transmit this data via Bluetooth for analysis using a compatible application on your smartphone.

The **CONNECTDROP®** device is designed for home use.

2 PRESENTATION

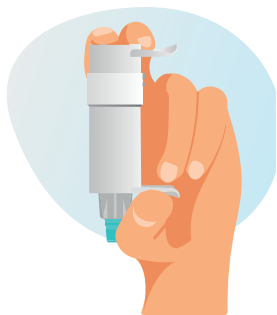
CONNECTDROP® device



The **CONNECTDROP®** device comprises a base (that contains the electronic card and battery) welded onto a cap and an activation button, used to detect each instillation.

CONNECTDROP® operates with an integrated 3V battery, non-rechargeable and non-replaceable. The battery life is sufficient to cover the lifetime of the device.

Eye drops bottle with the EASYGRIP® system



The **EASYGRIP®** system consists in an ophthalmic pump dispenser marketed by **LABORATOIRES THEA**.

3 SETTING UP THE DEVICE AND THE CONNECTDROP® APPLICATION

⚠ Before assembling the **CONNECTDROP®** device on the eye drops bottle: pair your device to your smartphone and press the eye drops bottle pumping mechanism down repeatedly until the first drop appears.

STEP 1 Pair the **CONNECTDROP®** device with your application



1. Download the **CONNECTDROP®** application via Google Play™ (Android) or via App Store® (Apple).
2. If you haven't yet done so, activate your smartphone's Bluetooth function.
3. Open the application and follow the instructions displayed on the screen to pair your **CONNECTDROP®** device:
 - Place your device close to your smartphone.
 - Press your device's activation button then wait a few seconds until you see confirmation of the pairing.

⚠ A device can only be paired with a single application / smartphone. If you decide to change your smartphone, you will first have to reset your device (see section 7 in these instructions).

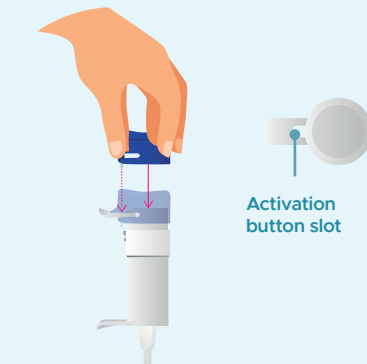
⚠ An application can only be paired with a single device. If you decide to change the device, you will first have to go to "Forget the device" in the "Device management" menu of your application.

STEP 2 Activate the bottle's pump mechanism



Follow the **LABORATOIRES THEA** instructions for use to prepare the eye drops bottle for its first use.

STEP 3 Assemble **CONNECTDROP®** on the eye drops bottle with the **EASYGRIP®** system

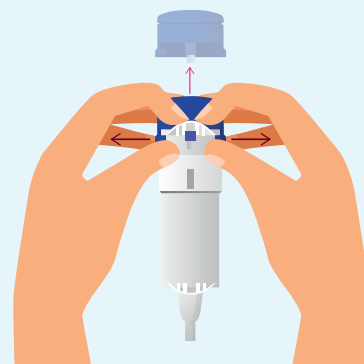


1. Hold the eye drops bottle with one hand.
2. Hold the **CONNECTDROP®** with the other hand and note the location of its activation button.
3. Insert the **CONNECTDROP®** activation button in the slot provided for this purpose on the upper tab of the **EASYGRIP®** system.
4. Clip **CONNECTDROP®** to the **EASYGRIP®** system, taking care not to press down on the eye drops delivery button.
5. The system is now ready for use.

STEP 4 Unclip **CONNECTDROP®** from the eye drops bottle with the **EASYGRIP®** system

You will have to unclip the device in the following cases: transferring to a new bottle, cleaning, resetting the device, etc.

The **CONNECTDROP®** device is reusable and can be transferred to a new eye drops bottle once the previous bottle is empty or has passed its use-by date.



1. Place both index fingers on the upper tab of the **EASYGRIP®** system.
2. Gently open the **CONNECTDROP®** clipping tabs in order to unclip the device and remove it from the **EASYGRIP®** system.

⚠ When transferring the device to a new eye drops bottle with the **EASYGRIP®** system, you will not need to pair your **CONNECTDROP®** device to your application again.

4 CLEANING THE CONNECTDROP® DEVICE



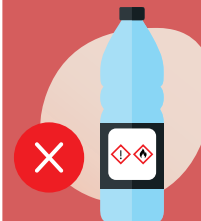
The **CONNECTDROP®** device can be cleaned as and when necessary:

1. Wipe the external surfaces with a slightly dampened soft cloth, containing a small amount of soap if necessary.
2. Dry the device using a soft, lint-free cloth.

⚠ The **CONNECTDROP®** device is not sterile and can only be reused by a single patient.



⚠ The **CONNECTDROP®** device is not leaktight. The device is not protected against the penetration of water or moisture. Do not immerse the device in water. Do not clean the device under running water.



⚠ Do not wipe the outer surface of the **CONNECTDROP®** with chemicals or solvents (e.g. acetone). This could discolour or damage the device.

5 USING YOUR DEVICE AND YOUR CONNECTDROP® APPLICATION

Once you have completed the set-up steps, you can use your eye drops bottle with the **EASYGRIP®** system as usual, and keep a day-to-day record of your daily instillations using your **CONNECTDROP®** device.

⚠ Follow the recommendations in the **LABORATOIRES THEA** instructions leaflet to instill your eye drops.

The **CONNECTDROP®** device starts up automatically with each instillation when you press the button, and then switches automatically to standby after a few minutes to allow the user time to collect the data on their **CONNECTDROP®** application.

5.1. Treatment tracking

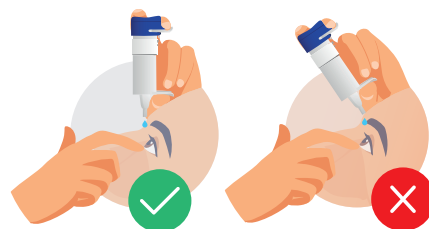
When the **CONNECTDROP®** device is paired with the **CONNECTDROP®** application, the application automatically retrieves and displays the instillation data on your smartphone.

Please note the following points to ensure that your instillation data is correctly transferred to the application:

- Check that the Bluetooth connection is activated on your smartphone (for an Android smartphone, the location function must be activated),
- The **CONNECTDROP®** application starts up and opens in the foreground,
- Make sure you place your device close to your smartphone after the instillation. Otherwise, you should wait until the next instillation to transfer your data from the device to your smartphone.

5.2. How to use the eye drops bottle

The **CONNECTDROP®** device measures the angle and orientation of the eye drops bottle during your instillations. The application tells you whether the eye drops bottle is oriented as described in the **LABORATOIRES THEA** recommendations so as to help you improve your treatment administration.



5.3. Lifetime of the **CONNECTDROP®** device

The **CONNECTDROP®** device communicates its battery level to the application, which informs the user when the device has less than one month left on its lifetime.

5.4. Managing the eye drops bottle

The **CONNECTDROP®** application lets you record the date on which you opened your eye drops bottle as well as the use-by date of the eye drops.

⚠ Check the instructions in the manufacturer's leaflet for more information on the functionalities of your application.

6 TROUBLESHOOTING INDICATION

If your device is faulty or has trouble synchronising, the drops actually instilled will not be correctly transferred or displayed on your application. In this case, please do as follows:

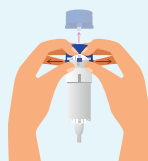
Step 1

Check that Bluetooth is activated on your smartphone. (for an Android smartphone, check that the location function is activated on your smartphone).

Step 2

Turn your smartphone off, and then on again. Start up your **CONNECTDROP®** application in the foreground of your smartphone.

Step 3



Unclip the **CONNECTDROP®** device from the **EASYGRIP®** system.

Step 4



Press the activation button on the **CONNECTDROP®** device. Place the device within 1 m of your smartphone. Wait for 2 minutes.

Step 5

If the instillation is correctly displayed on the application, your problem is solved. You can now clip your **CONNECTDROP®** device back onto the **EASYGRIP®** system and continue your instillations.

If the instillation is not displayed on your application:

1. Reset your device, as explained in the section "Reset" in these instructions.
2. Click on the "Forget device" button, at the bottom of your application's "Device management" menu.
3. Pair your device again, following the instructions displayed on your application's screen.
4. Press the activation button on the **CONNECTDROP®** device. Place the device within 1 m of your smartphone. Wait for 2 minutes.

If the instillation is correctly displayed on the application, your problem is resolved. You can now clip your **CONNECTDROP®** device back onto the **EASYGRIP®** system and continue your instillations.

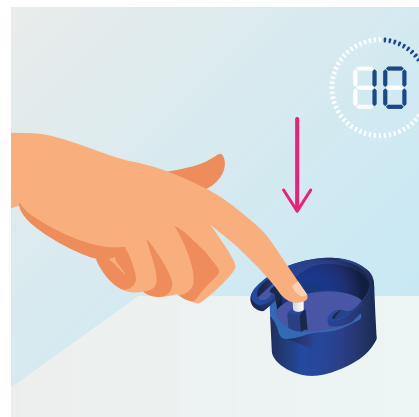
If the instillation still doesn't display on your application, please contact **BIOCORP PRODUCTION's** authorised retailer, whose contact details are given on the product packaging.

7 RESETTING YOUR CONNECTDROP® DEVICE

Your **CONNECTDROP®** device may need to be reset:

- To pair the device with another smartphone,
- To delete personal health data recorded on the device, e.g. prior to recycling,
- If the device malfunctions.

⚠ If you have to reset the **CONNECTDROP®** device: all the data recorded on the device will be deleted, in addition to the pairing with the application.



1. Turn the **CONNECTDROP®** device over with the activation button facing upwards.
2. Place the **CONNECTDROP®** device on a flat surface, e.g. a table.
3. Press the activation button for at least 10 seconds.

8 PROTECTION OF HEALTH DATA

The provisions of regulation (EU) 2016/679 of the European Parliament and the Council of 27th April 2016 applies to interactions between the **LABORATOIRES THEA** and the users of its products.

Accordingly, the **LABORATOIRES THEA** commits to fulfilling its obligations in accordance with the regulations applying to the protection of personal data, and makes every possible effort to guarantee the security, confidentiality and integrity of the personal data it processes.

The privacy policy (reference: PPCOD), available on the website and on the application **CONNECTDROP®**, describes the applicable provisions concerning the protection of personal data.

The contact details of the Data Protection Officer (DPO) are :
E-mail : dpo@theapharma.com
LABORATOIRES THEA
DPO, Service Juridique
12 rue Louis Blériot, Z.I. du Brézet
63100 Clermont-Ferrand, France

If, after having contacted the **LABORATOIRES THEA**, a user considers that their data protection and privacy rights have been infringed or that the provision concerning access control does not conform to data protection regulations, said user may submit a claim online, or by mail, to the competent national data protection supervisory authority.

9.1. Warning and precautions

Warnings: incorrect operation may result in serious injury or death

- If you are not certain that you instilled your medication, do not repeat your instillation. Monitor your treatment as instructed by your healthcare provider.
- Never leave **CONNECTDROP®** unattended when children are present so as to avoid any risk of suffocation.
- **CONNECTDROP®** is designed for use with a single patient. Never lend your **CONNECTDROP®** to anyone else
- Never use **CONNECTDROP®** in a hazardous environment: i.e. where there is a risk of explosion, or that contains volatile solvents (alcohol, etc.) or flammable substances (anaesthetics, etc.); never place the device near an oxygen-rich environment.
- Never place **CONNECTDROP®** in a microwave oven.

Precautions: incorrect use may cause physical injury or damage to property

- Before using the device following transportation and storage, make sure to leave the device to acclimatise for at least 30 minutes in a room with the intended operating conditions.
- If you need any help with assembly, operation or maintenance of the device, please contact **BIOCORP PRODUCTION's** authorised retailer, whose contact details are given on the product packaging.
 - The device must be used in the specified ambient conditions (do not expose the device to temperatures above 40°C (104°F), or to naked flames).
 - **CONNECTDROP** is not leaktight and is not protected against the penetration of water of moisture:
 - Do not immerse the whole device in water. Do not clean the device under running water.
 - Do not expose the device to humidity.
 - Do not attempt to disassemble, modify or repair **CONNECTDROP®** by yourself.
 - Entrust any repairs to **BIOCORP PRODUCTION's** authorised retailer, whose contact details are given on the product packaging. If the device is disassembled, modified or repaired by any person other than **BIOCORP PRODUCTION's** authorised retailer, the warranty will be declared null and void.
 - Do not carry out any maintenance on the device while it is in operation.
 - External, mechanical impacts (such as a blow, knock, fall, etc.) may cause the device to malfunction. If the device malfunctions, please contact **BIOCORP PRODUCTION's** authorised retailer, whose contact details are given on the product packaging.
 - The **CONNECTDROP®** device does not require regular maintenance. A simple daily inspection is all that is recommended.
 - In the event of visible damage, or unexpected operation or events, do not use **CONNECTDROP®** and contact **BIOCORP PRODUCTION's** authorised retailer, whose contact details are given on the product packaging, to request technical support.
 - Do not wipe the outer surface of the **CONNECTDROP®** with chemicals or solvents (e.g. acetone). This could discolour or damage the device.
 - Make sure the **CONNECTDROP®** is kept clean, and stored in a clean space, protected against dust and moisture.
 - Only use **CONNECTDROP®** with **LABORATOIRES THEA** eye drop bottles with the EASYGRIP® ophthalmic pump dispenser . Do not use the device with any other eye drops.
 - Protect your personal health data with a password on your smartphone.
 - Read carefully and follow the operating instructions in this instructions leaflet, as well as the instructions for use of the **LABORATOIRES THEA** eye drops bottle.

If adverse reactions or incidents occur, please notify the manufacturer and the French National Authority for Health.

9.2. Electromagnetic compatibility and the simplified Radio declaration of conformity

Warnings:

- Should the application and the connected device be used in a noisy environment (i.e. around electromagnetic signals close to 2.4Ghz), the communication will be impossible and the connection between the devices will be suspended. However, the device may continue to record instillation data. Once the interfering electromagnetic signals cease, the connection will be restored between the application and the connected device.
- Avoid using this device next to or stacked above other devices as this may cause poor performance. If such use is necessary, keep an eye on this device and the other devices to check that they are operating correctly.
- Do not use portable RF communications devices (including peripherals such as antenna cables and external antennas) within 30 cm (12 inches) of any part of the device or the EM system, including the cables specified by the manufacturer. Otherwise, this may affect the performance of these devices.
- Electrical medical systems and devices are subject to special measures concerning electromagnetic compatibility (CEM) and must be installed in accordance with the instructions on CEM given in this document.

9.2.1. Electromagnetic emission

ÉMISSION	
RF emissions	CISPR 11 / Groupe 1
Classe B	
Harmonic distorsions IEC 61000-3-2	Not applicable
Voltage fluctuations and Flicker IEC 61000-3-3	Not applicable

9.2.2. Electromagnetic immunity

IMMUNITY				
Test	Requirements		Level of compliance	
Electrostatic discharges (DES) IEC 61000-4-2	± 8 kV at the contact ± 2/4/8/15 kV in air		± 8 kV at the contact ± 2/4/8/15 kV in air	
RF radiated electromagnetic fields IEC 61000-4-3	10V/m 80MHz-2.7GHz 80% AM at 1kHz		10V/m 80MHz-2.7GHz 80% AM at 1kHz	
Near fields emitted by RF wire-less communications devices IEC 61000-4-3	Frequency (MHz)	Modulation	Required level (V/m)	Level of compliance (V/m)
	385	Pulse modulation: 18 Hz	27	27
	450	Pulse modulation: 18 Hz	28	28
	710 – 745 - 780	Pulse modulation: 217 Hz	9	9
	810 – 870 - 930	Pulse modulation: 18 Hz	28	28
	1720 – 1845 - 1970	Pulse modulation: 217 Hz	28	28
	2450	Pulse modulation: 217 Hz	28	28
Fast transients / bursts: IEC 61000-4-4	Power supply: ± 2 kV Input/output lines: ± 1 kV Repeat frequency: 100 kHz		Not Applicable	
Shock waves: IEC 61000-4-5	Between phases: ± 0.5 kV, ± 1 kV Between earth and phases: ± 0.5 kV, ± 1 kV, ± 2 kV		Not Applicable	
Interference conducted, induced by RF fields: IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM and amateur radio frequency bands between 05 MHz and 80 MHz 80 % AM at 1 kHz		Not Applicable	
Magnetic fields at network frequency: IEC 61000-4-8	30A/m		30A/m	
Voltage dips and interruptions: IEC 61000-4-11	0% UT; 0.5 cycle At 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	

9.2.3 Radio module specifications

CONNECTDROP® contains a BLE module with the following characteristics (Reception / Emission):

Type Bluetooth LE	BLE
Frequency range	[2400 – 2483.5] MHz
Number of channels	40
Channel spacing	2MHz
Bandwidth	1MHz
Max EIRP (Equivalent Isotropically Radiated Power)	1.7 dBm
RF emission	CISPR 11 / Groupe 1

9.2.4 Radio-communication statement

The undersigned **BIOCOP PRODUCTION** declares that the radio equipment of the CONNECTDROP® type complies with Directive 2014/53/EU. The full text of the EU Declaration of Conformity is available at the following internet address <https://biocorp.fr>

Model number	DF01
Planned use	To record and transfer via Bluetooth data on the dates, times and instillation of eye drops delivered by a compatible bottle, thereby making it easier to follow the patient's medical treatment by recording their instillation details.
Planned operators	Patients using eye drops bottles with the EASYGRIP® ophthalmic pump dispenser
Usage environment	Home (indoors)
Compatibility	EASYGRIP® ophthalmic pump dispenser, used with the LABORATOIRES THEA eye drops bottle
App compatibility	Contact BIOCOP PRODUCTION to obtain the list of compatible phones and applications
Contraindications	None with respect to the planned operators
Accuracy of the measurement	Detection of 95% of instillations when the user presses down fully on the eye drops bottle with the EASYGRIP® system
Essential performance	Single patient Reusable electro-medical device
Performances essentielles	None
Battery charging and lifetime	Non-rechargeable Lifetime matches the lifetime of the device: 1 year
Electricity consumption	3V DC non-rechargeable, non-replaceable battery
Battery	Button cell CR1632 Lithium
Communications	Bluetooth Low Energy Core Specification 4.2 : 2014 and later
Software version	Firmware version 1.0.7 and later
Materials	PC/ABS, POM
Dimensions	(37 x 24 x 32) mm
Weight	8 g
Storage conditions prior to first use	Temperature: +5°C to +40°C Pressure: 700 to 1060hPa Humidity: 10 to 90%
Transportation conditions prior to first use	Temperature: -10 to +40°C Pressure: 500 to 1060hPa Humidity: 10 to 90%
Use and storage/transport conditions between 2 instillations	Temperature: +15 to +30°C Pressure: 800 to 1060hPa Humidity: 30 to 70%
Operating period	Short duration (estimated at 2 minutes of contact per day during assembly/disassembly steps with the EASYGRIP® ophthalmic device and during the eye drops bottle instillation process)
Service life	1 year (standard use: 2 or 4 instillations per day, following prescribed treatment)

SYMBOL	INFORMATION ON THE MEDICAL DEVICE
	Refer to instruction manual / booklet. Follow instructions for use Note: the device shows a simplified version of this symbol
	Refer to instruction manual / booklet
	Caution
	Manufacturer
	Country and Date of manufacture
	Serial number
	Model number
	Catalogue reference
	Distributor reference
	Batch number
	Use-by-date
	Single patient – multiple use
	UDI (Unique Device Identifier)
	Medical device
	BF type applied part
	Protection index IP22 – Not Waterproof
	For indoor use only
	Device is sensitive to moisture
	Bluetooth Low Energy
	Temperature range to which the device can be exposed in all safety
	Humidity range to which the device can be exposed in all safety
	Pressure range to which the device can be exposed in all safety
	Do not use if the packaging is damaged or prematurely opened
	Do not dispose of the device along with household waste
	Medical device conform to EC regulations

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Apple and the Apple logo are trademarks of Apple Inc., registered in the United States and in other countries. App Store is a service mark of Apple Inc.
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12USE-BY DATE

Do not dispose of CONNECTDROP® along with household waste; recycle it with electronic waste in accordance with the directives 2012/19/EU WEEE and 2011/65/EU RoHS II.

13INFORMATION ON BIOCOP AND AUTHORISED RETAILERS

BIOCORP PRODUCTION
ZI DE LA VAUR
LA BECHADE
63500 ISSOIRE
FRANCE

Authorised dealers:
Please see the contact details shown on the product packaging.

If you have any technical issues with our product, please contact a **BIOCOP PRODUCTION** authorised retailer.