



USER MANUAL

This user guide helps you getting started with the new WAW DUO FUE system in its totality. All information about the system and its operation is contained in this manual.

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DEVROYE INSTRUMENTS

*Where technology meets
the human touch*

INTENDED USE

The WAW Duo FUE System is an accessory of a hair extraction punch medical device. The WAW Duo FUE System is intended to define and transmit movements to the hair extraction punch. The target patient group is adults with hair loss and the intended user is a healthcare professional (Doctors).

CONTENTS

01.

INTRODUCTION

Important information about the WAW DUO FUE system.

02.

OVERVIEW

Presentation of the WAW DUO FUE system with all its components.

03.

SETTING UP

Initial start-up and installation of the WAW DUO FUE system.

04.

HOW TO USE

Explanation of the operation and use of the WAW DUO FUE system.

05.

CARE & MAINTENANCE

Description of the cleaning and charging protocols of the WAW DUO FUE system.

06.

STORING

Details of the conditions of storage and return of the WAW DUO FUE system.

1. Important information

1.1 Safety symbols	04
1.2 Warnings	05

2. Overview of the system

2.1 Components	06
2.2 Packaging	07
2.3 WAW Wireless Handpiece	10
2.4 WAW Wired Handpiece	12
2.5 WAW Pedal	14
2.6 WAW Software	16
2.7 WAW Charging Station	18
2.8 External Sleeve Support Box	20
2.9 Assembly tools	22

3. Setting Up the system

3.1 Assembly Wireless	24
3.2 Assembly Wired	26
3.3 Installation WAW Pedal	28
3.2 Mobile Application	30
3.3 Positioning	32

4. How to use the system

4.1 Connection of devices	34
4.2 Display	36
4.3 Mode : Manual	40
4.4 Mode : Auto	42
4.5 Mode : Continuous	44
4.6 Punch selection	46
4.7 Updates	48
4.8 Advanced settings	50
4.5 Surgery report	52

5. Care & Maintenance

5.1 Cleaning with alcohol	54
5.2 Cleaning by autoclave	56
5.3 Loading devices	58
5.4 Damaged part	62

6. Storing the system

6.1 Storage conditions	64
6.2 Return	66
6.3 Waste Management	68

INTRODUCTION

The WAW DUO FUE system should be operated only after a reading of the entire user manual. The system is only intended for the specific use described in our documentation. The system may only be operated and manipulated by qualified personnel. Under no circumstances may the electrical components (motor block) be opened.

Devroye Instruments declines all responsibility for damage resulting from non-respect of these instructions.

1.1 SYMBOLS

 REF	Reference number		Refer to the instructions for use		CE Marking
 SN	Serial number		Manufacturer's address		Cleaning with alcohol
 UDI	Unique Device Identifier		Date of manufacture		Microfiber cloth
 MD	Medical device		Keep dry		DC current
 IP	Protection factor		Humidity limitation		Dispose of Properly
	Temperature limit		Atmospheric pressure limitation		

1.2 WARNINGS

- Any manipulation of the medical device must be done only after a complete reading of this user manual.
- The device may only be operated and used by qualified personnel.
- The device is only intended for the specific use described in this manual.
- Any unauthorised modification of the medical device is prohibited and will void the manufacturer's liability.
- No loss of essential performance due to EMC interference is to be expected with this device.
- Portable RF communications, including antennas, can affect medical electrical devices.
- The motor blocks supplied with the system must never be sterilized, opened, soaked in alcohol or clean with compressed air.
- The device should only be used in a dedicated location such as private specialist centres and clinics, hospitals, doctors' offices.
- This device has been tested according to the immunity test levels described in EN60601-1-2 for professional environment. For emission CISPR11 Group 1 class A was selected.
- Pictograms and warning signs on the devices must not be removed! If these signs are removed, the liability of Devroye Instruments is void.
- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
- This device must be used with accessories compatible with WAW Duo FUE System. Failure of the device/any part of the device caused by the use of a non-compatible accessory will void the warranty of the complete WAW Duo FUE system.

OVERVIEW

The WAW DUO FUE system is delivered in a split packaging of 2 boxes. This custom-made packaging ensures the protection of the system during the transport. This packaging is also to be used for the purpose of the return of defective or damaged systems requiring repair. Please keep both boxes in a safe place (see storage conditions).

2.1 COMPONENTS

BOX 1

- Motor block wireless
- Tablet
- User manual
- USB stick
- Information note
- External Sleeve Support Box
- Punch Support Box
- Transparent box for punches
- Assembly tools
- Magnetic ring x2
- Plactic cork X2
- Bounding plastic x2
- Silicone Grip X2

BOX 2

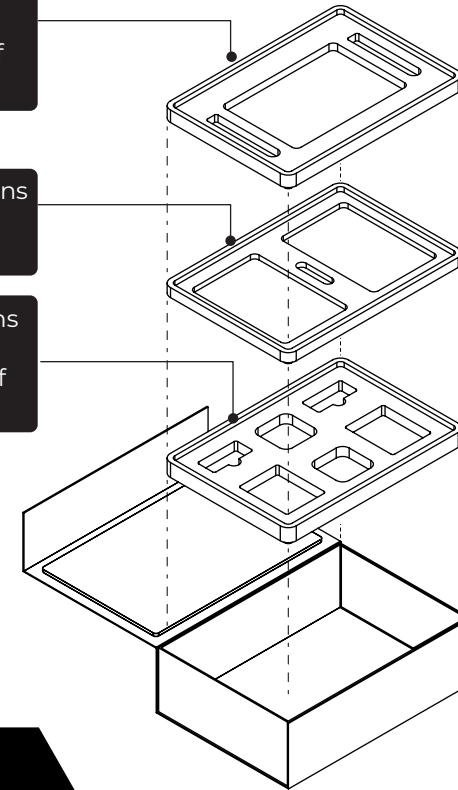
- Motor block wired
- WAW Pedal
- WAW Charging station
- USB-C cables x2
- USB-C Power Charger
- DC power cable
- AC Plug Type
- Stand

2.2 PACKAGING

Top part contains the instruments of the system.

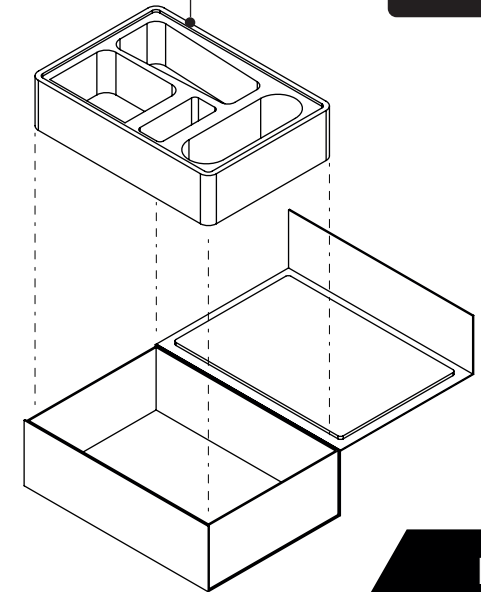
Middle part contains information about the system

Lower part contains the cleanable and disposable parts of the system.



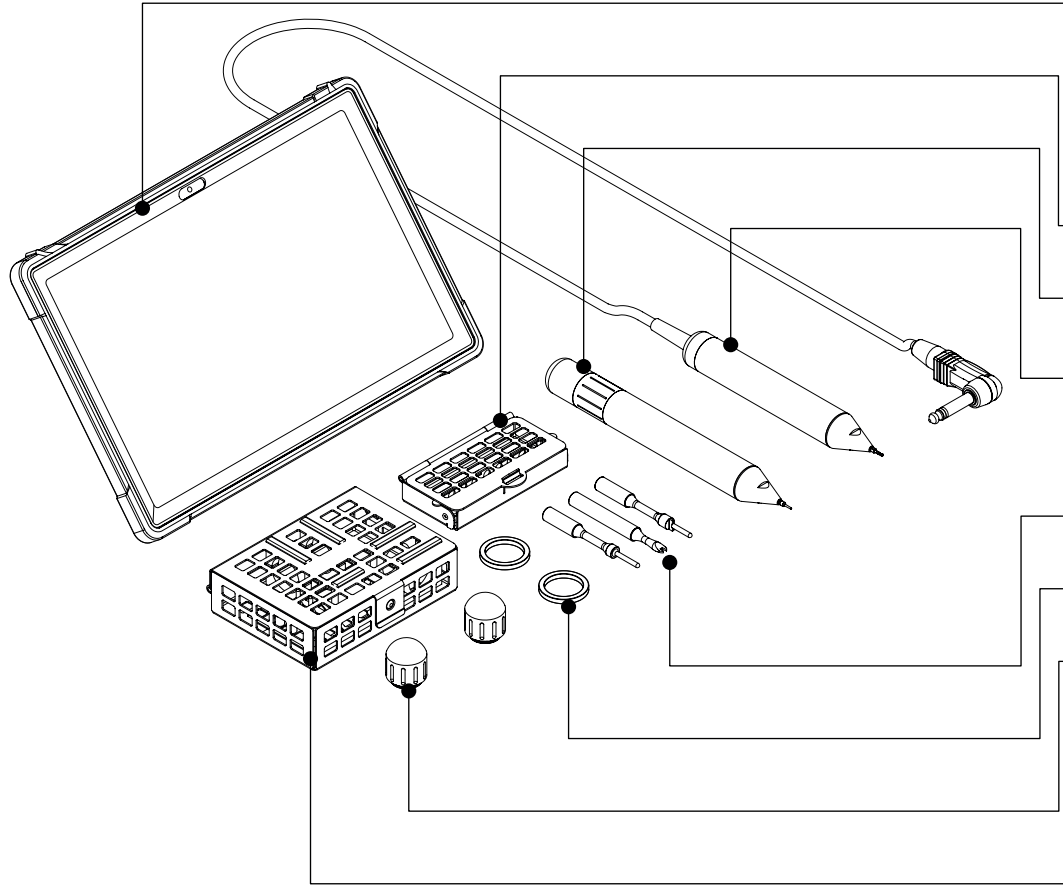
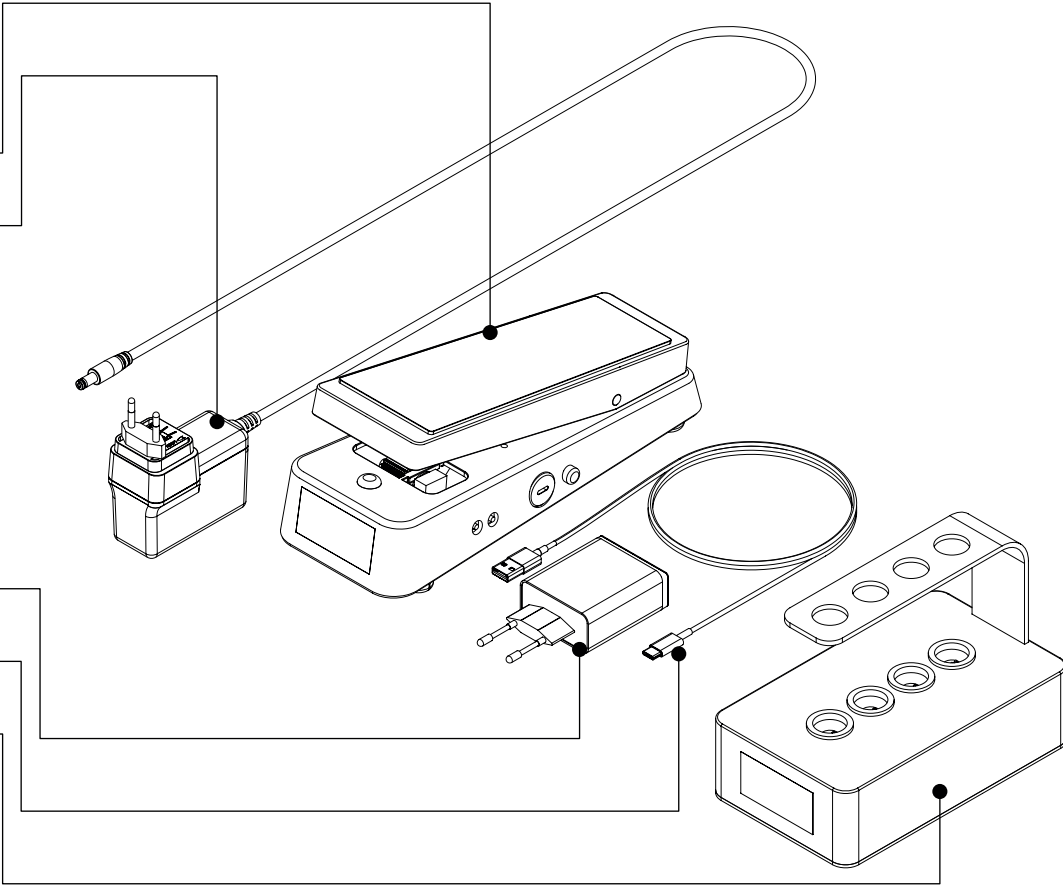
BOX 1

The part contains the large instruments of the system as well as the power cables and charger.



BOX 2

WAW PEDAL
 POWER CABLE
 USB CHARGER
 USB TYPE C X2
 WAW CHARGING STATION



WAW SOFTWARE
 PUNCH SUPPORT BOX
 WAW WIRELESS HANDPIECE
 WAW WIRED HANDPIECE
 ASSEMBLY TOOLS
 MAGNET RING
 PLASTIC CORK 2X
 EXTERNAL SLEEVE SUPPORT BOX

OVERVIEW

2.3 WAW WIRELESS HANDPIECE

The wireless system consists of a handpiece, which in turn consists of a motor block (internal) and various external parts. Only the external parts of the handpiece must be cleaned on a daily basis.

■ Wireless control

The new WAW Wireless Handpiece, with its wireless control, connects to the new WAW Pedal and WAW Software via Bluetooth connection. This new device guarantees better working conditions, allowing more control of the device through greater freedom of movement during surgery.

■ Motor block

One wireless motor block is provided with the complete system, but it's possible to order additional motor blocks as required. The purpose of the additional motor block is to provide surgeons with a back-up solution in case of problems with motor block due to different reasons, to ensure a smooth workflow. You can only use one motor block at once. However, motor blocks are not related to one WAW Pedal exclusively : if you own several systems, you can interchange the motor blocks.

■ Battery

The battery of the motor block is efficient enough to allow surgeons to perform an entire 3000 FUE session. Recharging the block motor is quick and is done using the WAW Charging Station which can charge several engine blocks simultaneously. You can recharge the motor block during a pause (lunch time).



Note that if the battery compartment does not close securely, stop using the product and keep it away from children.

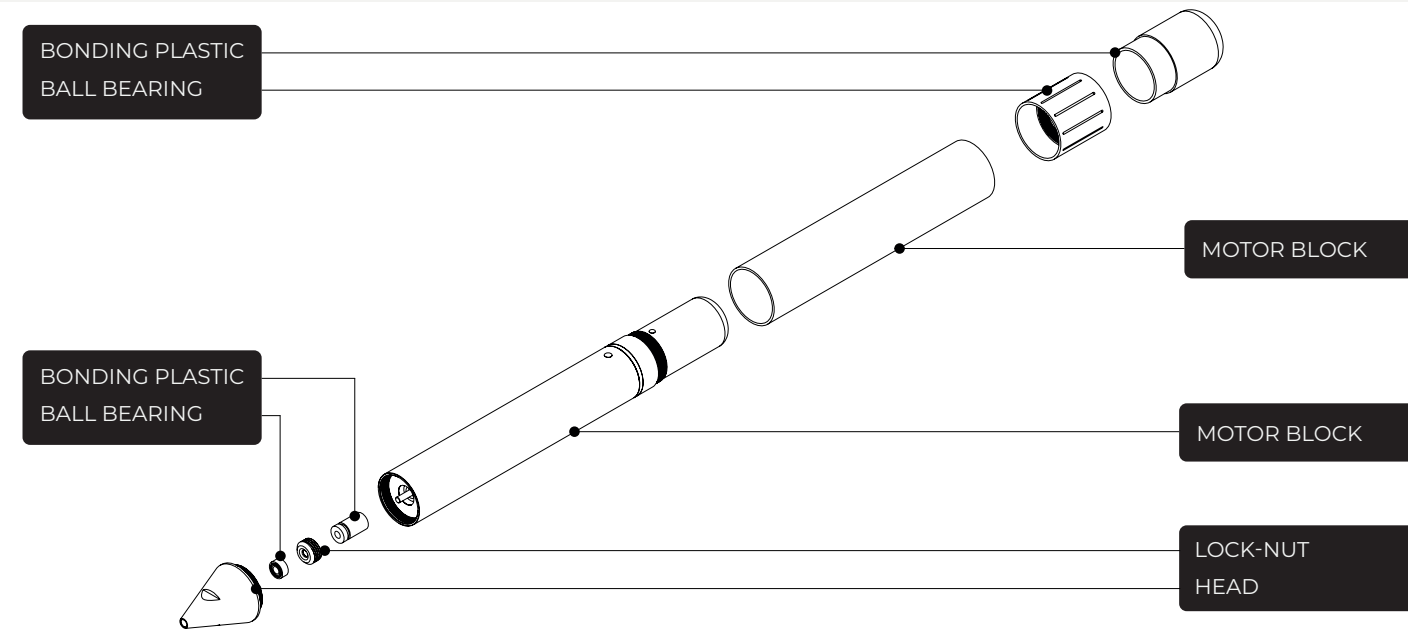
TECHNICAL INFORMATION

Weight : 120 g
Dimensions : ∅ 20.65 x 170 mm
Material : SS 316L/ALU/POM
Bluetooth : 5.0 **EIRP :** +7 dBm
Band : 2.4 GHz **Modulation :** GFSK

Charging time : 3 h
Autonomy : 10 h
Input : 4.2 V. $\overline{\text{---}}$ 0.75 A,
3.15 W MAX.

LEDS INDICATOR

VIOLET : WAITING **BLINKING GREEN :** PAIRING
YELLOW : BOOTING **GREEN :** CONNECTED
BLUE : IN MOTION **RED :** WARNING



- This device should not be used more than 2 metres from the foot switch and tablet.
- This device must never be opened, sterilized or soaked in alcohol.
- This device must be charged exclusively by the Devroye Instruments charger supplied with the system.
- Please contact our customer service if the LED remains red even after a reset.

OVERVIEW

2.4 WAW WIRED HANDPIECE

This new WAW Wired handpiece is designed with the possibility to use the same external parts of the wireless version, namely the head, the punches, and the external sleeve. It connects directly to the WAW Pedal via a jack plug and allows the use of multiphase as well as the different modes present in the wireless version.

■ Motor block

The new WAW Wired Handpiece is overall lighter than the wireless model. The motor block part cannot be sterilized, but its surface can be cleaned with medically approved disinfectant, and it will be completely covered by the external parts. The cable can be wrapped by a disposable plastic sheath. This cable can also be cleaned with medically approved disinfectant. It features the same working modes of the WAW Wireless Handpiece (see below).

■ No battery

A special feature of the WAW Wired Handpiece is that it does not contain any battery inside. This helps to reduce the weight of the motor block despite the fact that a cable is attached. The advantage is that no charging is required, which means that the WAW Wired Handpiece is always ready for use.

■ Nouvag

The old Nouvag handpiece can still be used with the new WAW Pedal: this will allow users to exhaust their stock of old punches. In fact, the new punches designed for the DUO WAW Wireless or WAW Wired handpiece are specific to these products and cannot be used with the old Nouvag handpiece (and vice versa).

TECHNICAL INFORMATION

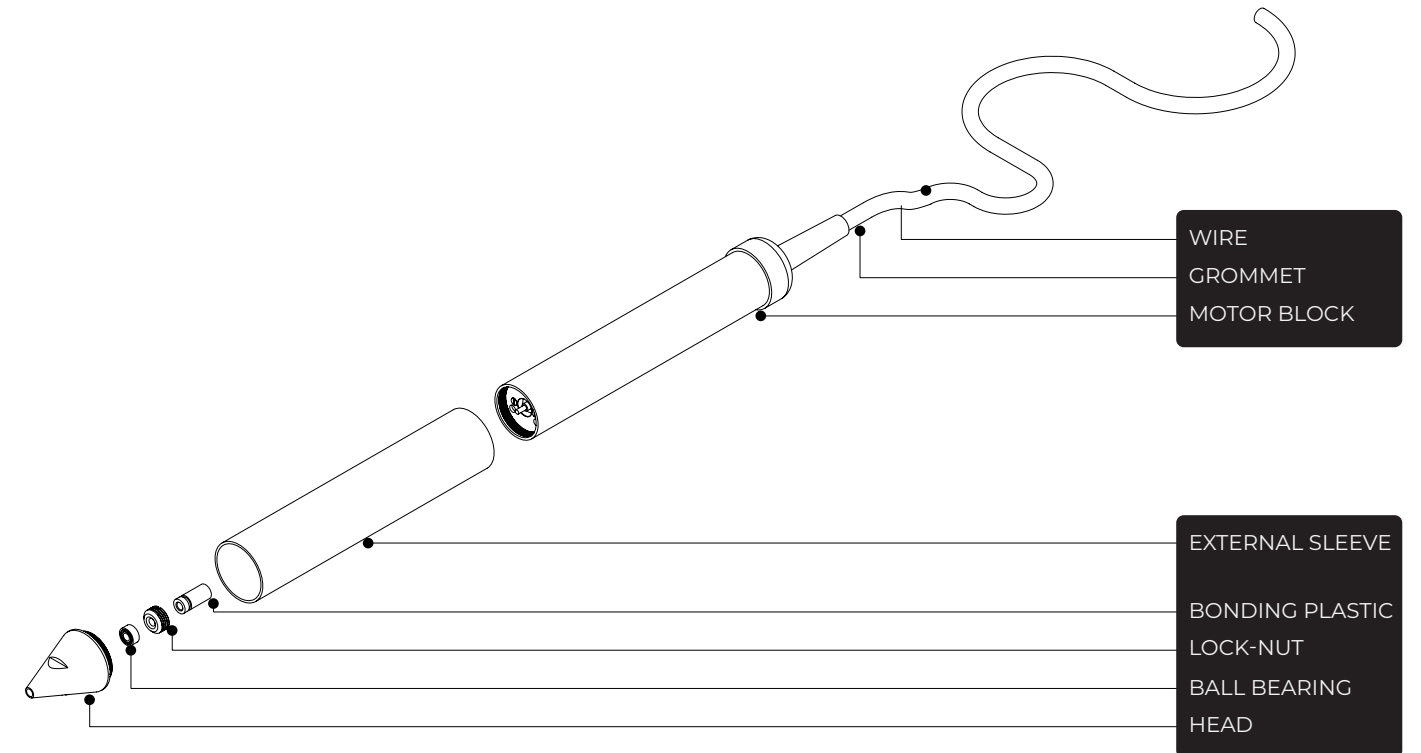
Weight : 120 g

Dimensions : \varnothing 20.65 x 160 mm

Material : SS 316L

Cable length : 2.5 m

Input : 3 V \equiv 1.2 A,
3.6 W MAX.



- This device must never be opened, sterilized or soaked in alcohol.
- This device may be used at a maximum distance of 2.5 metres from the foot switch, as this is the limit of the cable.

OVERVIEW

2.5 WAW PEDAL

The new WAW Pedal differs from its predecessor not only in terms of design, but also in the following new features; an ON/OFF switch, LED indicators for battery level and WAW Pedal status, and charging via USB-C. All these new additions facilitate a more user-friendly and ergonomic interface than ever before. There are no buttons on it anymore (except for the ON/OFF button) and all the settings are fully customizable from the mobile app. The sensitivity of the WAW Pedal can also be controlled via the app.

■ Wireless & Wired


The input jack on the right side of the WAW Pedal provides the option to work with the new WAW Wired Handpiece by plugging it into the WAW Pedal once the WAW Pedal is connected to the tablet via Bluetooth. The old Nouvag handpiece can still be used with the new WAW Pedal: this will allow users to exhaust their stock of old punches. In fact, the new punches designed for the DUO system are specific to this system and cannot be used with the old Nouvag handpiece (and vice versa).

■ LED indicator

The LED on the left side of the WAW Pedal provide information to the user. The first one gives the status of the WAW Pedal and the second one informs the user about the battery level.

■ USB-C charging

The battery of the new WAW Pedal lasts long enough for the surgeon to perform an entire FUE session. Charging is done using a universal USB Type C cable. This cable is supplied with the system.

 Note that if the battery compartment does not close securely, stop using the product and keep it away from children.

TECHNICAL INFORMATION

Weight : 1.770 g

Dimensions : 250 x 96 x 96 mm

Material : SS 316L/ALU

Bluetooth : 5.0/ 2.4 GHz
GFSK / +7 dBm

Charging time : 3 h


Autonomy : 10 h

Input : 5 V. $\overline{\text{---}}$ 3 A,
15 W MAX.

Output : 3 V. $\overline{\text{---}}$ 1.2 A,
3.6 W MAX.

LED INDICATOR

STATUS

 VIOLET : WAITING

 YELLOW : PAIRING

 GREEN : CONNECTED


 BLUE : IN MOTION

 RED : WARNING

BATTERY

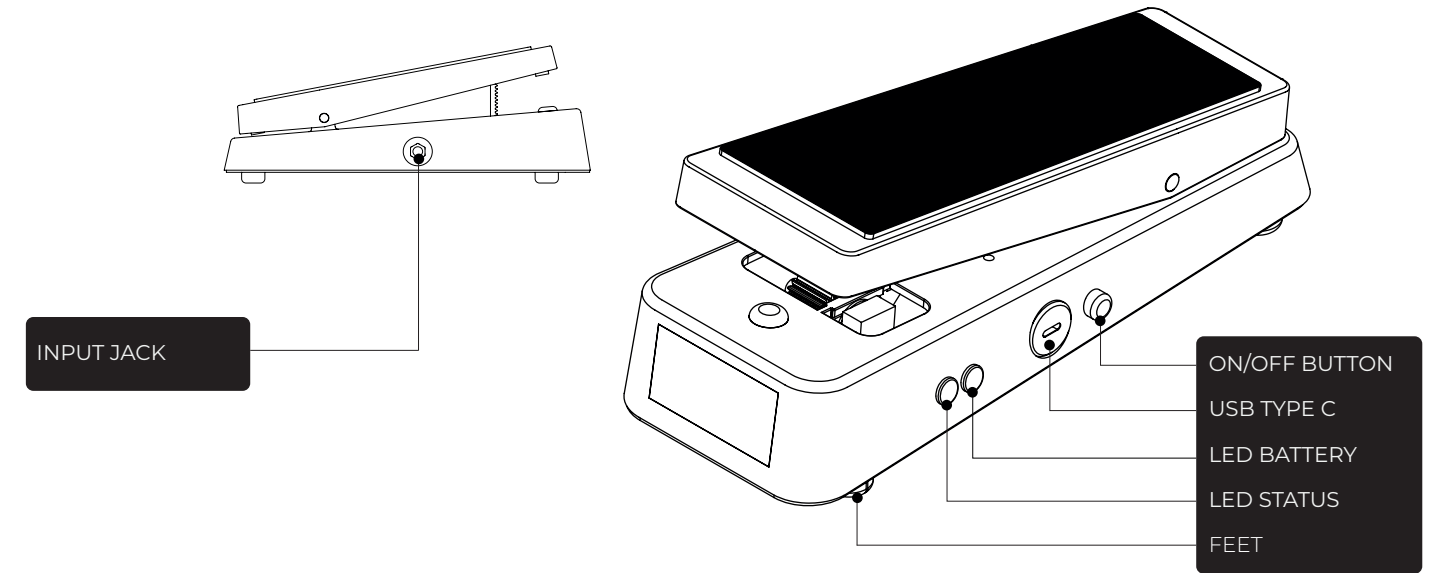
 SOLIDE WHITE : FULL CHARGED

 WHITE BLINKING : CHARGING

 GREEN : HALF BATTERY

 YELLOW : LOW BATTERY

 RED : NO BATTERY



- This device must never be opened, sterilized or soaked in alcohol.
- This device must be charged exclusively by the Devroye Instruments charger supplied with the system.
- Only the supplied adapter should be used for charging the WAW Pedal.
- Please contact our customer service if the LED Status shows red.

OVERVIEW

2.6 WAW SOFTWARE

The mobile app is a central part of the system: it allows instructions to be sent to the WAW Wireless Handpiece and the WAW Pedal. The “Devroye Instruments” application comes pre-installed on the tablet. The user can configure the settings on the tablet to perform the desired movements on the handpiece.

■ Multiphase

A perfect balance between technology and human touch. The new version of the mobile application allows surgeons to achieve a higher level of performance through precise and technical configuration of rotation and oscillation movements.

■ Modes

The new mobile application offers different working modes that allow you to control the rotation and oscillation movements. You can customise all the parameters, with the possibility of defining the speed and duration of the movements.

■ Models

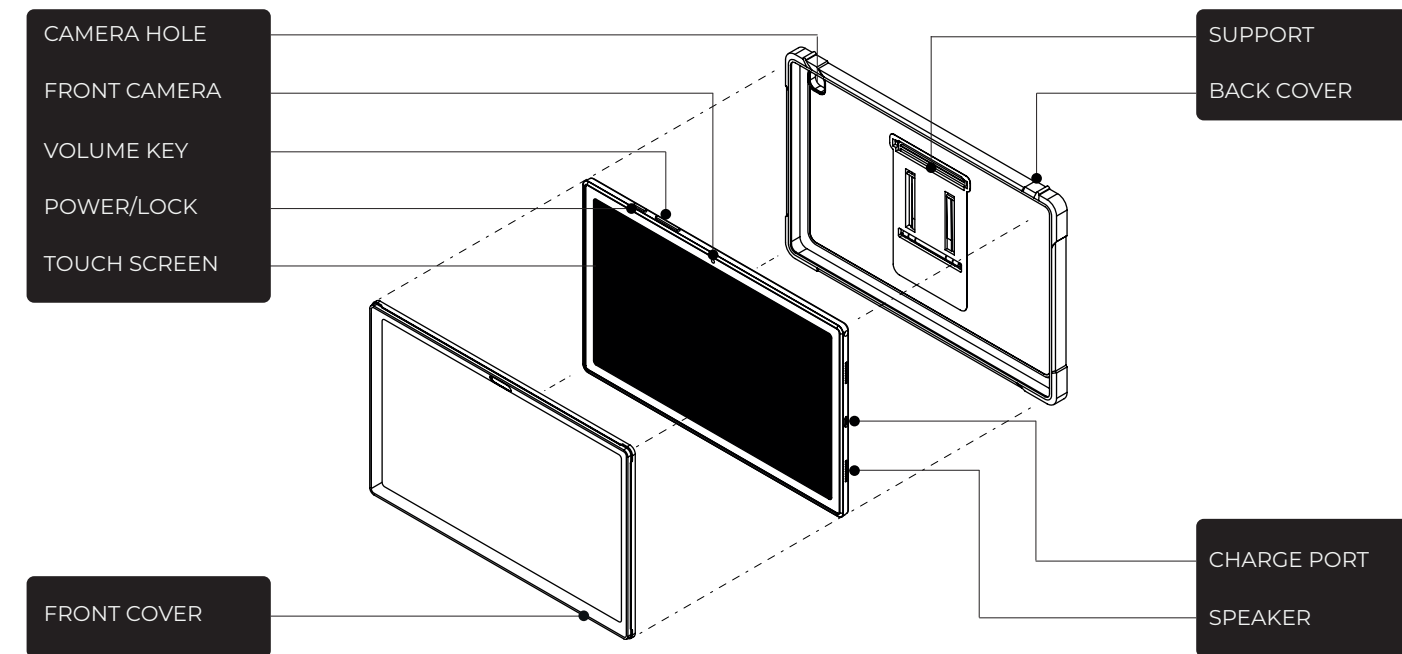
The use of the Nouvag handpiece and motor from the previous WAW FUE system is also possible with the new mobile application

TECHNICAL INFORMATION

Weight : 476 g
Size : 157.4 x 247.6 x 8 mm
Display : 10.4 inches

Capacity : 3 h
Autonomy : 10 h
Bluetooth : 2.4 GHZ

Resolution : 2000x1200 pixels
Connectivity : WIFI-USB-C



- The WAW tablet must never be opened, sterilized or soaked in alcohol.

OVERVIEW

2.7 WAW CHARGING STATION

The WAW charging station makes the wireless version of the system absolutely free of wires and allows the surgeons to have one or more spare motor blocks in charge.

■ Power supply

The WAW Charging Station housing has an output charging plug that must be connected to the power supply while charging. Connect the corresponding end of the power cord to the WAW Charging Station and the other end to a mains power outlet.

■ Charging

Before charging the cordless handpiece, be sure to remove the outer body (external sleeve + head + grip cap) off the handpiece. Once the outer body is removed, protect the front of the motor block with the plastic cork before charging. Never leave the motor block unprotected. Then simply place the motor block of the handpiece (plastic cork end up) into one of the bores of the stainless steel holder of the WAW Charging Station. It is quite simple and user-friendly.

■ LED indicator

The LED on the WAW Charging Station indicate the battery level of the WAW Wireless Handpiece. The battery is fully charged when 3 green and no red LEDw are flashing.

TECHNICAL INFORMATION

Weight : 470 g

Dimensions : 174 x 105 x 128 mm

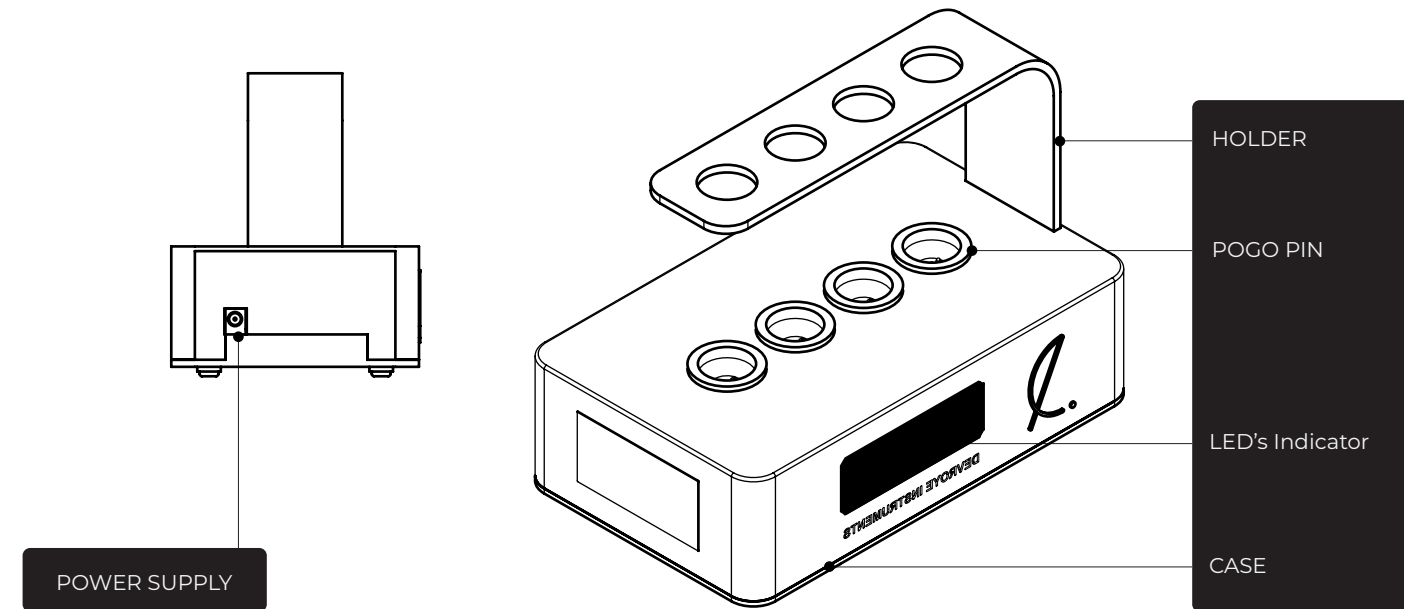
Material : SS 304L/PU

Input : 9 V - 12 V $\overline{\text{---}}$ 1 A,
12 W MAX.

Output : 4 x (4.2 V DC \pm 1% / 375mA),

LEDS INDICATOR

- : FULL BATTERY
- : HALF BATTERY
- : LOW BATTERY
- : WARNING MODE



- This device must never be opened, sterilized or soaked in alcohol.
- This device must be charged exclusively by the Devroye Instrument charger provided with the WAW FUE DUO system. During charging, third party cords can cause malfunction, overheat and even fire on the WAW Charging Station. Damages caused by the usage of unofficial cords are not covered by the official warranty. Please contact our customer service if the LED Status shows red.

OVERVIEW

2.8 EXTERNAL SLEEVE SUPPORT BOX

At the end of each FUE session, the external parts of the handpiece must be subjected to cleaning in order to maintain the system in good operating condition. Before proceeding with the cleaning, the WAW Wireless Handpiece must be disassembled to remove the motor block; the removable parts can then be placed into the External Sleeve Support Box.

Positioning

Each cleanable part has a specific location. Please refer to the figure beside.

Cleaning

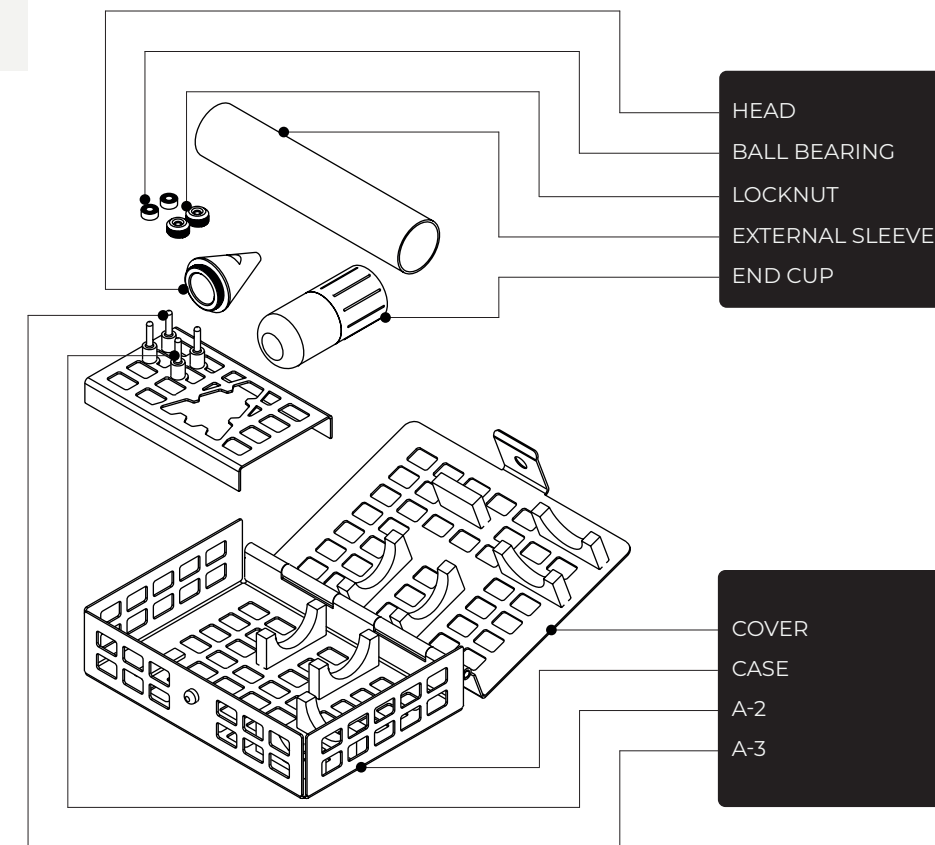
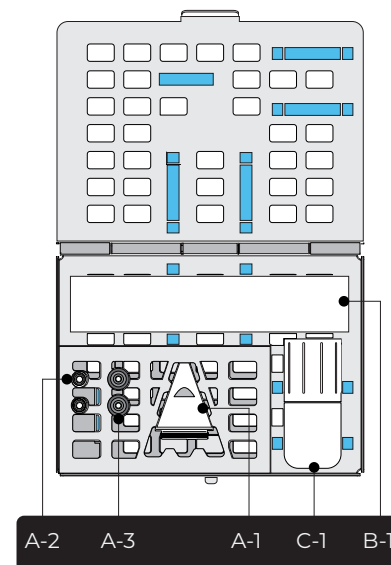
The External Sleeve Support Box can be placed into an autoclave at :

- 121°C (250F°) for 20 minutes
- 126°C (258,8 F°) for 15 minutes
- 134°C (273,2 F°) for 10 minutes

TECHNICAL INFORMATION

- Weight : 165 g
- Dimensions : 110 x 84 x 31.60 mm
- Material : SS 304L

PLACEMENT



- Please follow the cleaning conditions.

OVERVIEW

2.9 ASSEMBLY TOOLS

These 3 mounting tools allow to assemble and disassemble the handpieces.

■ Tool N°1

The **tool N°1** is used to place the **ball bearing** and the **lock-nut** inside the **head**. Place the **ball bearing** and lock-nut notch on the tool and gently turn clockwise until it is fixed. You can use this tool also to remove the **ball-bearing** and **lock-nut**, by turning it anticlockwise.

■ Tool N°2

This tool is used for disassembling of the handpiece. The ball-bearing often follows the **lock-nut**. If this does not happen, the **tool N°2** must be used. The **tool N° 2** is used to pull the **ball-bearing** out if the **lock-nut** removal did not suffice to remove it.

■ Tool N°3

The **tool N°3** allows for placing the **punch** in the **head**. The tip of this tool must be placed into the notches of the **punch**; then, push the **punch** completely into the **head**. To remove the **punch**, you must perform the opposite operation, using the same tool.

■ Magnet Ring

The two magnet rings provided with the system allow for performing a manual reset of the **WAW Wireless Handpiece**. In case of loss of the supplied magnets, it is possible to get new ones in the market, as long as they are neodymium magnets, as a high force of attraction is required to perform the reset.

TECHNICAL INFORMATION

Weight : 10 g

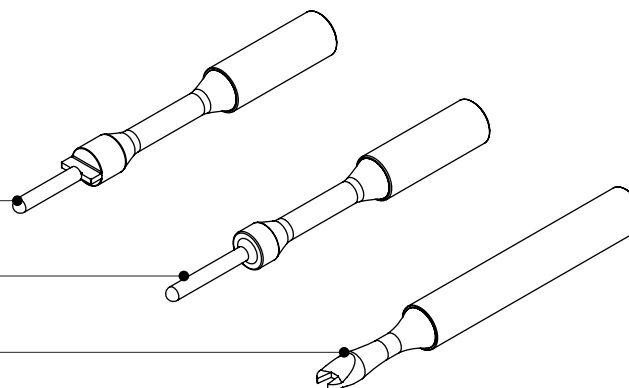
Dimensions : \varnothing 7,30 x 70mm

Material : SS 316L

TOOL N°1

TOOL N°3

TOOL N°2



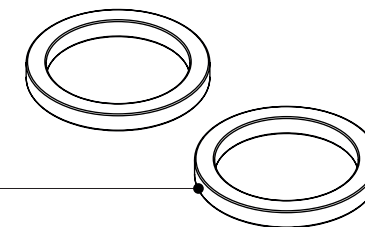
TECHNICAL INFORMATION

Weight : 6 g

Dimensions : \varnothing 27 x 3 mm

Material : Neodymium

MAGNET RING



- Cleaning of the 3 assembly tools must be done by autoclave using the External Sleeve Support Box.
- Do not place the magnet in the autoclave, the resulting heat may demagnetise the magnet
- Please contact our customer service if the LED Status shows red.

SETTING UP

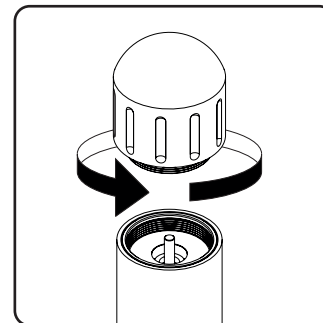
3.1 ASSEMBLY OF THE WAW WIRELESS HANDPIECE

The handpiece is mainly composed of seven different parts. This feature allows for a fast assembly and an easier cleaning of the device.

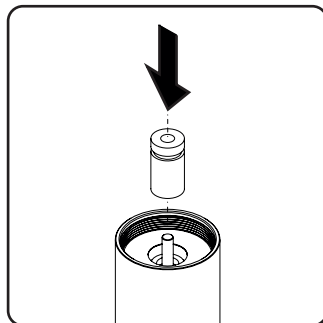
Here are the steps to follow for the assembling of the WAW Wireless Handpiece:

- **STEP 1:** To assemble the wireless handpiece, first remove the **plastic cork** of the **motor block**.
- **STEP 2:** Take the **plastic bonding** and fix it gently on the shaft of the **motor block**.
- **STEP 3:** Place the **lock nut** and the **ballbearing** on the **tool N°1**.
- **STEP 4:** Use the notch set for this purpose to screw the **lock-nut**.
- **STEP 5:** Mount the **head** onto the **motor block** and turn clockwise.
- **STEP 6:** Slide the **external sleeve** on the **motor block**.
- **STEP 7:** After, fasten the **end cup** (plus the **plastic cap**) on the bottom side of the **motor block**. Be careful to place it on the right direction. The plastic cap is fitting only one side of the end cup.
- **STEP 8:** The handpiece is almost ready : now, choose the correct punch size and, using the **tool N°3**, insert the **punch** into the head and push on it.

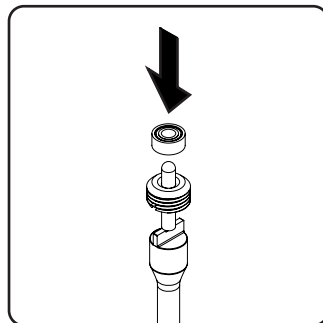
STEP 1



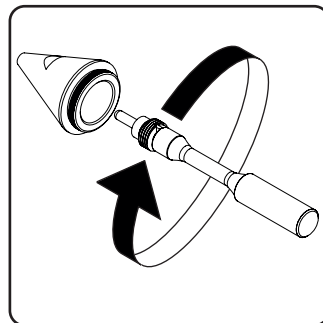
STEP 2



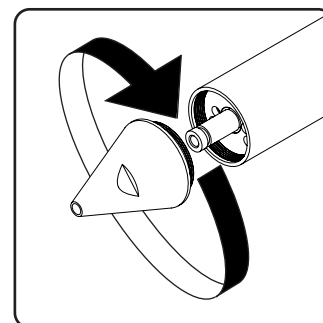
STEP 3



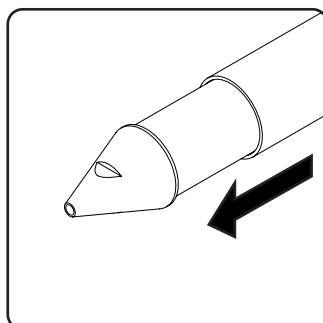
STEP 4



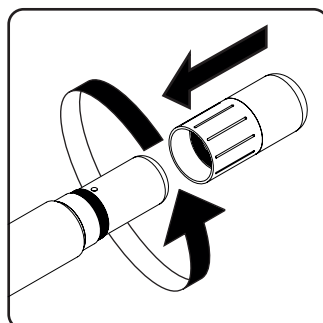
STEP 5



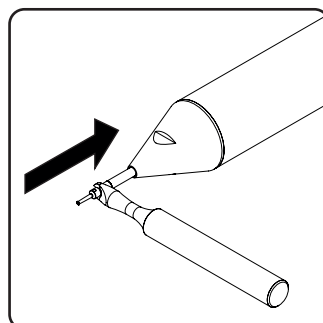
STEP 6



STEP 7



STEP 8



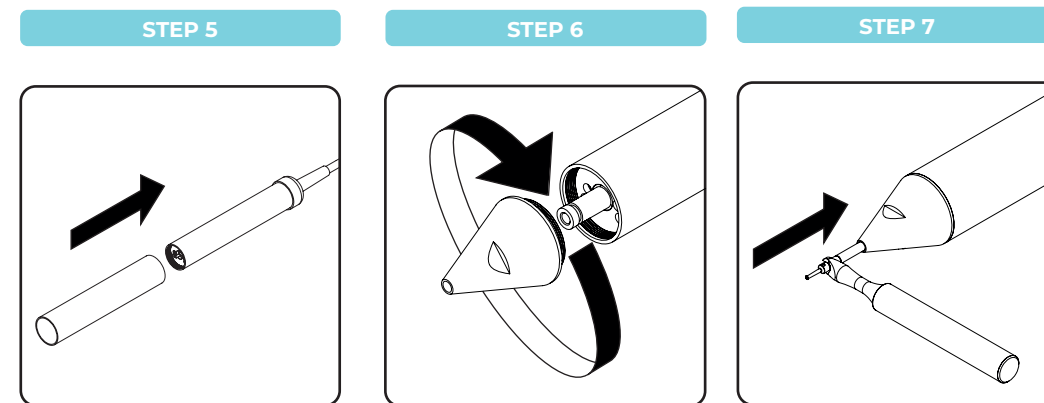
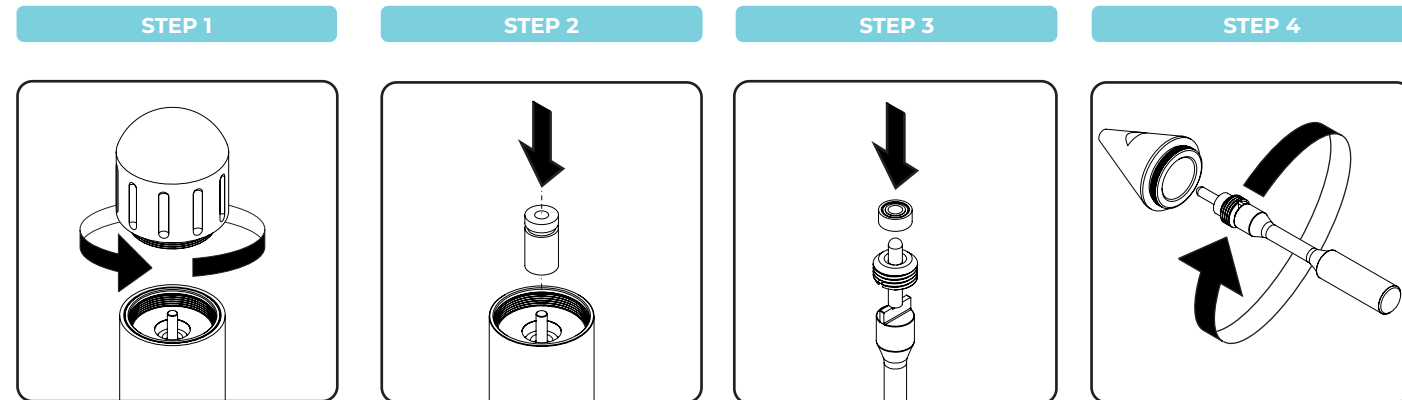
SETTING UP

3.2 ASSEMBLY OF THE WAW WIRED HANDPIECE

The handpiece is mainly composed of 6 different parts. This feature allows for a fast assembly and an easier cleaning of the device.

Here are the steps to follow for the assembling of the WAW Wired Handpiece :

- **STEP 1:** To assemble the WAW Wireless Handpiece, first remove the **plastic cork** of the **motor block**.
- **STEP 2:** Take the **plastic bonding** and fix it gently on the shaft of the **motor block**.
- **STEP 3:** Place the **locknut** and the **ball bearing** on the **tool N°1**.
- **STEP 4:** Use the notch set to fix the **lock nut** into the **head**.
- **STEP 5:** Mount the **head** onto the **motor block** and turn clockwise.
- **STEP 6:** Slide the **external sleeve** on the **motor block**.
- **STEP 7:** The handpiece is almost ready : now, choose the correct punch size and, using the **tool N°3**, insert the punch into the head and push on it



- The cable of the WAW Wired Handpiece can be cover with a sterile, single-use protective sleeve to keep it clean.

SETTING UP

3.3 INSTALLATION OF THE WAW PEDAL

Depending on the handpiece selected (wireless or wired) for the surgery, the steps to install the WAW pedal change somewhat :

WAW WIRELESS HANDPIECE

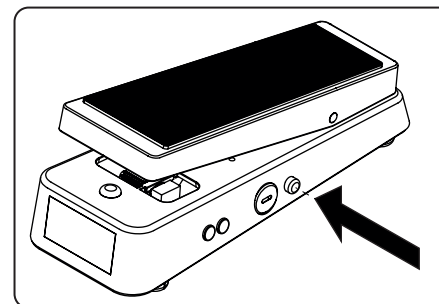
- **STEP 1:** Press the ON/OFF button on the WAW Pedal to activate it.
- **STEP 2:** Check the charge level of the WAW Pedal on the second LED. If the light is red, please proceed to charge the pedal.
- **STEP 3:** Place the WAW Pedal on the floor of your working area.

WAW WIRED HANDPIECE

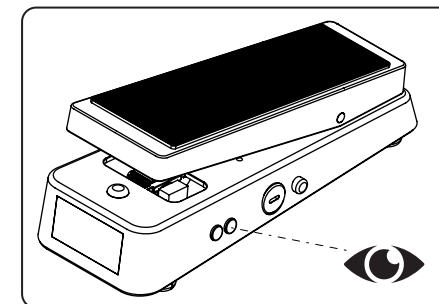
- **STEP 1:** Press the ON/OFF button on the WAW Pedal to activate it.
- **STEP 2:** Check the charge level of the pedal on the second LED. If the light is red, please proceed to charge the WAW Pedal.
- **STEP 3:** Run the end of the cable from your WAW Wired Handpiece to the jack on the WAW Pedal and place it on the floor of your working area.

WIRELESS

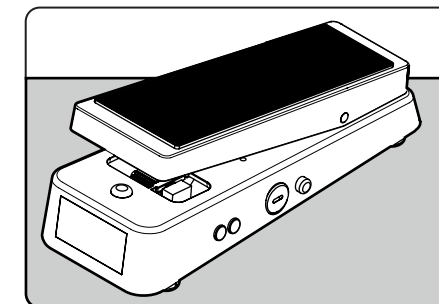
STEP 1



STEP 2

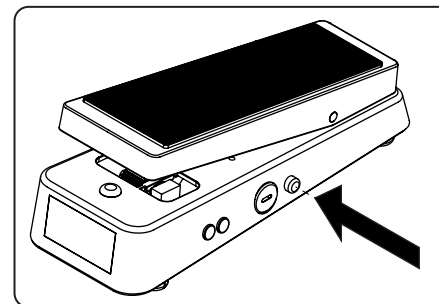


STEP 3

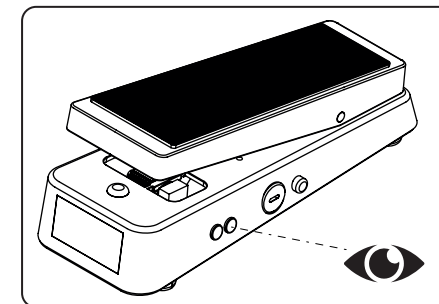


WIRED

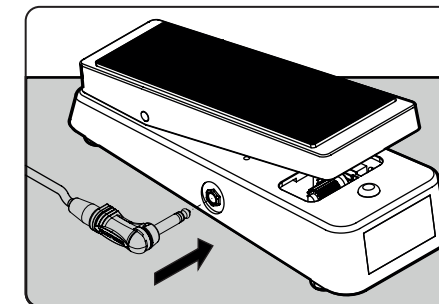
STEP 1



STEP 2



STEP 3



SETTING UP

3.4 LAUNCHING THE MOBILE APP

Opening the DEVROYE INSTRUMENTS mobile application for the first time requires a quick setup of the app you must log in with your personal ID and password as well as accepting the terms of the EULA. This procedure only needs to be done once.

- **STEP 1:** Press the power key on the tablet and open the DEVROYE INSTRUMENTS mobile application.
- **STEP 2:** Read and accept the terms of the end-user license agreement (EULA).
- **STEP 3:** After typing the password you received by email, enter your new password. Your password is personal and confidential, and shall not be disclosed or shared with third parties.



- For the first launch of the DEVROYE INSTRUMENTS mobile application, an internet connection is required in order to complete the various steps. a
- The use of the Samsung tablet is dedicated exclusively to the DEVROYE INSTRUMENTS mobile app. The installation of other applications or files will void the our liability for malfunction and/or damages
- The system comes with the DEVROYE INSTRUMENTS application already installed on the tablet. If, due to an inadvertent error, the application is deleted, you can still download it again from the Google Play Store.
- It is important to install Android system updates to protect the tablet against threats (viruses, hackers, etc.). In addition to security issues, updating your device will also improve its performance.

SETTING UP

3.5 POSITIONING

Before using the system, make sure that the 3 devices (WAW Wireless Handpiece, WAW Pedal and WAW Software) are adequately charged. Afterwards, place the 3 devices in close proximity in order to connect them

■ WAW Wireless Handpiece

Before installing the system, check that the WAW Wireless Handpiece is sufficiently charged. It is recommended that the device is charged one full night before its usage. Once the motor block is covered by its external parts, place the handpiece near the WAW pedal (at 1.5m)

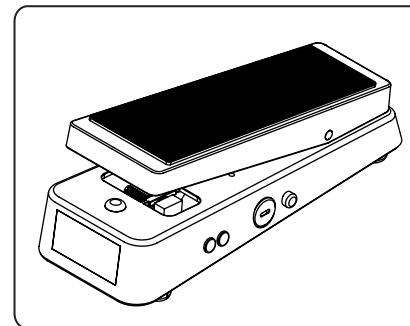
■ WAW Pedal

After fully charging the WAW Pedal with the USB-C charger; press the ON/OFF switch to activate it. Place it on the ground, 1.5 m far from the handpiece.

■ WAW Software

Verify that the tablet is fully charged. Afterwards, unlock the tablet and click on the app to link your email address. It is often compulsory to keep the tablet charging during its usage since the tablet, contrarily to the handpiece and the WAW Pedal, might not have enough battery capacity to last the whole surgery.

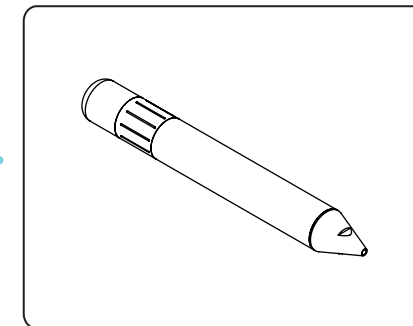
WAW PEDAL



IDENTIFICATION

- The visual identification of the WAW Pedal is done by the serial number located on the back.
- The visual identification of the WAW Wireless Handpiece is possible by the serial number engraved on the motor block.

WAW WIRELESS HANDPIECE



OPERATING CONDITIONS

- Ambient temperature :
-10 °C to 40 °C (+23 °F to 100 °F)
- Relative humidity :
10% RH to 60% RH (non-condensing)
- Atmospheric pressure :
0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

WAW SOFTWARE



- **Note** : The EMISSIONS characteristics of this system make it suitable for use in industrial areas and hospitals (CISPR 11 Class A). If it is used in a residential environment (for which CISPR 11 Class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

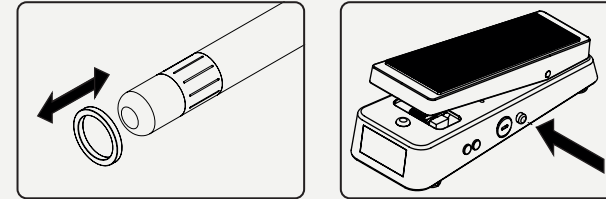
HOW TO USE

4.1 CONNECTION

The WAW Wireless Handpiece and WAW pedal must be rebooted before establishing a connection between them. To reboot the WAW Wireless Handpiece, take the magnetic ring and move it through the bottom of the handpiece until the colour becomes violet. To reboot the WAW Pedal, you simply need to press the button ON/OFF to switch the light off, then press it again to turn the light violet.

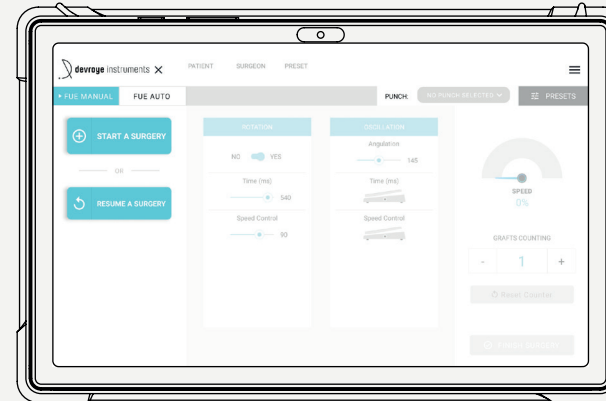
- **STEP 1:** Open “Devroye Instruments” app on the samsung tablet and type the surgeon’s as well as the patient’s name.
- **STEP 2:** Select whether you perform a new surgery or wish to continue a previous one. Afterwards, choose the system version with which you wish to work : WIRELESS or WIRED.
- **STEP 3:** If you use the wireless version, the first step involves connecting the WAW Wireless Handpiece. Select the wireless handpiece to be connected, then select the WAW Pedal to control the WAW Wireless Handpiece from the Bluetooth devices available on the mobile application. Once the devices are connected, the LED on the handpiece turn green. Please note that it is possible to change devices even when these are connected.
- **STEP 4:** If you chose the wired version, you must choose the WAW Pedal with which you want to work and then plug the WAW Wired Handpiece.

REBOOT OF THE DEVICES

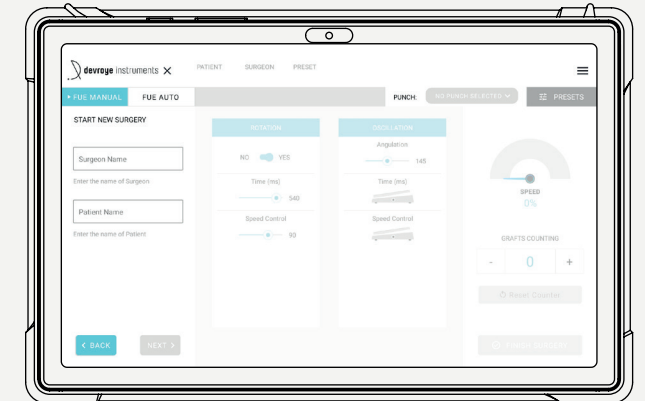


- Pass the magnetic ring around the WAW Wireless Handpiece.
- Press the ON/OFF button on the WAW pedal.

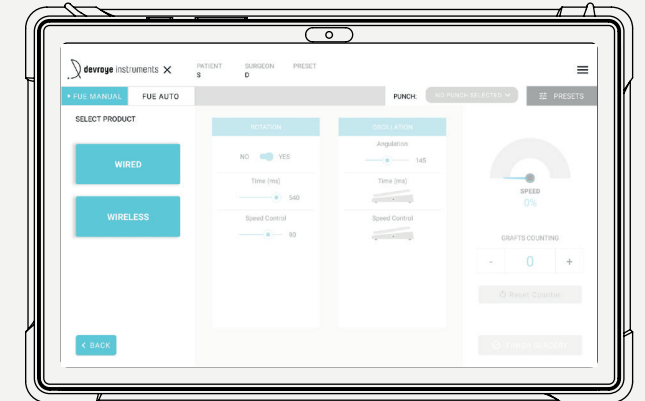
STEP 2



STEP 1



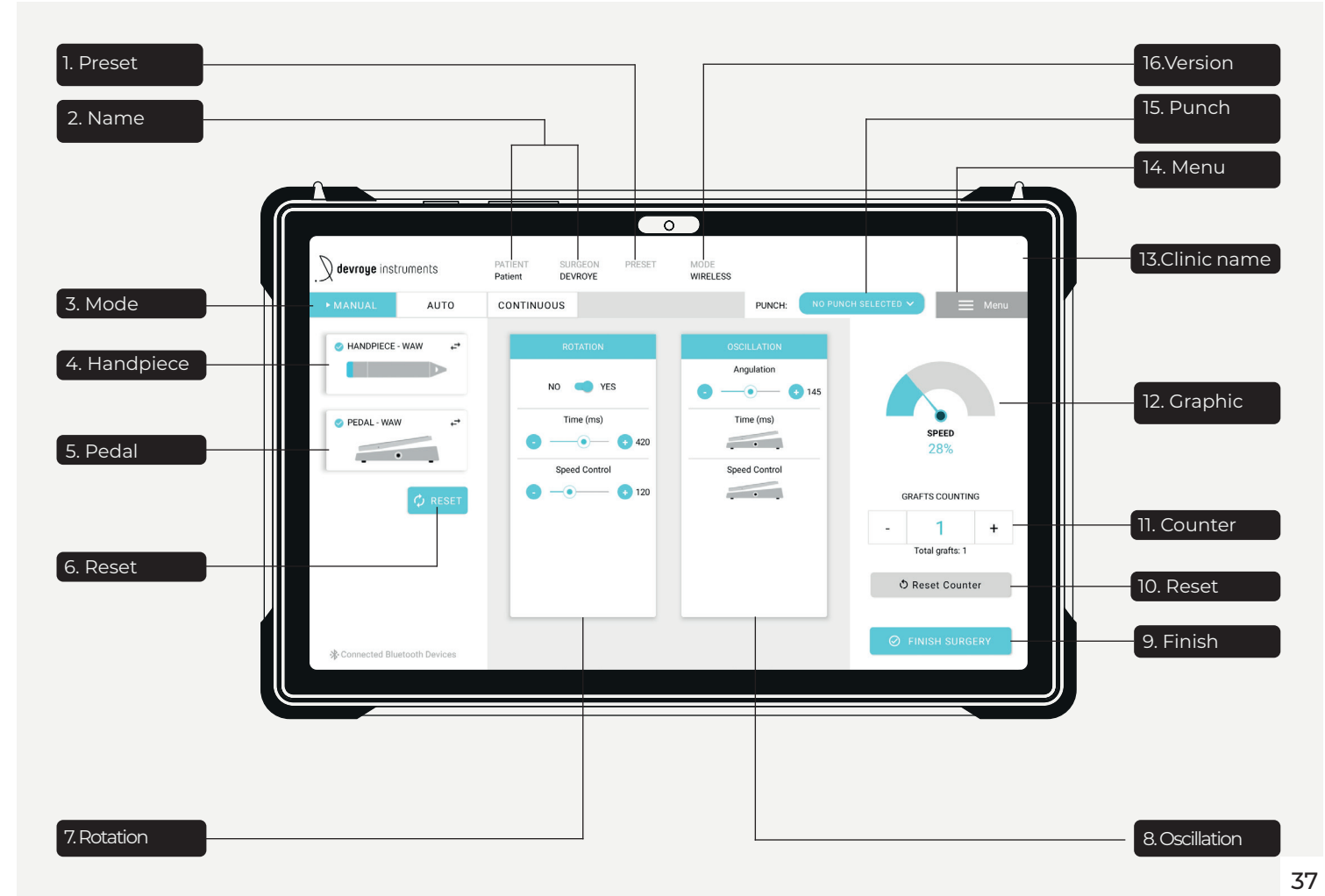
STEP 3



HOW TO USE

4.2 DISPLAY

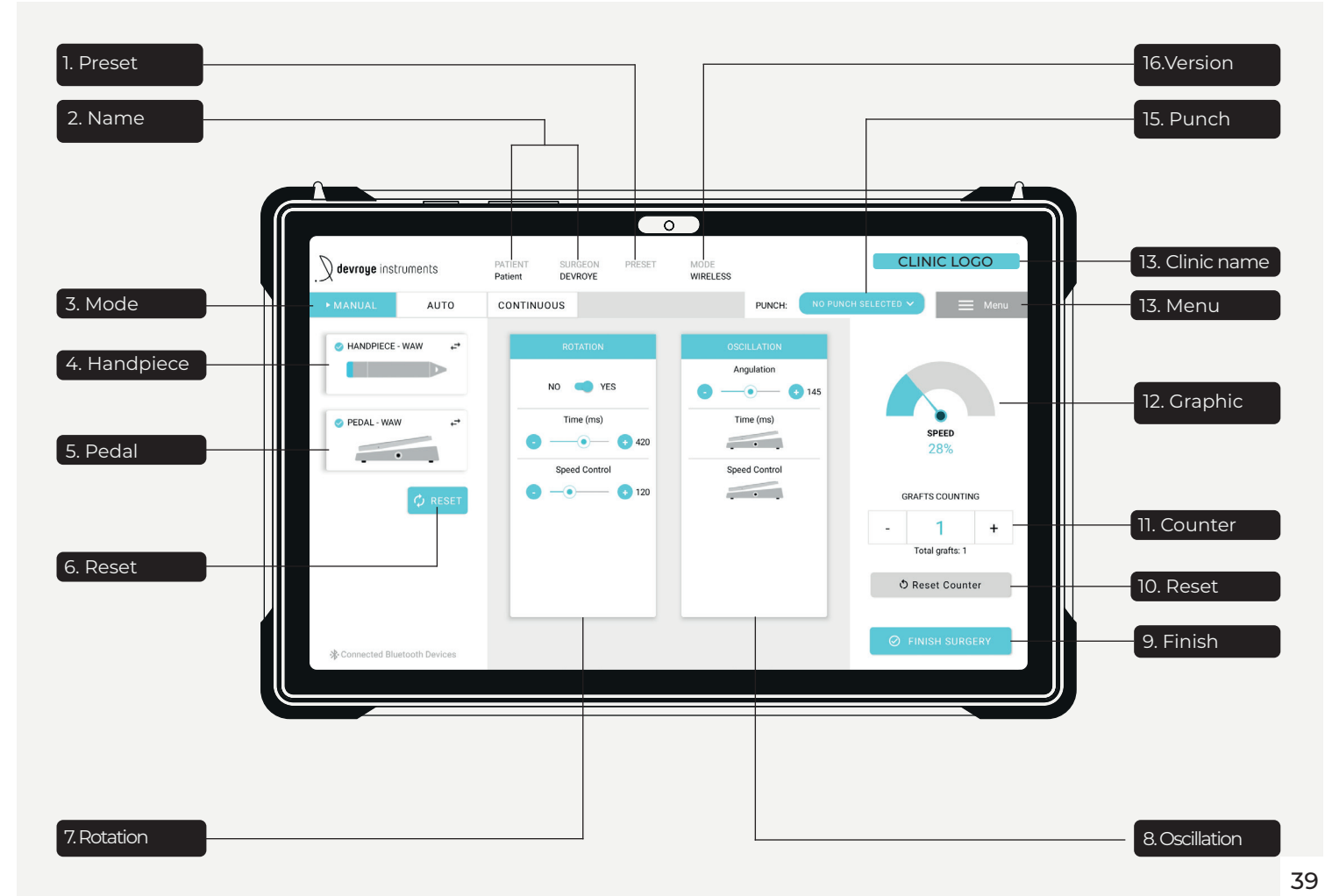
- Preset** : The mobile app allows users to create and save their own presets. A factory preset named DEVROYE is already available.
- Name** : At the beginning of each session, it is required to register the name of the patient and the surgeon performing the surgery.
- Mode** : 3 distinct modes are available on the mobile application to offer different ways of working.
- Handpiece** : Information such as the serial number or the remaining battery capacity of the connected device is shown here. You can check it this by clicking on the 2 arrows.
- Pedal** : Information such as the serial number or the remaining battery capacity of the connected device is shown here. You can check it by clicking on the 2 arrows.
- Reset** : If the connection between the devices is broken at any point of time during the surgery. Use this button to reset the connection and select another device.
- Rotation** : The first movement is rotation, whose time and speed parameters can be controlled from the mobile application. Rotation is optional however it's considered efficient to cut the epidermal part of the skin.
- Oscillation** : The second movement is an oscillation, whose angulation value is defined by the mobile app. According to the mode, speed and time parameters can be managed from the mobile app or by pressing the WAW Pedal. Oscillation is a little slower than rotation, but it is smoother for soft cutting and reduces the transection rate.



HOW TO USE

4.2 DISPLAY

- 9. **Finish** : When the surgery is finished, click on the “finish surgery” button to display the surgery report. It is always possible to return to the current surgery.
- 10. **Reset** : This button allows clearing the graft counter.
- 11. **Counter** : All movements made are noted and displayed here.
- 12. **Graphic** : A graph showing the movement performed as a speedometer in manual and continuous mode and as a bar graph in auto mode.
- 14. **Clinic name** : The mobile app allows you to personalize your product by displaying your clinic’s logo or name in this location.
- 14. **Menu** : The menu gives access to all performed surgeries as well as to the advanced system settings, updates, etc
- 15. **Punch** : It is possible to record the type and size of the punch used during surgery.
- 16. **Model** : The handpiece model can be chosen between Wireless and Wired.



HOW TO USE

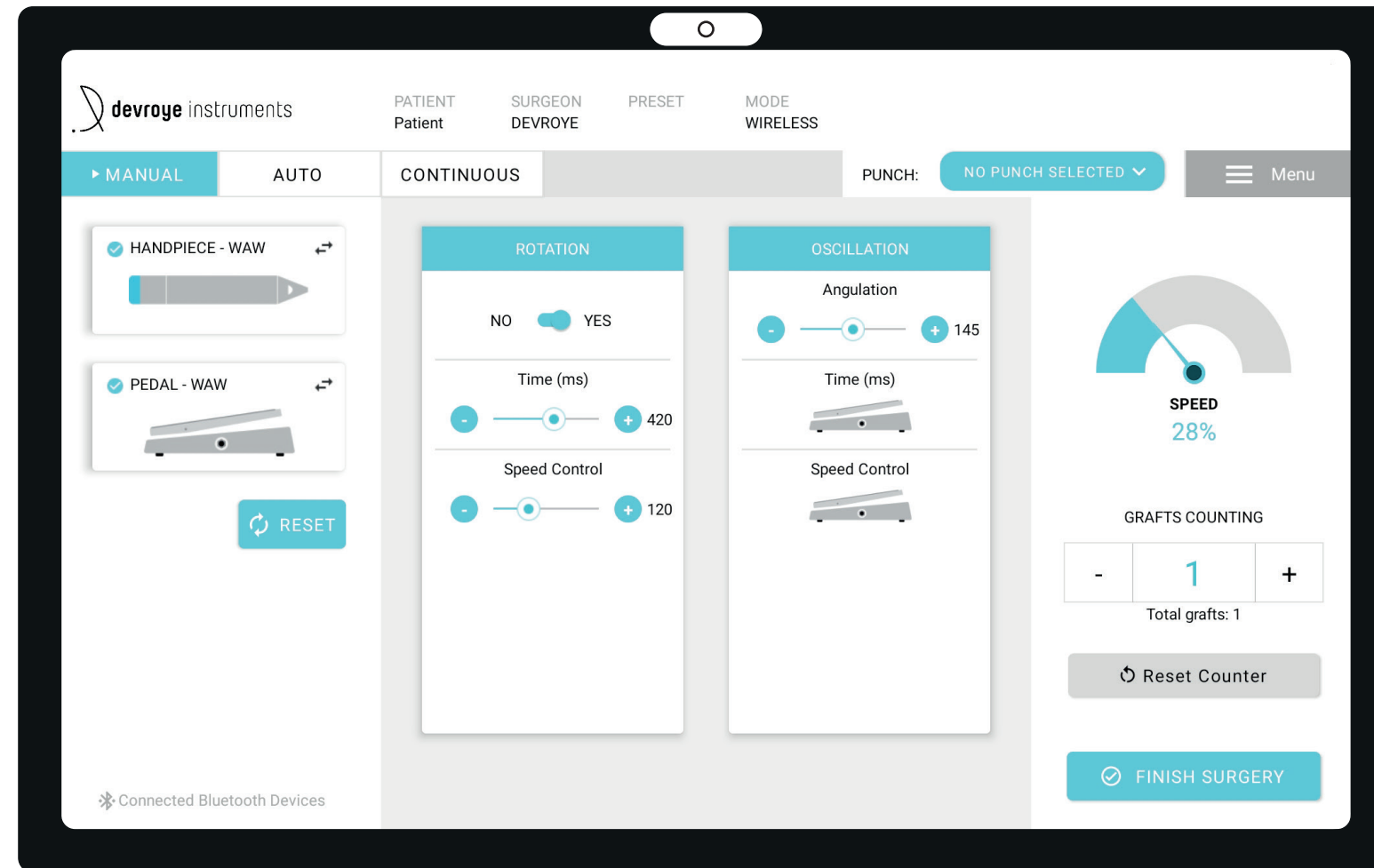
4.3 MODE : MANUAL

The manual mode is activated by a direct connection between the WAW Pedal and the handpiece. That means the handpiece oscillation and rotation movements are generated by the WAW Pedal. By pressing on the WAW Pedal, you can activate an oscillation motion, whose angulation (between 90° and 360°) can be adjusted via the application. The oscillation power is proportionate to the pressure applied to the WAW Pedal.

By adjusting the reactivity of the WAW Pedal in the advanced settings available on the app, it's possible to increase the sensitivity of the WAW Pedal: in this way, a faster acceleration is obtained with the same pressure applied to the WAW Pedal. The WAW Pedal is now more reactive and sensitive to its movements.

It is also possible to add a rotation movement before the oscillation. The speed and duration of this rotation are managed entirely from the mobile application.

- **STEP 1:** Define the angulation of the oscillation.
- **STEP 2:** Choose whether you wish to add a rotation before the oscillation or not.
- **STEP 3:** Press the WAW Pedal and start working.



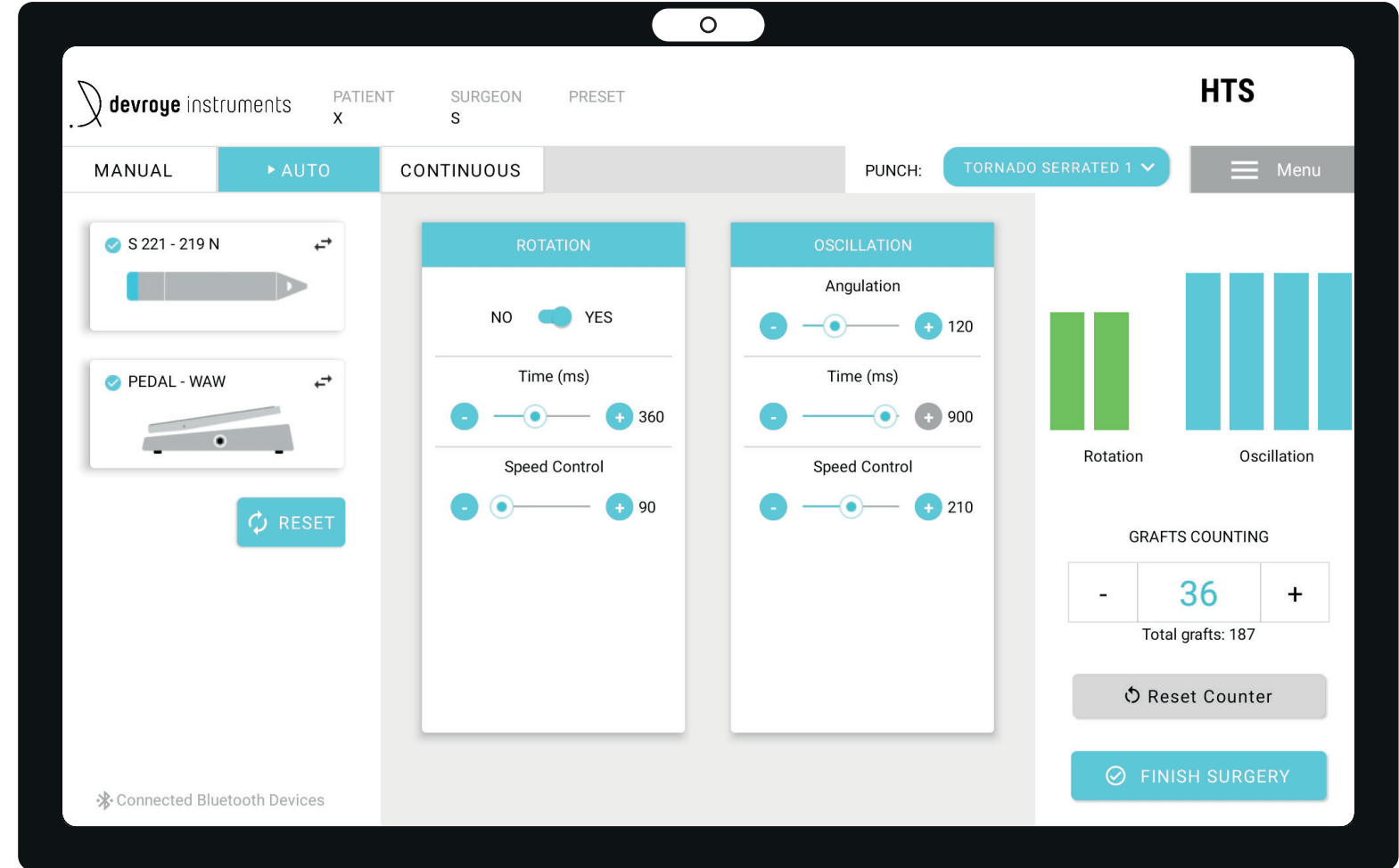
HOW TO USE

4.4 MODE : AUTO

The auto movement is activated by adjusting the movement parameters entirely from the mobile application. In fact, the WAW Pedal is used as an activator (ON/OFF). The intensity, duration, and angulation of the oscillation movement can be adjusted using the sliders in the mobile application. A slight push on the WAW Pedal will trigger a movement corresponding to the defined parameters.

As for the manual mode, it is also possible to add a rotation motion before the oscillation. The speed and the duration of this rotation movement are entirely controlled via the mobile application.

- **STEP 1:** Define the angulation, duration, and power of the oscillation.
- **STEP 2:** Choose whether you wish to add a rotation before the oscillation or not.
- **STEP 3:** Press the WAW Pedal and start working with the preset movement. To switch to a second movement, press the WAW Pedal again.




HOW TO USE

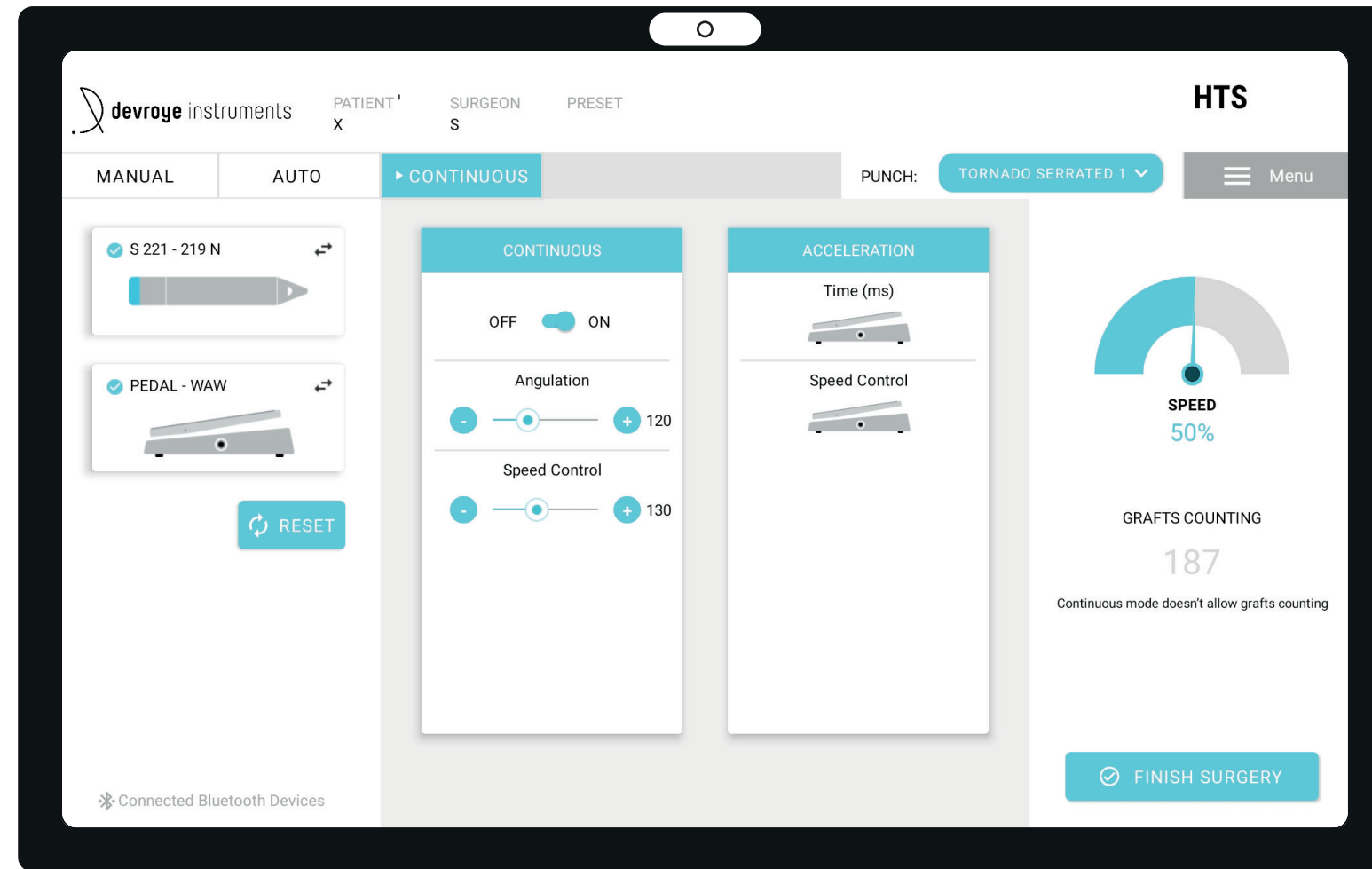
4.5 MODE : CONTINUOUS

In continuous mode, the WAW Wireless and WAW Wired handpiece motor runs continuously without the need to press the WAW Pedal. To activate the continuous oscillation, just set the slider to " ON ". The speed of this continuous oscillation can be adjusted on the mobile application. It's possible to accelerate the movement by pressing the WAW Pedal. when you release the WAW Pedal the speed decrease to the minimum previously defined.

The continuous mode is always set to OFF.
The user must manually activate the mode by turning the slider to ON.

- STEP 1:** From the moment the slider is set to ON, the motor will start and run at the speed indicated by the speed controller.
- STEP 2:** The oscillation speed changes when the speed control value is changed on the mobile application.
- STEP 3:** The oscillation speed can be accelerated when the WAW Pedal is pressed. This acceleration is defined in time and power by the pressure on the WAW Pedal.

 Note that it is not possible to count the movements made in continuous mode as the mode runs continuously and the counting is only done when the WAW Pedal is pressed.



HOW TO USE

4.6 PUNCH SELECTION

The new mobile application integrates the 2 varieties of punches available for the new wireless system. It possible to specify the different sizes and levels of sharpness. The punches used and their size will appear in the report at the end of the surgery.



Punch Tornado

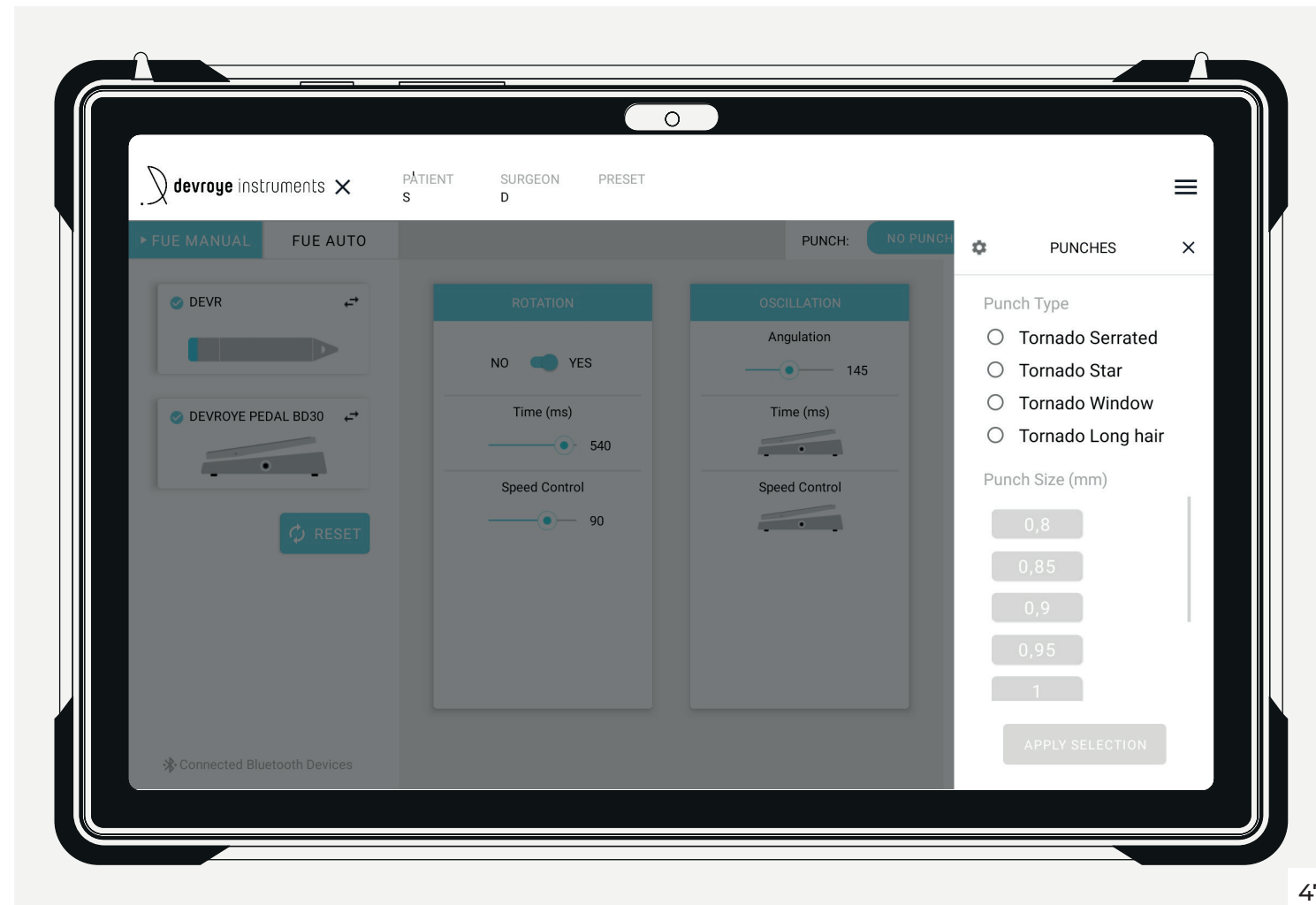
The Hybrid Tornado punch shares the advantages of both sharp and blunt punches in one: it allows to penetrate the skin deeper with minimal trauma to grafts.



Punch Star

This beard punch, with its special cutting edge, greatly reduces the rate of buried grafts, resulting in high quality, fuller and richer grafts.

- **STEP 1:** Select the type of punch used among the suggested ones.
- **STEP 2:** Specify the diameter of the punch used among the suggested ones.



HOW TO USE

4.7 UPDATES

The new Devroye Instruments application allows updating the software remotely in order to take advantage of the latest improvements and new features. Note that it is possible to update several devices simultaneously.

WAW Wireless Handpiece

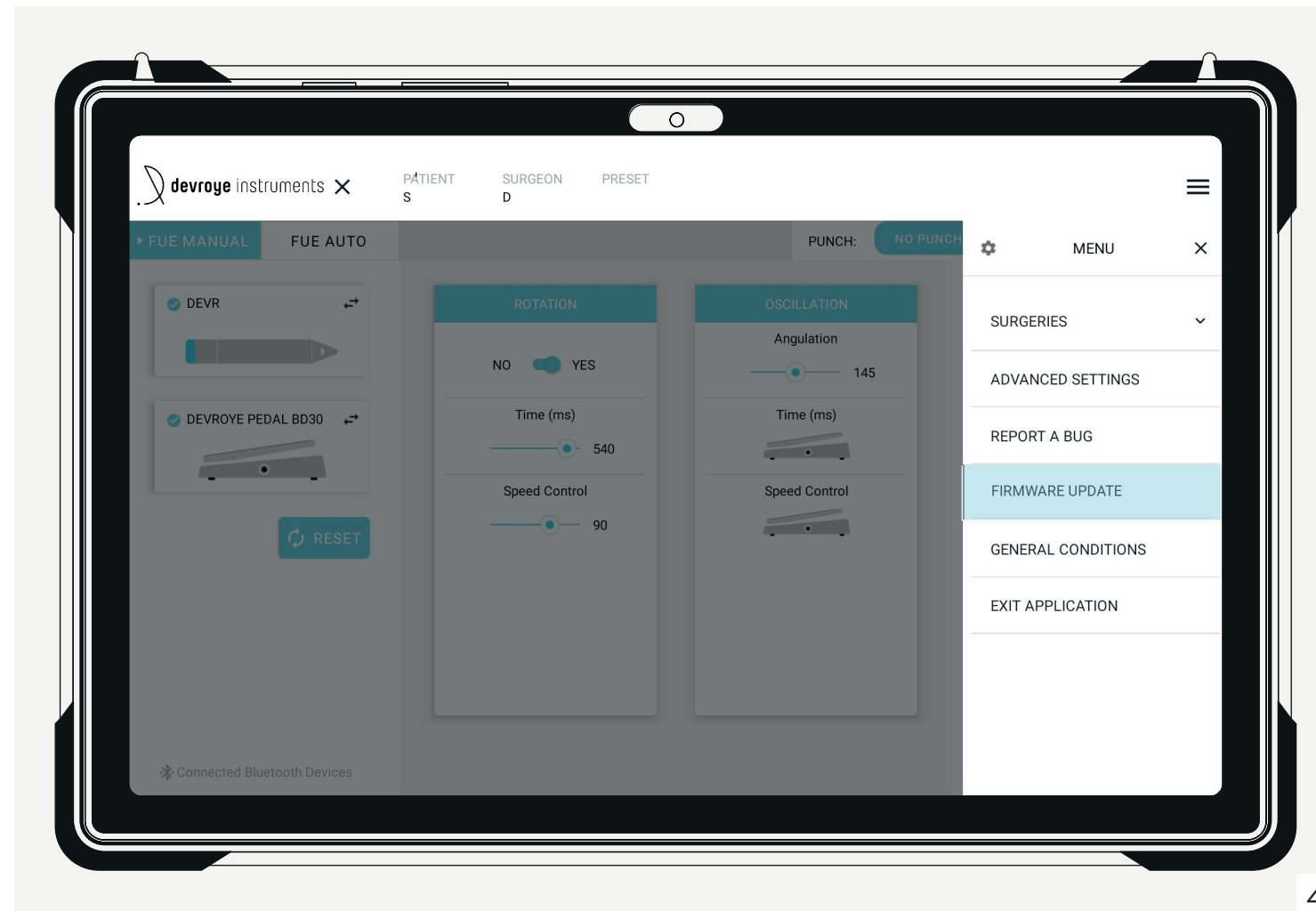
- STEP 1:** To update the WAW Wireless Handpiece ; go to the menu and select “Firmware update” and click on the tab “Handpiece”.
- STEP 2:** Select the device to be updated from the list and then click on the button “Update”.

WAW Pedal

- STEP 1:** To update the WAW Pedal; go to the menu and select “Firmware update” and click on the tab “Pedal”.
- STEP 2:** Select the device to be updated from the list and then click on the button “Update”.

WAW Software

WAW Software is updated automatically on the tablet as soon as it has an internet connection. However, it is also possible to install the latest update by searching for the application on the Google Play Store.



HOW TO USE

4.8 ADVANCED SETTINGS

The new mobile application “Devroye Instruments” has different technical settings to obtain a high precision in the practice of FUE.

■ Counting threshold

Counting threshold ensures that every movement is counted by the system. CAUTION : Please note that movements are only counted when pressure is applied on the WAW Pedal. While on continuous mode, the system will not count movements if no pressure is applied on the WAW Pedal.

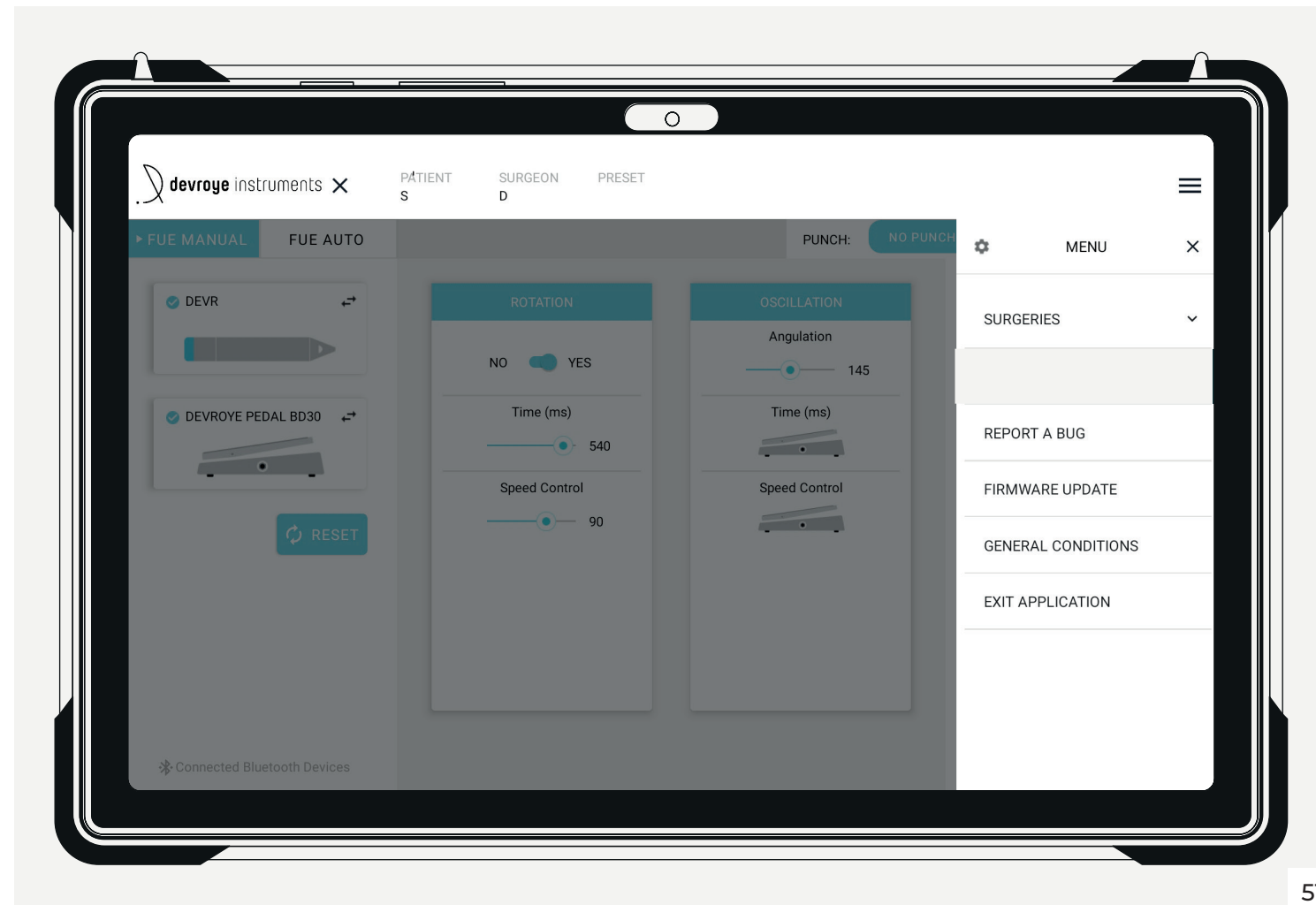
■ Pedal reactivity

The pedal reactivity allows you to adjust the sensitivity of the WAW Pedal. Depending on the selected sensitivity, you will have to apply more or less pressure on the WAW Pedal. The slider goes from 1 to 7, 1 being the least sensitive value so you will have to push harder on the WAW Pedal while 7, being the most sensitive value, a small pressure will quickly activate the movement.

■ **STEP 1:** To access the system settings, go to the menu and select Advance settings.

■ **STEP 2:** Use the slider to change the value. The change is applied instantly.

■ **STEP 3:** Once the value is defined, click on the X to close the menu.



HOW TO USE

4.9 SURGERY REPORT

The new Devroye Instruments mobile application offers the possibility to obtain a summary of the surgery in the form of report. These reports include several information about the surgery, such as : the devices used, the movements performed, the parameters chosen, the number of grafts extracted, ... This information is stored on the mobile app. To get access:


My files ▶ Internal storage ▶ Documents ▶ Devroye Instruments

■ Save a surgery

When the surgery is finished, click on “Finish Surgery” to generate the extraction report. You can always resume this operation by clicking on “Return”. If you click on “Save”, the report is automatically saved as a PDF file in the tablet’s documents.

■ History of surgeries

All the surgeries performed can be viewed from the Devroye Instruments mobile application. Just go to the menu and select “History of surgeries” to access them. History of surgeries allows for consulting all the saved surgeries and even resuming a previous surgery.

 Surgery reports are saved in the tablet’s internal storage. This data belongs to you and can only be accessed from the tablet. (See Privacy policy)



CARE & MAINTENANCE

5.1 CLEANING WITH ALCOHOL

The WAW DUO FUE system is delivered non-sterile. Clean and disinfect the instruments and accessories before the first application. The medical device and its accessories must be disinfected and cleaned daily. This could be done by alcohol-based products or autoclaving.

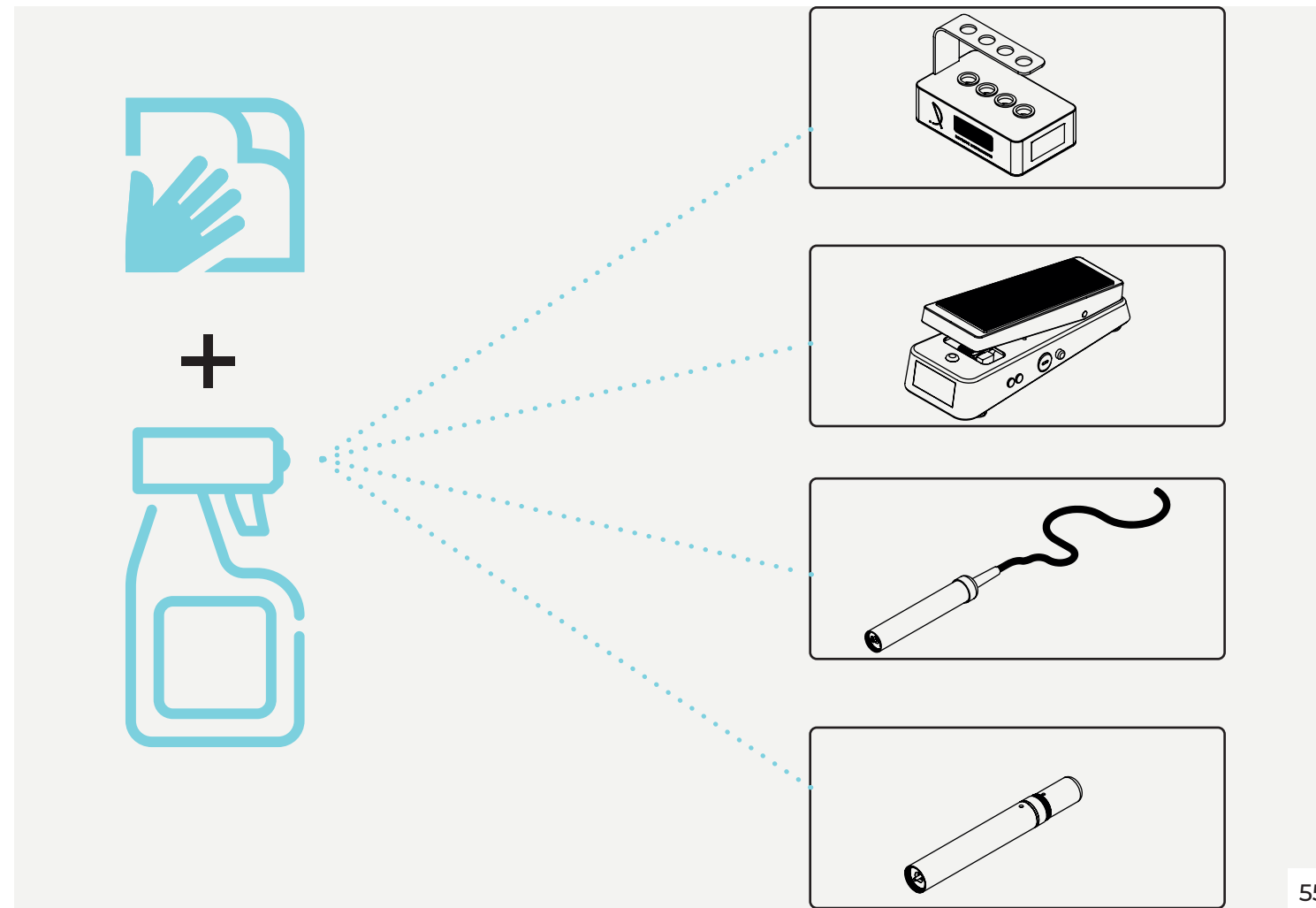
The cleaning with alcohol is done with a soft microfiber cloth on which alcohol has been sprayed. The system components that require this daily procedure are the wireless and wired motor block, the WAW pedal and the tablet. Under no circumstances should these devices be opened, sterilized or soaked in alcohol.

■ Stainless steel material

The maintenance of stainless steel material is limited to periodic cleaning of the surface. This cleaning is essential, if only to keep them clean, but it is generally a simple operation, greatly facilitated by the surface qualities of stainless steels. A wide range of cleaning products and methods can be used but we recommend the use of an alcohol-based product.

■ Plastic material

The use of alcohol-based commercial cleaning agents is suitable for PVC, ABS or POM materials. To brighten up the surface, you can use plastic renovators. Please note that no solvents or abrasive products should be used.

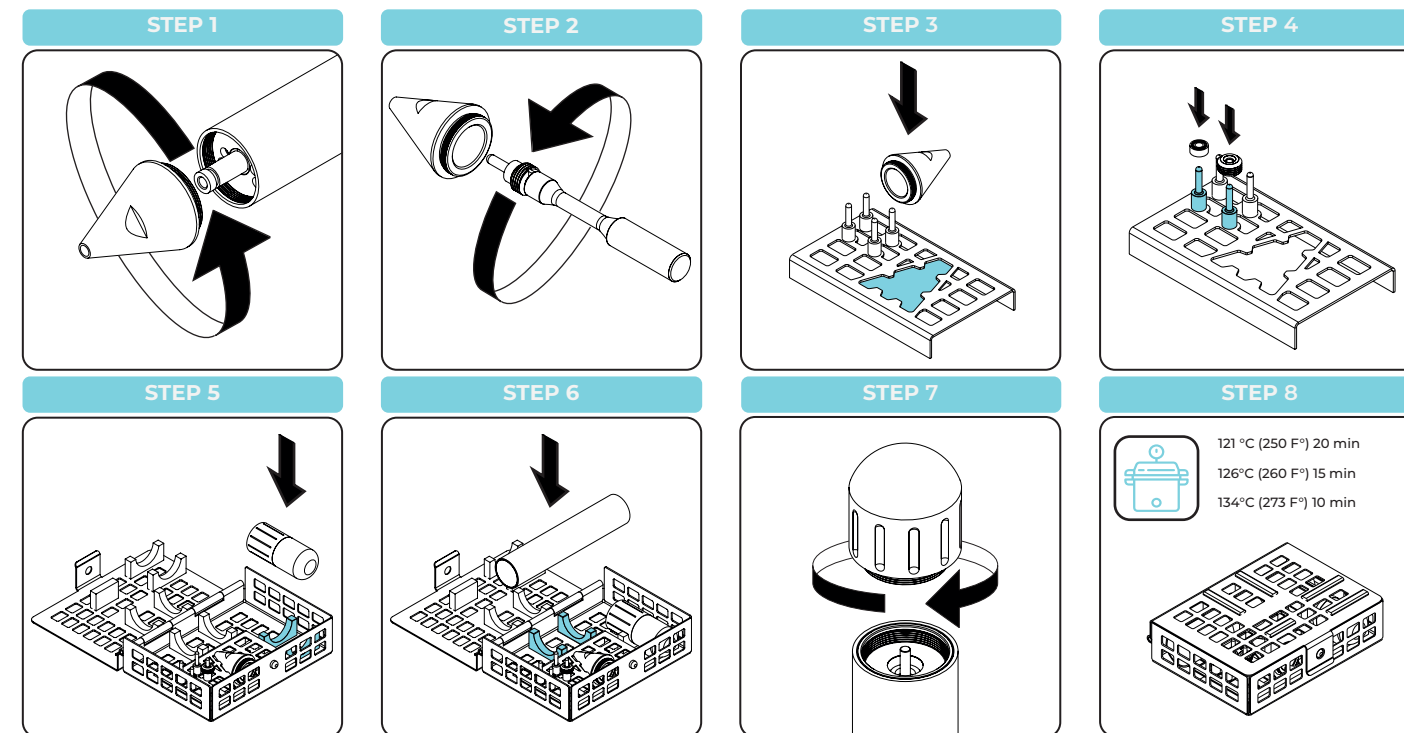


CARE & MAINTENANCE

5.2 CLEANING BY AUTOCLAVE

Autoclave cleaning is carried by using the External Sleeve Support Box provided by the system. The various external parts that compose the handpieces must be dismantled and placed in the External Sleeve Support Box according to the following steps:

- **STEP 1:** Remove the WAW Wireless Handpiece head.
- **STEP 2:** Pull the lock-nut and the ball bearing apart using the tool N° 3. If necessary, use tool N°2 to remove the ball bearing from the head.
- **STEP 3:** Place now the handpiece head inside the External Sleeve Support Box in the site A-1.
- **STEP 4:** Place the ball bearing and the lock-nut in their respective sites A-2 and A-3.
- **STEP 5:** Unscrew the WAW Wireless Handpiece end cup and place it into the C-1 site of the External Support Box.
- **STEP 6:** Place the handpiece external sleeve into B-1.
- **STEP 7:** Before proceeding with the cleaning, secure the motor block rotational axis using the plastic cap and charge it (if necessary).
- **STEP 8:** The External Sleeve Support Box can be placed into an autoclave system at 121 C° (250 F°) for 20 minutes, or at 126° C for 15 minutes, or at 134 C° for 10 minutes.



- Due to the classification of the device, sterilisation is not a compulsory procedure for cleaning the handpiece and its accessories. However, they must be cleaned daily in order to maintain the system in good operating condition. Before proceeding with the cleaning, the handpiece must be disassembled to remove the motor block; the removable parts can then be placed into the External Sleeve Support Box.
- The anodised aluminium parts have been provided with a coating to protect them from oxidation. For cleaning and maintenance, it is imperative not to use abrasive and/or corrosive products to avoid damaging this protective layer. Clean these parts by autoclaving them. If necessary, a suitable disinfectant can be used on the anodised surface.

CARE & MAINTENANCE

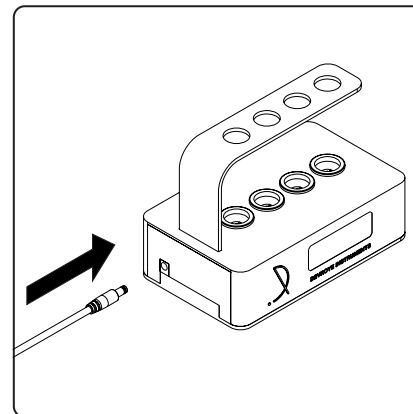
5.3 LOADING DEVICE

After a complete cleaning of the system elements, it is recommended to proceed with the loading of the motor block wireless as well as the WAW pedal and the WAW Software. Indeed, it is important to charge the devices at the end of the surgery in order to make them ready for the next one.

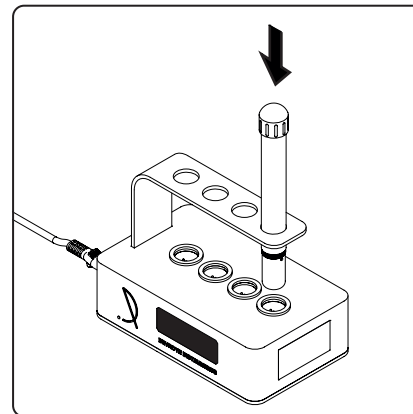
LOADING OF THE WAW WIRELESS HANDPIECE

- **STEP 1:** Connect the power cord to the back of the WAW Charging Station. Then connect the cable to the mains.
- **STEP 2:** Insert the wireless motor block into the WAW Charging Station holder.
- **STEP 3:** Check that the charge has been completed by looking at the indicator lights. When the LED is flashing it means that the handpiece is fully charged and ready for use.

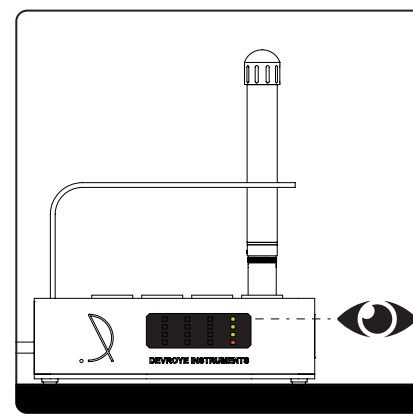
STEP 1



STEP 2



STEP 3



- An initial load is always recommended. Never do a quick charge.
- The WAW Charging Station should be placed on a flat, stable surface at a height of about 1.5 metres.
- The motor block of the WAW Wired Handpiece does not need to be loaded.
- To ensure that the battery can deliver the specified starting power, it must first be fully charged. We recommend checking that your battery is fully charged before installation to ensure a long life.

CARE & MAINTENANCE

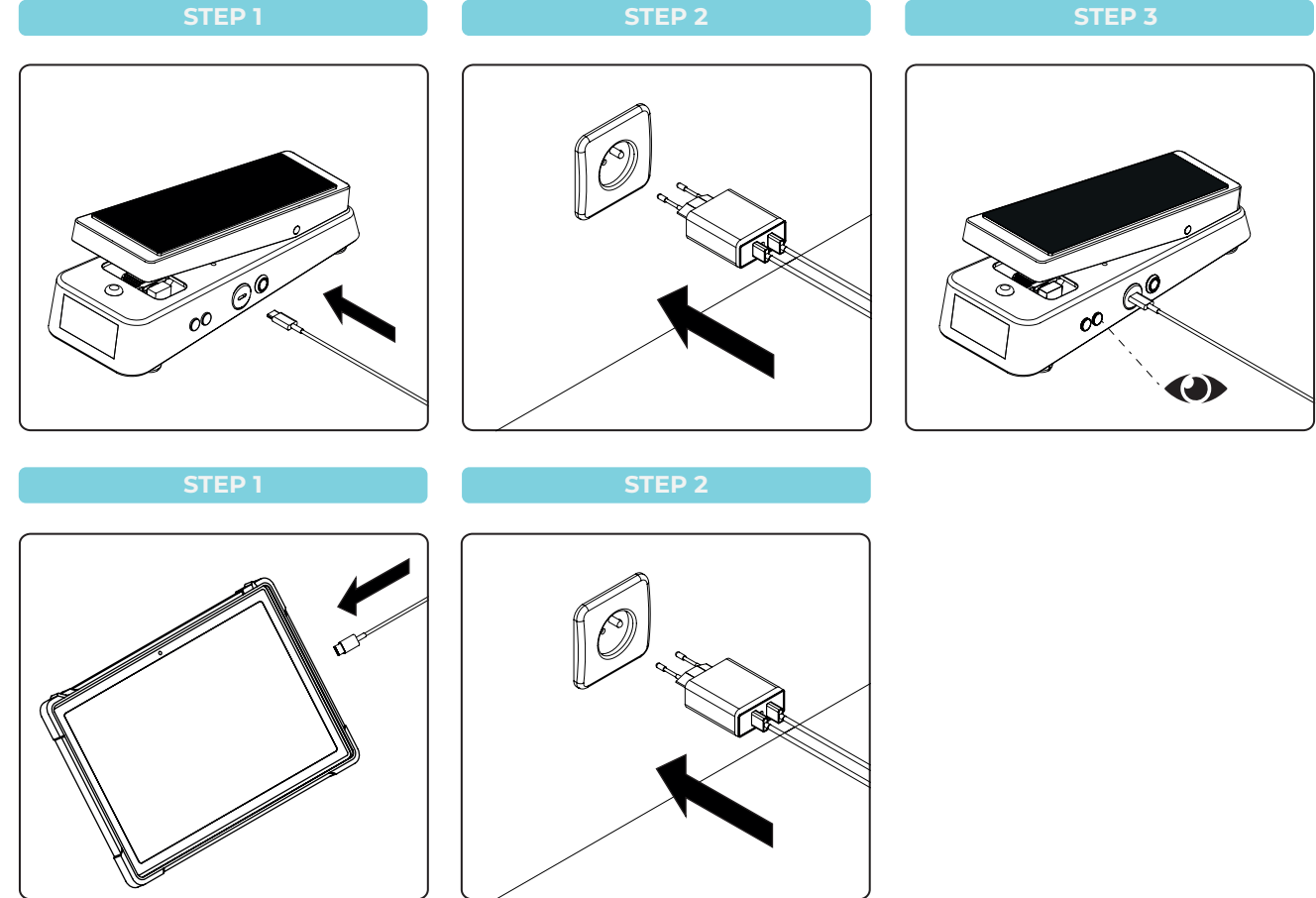
5.3 LOADING DEVICE

LOADING OF THE WAW PEDAL

- **STEP 1:** Plug the USB cable supplied with the system into the port on the left side of the WAW Pedal.
- **STEP 2:** Then plug the cable into the double input charger and then into the mains and . The 2nd LED indicating the battery level.
- **STEP 3:** Once the charge is complete, the indicator light will no longer flash but will remain white. This means that the WAW Pedal is fully charged and ready for use.

LOADING OF THE TABLET

- **STEP 1:** Plug the USB cable supplied with the system into the USB-C charge port of the WAW Pedal.
- **STEP 2:** Then plug the cable into the double input charger and then into the mains and check on the screen that the charging is taking place.



CARE & MAINTENANCE

5.4 DAMAGED PART

The different parts that compose the WAW DUO FUE system must be checked daily. Checking the integrity of the parts before each surgery is an important step to ensure that the surgery goes smoothly. If a part is damaged, it must be returned to Devroye Instruments for repair or replacement.

CAUSE DE MAL FONCTIONNEMENT

■ Impact

A shock from a hard fall can cause irreparable damage to devices such as the tablet or WAW Wireless Hand-piece. To avoid this, be careful when handling the items and avoid being distracted or moving quickly with the devices in hand.

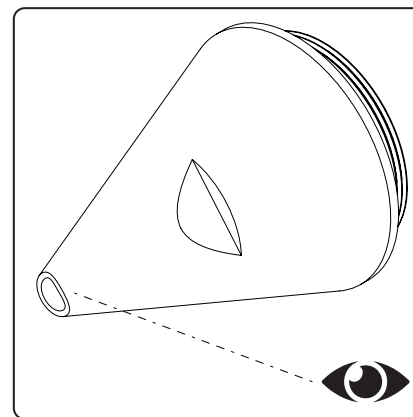
■ Screwing

If the threaded parts are not screwed in properly, the thread may be damaged and the threaded parts may no longer screw together. To avoid this, always screw the parts in smoothly and if this is not enough, apply oil to the threads.

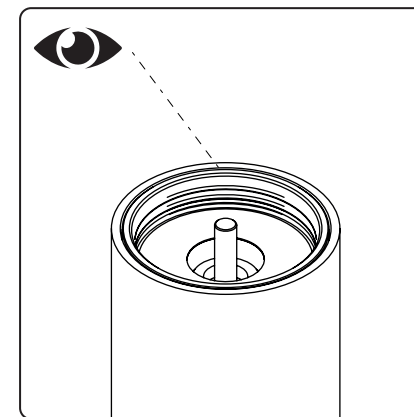
■ Electric fault

Please use the cables and chargers supplied with the systems or compatible ones to avoid damage to the internal batteries of the parts. Please also follow the charging instructions for each device to avoid system failure.

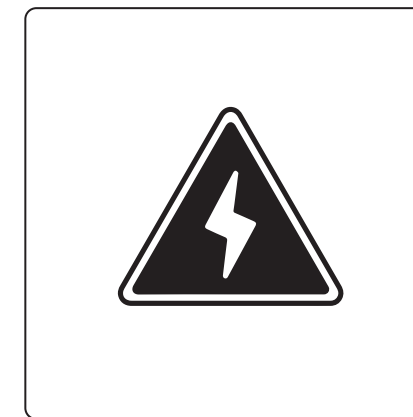
IMPACT



SCREWING



ELECTRIC FAULT



- Do not use a device that has been damaged during transport
- Any serious incident that has occurred in a relation to the device should be reported to the Devroye Instruments via email : info@devroyeinstruments.com and the competent authority of the Member State in which the user and/or patient is established.
- The device can be reused only after a complete cleaning and assembly.

STORING

6.1 STORAGE CONDITIONS

The WAW DUO FUE system is delivered in a packaging split into 2 boxes. This custom-made packaging not only protects the system during transport but also during storage for an indefinite period. This packaging is also intended for the potential return of defective or damaged systems requiring repair. Please keep both boxes in a safe place (see storage conditions).

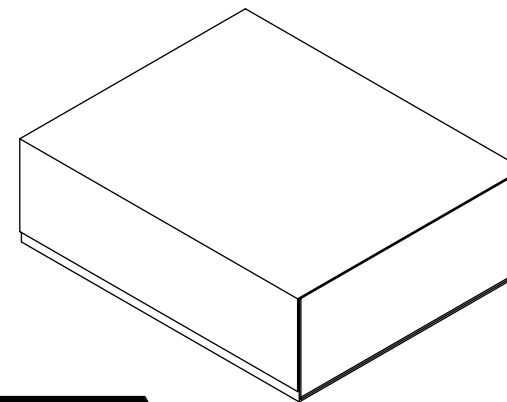
OPERATING CONDITIONS

- Operating temperature :
10 °C to 40 °C (+50 °F to 104 °F)
- Relative humidity :
10% RH to 65% RH (non-condensing)
- Atmospheric pressure :
0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

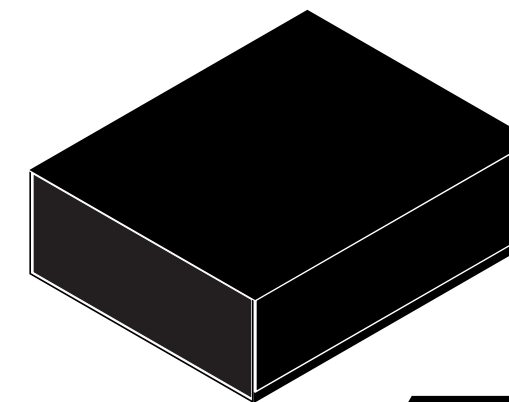
TRANSPORT AND STORAGE CONDITIONS

- Transport and Storage temperature :
-5 °C to 40 °C (+30.2 °F to 104 °F)
- Relative humidity :
10% RH to 65% RH (non-condensing)
- Atmospheric pressure :
0.5 bar to 1.05 bar (500 hPa to 1050 hPa)

ORIGINAL PACKAGING



BOX 1



BOX 2



Storage should be carried out in accordance with the following recommendations:

- Clean, airy and temperate room.
- Material stored away from the weather and direct sunlight.
- Non-humid room.
- Material stored in a shock-free environment.
- Do not store in a place subject to frequent traffic.
- Storage in the original packaging until the final destination.

STORING

6.2 RETURN

The return of defective or damaged systems in need of repair is done by using the packaging. Please keep both boxes in a safe place (see storage conditions). A cardboard box is resistant and ideal for packing, protecting and shipping all your products; it can also support stacking.

- **STEP 1:** Place the system components into the boxes in the packaging in the positions provided.
- **STEP 2:** Put the packaging boxes, starting with the black one, followed by the white one, in a cardboard box with a minimum size of 45x35x30 cm.
- **STEP 3:** Then place bubble wrap inside to ensure that the boxes will not move during transport and seal the cardboard box securely with tape.



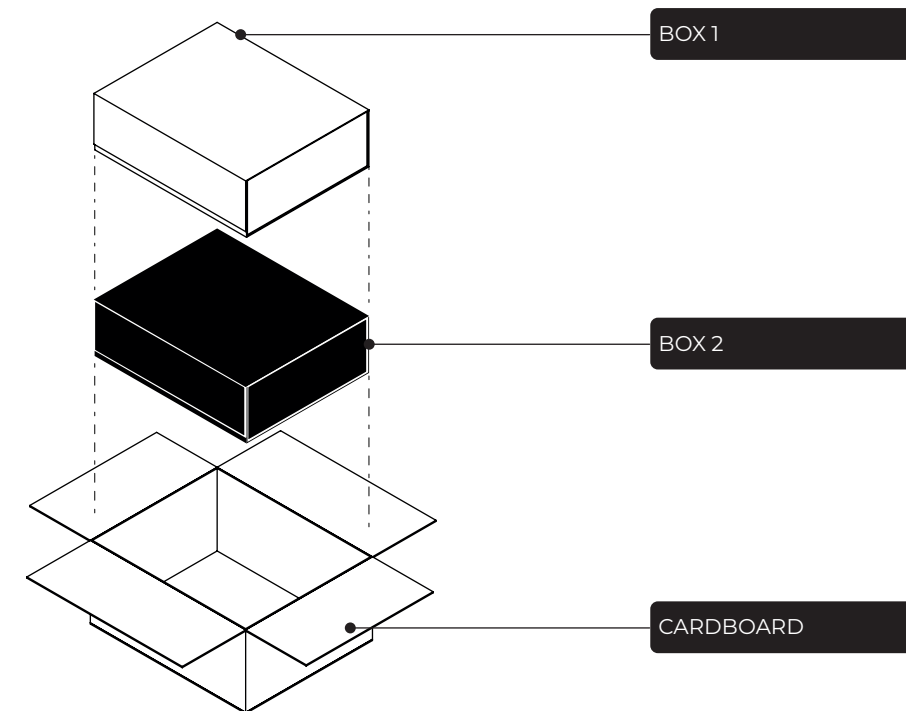
Devroye Instruments undertakes to replace defective parts returned to it during the applicable warranty period, which, after examination by Devroye Instruments, are found to be defective. Devroye Instruments is responsible for after sales service during and after the warranty period.

BOX 1

- WAW Wireless Handpiece
- User manual
- External Sleeve Support Box
- Punch support Box
- External parts
- Assembly tools
- Plastic Cork
- Magnet Ring
- WAW Software

BOX 2

- WAW Pedal
- WAW Charger Station
- Power cable
- USB Charger
- USB type C
- WAW Wired Handpiece



- The abstract of your order can be found on a checklist placed in the packaging.. On this checklist is listed the serial numbers and information of all the devices in your system. Place the checklist in the packaging before returning your system.

STORING

6.3 WASTE MANAGEMENT



When any of the WAW DUO FUE system device(s) can no longer be repaired, they must be returned using a secure packaging. Devroye Instruments is committed to be taking care of and processing the out-of-service devices in an environmentally friendly manner. By ensuring collection, transportation, reporting and recycling of the waste.

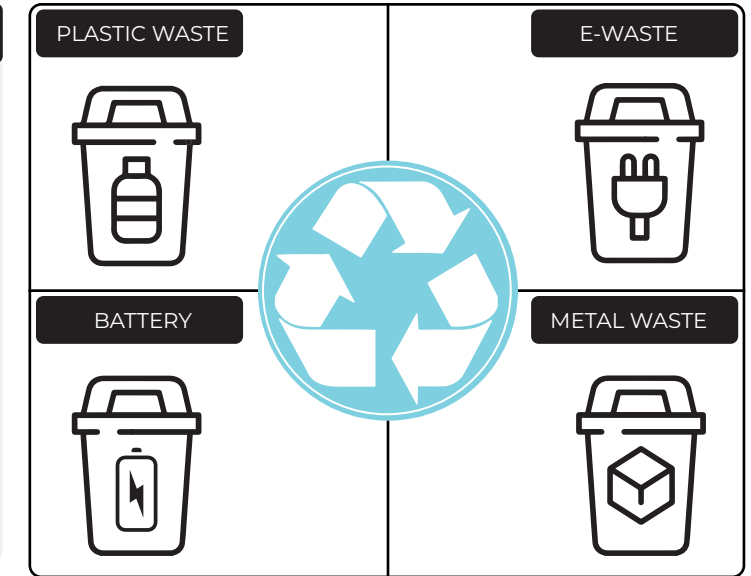
- **BATTERY :** This product contains batteries. Batteries are special domestic waste that do not belong in the normal domestic waste cycle, and are needed to be treated in a safer way. Keep new and used batteries away from children. If you think the battery might have been swallowed or placed inside any part of the body, seek immediate medical attention. At the end of their life, batteries are handed over to an approved management organisation for safer recycling of used batteries. Before disposal, always cover the battery in plastic tape to avoid possible short-circuit.
- **E-WASTE :** Electronic waste is sorted and taken to an authorised collection points for processing and recycling. This waste is dismantled, depolluted so that a large part of the components they contain can be revalued and recycled to find a new life in a product(s) resulting from recycling.
- **METAL :** Metal parts in damaged condition that can neither be repaired or reconditioned are transferred to an approved organisation specialised in the treatment of metal waste collection, dismantling, shredding and valorization to become secondary raw materials for industry.
- **PLASTIC :** Devroye Instruments takes the right to recover plastic products that can still be perfectly reused, on condition that they are inspected and reconditioned to be marketed again. This guarantees less waste and reduces the production cost per device. Items that are irreparable and irrecoverable will be sent to an approved sorting centre, which recycles the plastic waste to prevent it from being dumped in landfills, burned in the open air or dumped in the marine environment.

⚠ CAUTIONS: Potential causes of battery explosion

- Risk of explosion if the battery is replaced by an incorrect type.
- Disposal of a battery into fire or a hot oven, or mechanically crushing or cutting can result in an explosion of the battery.
- Leaving the battery in an extremely high temperature surrounding environment can result in an explosion or the leakage of flammable liquid or gas of the battery.
- If the battery is subjected to extremely low air pressure, it may result in an explosion or the leakage of flammable liquid or gas of the battery.



- Corresponding to the provisions of the European Directive 2002/96/EEC about Waste Electrical and Electronic Equipment (WEEE), the product may not be disposed of as normal household garbage but must be collected separately. To dispose of the WAW Foot Pedal, WAW Charging Station, WAW Wireless Handpiece and WAW Wired Handpiece, national regulations/laws must be observed.
- Devroye Instruments undertakes to replace defective parts returned to it during the applicable warranty period, which, after examination by Devroye Instruments, are found to be defective. Devroye Instruments is responsible for after sales service during and after the warranty period.



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