xpert.unit®

XPERT UNIT

en – Instructions for use

ANTHOGYR
A Straumann Group Brand

TABLE OF CONTENTS

Implantology motor

1. DESCRIPTION OF SYMBOLS

The following table describes the symbols that may be printed on the packaging label. Please refer to the label on the packaging for the applicable product symbols.

Symbol	Description of symbol	Source of symbol
	Alternating current	NF EN ISO 9687
	Caution	NF EN ISO 15223-1
	Protective earth (ground)	NF EN ISO 9687
	Manufacturer	NF EN ISO 15223-1
	Date of manufacture	NF EN ISO 15223-1
CE 0459	CE marking – compliance with current regulations	MDR (EU) 2017/745
	Washer-disinfector for thermal disinfection	NF EN ISO 9687
	Sterilisable in a steam steriliser (autoclave) at temperature specified	NF EN ISO 9687
	Do not use if packaging is damaged and consult instructions for use	NF EN ISO 15223-1
	Keep away from sunlight	NF EN ISO 15223-1
	Temperature limit	NF EN ISO 15223-1
MD	Medical Device	NF EN ISO 15223-1
	Fragile, handle with care	NF EN ISO 15223-1
	Keep dry	NF EN ISO 15223-1
	Stacking limit by mass	ISO 7000 – 0630
	Handle with care	Anthogyr packaging
	Use-by date	NF EN ISO 15223-1
LOT	Batch code	NF EN ISO 15223-1
SN	Serial number	NF EN ISO 15223-1
	Humidity limitation	NF EN ISO 15223-1
	Atmospheric pressure limitation	NF EN ISO 15223-1
REF	Catalogue number	NF EN ISO 15223-1
	This way up	ISO 7000 – 0623
	Do not discard in a domestic bin	Directive 2012/19/EU
	Do not tilt	Anthogyr packaging
IP4x	Protection against foreign bodies > 1 mm	NF EN 60529
IPx6	Protection against strong water spurts in all directions	NF EN 60529
	Consult instructions for use or consult electronic instructions for use	NF EN ISO 15223-1
	Non sterilisable in a steam steriliser (autoclave) at temperature specified	Anthogyr
	Refer to instruction manual/brochure	ISO 7010-M002
	Risk of crushing – Do not touch rotating parts with your fingers when the pump is on	Pump sticker provided by Watson Marlow
	U.S. federal law restricts this device to sale by or on the order of a dental professional	21 CFR 801.109(b)(1)
	Non-ionising electronic radiation	ISO 7000-5140
	Fuse	ISO 7000-5016

2. INTRODUCTION

You have just acquired your new dental implantology Xpert Unit® motor.

Anthogyr congratulates you on your choice and thanks you for your confidence in this product.

In order to obtain a complete and sustainable benefit from this product, it is recommended that you read this user guide first and perform the recommended inspection and maintenance tasks.

This Anthogyr product is to be used exclusively with the accessories provided by Anthogyr (micromotor, pedal, power supply cable). The use of any other accessories is prohibited.

The micromotor is compatible with most of the surgical contra-angles and handpieces available on the market. However, displayed values (torque and speed) of this product are valid only with the Anthogyr Mont Blanc® contra-angle. Indications of torque and speed might be slightly different if non-Anthogyr contra-angles are used.

Moreover, it is mandatory to use the irrigation lines supplied by Anthogyr with the Xpert Unit® motor. The use of any other irrigation lines can lead to malfunction for which Anthogyr cannot be held responsible in any way.

See sections 20 and 21 of this document for more information.

It is essential to take all the precautions mentioned with the ⚠ symbols in order to keep the equipment in optimal condition with total safety.

The manufacturer reserves the right to make changes or improvements to the equipment as a result of new technical developments. This does not give retrospective rights to equipment already installed.

To ensure that the Anthogyr product is operational at all times and to maintain it in good working condition, adhere to the maintenance, disinfection, and sterilisation instructions (see section 11 “Cleaning, disinfection and sterilisation” and section 18 “Technical safety inspection by agency”).

Only Anthogyr technicians or those trained by Anthogyr are authorised to repair the medical device. (Check your equipment control parameters after maintenance operations; it is possible that these have been set to default values.)

Implant surgery is a complex dental procedure. Incorrect techniques can cause implant failure and/or loss of bone support.

Appropriate training and qualification and a good knowledge of surgical techniques with Anthogyr products are required. Anthogyr offers specific training.

These instructions may not be copied and distributed without the prior written consent of Anthogyr. The user is required to:

- Use only products that are free of defects.
- Protect patients, third parties, and oneself from any danger.
- Prevent the spread of any contamination through the product.

The user is responsible for checking the operational safety and the condition of the equipment before each use. While using the product, it is essential to adhere to the national legal provisions, particularly:

- Provisions applicable to connecting and starting the medical device.
- Provisions applicable to work safety.
- Provisions for prevention of accidents.

3. AREA OF USE

3.1. PATIENT POPULATION AND CONDITION TO BE TREATED

Patients in need of dental, maxillofacial or implant surgery.

3.2. INTENDED USER

A dental surgeon or an oral and maxillofacial surgeon.

3.3. INTENDED USE

The Xpert Unit® motor is intended to drive the micromotor and dental handpieces equipped with instruments to cut hard and soft tissues in the mouth and to insert dental implants, while monitoring tool speed, torque and irrigation supply.

The Xpert Unit® motor is intended only for use in the field of dentistry, for implantology and dental surgery. It must be used by expert medical staff only. Any use other than that for which this product is intended is unauthorised and may be dangerous. The device also provides an indication of the torque applied in implant placement when used in combination with Anthogyr Mont Blanc® contra-angle handpieces.

An interface (screen or pedal) allows the user to adjust and memorise different settings for the parameters of speed, torque, pump flow, and reduction gear.

The Xpert Unit® mobile application establishes a Bluetooth connection with the motor device and allows to update the motor’s firmware, retrieves torque data and transmits it to web interface.

4. INDICATIONS AND CONTRAINDICATIONS

4.1. INDICATIONS

The Xpert Unit® motor is indicated for the surgical treatment of patients requiring dental surgery or dental implant placement.

4.2. CONTRAINDICATIONS

Any uses other than those described in the intended use section are prohibited.

Patients for whom an oral surgical procedure is contraindicated.

5. SAFETY

5.1. RESIDUAL RISKS AND SIDE EFFECTS

Misuse of the Xpert Unit® motor (caused by an error in selecting or tuning predefined surgical sequences, rotation speed or direc- tion, or pre-selection of operating limits) may lead to patient injuries.

The following residual risks and possible side effects are related to dental surgery and may lead to additional dental treatment at the dental practice:

Residual risks:

- additional treatment at dentist's office
- bone damage
- discomfort
- electric shock
- hypersensitivity/allergic reaction
- local or systemic infection (including peri-implantitis, periodontitis, gingivitis, fistula)
- injuries of gingiva
- local pain
- nerve damage possibly resulting in chronic pain
- possibility of prolongation of surgery
- recall to the dentist's office

Side effects:

- swelling
- local inflammation
- bruising
- resorption of maxillary/mandibular ridge bone
- local infection
- minor bleeding

5.2. WARNING SIGN

In order to avoid any physical or material damage, this document divides the safety instructions into three levels of danger.

	Warning sign

ATTENTION	Indicates a hazardous situation that may cause material damage or minor to moderate injuries.

WARNING	Indicates a hazardous situation that may cause serious/fatal injuries.

DANGER	Indicates maximum danger created by a situation that may immediately cause serious/fatal injuries.

5.3. SAFETY INSTRUCTIONS

5.3.1. External interference

The equipment is certified to comply with the electromagnetic compatibility standards currently in force.

ATTENTION	However, the user must ensure that no further risk is created by electromagnetic disturbance. To avoid disturbing the proper functioning of the electromagnetic equipment, it is recommended to adhere to the stipulated distances among devices (see section 19 “Electromagnetic compatibility”).

WARNING	This equipment is not designed to withstand shocks from an electric defibrillator.

5.3.2. Electrical connection

DANGER	**ELECTRIC SHOCK/ELECTROCUTION** Non-compliant electrical connection. Compulsorily check that the power supply voltage is identical to that indicated on the control box. Check the power supply cable before every use. Never insert or pull the plug from the wall socket with wet hands.

WARNING	To avoid any risk of an electric shock, this equipment must only be connected to a power supply network equipped with protective earthing.

5.3.3. Environment

ATTENTION	Ensure that the cords do not obstruct the free movement of persons. Do not use the device near ionising radiation. The device must be connected to a nearby wall socket that is easily accessible. The required power cords include a plug that can bear at least 125% of the rated current of the device. Use a maximum impedance network of 4Ω.

DANGER	Do not use this product in premises with explosion hazards. Do not expose the equipment to water splashes or water mist. In order to avoid risk of electric shock, short-circuit, or emission of dangerous substances, do not insert metallic objects into the equipment.

DANGER	**ELECTROCUTION** Accidental penetration of liquid in the fuse box. Before every use, check and ensure impermeability of containers of liquids. If any liquid should penetrate the equipment, do not touch it and immediately disconnect the power supply cable from the electricity network. Make sure that the surface of the equipment is completely dry before reconnecting the power supply cable.

5.3.4. Use of the device

ATTENTION	Do not move the device while in use. We strongly recommend that the torque be limited so as not to exceed the manufacturers' recommendations for the instrumentation used. This is to limit the risk of injury and deterioration of instruments. Gloves must be used by the user. Avoid direct contact of the console with the patient.

WARNING	Once the servicing work is completed, switch off the device. Unplug it from the electrical mains in the event of prolonged non-use.

5.3.5. Storage conditions

ATTENTION	**Recommended conditions:** protect from moisture and store at room temperature. Keep away from sunlight, sparks and other sources of ignition. **Temperature:** from -20 °C to +70 °C. **Air humidity level:** from 5% to 95%. **Incompatible materials:** acids and other solvents.

5.3.6. Peristaltic pump

ATTENTION	Do not operate the pump if the irrigation line is blocked or closed by a clamp. Always place the fluid to be pumped above the pump, in order to ensure optimal operation of the latter. Always keep the pump head rollers and all moving parts clean and free of contamination and debris.

ATTENTION	Do not open the guard when the pump is rotating. Do not touch the rotating parts with your fingers when the pump is in operation.

DANGER	Never attempt any repair alone.

5.3.7. Micromotor and micromotor cable

Refer to the instructions for use supplied with the micromotor and/or micromotor cable to familiarise yourself with all safety and usage aspects.

5.3.8. Mobile application

ATTENTION	The mobile application must be used outside of any surgery and exclusively with the Xpert Unit® device Malfunction or incompatibility are possible depending on the mobile device model

5.3.9. Hygiene and maintenance

ATTENTION	Do not use any spray directly on the device to clean it; the use of wipes is preferred.

DANGER	Sterilisable products are supplied in a non-sterile condition and must be decontaminated and sterilised before the first use, as well as immediately after each use.

5.3.10. Malfunction

In the event of abnormal operation (flickering screen, noisy pump motor):

- Immediately stop using the device.
- Try to locate or eliminate the problem with the help of the descriptive document (see section 16 “Anomalies and faults”).
- If it is not possible to locate or eliminate the problem with the help of the descriptive document, switch off the device and call the Anthogyr After-Sales Service.

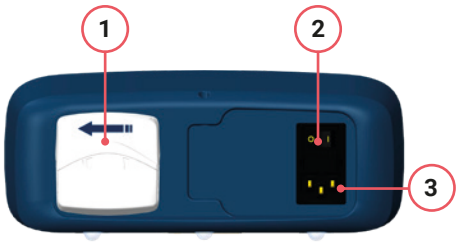
DANGER	Never attempt any repair alone.

Anthogyr After-Sales Service - Tel.: +33 (0)4 50 58 50 53 - contact@anthogyr.com

6. DESCRIPTION

N°	Name
A	Wireless pedal
B	Console
C	Adapter
D	Power cord

N°	Name
E	Bracket
F	Clips for irrigation line
G	Micromotor support



Rear

Front

N°	Name
1	Peristaltic pump
2	ON/OFF Button (I/O)
3	Power socket 220V / 110V
4	Touch screen
5	Connector for micromotor cable

Technical Specifications		
Dimensions	Console (w x d x h)	243 x 222 x 102 mm
	Pedal (l x d x h)	280 x 170 x 70 mm
Weight	Console	2.5 kg
	Pedal	1 kg
Electrical	Input power supply	From 100 to 240 V (50-60 Hz)
	Power consumption	200 to 300W
	Input fuse	Ø 5 x 20 - T5A 250 V
Degrees of protection (IP code)	Console	IP4X
	Pedal	IPX6
Electrical classification	Class	I according to IEC 60601-1
	Type	B
Bluetooth Classification	Group	1
	Class	B
	FCC ID	QOQBGM111
	IC	5123A-BGM111
Peristaltic pump	Maximum flow rate at 100% with Anthogyr line	120 ml/min
	Pump pipe Ø ext	Ø 7 mm
	Pump pipe Ø int	Ø 4 mm
Display	N·cm	Torque (Newton-centimetre)
	rpm	Speed (revolutions per minute)

7. CONNECTIONS AND INSTALLATION

⚠ It is extremely important to familiarise yourself with all safety instructions before installation and use of the device (see section 5 “Safety”).

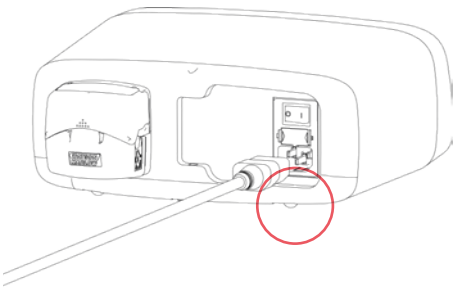
Refer to the instructions for use supplied with the micromotor and/or micromotor cable to familiarise yourself with all safety, maintenance and usage aspects.

⚠ The red flashing colour is not considered as an alarm signal indicating danger and action required by the user but just provides information about the Bluetooth connection or reverse operation.

7.1. MAINS CONNECTION

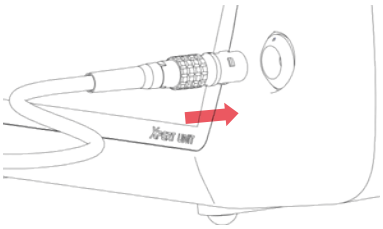
⚠ Use only the power cable supplied by the manufacturer.

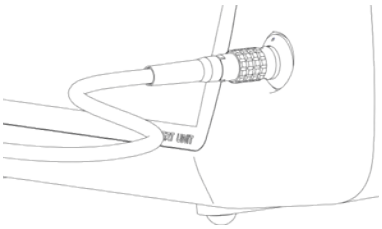
Do not forget to verify that the supply voltage is exactly the same as that indicated on the console and that the power switch is in **Position O**.

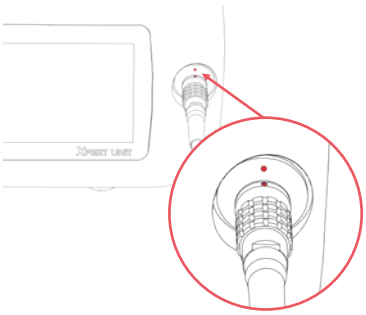


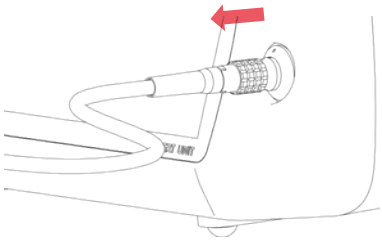
7.2. CONNECTION/DISCONNECTION OF THE MICROMOTOR

To connect, align the red dot of the micromotor socket with the red dot of the connector on the face of the console and engage until you hear a click:

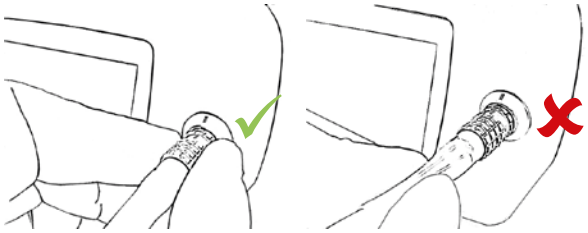








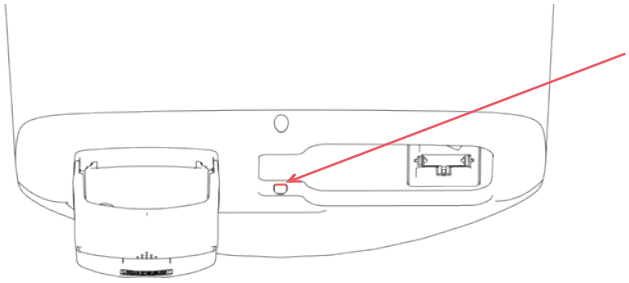
To disconnect, pull the mobile part of the connection in the direction of the arrow.



Do not try to disconnect the micromotor cable by pulling on the cable.

ATTENTION	The Xpert Unit® is not compatible with LED contra-angles.

7.3. POSITIONING OF THE BRACKET AND THE BAG

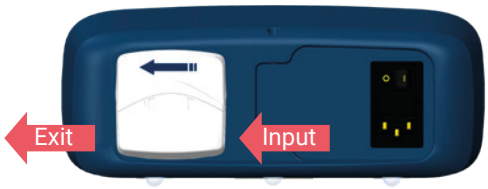


Insert the bracket in the rear of the console.

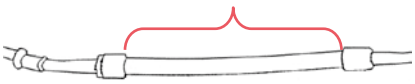
The positioned bracket must not turn by itself.

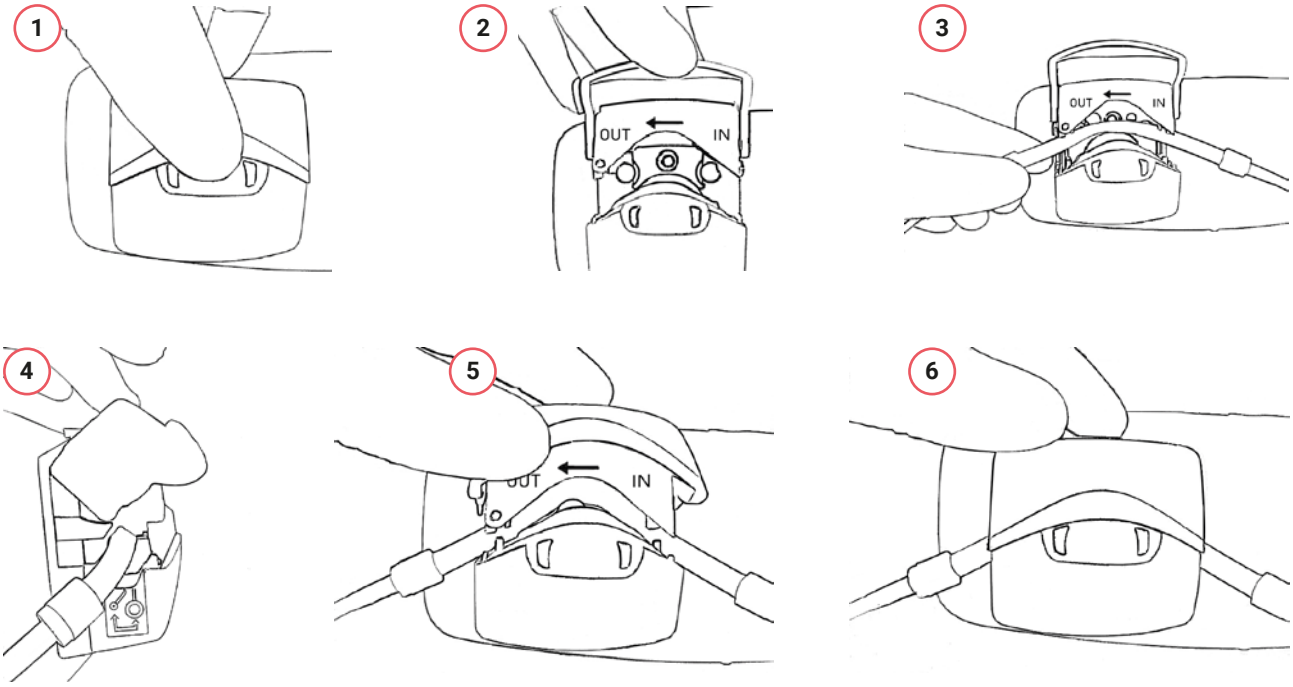
Suspend the bag of physiological liquid on the bracket.

7.4. PLACEMENT OF THE IRRIGATION LINE IN THE PERISTALTIC PUMP



Exit - Input





ATTENTION	Do not operate the pump if the irrigation line is blocked or closed by a clamp. Always place the fluid to be pumped above the pump in order to ensure optimal operation of the latter. Always keep the pump head rollers and all moving parts clean and free of contamination and debris. Do not open the guard when the pump is rotating. Do not touch rotating parts with your fingers when the pump is in operation.

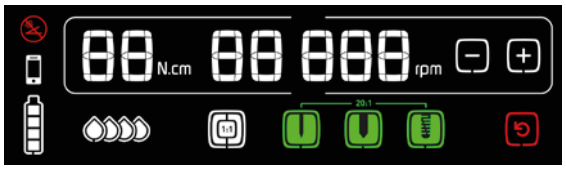
7.5. PLACEMENT OF IRRIGATION CLIPS

Place the irrigation clips on the micromotor cable at regular intervals (between 15-20 cm).
Position the irrigation line along the micromotor cable by inserting it into the clips.

8. INITIALISING THE CONSOLE

8.1. POWER-UP

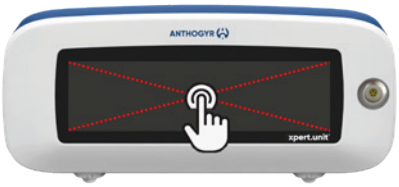
Set the power switch to **position I**.



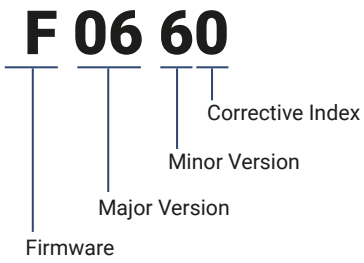
At startup, all the symbols on the screen light up and the device emits a beep.

** The code Er02002 at startup means there is an anomaly with the date and time. The date and time synchronise automatically with the mobile app when you are connected.*

To display the firmware version, please touch the centre of the screen within 5 seconds after switching ON the Xpert Unit®



Version and build number convention of the Xpert Unit® software, see example below:



8.2. WIRELESS PEDAL CONNECTION

8.2.1. On first use

At unit startup, if the symbol is displayed, the pedal is on standby.

Press on the pedal lever to exit standby mode.

- As soon as the symbol is displayed, the pedal is ready to be used.
- If the symbol remains lit up, the pedal needs to be paired with the console (see section 8.2.3).

8.2.2. When using daily

At startup, after a few seconds, the symbol disappears and the symbol appears.

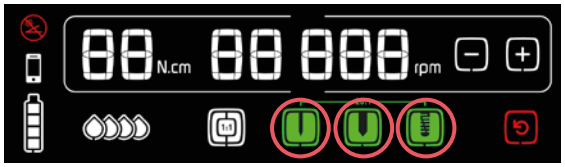
If the symbol remains activated after startup, press on the pedal lever to exit standby mode.

- As soon as the symbol is displayed, the pedal is ready to be used.
- If the symbol remains activated, proceed to pair the pedal with the console (see section 8.2.3).

8.2.3. How to pair the pedal with the console

1 - Press on the pedal lever.

2 - Press the three green buttons on the screen at the same time.



3 - The symbol flashes until pairing is complete (time to achieve pairing = about 30 sec).

4 - Press the two end buttons on the pedal.

5 - A beep at the console confirms the pairing: the symbol disappears and the symbol is displayed.

¬ If the symbol remains activated, see section 16 “Anomalies and faults”.

8.2.4. How to place the pedal in extended standby

If you do not plan to use your motor for an extended period of time (> 30 days), or if you wish to transport it by air, placing the pedal in extended standby mode is recommended.

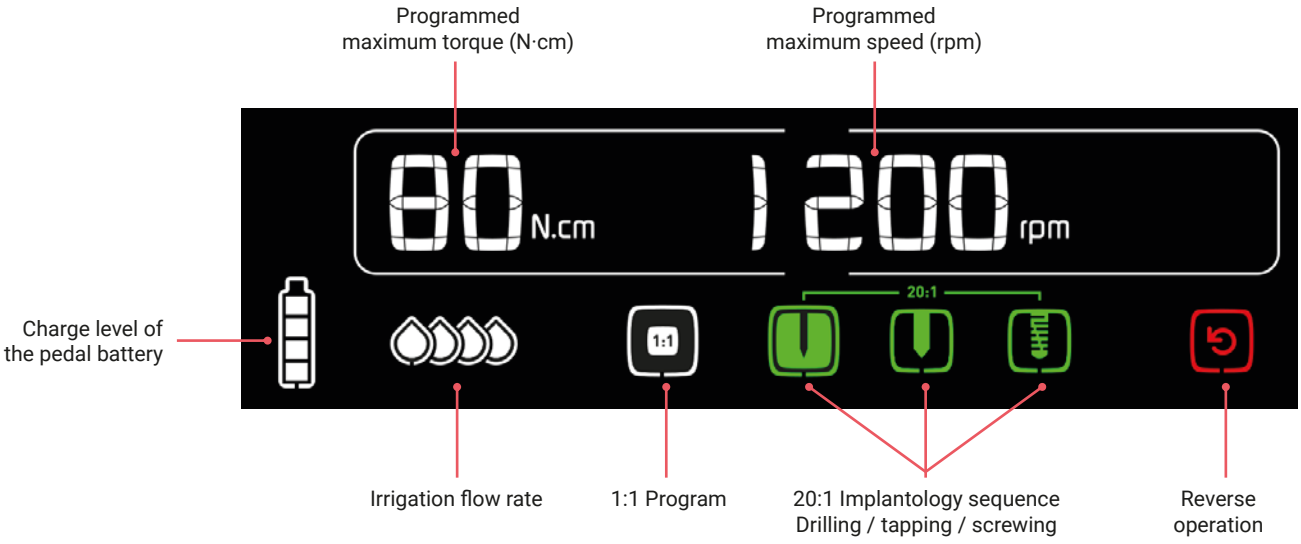
To do this, just press on the three pedal buttons simultaneously.

The persistent display of the symbol on the screen confirms that the pedal is in standby mode.

To exit standby mode, just press on the pedal lever (see section 8.2.1).

9. USE

9.1. DEFINITION OF THE DISPLAY



** the coloured square indicates the current program.*

Pump				
0%	25%	50%	75%	100%
				

Battery				
0%	25%	50%	75%	100%
				

9.2. PARAMETERS OF PROGRAMS (FACTORY SETTING)

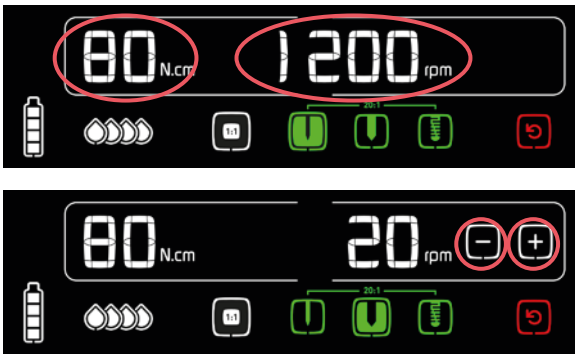
To select a program on the screen, press on the symbol of the desired program. For navigation to the pedal between the implantology sequence programs, see section 9.5 “Use of the pedal”.

	In normal mode				In reverse mode			
	20:1 Drilling	20:1 Tapping	20:1 Screwing	1:1 Ratio	20:1 Drilling	20:1 Tapping	20:1 Screwing	1:1 Ratio
Speed *(rpm)	1200	20	15	40,000	2000	40	30	15,000
Torque **(N·cm)	80	80	80	80	80	80	80	80
Direction of rotation	right	right	right	right	left	left	left	left
Pump	100%	100%	0%	100%	0%	0%	0%	0%
Display of torque	NO	YES	YES	NO	NO	YES	YES	NO
Display of speed	YES	YES	YES	YES	YES	YES	YES	YES
Beep	/	/	/	/	YES	YES	YES	YES

At startup, the “drilling” program is active. The program parameters can be changed by following the instructions given below.

** These speed values are valid only for Anthogyr contra-angles and handpiece. With these devices, the accuracy of speed is ± 5% (from 300 to 40,000 rpm).*
*** Setting ranges from 5 to 80 N·cm. These values are valid only for Anthogyr contra-angles. With these contra-angles, the accuracy of torque is ± 10% from 5 to 80 N·cm.*

9.3. SETTING THE SPEED/TORQUE/FLOW RATE VALUES



9.3.1. Setting rotation speed and maximum torque

1 - Press on the parameter to be changed (speed or torque).
2 - The parameter starts flashing and the +/– buttons appear.
3 - Adjust the value of the parameter with the + or – buttons.
4 - Press on the parameter to validate. The parameter stops flashing.
5 - The parameter automatically stops flashing after 5 seconds and the set value is saved.

NOTE 1: The value of the parameter is permanently saved for the program.
NOTE 2: You cannot operate the pedal during the setting of parameters.

9.3.2. Setting the irrigation flow rate

For setting the irrigation flow rate, press on the symbol.
Each press increases the flow rate by 25% (display of an additional drop).

At 100%, pressing the symbol sets the irrigation flow rate to 0%.
To cut off the irrigation and reset to a given flow rate, use the pedal’s ON/OFF function. (See section 9.5 “Use of the pedal”).

9.4. DISPLAYING THE LAST TORQUE REACHED

The Xpert Unit® motor allows you to validate the tightening torques to be saved. These torques will be exported with the Xpert Unit® mobile app and used on the web portal.

Displaying and saving the tightening torques

When the motor has stopped in tightening mode, (button lit up) the torque displayed is the maximum torque programmed (image A).

A

When the motor is rotating, the torque displayed on the screen is the instantaneous torque (image B).

B

When the motor stops, the last torque remains displayed **for 30 seconds** before the display returns to the maximum torque programmed (image A).

** To re-display the last torque, long press on the torque shown on the setpoint screen (image A).*

The last torque obtained is displayed with the active patient number (image C).

C

When **long** pressing on the value of the torque, **the value of the torque is saved** (a confirmation beep is heard).

To return to the setpoint screen without saving the torque value with the patient number, press .

Patient numbering

To make it easier to identify the saved torques, you can enter the patient number corresponding to the saved torques. This information will appear in the data exported with the mobile app.

To edit the patient number, press on the **Pxx** area. This area will start flashing and the + and - buttons will appear.

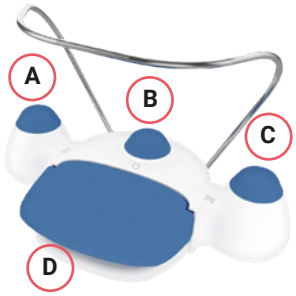
Once adjusted, press on the **Pxx** area to validate or wait 3 seconds without doing anything.

To return to the setpoint screen without saving the torque value with the patient number, press .
You may also edit the patient number after the setpoint screen (image A) by pressing if this is already lit.

IMPORTANT: EACH TIME THE PEDAL IS PRESSED, THE LAST TORQUE OBTAINED IS ERASED.
IMPORTANT: EACH TIME THE EQUIPMENT IS TURNED ON, THE PATIENT NUMBER RESETS TO P01.

9.5. USE OF THE PEDAL

Description of pressing different buttons and lever.



Pressing lever (D)	Variation in the rotation speed of the micromotor
Pushing lever (D)	Illumination of the light for 3 seconds
Short press on the left button (A)	Irrigation ON/OFF (the flow rate set on the screen is preserved)
Long press on the left button (A)	Startup of the pump at the maximum flow rate without the micromotor rotating (rinsing function)
Short press on the middle button (B)	Activation/deactivation of reverse mode
Long press on the middle button (B)	Torque reduced by 5 increments
Short press on the right button (C)	Moving from one sequence to the next
Long press on the right button (C)	Torque increased by 5 increments

9.6. BACKUP POWER FOR THE WIRELESS PEDAL

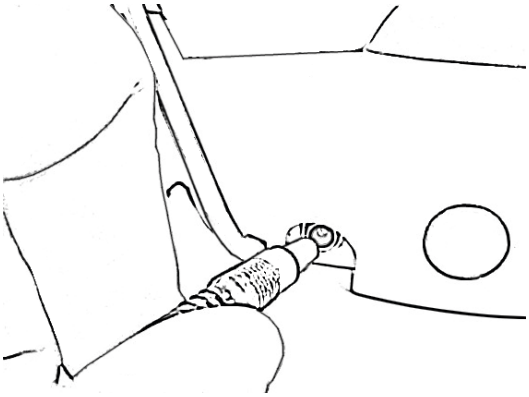
This symbol represents the charge level of the pedal battery.

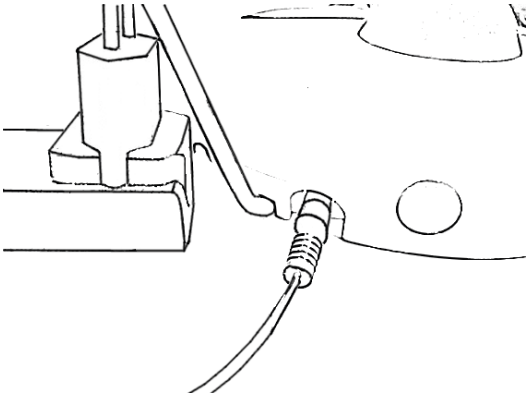
When the battery charge level has reached 25%, at least one day of pedal use will remain. The device beeps and the symbol flashes, indicating the need to recharge soon (see instructions below).

When the battery charge level reaches 0%, the device will beep every 30 seconds, and it will not be possible to use the motor. Recharge according to the following instructions.

9.7. RECHARGING THE PEDAL BATTERY

ATTENTION	Always use the Anthogyr adapter to charge the pedal battery. Max voltage: 5V





Connect the charging adapter to the pedal with the connector located at the rear of the pedal.
Connect the adapter to the mains to power it up.

On screen, this symbol is activated to indicate that charging is in progress.

When this symbol is displayed, the battery is fully charged.

¬ **The motor can be used normally during the charging of the pedal battery.**

9.8. USE OF THE MOBILE APPLICATION & WEB INTERFACE

Only mobile application is considered as a medical device because it allows to update the firmware of the Xpert Unit®. Other functionalities ensured by application mobile and web interface are optional services without medical impact.

These services allow the user to update the firmware of the Xpert Unit®, export surgery data, edit reports, connect them to the patient folder and/or share them with other specialists and facilitate the support from Anthogyr (video, tutorials, photo...)

For additional information, please contact the Anthogyr After-Sales Service:

+33 (0)4 50 58 50 53

contact@anthogyr.com

9.8.1. How to install the mobile application

1 - Download the application by typing Xpert Unit® in the App Store or Google Play

2 - Create your account in a few clicks

9.8.2. How to add your Xpert Unit® to your account

Follow the instructions on the screen of your mobile device to connect your Xpert Unit®

If the smartphone logo is displayed on the screen, your Xpert Unit® is connected and registered.

9.8.3. How to connect and use the web application

The web interface allows you to supervise your surgery data, edit reports for your patient folder or transfer them to other specialists

1 - Go to the web site: xpertunit.anthogyr.com

2 - Enter your email and password or create an account

3 - Then you can add supplementary information or export a report to save or share it easily

9.8.4. How to update the software of your Xpert Unit®

If a new update of your Xpert Unit® software is available, a notification will appear in the mobile application.

You can start the update by clicking on “start update”.

The update process takes approximately 30 minutes. Do not start the update before or during surgery.

Once the update is successfully installed on your motor, a message will be displayed in the mobile application.

9.8.5. Compatibility with device, navigator and version of operating system

The mobile app and web interface have been tested with the following configurations:

Hardware items:

- Mobile phone models: Samsung S20 FE Edition with Android 13 and iPhone 16 Pro with iOS 18.1,
- Tablet models: Samsung Galaxy S6 Lite and iPad 10,
- PC models: PC Lenovo and Mac Book Air.

Software:

- Web browser: Chrome v130.X, Edge v130.X and Safari v17.6,
- Microsoft Excel to read exported files,
- Microsoft Word and Excel to read test and record results,
- Software to firmware downgrade: FlashMagic v13.65 Cortex, ARM7.

⚠ Malfunction or incompatibility are possible depending on the mobile device model

9.9. STOPPING THE XPERT UNIT® MOTOR

At the end of the dental procedure:

- ¬ Set the switch to position O.
- ¬ Remove the tool fixed to the contra-angle.
- ¬ Remove the bottle or the bag of physiological liquid from the bracket.
- ¬ Detach the drill from the irrigation line coming from the bottle or the bag of physiological liquid.
- ¬ Remove the clips for irrigation lines.
- ¬ Disconnect the contra-angle from the micromotor.
- ¬ Lay the micromotor on the micromotor support.

9.10. LIFETIME OF PRODUCTS

The Xpert Unit® and the pedal have a lifetime corresponding to 5 years of use.

Sterilisable accessories have a lifecycle corresponding to 250 cleaning and sterilisation cycles.

However, these indications are not a warranty because wear may appear prematurely, depending on how the device is maintained (see section 11 “Cleaning, disinfection and sterilisation” and 18 “Technical safety inspection by agency”).

10. PARAMETER MANAGEMENT

10.1. ACTIVATION/DEACTIVATION OF AUDIBLE WARNINGS

10.1.1. List of audible warnings

Description	Can be deactivated
Weak battery	NO
Reverse operation	NO
Programmed maximum torque reached	YES*
Validation of sending data to a connected device	YES*
Pairing of the pedal to the console	NO
Complete integrity at console startup	NO

*To activate/deactivate audible warnings, press the REVERSE button on illumination of the console.

11. CLEANING, DISINFECTION AND STERILISATION

DANGER	Sterilisable accessories (BRACKET, MICROMOTOR SUPPORT and FIXATION CLIPS) are supplied in a non-sterile condition and must be decontaminated and sterilised before the first use, as well as immediately after each use.

Anthogyr recommends following the protocol described in the cleaning and sterilisation manual available at ifu.anthogyr.com or on request from Anthogyr at the above address.

After completion of sterilisation, asepsis rules must be followed.

ATTENTION	Do not use any spray directly on the medical device to clean it; it is preferable to use wipes.

11.1. OVERVIEW OF MAINTENANCE

Thermodisinfectable	Cleanable by wipes and non-sterilisable	Cleanable and sterilisable
• Micromotor support	• Console • Pedal	• Bracket • Micromotor support • Fixation clips

12. CONDITIONS OF USE AND STORAGE

	Conditions of use
Temperature	+10 °C to +35 °C (50 °F to 95 °F)
Relative humidity	15 to 80%
Atmospheric pressure	70 to 106 kPa
	Conditions of storage
Temperature	-20 °C to +70 °C (-4 °F to 158 °F)
Relative humidity	5 to 95%
Atmospheric pressure	70 to 106 kPa

13. WARRANTY

24 month warranty

- This device is guaranteed for parts and labour against any manufacturing defect for a period of 24 months from the date of invoice.
- This warranty does not apply to part wear.
- Any modification or addition to the product without the express consent of the Anthogyr company will render this warranty null and void.
- The warranty will lapse in case of non-observance of the technical instructions provided with all our devices.
- Anthogyr cannot be held responsible for damages and consequences resulting or possibly resulting from normal wear and tear, incorrect use, cleaning or maintenance, non-observance of the instructions regarding use or connection, scaling or corrosion, impurities in the water supply system, or chemical or electrical influences that are unusual or non-compliant with the user guide, maintenance and assembly instructions of Anthogyr and other instructions of manufacturers.
- The transport expenses for return of goods for repair at Anthogyr are to be borne by the customer, even if the repair is done under warranty.
- The warranty covers shipping costs for return of the items to the customer.
- In order to consider warranty claims, please keep a copy of the invoice or a copy of the delivery note along with the device.
- Medical devices must be returned in a cleaned and sterilised condition in a closed bag with proof of passage through the autoclave, the authentic coloured indicator, with a letter stating the reason for return.
- The renewal of spare parts is assured for 7 years after the commercial stoppage of the product.

14. MANUFACTURER'S RESPONSIBILITIES

The present instruction does not replace instructions for peripheral products.

Anthogyr reserves the right to modify the device and/or the user guide without prior notice.

The following points, if not followed, will void the responsibility of Anthogyr:

- All the recommendations of Anthogyr must be respected during installation (voltage supply, electromagnetic environment, etc.)
- The device must be used in an electrical installation conforming to the regulations in force.
- The use of this device must be restricted to the operation for which it has been designed.
- No subsequent modification, extension or settings may be made by a third party or any other person.
- Opening and repairs may only be carried out by persons trained by Anthogyr or authorised persons.
- Only original Anthogyr spare parts may be used.
- The product must be used in accordance with the assembly, service and maintenance instructions.
- All the instructions contained in this document must be followed.

15. WASTE TREATMENT

As electrical and electronic equipment, disposal of the product must be carried out as for a specialised collection, removal, and recycling or destruction chain (particularly in the European market, with reference to Directive 2012/19/EU.

When the product reaches its end of life, we recommend that you contact ECOSYSTEM (www.ecosystem.eco) for EU only or your dental equipment reseller to find out how to proceed.

Anthogyr is compliant with Directive 2012/19/EU (IDU no. FR000019_059MOH).

ATTENTION	It is prohibited to discard the console and the pedal in a domestic bin.

The console and the wireless pedal include components that must be treated as non-residential waste.

Sterilisable accessories must be handled as medical waste under the responsibility of the user.

16. ANOMALIES AND FAULTS

This part is intended to help the user in case of problems.

In the event of abnormal operation (flickering screen, noisy pump motor, vibrating micromotor), immediately stop using the device and call the Anthogyr After-Sales Service. If it is not possible to locate or solve a problem with the help of this descriptive document, or if the malfunction signals still remain active, switch off the device and call the Anthogyr After-Sales Service. Do not attempt to disassemble the console, the motor or the pedal.

DANGER	Never attempt to carry out repairs alone.

16.1. ERROR CODES AND MEANINGS

It is possible to remove the error message from the screen by pressing on it. In the event of a major problem, the console restarts. If the error message reappears, please contact the Anthogyr After-Sales Service.

Error code	Description of the fault	Possible solutions
Er 02 001	• Torques and system parameters (setting, error file) are no longer saved. • Check the different parameters of the sequences (speed, torque, flow rate).	The assembly can still be used. Contact the Anthogyr After-Sales Service for more information.
Er 02 002	• The date and time are incorrect. • The date and time can be updated using the mobile application. • Attention: if the date and time are not correct, the retrieval of information using the mobile application will be inaccurate.	
Er 05 001	• The motor is still usable, but the pump runs the risk of not operating.	
Er 02 004	• The screen encounters operating problems. • The Xpert Unit® motor can still be used safely with the pedal to complete the treatment in progress.	**If the problem persists, stop using the Xpert Unit® motor.** Contact the Anthogyr After-Sales Service for more information.
Er 02 005	• The touch bar encounters operating problems. • The Xpert Unit® motor can still be used safely with the pedal to complete the treatment in progress.	
Er 02 006 Er 02 007	• Update the console software using the mobile application.	
Er 04 006	• Overheating of the micromotor. • Let the micromotor be idle for 30 minutes to 1 hour so that it cools.	
Er 02 005 - Er 02 006 Er 02 007 - Er 04 001 Er 04 002 - Er 04 003 Er 04 004 - Er 04 005 Er 04 006 - Er 04 007 Er 04 008 - Er 04 009 Er 04 010 - Er 04 011 Er 04 012 - Er 05 001	• The electronics have encountered a hardware or software failure.	**Stop using the Xpert Unit® motor.** Return to the Anthogyr After-Sales Service is mandatory

⚠ If it is not possible to locate or solve the problem with the help of different descriptive documents, switch off the device and call the Anthogyr After-Sales Service.

Depending on the error code, it is also possible to use the mobile application to send information to the Anthogyr After-Sales Service.

16.2. MALFUNCTION

Malfunction	Probable causes	Possible solutions
The micromotor does not rotate	• The micromotor is not connected to the console • The micromotor is jammed • The pedal is not detected and no longer allows interaction with the console	• Ascertain that the cable is connected to the console • Mount a contra-angle with a tool of large diameter and try to rotate it • See pedal problems below
The pedal is not detected by the console	• The pedal is not (or is no longer) paired with the console/The pedal is off • The battery is completely discharged	• Proceed to the pairing of the pedal (see section 8.2.3) • Turn on the pedal (see section 8.2.1) • Recharge the pedal
The battery symbol indicates that recharging is not taking place (no activation)	• The battery does not get charged • The charger is defective or assembled incorrectly	• Contact the After-Sales Service
After setting the pedal battery for charging, the battery symbol is constantly flashing and the level has remained at 25%	• The battery does not get charged	• Contact the After-Sales Service

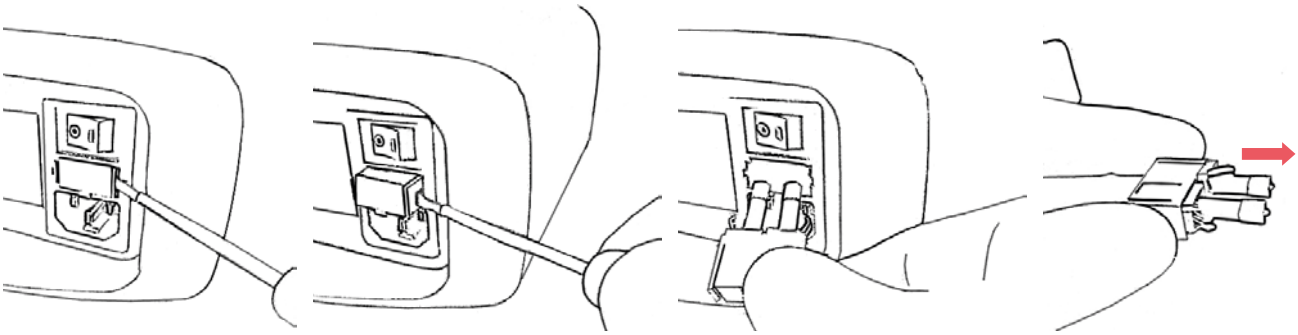
Malfunction	Probable causes	Possible solutions
No spray or low flow rate, or leakage problem	• The flow rate of the pump is 0% or too low • The irrigation line has not been placed correctly • The irrigation line is defective or has been pinched*	• Adjust the flow rate of the pump on the screen • Check the positioning of the line in the pump • Check the mounting direction of the line in the pump • Change the irrigation line • Use the irrigation line supplied by Anthogyr
The tool of the contra-angle does not turn	• Bad connection of the tool in the contra-angle • The contra-angle has been damaged • The motor is jammed	• Check the tool and its placement • Change of contra-angle • Check the integrity of the motor, if the cable is connected properly to the console
The screen does not light up	• The power to the device has been switched off • The fuses have blown • The power socket is defective • The differential circuit breaker of the electrical installation is OFF • The power cord is defective • The electronic card and/or the screen are out of service	• Ascertain that the console is attached properly to the mains and/or that the (I/O) button is on position I • Replace the fuses (see section 17) • Change the wall socket • Reset the differential circuit breaker of the electrical installation • Replace the power cord • Contact After-Sales Service

**The use of any other irrigation lines may generate malfunctions. The use of irrigation lines supplied by Anthogyr is mandatory.*

If it is not possible to locate or eliminate the problem with the help of above different descriptive documents, switch off the device and call the Anthogyr After-Sales Service.

Anthogyr After-Sales Service
Tel.: +33 (0)4 50 58 50 53
contact@anthogyr.com

17. TROUBLESHOOTING OPERATIONS BY THE USER



Inspecting and replacing fuses.

- ¬ Switch off the console with the ON/OFF button (I/O).
- ¬ Unplug the power cord from the wall socket.
- ¬ Unplug the power cord from the console.
- ¬ Remove the fuse box located between the (I/O) switch and the power socket with a flat screwdriver.
- ¬ Take out the two fuses.
- ¬ Check the status of the fuses and, if necessary, change them (SPT Ø 5x20-T5A-250 V with a breaking capacity of 1500A).
- ¬ Replace the two fuses in the fuse box.
- ¬ Replace the fuse box.

DANGER	Do not attempt to disassemble the control console or the control pedal.

18. TECHNICAL SAFETY INSPECTION BY AGENCY

The Xpert Unit® motor for implantology and dental surgery must undergo technical inspection by a regular agency at least once every three years (unless current country legislation indicates otherwise).

⚠ **The technical safety inspection must be carried out by an agency authorised by Anthogyr.**

- Visual inspection of all the external parts
- Measurement of leakage current of the device (console + pedal)
- Measurement of leakage current on the patient side
- Measurement of electrostatic discharge (ESD)
- Inspection of motor operation
- Inspection of pedal operation
- Inspection of pump operation
- Inspection of screen operation
- Internal visual inspection, if external damage, signs of overheating, or abnormal noise or failures are observed.

Anthogyr After-Sales Service
Tel.: +33 (0)4 50 58 50 53
contact@anthogyr.com

19. ELECTROMAGNETIC COMPATIBILITY

- This product requires special precautions to be taken regarding electromagnetic compatibility. It must be installed and initialised according to the instructions given in section 7 “Connections and installation”.
- Certain types of mobile telecommunication devices, such as mobile phones, are likely to interfere with this product. Therefore, it is not recommended to use them during the use of this device.
- The separation distances recommended in this paragraph must therefore be followed.
- This product must not be used near or on another device. If this cannot be avoided, it is necessary to check its proper operation prior to use under the conditions of use.
- The use of accessories other than those specified or sold by Anthogyr as replacement parts, can result in increased radiation or decreased immunity of this product.

Directives and declaration of the manufacturer - Electromagnetic radiations

The Xpert Unit® motor is intended to be used in the environment specified below.
It is advisable for the customer or user of the Xpert Unit® motor to ensure that it is used properly in such an environment.

Radiation test	References to standards	Compliance
RF radiation	CISPR 11 Group1 Class B	Speaker port: Group 1 Class B 10 m • 30 MHz - 230 MHz = 30 dBµV/m • 230 MHz - 1 GHz = 37 dBµV/m
		Input power: 240Vac / 50 Hz Limits: Group 1 Class B 0.15 MHz to 0.5 MHz • 66 to 56 dBµV QP/56 to 46 dBµV AV 0.5 MHz to 5 MHz • 56 dBµV QP/46 dBµV AV 0.15 MHz to 0.5 MHz • 60 dBµV QP/50 dBµV AV
Harmonic radiation	IEC 61000-3-2	220Vac 50 Hz access: Limit Class A
Voltage fluctuation/flicker	IEC 61000-3-3	230Vac 50 Hz access: PST <1 PLT> 0.65

The Xpert Unit® motor uses RF power only for its internal functions. Therefore, its RF radiation is very low and not likely to cause any interference in nearby electronic equipment.
The Xpert Unit® motor is suitable for use in all premises, including domestic premises and those directly connected to the low-voltage public electricity supply network feeding buildings for domestic use.

Directives and declaration of the manufacturer - Electromagnetic immunity			
The Xpert Unit® motor is intended to be used in the environment specified below. It is advisable for the customer or user of the Xpert Unit® motor to ensure that it is used properly in such an environment.			
Radiation test	**References to standards**	**Compliance**	**Electromagnetic environment - directives**
Off-peak period of power, short interruptions and voltage fluctuations in electrical power supply input lines	IEC 61000-4-11	AC power supply: 100-240V @50-60 Hz • **0% U_T:** 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° (criterion A) • **0% U_T:** 1 cycle - Single phase at 0° (criterion A) • **70% U_T:** 25 cycles - Single phase at 0° (criterion A) • **0% U_T:** 250 cycles (criterion C)	It is advisable that the quality of the electricity supply network be that of a typical commercial or hospital environment. If use of the Xpert Unit® motor requires continuous operation during interruptions in the electricity supply network, it is recommended to power the Xpert Unit® motor from an uninterrupted power supply or a battery.
Conducted RF disturbances	IEC 61000-4-6	6V in ISM frequency band: 0.15 MHz and 80 MHz	It is advisable that portable and mobile RF communication devices not be used near any part of the Xpert Unit® motor, including cables, closer than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2√P
Electrostatic discharges	IEC 61000-4-2	±8kV at the contact ±2kV, ±4kV, ±8kV, ±15kV in the air (criterion B)	It is advisable that the floor be made of wood, concrete or ceramic tiles. If floors are covered with synthetic materials, then the relative humidity should be at least 30%.
Fast transient bursts	IEC 61000-4-4	AC power supply: ±2kV (100 Hz) / 240Vac @50 Hz DC power supply: ±2kV (100 Hz) Line input/output: ±1kV (100 Hz) (criterion B)	It is advisable that the quality of the electricity supply network be that of a typical commercial or hospital environment.
Magnetic field at the electrical power supply network frequency (50/60 Hz)	IEC 61000-4-8	Level: 30A/m (50 Hz) (criterion A)	It is advisable that the magnetic fields at the electrical power supply network frequency have characteristic levels of a representative location in a typical commercial or hospital environment.
Radiated RF disturbances	IEC 61000-4-3	10V/m from 80 MHz to 2.7 GHz (criterion A)	Recommended separation distance: • d = 0.4√P from 80 MHz to 800 MHz • d = 0.7√P from 800 MHz to 2.5 GHz where P is the characteristic of maximum output power of the transmitter in watts (W), according to the manufacturer of the transmitter and d is the recommended separation distance in metres (m). It is advisable that the field intensities of fixed RF transmitters, determined by an on-site electromagnetic investigation[a], be below the level of compliance in each frequency range[b]. Interference may occur close to the device marked with the following symbol: (((•))).
Surge voltage	IEC 61000-4-5	AC power supply: 240Vac @50 Hz • ±0.5kV, ±1kV, ±2kV between phase and earth • ±0.5kV, ±1kV, between phases DC power supply: • ±0.5kV, ±1kV, ±2kV between phase and earth • ±0.5kV, ±1kV, between phases Line input/output: ±2kV (criterion B)	It is advisable that the quality of the electricity supply network be that of a typical commercial or hospital environment.
Immunity to proximity magnetic fields	IEC 61000-4-39	- 8A/m 30 KHz CW - 65A/m to 134.2 KHz /modulation Pulse 2.1 KHz - 7,5A/m to 13.56 MHz / Modulation Pulse 50 KHz	
Proximity fields From RF wireless communications equipment	IEC 60601-1-2	- 9V/m: 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz - 27V/m: 385 MHz - 28V/m: 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	

Recommended separation distances between portable and mobile RF communication devices and the Xpert Unit® motor			
The Xpert Unit® motor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Xpert Unit® motor can contribute to preventing electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication devices (transmitters) and the Xpert Unit® motor as recommended below, depending on the maximum transmission power.			
Rated maximum output power of the transmitter in W	**Separation distance depending on the transmitter frequency (m)**		
	From 150 kHz to 80 MHz d = 1.2√P	**From 80 MHz to 800 MHz d = 0.4√P**	**From 800 MHz to 2.7 GHz d = 0.7√P**
0.01	0.12	0.04	0.07
0.1	0.38	0.13	0.22
1	1.20	0.40	0.70
10	3.80	1.30	2.20
100	12.00	4.00	7.00

For transmitters for which the rated maximum output power has not been given above, the recommended separation distance “d” in metres (m) can be estimated by using the equation applicable to the transmitter frequency, where “P” is the characteristic of maximum transmission power of the transmitter in watts (W), according to the manufacturer.

NOTE 1: U_T is the AC voltage of the network before application of the test level.
NOTE 2: At 80 MHz and at 800 MHz, the higher frequency range applies.
NOTE 3: These directives may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection by structures, objects and persons.

[a] The field intensities of fixed transmitters, such as the base stations for the radio phones (cellular/wireless) and land mobile radios, amateur radio, AM and FM broadcasting and TV broadcasting, cannot be provided theoretically with accuracy. To evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to consider an electromagnetic investigation on site. If intensity of the field, measured at the location where the Xpert Unit® motor is used, exceeds the applicable RF compliance level as above, it is advisable to monitor the Xpert Unit® motor to verify that its operation is normal. If abnormal performance is observed, then additional measures may be necessary, such as reorientation or relocation of the Xpert Unit® motor.
[b] Over the frequency range from 150 kHz to 80 MHz, it is advisable that field strengths be less than 3 V/m.

20. REFERENCES

Only the following accessories must be used with the Xpert Unit®:

Reference number	Description
XPE100	XPERT UNIT®
XPE200	XPERT UNIT® PEDAL (Accessory)
XP411	XPERT UNIT® MOTOR SUPPORT (Accessory)
XP412	XPERT UNIT® FIXATION CLIPS (x10) (Accessory)
XP415	XPERT UNIT® BRACKET (Accessory)
XP216*	8W-5V AC/DC POWER SUPPLY (Accessory)
XP217*	XPERT UNIT® POWER CABLE (Accessory)
XPERTUNIT-APP	XPERT UNIT® MOBILE-APP+WEB

* For power supply accessories, please check with your local supplier the socket type before ordering.

21. COMPATIBILITY INFORMATION

Only the following devices have been validated and are compatible with the Xpert Unit®:

Reference number	Description
1601242-001	XPU MMOTOR LIGHT (legal manufacturer: Bien-air Dental SA)
1601244-001	XPU MMOTOR NO LIGHT (legal manufacturer: Bien-air Dental SA)
1601243-001	XPU MMOTOR CABLE (legal manufacturer: Bien-air Dental SA)
32.F0209.00	Complete tube for bag or bottle (legal manufacturer: Omnia Srl.)
32.U0022.00	Transparent adhesive film for screen (legal manufacturer: Omnia Srl.)
22.U0001.00	Tubing sleeve 240x7 w/fixing elastics (legal manufacturer: Omnia Srl.)

22. FURTHER INFORMATION

For more information on the use of Anthogyr products, please contact your local Anthogyr sales representative or Anthogyr customer service, or visit ifu.anthogyr.com and www.anthogyr.com.

For more specific information on the Xpert Unit® and its accessories, please refer to:

- Cleaning and sterilisation User Guide (063NETT-STE_NOT)
- All implants IFU and manuals for further information about sequence settings (speed, maximum torque, etc.)

23. NOTES

The practitioner must have the necessary knowledge to practice dental implantology and must be familiar with the handling instructions for Anthogyr products as described in this document in order to use Anthogyr products safely and in accordance with their instructions for use.

Anthogyr products must be used in accordance with the manufacturer's instructions for use. The dental surgeon is solely responsible for the proper use of Anthogyr products in accordance with their instructions for use and to determine whether the product is suitable for the individual patient's situation.

Anthogyr products are part of a complete range and must be used in combination with the corresponding original components and instruments distributed by Anthogyr, its parent company and any affiliates or subsidiaries of the parent company ("Straumann"), unless otherwise specified in these instructions for use. The use of third-party products not distributed by Anthogyr voids any warranty or other obligation, express or implied, of Anthogyr.

Any product-related issues must be reported to the local Anthogyr organisation together with the product in question. In the event of a serious incident, the user must file a report with the local Anthogyr organisation and the appropriate competent authority in accordance with local regulations. Anthogyr also offers an online complaint service in the countries concerned.

24. VALIDITY

The publication of this document supersedes and replaces all previous versions.

25. AVAILABILITY

Some components of the Xpert Unit® are unavailable in certain countries.

CE 0459

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