# **User Manual**



# **Newtron P5 XS B.LED**



This document is an English translation of the original French version. Reference J62150 version V11 and drawing number NBADFR030K

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# 1 Documentation

This document contains the following information:

- · Indications for use
- · Medical device description
- · Installation of the medical device
- · Medical device use
- · Preparation for cleaning and disinfection of the medical device
- Monitoring and general maintenance of the medical device
- · Maintenance to be performed by the user

## 1.1 Associated documentation

This document must be used in association with the following documents:

Document title	
Consulting electronic user instructions	J00007
General instructions relating to the complete range of dental ultrasonic generators	J00051
Cleaning, disinfection and sterilisation instructions for keys	J81001
Cleaning, disinfection and sterilisation instructions for tips	J02001
Cleaning, disinfection and sterilisation protocols for handpieces	J12911
Ultrasonic generator power settings table	J58000
Newtron P5 XS B.LED User Manual	J62151
Quick Clean Newtron P5 XS B.LED	J62101
Quick Start Newtron P5 XS B.LED	J62100
Newtron P5 XS B.LED application user manual	J62111
SLIM handpiece user manual	J12921

The Quick Start and Quick Clean documents are summaries created for your approval. The only binding instructions are the user manuals and regulatory documentation associated with the medical device.

#### 1.2 Electronic documentation





The user instructions for your device are available in electronic format on the specified website and not in printed format. If the website is unavailable, try again later. You can also request a free printed copy of the user instructions within seven days via our website, by telephone or in writing.

The electronic user instructions are available in PDF format (Portable Document Format). You will need to have a PDF file reader installed to read the electronic user instructions. It is important for you to have read and understood the content of the user instructions relating to the use of your device and its accessories.

Never use your device without first reading the user instructions.

The device user instructions can be consulted at www.satelec.com/documents

When you receive your device, you are asked to print and/or to download all documents or sections of documents that you may need to refer to in the event of an emergency, if you are unable to connect to the internet or if your electronic display tool is not working (computer, tablet, etc.). We recommend that you visit the website regularly to consult and to download the latest version of your device's user instructions. Users are asked to keep documentation close at hand for reference when necessary.

All paper or electronic documentation relating to your medical device must be kept for the device's entire service life. Keep the original documentation for your medical device and its accessories for future reference. When loaning out or selling the medical device, the documentation must be provided with it.

# 2 Required information

#### 2.1 Indication for use

The Newtron P5 XS B.LED is a command unit used in combination with the following items.

A dental ultrasonic handpiece and a dental tip. This combination is intended for use in conventional dental treatments including prophylaxis, periodontics, endodontics and conservative and restorative dentistry.

## 2.2 Operating principle

An electrical signal emitted by the medical device is supplied to the ultrasonic handpiece. This is connected to the medical device via a cord. The handpiece comprises a piezoelectric ceramic transducer, which transforms the electrical signal into ultrasonic vibrations.

Mechanical vibrations are transmitted to a tip or a dental file attached to the end of the ultrasonic handpiece.

## 2.3 Using accessories not supplied by the manufacturer

The handpiece is designed to operate with SATELEC, a company of Acteon group dental tips and files. The use of tips or files made by other manufacturers will damage the handpiece, break tips and files and void the warranty.

## 2.4 Connecting and disconnecting accessories during use

Do not tighten or loosen the tips when the handpiece is activated.

# 2.5 Repairing or modifying the medical device

Contact the supplier of your device. Using the services of an unapproved repairer could render your device dangerous for you and your patients.

Do not repair or modify the device without seeking the prior permission of SATELEC, a company of Acteon group.

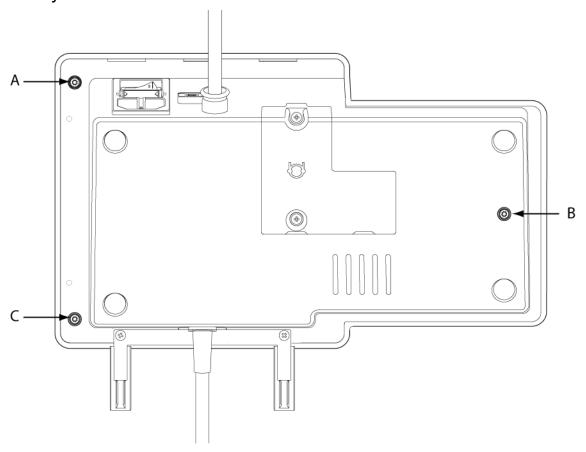
If the device is modified or repaired, specific checks and tests must be carried out to ensure that the medical device is still safe to use.

In the event of doubt, contact an approved dealer or the SATELEC, a company of Acteon group Customer Service team: Tel: +33,800,702,014

sav@acteongroup.com

SATELEC, a company of Acteon group, at the request of technical personnel working for the network of approved dealers, will provide any information required to repair defective parts on which they may perform repairs.

# 2.6 Warranty



The screws marked A, B and C must not be unscrewed by the user under any circumstances as this may void the warranty for the medical device.

# 2.7 Latest document update

01/2023

# 2.8 Date of first CE marking

2013

# 3 Unpacking the medical device

When you receive your medical device, check for any damage that may have occurred during transportation. If you have received this medical device by mistake, please contact the supplier to arrange for it to be collected. If you have any questions or requirements, contact your supplier.

The Newtron P5 XS B.LED includes the following items:

- A Newtron P5 XS B.LED unit with non-detachable footswitch cord, a non-detachable handpiece cord, a 300 or 500 ml tank and a handpiece support SLIM
- · A Newtron SLIM handpiece, with, depending on configuration, an installed blue LED ring, a white LED ring
- A box containing disclosing liquid F.L.A.G.™ (depending on selected options)
- A LED handpiece Quick Start-Clean guide [J12930]
- A Newtron P5 XS B.LED [J62100] Quick Start guide
- A Newtron P5 XS B.LED [J62101] Quick Clean guide
- Tips and wrenches depending on selected options
- A power cord

# 4 Connect the medical device

# 4.1 Connecting the medical device to the electrical network

Have your medical device connected to the mains power by an approved dental installation technician.

Check that the mains voltage is compatible with that indicated on the medical device or its mains adapter.

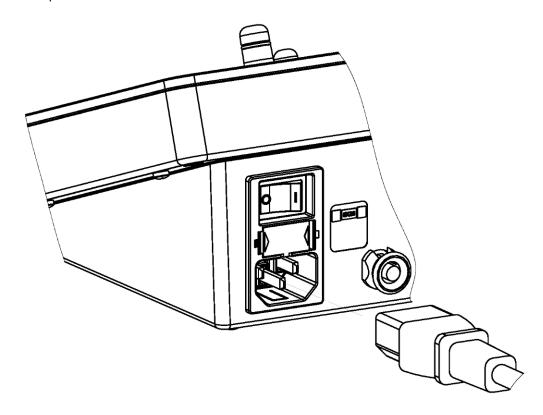
A different voltage would cause damage to the medical device and could injure the patient and the user. Any variation in the electrical network voltage or electromagnetic field that is non-compliant with the limits in force, could interfere with the medical device's operation.

Medical devices equipped with a protective earth must be connected to a supply network equipped with a protective earth.

Do not plug the medical device into an extension lead and do not put the mains cord in a cable cover or cable tray.

## 4.2 Connecting the medical device to the electrical network

- 1. Set the medical device's mains switch to "O" OFF position.
- 2. Connect the mains cord to the control unit's mains connector.
- 3. Connect the power lead to the mains socket.



# 5 Installing the medical device

Place the medical device in the position that is suitable for your activity.

The medical device must be placed on a secure and flat surface or a surface with a maximum slope of five degrees.

Check that the cords do not hinder the movement or free circulation of anyone.

Adjust the position of your medical device to correspond to your angle of vision and the characteristics of your workstation, e.g. lighting or distance between the user and the medical device.

Ensure that your mains power disconnecting device is readily accessible. The mains power disconnecting devices - the switch and the power plug - must be easy to access.

Do not install your medical device near or on another device.

#### 5.1 Install cords

Never rotate the handpiece connector on its cord as this can damage your medical device.

Never wrap the handpiece cord around the medical device.

The cord attached to its handpiece must be easily accessible. Make sure that the cord is slack during use.

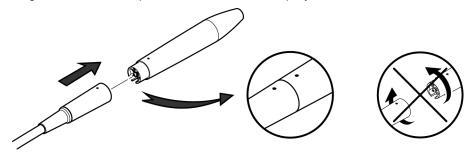
## 5.2 Installing the control pedal

The control pedal must be positioned near the feet of the operator and must be readily accessible.

## 5.3 Connecting the handpiece

Check for any traces of humidity on the handpiece connections. If the connections are damp, dry them with the multi-purpose syringe.

Lubricate the irrigation circuit seal located on the metal shaft on the back of the handpiece with silicone paste. This will prolong its service life and prevent leaks. Do not use spray lubricant on dental instruments.

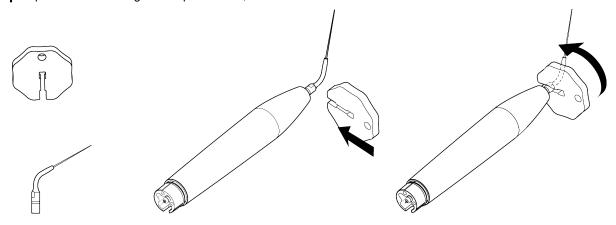


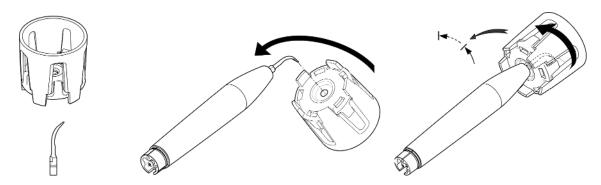
Connect the handpiece to the socket by aligning the indexing points, without rotating it.

# 5.4 Attaching a tip or a file

A tip or a file vibrates correctly when it is perfectly tightened without being forced beyond its stop point. Tighten the tip with the torque wrench (F81320, F81321, F81322 or F81323) to ensure optimum ultrasonic function. Over-tightening of the tip or file with the open-ended wrench can result in breakage of the tip, file or handpiece.

To prevent self-locking of the tip or the file, the latter must be removed and sterilised after each use.





The torque wrenches must be replaced every year.

# 6 Dispensing a treatment

## 6.1 Accessory usage conditions

The accessories, tips and handpiece must be cleaned, disinfected and sterilised before use.





Refer to the cleaning, disinfection and sterilisation protocols for accessories listed in the chapter *Associated documentation page 3*.

## 6.2 Preparation for use

Remove the tank from the medical device by pulling it upwards. Fill the irrigation solution tank up to the MAX mark with an irrigation solution that is approved for the medical device.





To prepare your medical device, follow the steps below:

- 1. Wear safety goggles and protective gloves.
- 2. Clean the unit with an alcohol disinfectant wipe.
- 3. Remove the handpiece from its sterilisation bag.
- 4. Remove the wrench from its sterilisation bag.
- 5. Remove the tip from its sterilisation bag.
- 6. Screw the tip onto the handpiece, first manually and finishing with the wrench.
- 7. Connect the handpiece to the handpiece cord socket.
- 8. Place the handpiece on its support.
- 9. Switch on the medical device.
- 10. Check the irrigation parameters depending on the tip chosen.
- 11. After water drainage, check that the spray works correctly.

Your medical device is now ready to use.

# 7 Medical device description

#### 7.1 Control unit

The control unit incorporates Newtron® technology patented by SATELEC, a company of Acteon group.

Newtron® technology emits ultrasonic vibrations in a controlled way. These vibrations, relayed by SATELEC, a company of Acteon group tips, are used to deliver effective treatments and to ensure patient safety.

The control unit incorporates an dental ultrasonic generator equipped with a piezoelectric command.

#### 7.1.1 Light indicator

The light indicator is designed to provide information about the status of the medical device.

When the light indicator is illuminated, the medical device is on and ready to use.

Each colour corresponds to the power level range.

#### 7.1.2 Switch

The mains switch is used to switch on (position I) or to stop (position O) the medical device.

#### 7.1.3 Mains Connector

The mains connector with its earthing pin is used to connect the device to the electrical network via a disconnectable mains cord.

#### 7.1.4 Air inlets

Air inlets ensure correct ventilation of the control unit. Leave them uncovered to allow air to circulate.

#### 7.1.5 Irrigation solution tank

The medical device is equipped with a tank designed to hold 300ml or 500ml of irrigation solution depending on the option chosen. The maximum capacity is shown by the MAX mark on the tank.

The irrigation solution tank is fitted with a plug. Neither the tank nor the plug can be sterilised.

The following solutions are approved for use with the device:

- Hydrogen peroxide < 3%
- Chlorexidine < 3%
- EDTA Ethylenediaminetetraacetic acid < 1%
- Sodium Hypochlorite < 0.9%
- · Sterile water, distilled water, deionised water, demineralised water
- Saline solution at 0.9%

The following solutions must not be used:



- Hextril<sup>®</sup> Hexedrin
- Bleach
- Betadine® Povidone-iodine

#### 7.1.6 Cassette

The medical device is fitted with a peristaltic pump. This pump is subject to wear and must be replaced by the practitioner using the kit provided, or by the Acteon Customer Service team. Wear of the peristaltic pump depends on your use. However, it is advisable to replace the peristaltic pump at least once to twice per year.

Refer to the chapter Replacing the irrigation cassette page 20 for full instructions.

## 7.2 Overview of the interface

#### 7.2.1 Unit interface

The ultrasound power configuration button is used to set the operating power: 1 to 20.

Rotating the button causes the colour of the medical device's backlighting to change.

- Green: 1 to 6: very low to low power, used mainly for periodontics.
- Yellow: 6 to 11: medium power, used mainly for endodontics.
- Blue: 11 to 16: high power, used mainly for scaling and preservation and restoration dentistry.
- Orange: 16 to 20: very high power, used mainly for loosening.

The ultrasound power configuration button can be removed by the user to facilitate the cleaning and disinfection of the control unit. The button cannot be sterilised.

The removal of the button inhibits the activation of ultrasounds. The top surface of the control unit lights up white and the control pedal can be pressed to activate the purge function. The purge function can be stopped at any time by pressing the control pedal again.

#### 7.2.2 Overview of the pedal

The ON/OFF type control pedal is used by the practitioner to operate the medical device.

Pressing the footswitch automatically activates the handpiece ultrasounds, and the irrigation function if it is not deactivated.

The footswitch equipped with its cord cannot be disconnected. Its weight and antislip pad ensure good stability.

The light function remains active for approx. 9 seconds after the pedal is released.

#### 7.3 Accessories

#### 7.3.1 Handpiece

There is a handpiece with SLIM B.LED to white LED connector and a handpiece with SLIM B.LED to blue LED connector. Refer to the Newtron handpiece user manual [J12921] for more information.

The handpieces are designed to operate exclusively with SATELEC dental ultrasonic generators.

#### 7.3.2 Handpiece support

The support holds the handpiece or the cord sleeve.

The handpiece support can be fixed to the front face or the right side face of the medical device. To change the position of this support, unscrew the two screws located under the support, position the support over the two holes located on the right side face and insert and tighten the two fastening screws.

#### 7.3.3 Handpiece cord

The SLIM cord is only compatible with Acteon handpieces with SLIM connector.

The cord enables irrigation flow and provides an electrical connection between the medical device and the handpiece.

## 7.4 Adjustments

#### 7.4.1 Ultrasound power

The ultrasound power must be adjusted in accordance with the tip used and the required treatment. The operating power of the tips must be selected in compliance with the Acteon tips color coding system (CCS tips).

Each tip must be used in accordance with the settings defined in the ultrasonic generator irrigation and power settings table [J58000].

## 7.4.2 Irrigation

Because work habits, feedback and professional training differ from one professional to another, the user must ensure that the irrigation flow is compatible with the procedure to be carried out to prevent burns to the clinical site.

Adjust the irrigation flow using the irrigation flow configuration button. The flow rate must be adapted to the tip used and to the required treatment.

The medical device must be set to minimum power to adjust the irrigation flow rate. Press the footswitch until a spray appears.

The configuration range goes from stopping the irrigation function at the minimum stop marked by "O" to activating the

purge function at the maximum stop marked by



The irrigation flow configuration button can be removed to clean the medical device. The button cannot be sterilised. Each tip must be used in accordance with the settings defined in the ultrasonic generator irrigation and power settings table [J58000].

# 8 Disinfection and sterilising

The instructions relating to cleaning, disinfection and sterilisation protocols for accessories supplied by SATELEC, a company of Acteon group have been approved for each medical device and accessory. The applicable guides are listed in the chapter *Associated documentation page 3*.

They can be downloaded at the following address: www.satelec.com/documents.



In all cases, the local regulations in force relating to the cleaning, disinfection and sterilisation protocols for accessories take precedence over the information provided by SATELEC, a company of Acteon group.

#### 8.1 Clean and disinfect the medical device

Do not immerse the handpiece.

The medical device's control pedal must be cleaned and disinfected daily.

The handpiece must be cleaned, disinfected and sterilised after each use.

The medical device's control unit must be cleaned and disinfected daily.

The medical device must be in OFF or O stop position during cleaning and disinfecting procedures.

Refer to the instructions in the chapter Cleaning the irrigation system page 19.

Use alcohol disinfectant wipes.

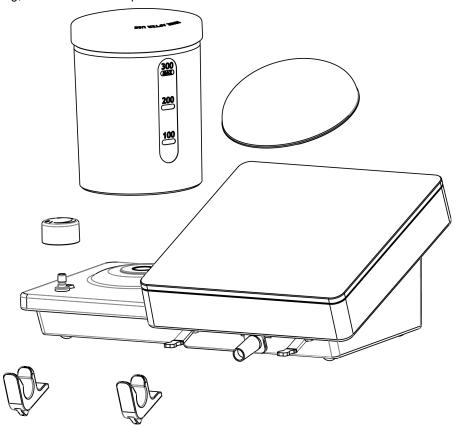
Avoid using cleaning and disinfection products that contain flammable agents.

Otherwise, ensure that the product has completely evaporated or that there is no fuel left on the medical device and its accessories before switching it on.

Do not use an abrasive product to clean the medical device.

Never apply sprays directly to the medical device to clean it. Always spray the product onto a wipe, then clean the medical device.

To prepare for cleaning, remove the various parts of the Newtron P5 XS B.LED as shown here.



# 8.2 Cleaning, disinfecting and sterilising accessories Refer to the cleaning, disinfection and sterilisation instructions for accessories listed in the chapter Associated documentation page 3.

# 9 Monitoring and routine maintenance

The only preventive maintenance the medical device requires is:

- · Monitoring of accessories
- · Routine cleaning, disinfection and sterilisation
- Cleaning

Check the cleanliness of the air inlets on the control unit to prevent any heating.

Check the cleanliness of the handpiece nosepiece. It must be clean, smooth and corrosion-free. The handpiece must screw easily and firmly inside it.

Check the condition of the handpiece rear seals, which must not be distended, torn or broken.

Before and after use, check the medical device and its accessories entirely for any problems. This is necessary to detect any electrical isolation fault or damage. If necessary, replace damaged parts.

# 9.1 Cleaning the irrigation system

Operate the device at minimum power, at maximum irrigation flow rate for two minutes.



The purge function is activated by pressing the footswitch or by moving the irrigation configuration button into the position.

The purge takes approximately 4 minutes and can be stopped by pressing the footswitch again.

If your medical device has a tank:

- 1. Fill the tank with hypochlorite diluted at less than 3%.
- 2. Position the irrigation flow configuration button on purge.
- 3. Operate the irrigation spray for two minutes to rinse the medical device's internal water system.
- 4. Refill the tank with demineralised or distilled water, or even drinking water.
- 5. Rinse the system for two minutes.

When the irrigation system has been cleaned, perform the following operations:

- 1. Disconnect the handpiece and refer to the handpiece cleaning, disinfection and sterilisation instructions [J12911].
- 2. Clean and disinfect the medical device as indicated in the chapter Clean and disinfect the medical device page 17.
- 3. Follow the instructions of protocols for cleaning, disinfecting and sterilising SATELEC, a company of Acteon group accessories [J81001] and [J02001].

#### 9.2 Corrective Maintenance

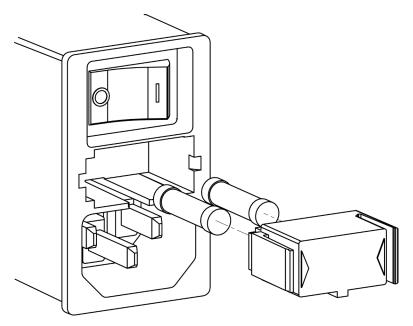
In the event of faulty operation, the following corrective maintenance actions may be performed by the user.

#### 9.2.1 Replacing the fuses

The medical device is protected by two fuses in the mains connector.

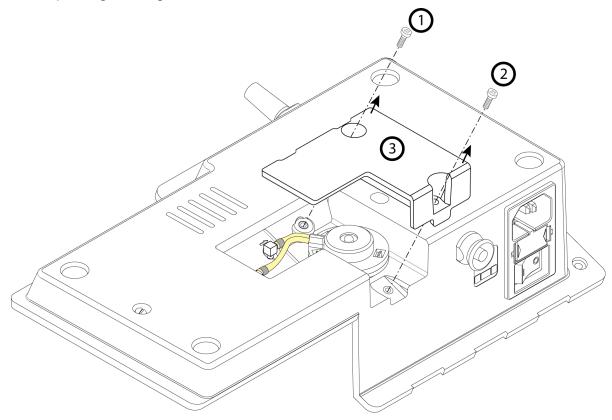
To replace the fuses, perform the following operations:

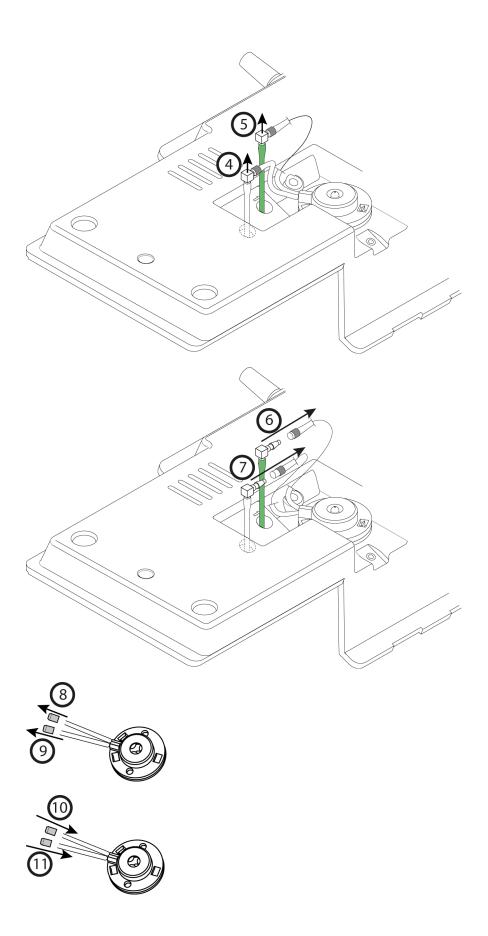
- 1. Stop the medical device (position O).
- 2. Disconnect the mains cord from the electrical network.
- 3. Disconnect the mains cord from the mains connector.
- 4. Insert the tip of a flathead screwdriver into the notch on top of the fuse holder to release it.
- 5. Remove the used fuses.

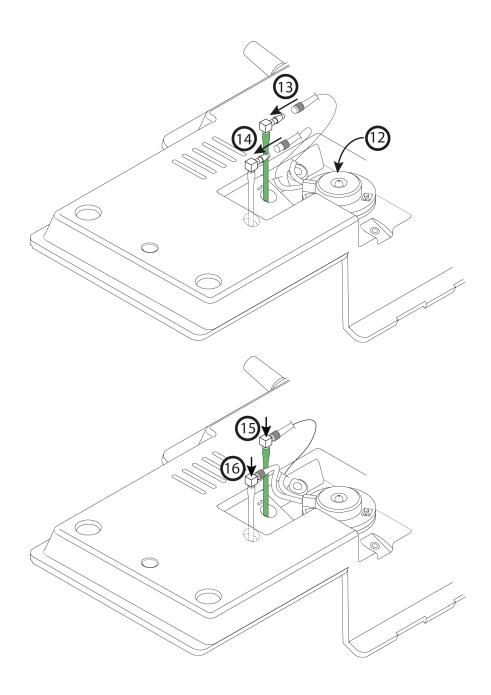


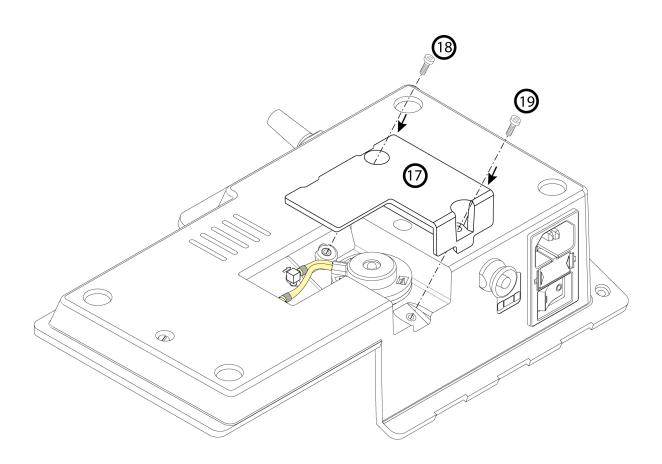
- 6. Replace the used fuses with fuses of the same type and same rating.7. Place the fuse holder in its recess by pushing it until you hear a click that confirms it is in the correct position.8. Connect the mains cord to the connector.
- 9. Connect the mains cord to the electrical network.

## 9.2.2 Replacing the irrigation cassette









# 10 Identifying incorrect operation

In the event of incorrect operation, refer to the tables below to quickly identify and repair the non-complex parts of the medical device.

If the incorrect operation is not described in the tables below, please contact your supplier or the customer service team at SATELEC, a company of Acteon group.

Do not use the medical device if it appears to be damaged or faulty. Isolate the medical device and make sure that it cannot be used.

## 10.1 Not working

Symptoms: the light indicator on the medical device is off and the medical device is not working.

Possible causes	Solutions
No electrical current	Contact your electrician
Mains switch in position O	Set the mains switch to position I
Faulty connection between the mains cord and the electrical wall socket	Connect the mains cord to the electrical wall socket
Faulty connection between the mains cord and the mains connector	Connect the mains cord to the mains connector
Internal fuse not working	Return to the Acteon Customer Service team
Mains fuses in the mains connector not working	Replace the mains fuses with fuses of the same type and rating

The internal fuse (ref. FU1 on the printed circuit board) cannot be accessed by the user.

## 10.2 No spray

Symptom: There is no water spray at the tip.

Possible causes	Solutions
Flow configuration button on minimum	Adjust the flow control button
Tip or file blocked	Unblock the tip or file using an ultrasonic tank
Incorrect choice of tip	Check the tip
Inadequate amount of spray	Adjust the spray
No irrigation solution in the tank	Fill the tank with irrigation solution
Worn irrigation cassette	Replace the irrigation cassette as detailed in the chapter Replacing the irrigation cassette page 20

# 10.3 The power is not as expected

Symptoms: the tip does not vibrate at the expected frequency, the treatment is not progressing as normal and is taking longer or is at a standstill.

Possible causes	Solutions
Worn or bent tip	Replace the tip
Incorrect use: incorrect angle of incidence or inadequate pressure	Refer to the user instructions available at www.acteongroup.com
Presence of liquid or moisture between the handpiece and cord	Dry the electrical contacts
Faulty handpiece seal	Replace the handpiece seal using the purpose-provided kit.

# 10.4 Ultrasounds not working

Symptoms: the tip does not vibrate.

Possible causes	Solutions
The tip is incorrectly tightened	Fasten the tip using the wrench Replace your torque wrench once a year
Faulty connector contact	Clean the cord contacts
Handpiece cord wire(s) cut	Return to the Acteon Customer Service team to replace the cord

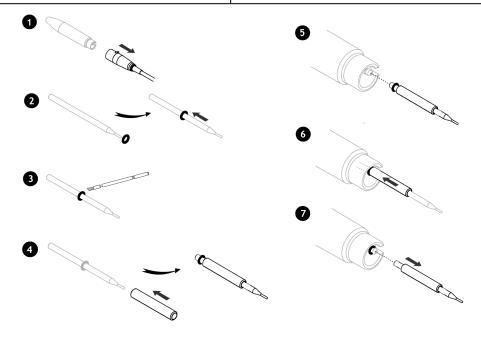
# 10.5 Water leakage

Symptoms: water is leaking between the base of the handpiece and its cord.

Symptoms: Water is leaking from one of the following places:

- under the tank;
- under the medical device.

Possible causes	Solutions
Wear of 1.15 mm x 1 mm handpiece seal	Replace the seal using the purpose-designed kit.
Wear of the tank seal	Contact SATELEC, a company of Acteon group's Customer Service team to replace the tank seal.
	Replace the irrigation cassette using the purpose-designed kit as detailed in the chapter Replacing the irrigation cassette page 20



# 11 Technical specifications of the medical device

# 11.1 Identification

Manufacturer	SATELEC, a company of Acteon group
Name of the medical device	Newtron P5 XS B.LED

## 11.2 Generator

Supply voltage	100 - 240 VAC
Supply voltage	100 - 240 VAC
Power supply frequency	50/60 Hz
Power consumption	60 - 60 VA
Voltage supplied to handpiece	150 VAC
Output frequency	Minimum 28 kHz
Power setting range	1 - 20
Type of leakage currents	BF
Operating mode	Intermittent: 10 minutes ON / 5 minutes OFF
Electrical rating	I
Internal fuse not accessible to the user	Ref: FU1 / T 1,5 AL 125 V - SMD - Interrupting capacity: 50 A
Fuse (mains connector)	2 fuses T 1 AL 250 VAC – 5 mm x 20 mm - Interrupting capacity: 35 A
Width	260 mm
Height	102 mm, 138 mm with 300 ml tank
Depth	185 mm
Weight	1800 g with pedal, handpiece cord and 300 ml tank

# 11.3 Length of cords

Handpiece cord	2 500 mm +/- 50 mm
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Control pedal cord	2 500 mm +/- 50 mm

# 11.4 Irrigation

Tank capacity	300 ml or 500 ml
Nominal water output flow at the end of the handpiece	5 ml/min to 40 ml/min
Maximum water output flow at purge	80 ml/min

# 11.5 Footswitch

Width	72 mm
Height	30 mm
Depth	105 mm
Weight	220 g
Ingress protection rating	IPX1

# 11.6 Environmental characteristics

Ambient operating temperature	+10°C to +30°C
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Operating RH	30% to 75%
Atmospheric operating pressure	Between 800 hPa and 1060 hPa
Maximum operating altitude	Equal to or less than 2000 metres
Storage temperature	0°C to +50°C
Storage RH	10% to 100%, including condensation
Atmospheric storage pressure	Between 500 hPa and 1060 hPa
Transportation temperature	0°C to +50°C
Transportation RH	10% to 100%, including condensation
Atmospheric transportation pressure	Between 500 hPa and 1060 hPa

# 11.7 Environmental restrictions

Usage premises	Usable in all medical premises. The medical device must not be used in an operating theatre or outdoors.
Use in gas-filled atmosphere	The medical device is not designed for use in a type AP or APG gas-filled atmosphere or in the presence of anaesthetic gases.
Immersion	The console must not be immersed.
Immersion	The handpiece must not be immersed.

# 11.8 Main performance characteristics

Ultrasonic vibrations of the tip or file fitted to the end of the conventional dental ultrasonic handpiece.

- Vibration frequency ≥ 28 kHz.
- Tip amplitude ≤ 200 µm.

# 12 Regulations and standards

# 12.1 Applicable standards and regulations

This medical device complies with the essential requirements of European Directive 93/42/EEC. It was designed and manufactured in accordance with an EN ISO 13485-certified quality assurance system.

This equipment is designed and developed in compliance with the Electrical Safety standard IEC60601-1 in force.

## 12.2 Medical class of the device

Class of medical device: Ila according to 93/42/EEC directive

## 12.3 Symbols

Symbol	Meaning
0	Switching off (OFF)
I	Switching on (ON)
	Always wear safety goggles
	Always wear protective gloves
	Refer to the supporting documentation
Consult Instructions for Use	Consult the User Manual
Electronic User Information	The accompanying documentation is available in electronic format
<b>□</b>	Pressure limit
	Temperature limit
<u></u>	Humidity limit
	Packaging unit

Symbol	Meaning
Ţ	Fragile, handle with care
<del>*</del>	Store in a dry place
	Biohazard
134°C	Sterilisation at 134°C in an autoclave
132°C 555	Sterilisation at 132°C in an autoclave
「川	Washer-disinfector for thermal disinfection
	Ultrasonic bath
★	Type BF part in contact
~	Alternating current
	Intensity
<b>→</b>	Purge
Ь	Peristaltic pump
((•))	Electromagnetic interference
CE Warking	CE marking
C€	CE marking

Symbol	Meaning
YYYY	Year of manufacture
	Manufacturer
Do not dispose of as household waste	Do not dispose of as household waste
recylum Eco-organisme a but non lucretif	Recycle your lamps and professional electrical equipment with Récylum
Rx Only	Under the United States Federal Law, this medical device must only be sold by or under the orders of a qualified doctor.
SN	Serial Number
PN	Packaging Number

# 12.4 Quick Start and Quick Clean symbols

	Use a dipping tank for cleaning
	Use a soft brush for cleaning
	Use a lint-free cloth for cleaning
	Use an ultrasonic tank for cleaning.
	Use a swab for cleaning
H <sub>2</sub> O	Use deionised or osmosis-purified water for cleaning

	Use an alcohol disinfectant wipe for pre-disinfection and cleaning.
	Do not use the ultrasonic tank for cleaning.
(P)	Clean under running water
	Use a syringe for cleaning
	Use a washer-disinfector for cleaning and disinfection
	Use a pre-vacuum air autoclave for sterilisation

# 12.5 Manufacturer identification



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## 12.7 Disposal and recycling

As an item of Electrical and Electronic Equipment, the medical device must be disposed of via a specialist collection, removal, recycling or destruction channel. This applies in particular to the European market, with reference to Directive no. 2012/19/EC of July 2012.

When your medical device has reached the end of its service life, contact your nearest dental equipment dealer, or the Acteon head office or one of the company branches to find out how to proceed. The relevant contact details are given in the chapter *Branch addresses page 32*.



The indication below applies to France only.

In compliance with the provisions of the French Environment Code relating to the disposal of electronic and electrical equipment waste or WEEE (Decree no. 2012-617 dated 2 May 2012), our Company fulfils its obligations to reclaim and dispose of its electrical and electronic equipment through the means established by the approved organisation Récylum, NOR approval: DEVP1427651A.

As a manufacturer, our Company is listed in the National Register of Producers kept by the ADEME (French Environment and Energy Management Agency). Professionals buying our products directly from the distribution chain are responsible for passing on this information about our established recycling methods to the end user.

In addition, the buyer agrees to take back our brand's devices at the end of their service life and to transfer them to one of the collection centres set up by Récylum for recycling (see list of collection centres on the site http://www.recylum.com/.

If necessary, Récylum can come and collect these devices from you free of charge once the quantity of devices has reached a certain level in the pallets-containers with which you are provided to store this waste.



An accessory that has reached the end of its service life must be disposed of in infectious clinical waste containers.

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