Instructions for Use

BRASSELER USA®



HPX-Foot Control

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Symbols



WARNING!
(risk of injury)

SN

Serial number



Foot control
cordless C-NW



ATTENTION!
(to prevent damage
occurring)

REF

Catalogue number



Reset



General explanations,
without risk to persons
or objects

QTY

Quantity

IPX1

Protection against
dripping water



Consult Instructions for
Use



Date of manufacture



Class II medical
electrical equipment

Symbols



Non-ionizing electromagnetic radiation



DC – direct current



Do not dispose with domestic waste



This way up



Keep dry



UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements



“Der Grüne Punkt” (The Green Dot) trademark of Duales System Deutschland GmbH



Fragile, handle with care



Trademark of RESY OfW GmbH for identification of recyclable transport and outer packaging of paper and cardboard



Data Matrix code for product information including
UDI (Unique Device Identification)

Symbols

℞only Caution! According to Federal law restricts this device to sale by or on the order of a physician, dentist, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

Contains FCC ID: QOQBGM113
Contains IC: 5123A-BGM113 FCC / IC – USA / Canada*

Symbols

* This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

  This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

  > Reorient or relocate the receiving antenna.
  > Increase the separation between the equipment and receiver.
  > Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
  > Consult the dealer or an experienced radio/TV technician for help.

1. Introduction

For your safety and the safety of your patients
These Instructions for Use explain how to use your medical device. However, we must also warn against possible hazardous situations. Your safety, the safety of your team and, of course, the safety of your patients are of paramount importance to us.



Observe the safety notes.

Indications for use
Foot control for operation of medical electrical equipment.



Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user
We have based our development and design of the medical device on the target group “dentist, dental hygienist, dental employees (prophylaxis) and dental assistants”.

Hereby, the manufacturer declares that the medical device is in compliance with Directive 2014/53/EU (RED). The full text of the EU declaration of conformity is available at the following internet address https://wh.com

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

> The medical device must be used in accordance with these Instructions for Use and with the Instructions for Use of the drive unit.
> Modifications or repairs must only be undertaken by an authorized Brasseler service partner (see page 40).
> The medical device has no components that can be repaired by the user.

- The electrical installation at the premises must comply with the regulations laid out in IEC 60364-7-710 (“Installation of electrical equipment in rooms used for medical purposes”) or with the regulations applicable in your country.
- Unauthorized opening of the medical device invalidates all claims under warranty and any other claims.

Improper use, unauthorized assembly, modification or repair to the medical device, non-compliance with our instructions or the use of accessories and spare parts which are not approved by Brasseler, invalidates all claims under warranty and any other claims.



Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

2. Scope of delivery

REF	Description
5028680U0	HPX- Foot Control with Stick

3. Safety notes



> Before using the medical device for the first time, store it at room temperature for 24 hours.
> Check the medical device for damage and loose parts each time before using.
> Do not operate the medical device if it is damaged.
> Always ensure that the correct operating conditions are provided.
> Perform a test run each time before using.
> Never touch the patient and the electrical contacts on the medical device simultaneously.
> Keep the medical device away from magnetic fields.
> Replace the medical device as soon as the resistance is noticeably reduced.
> The medical device is not approved for operation in potentially explosive atmospheres.
> The medical device is not approved for operation in oxygen rich Environment.



> Do not expose the medical device to any violent mechanical impacts.

Battery

> Do not charge the battery unattended.
> As soon as the charging cycles start to deteriorate send the medical device to an authorized Brasseler service partner.
> Defective or worn-out batteries must only be replaced by an authorized Brasseler service partner.

> Charge the battery of the medical device as soon as the status LED flashes.
> Incorrect use of the rechargeable battery can cause fire or corrosion.

Charger

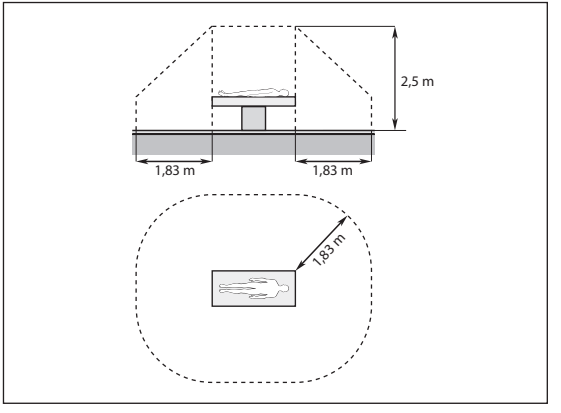
> Only use chargers approved by Brasseler.

System failure
A total system failure does not constitute a critical fault.
Simply switch the unit off and then on again.

Hygiene and maintenance prior to initial use
> Clean and disinfect the medical device.

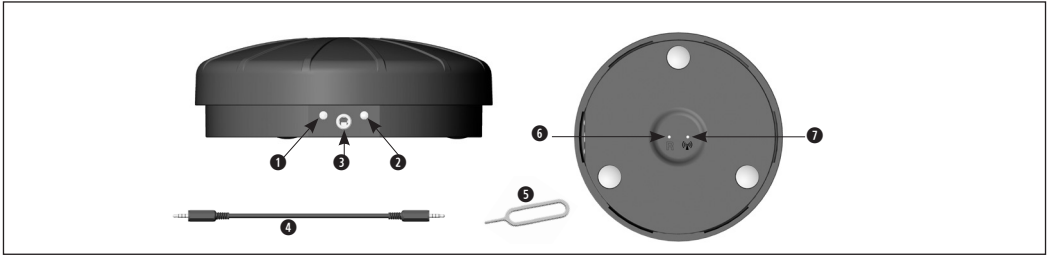
Risks due to electromagnetic fields
The functionality of active implantable medical devices (AIMD) (e.g. cardiac pacemaker, ICD) can be affected by electric, magnetic and electromagnetic fields.

> Find out if the patient has active implantable medical devices (AIMD) before using the medical device and inform about the risks.



The patient environment (see diagram) encompasses the area up to 2.50 m above the patient and 1.83 m in all horizontal directions.

The charger must not be used within the patient environment.



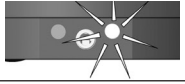
❶	Charging LED (orange)	❺	Stick
❷	Status LED (green)	❻	Reset button
❸	Connection for cable (pairing/charging)	❼	Pairing button
❹	Cable (pairing/charging)		



Standby mode

> The foot control can be activated by pressing.

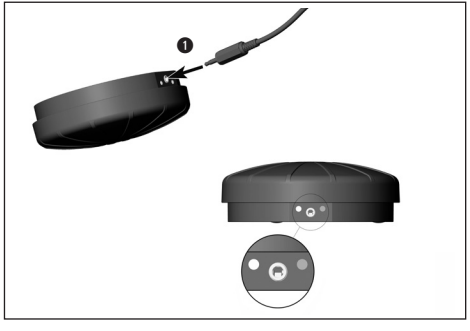
LED	steady	steady
		
GREEN		➔ Connection to paired medical device established
ORANGE	➔ Battery is charging	

LED	flashes	flashes intermittently*
		
GREEN	➔ Foot control is attempting to establish a connection to the paired medical device	➔ Battery is flat > Charge the battery
ORANGE		

* The LED flashes for 40 milliseconds every 4 seconds

Charging the battery

Charge the medical device fully before you use them for the first time.



❶ Connect the charging cable into the foot control charging socket.

LED orange:
Battery is charging

LED off:
Battery is charged

Pairing foot control with handpiece drive / control unit


Follow the instructions in the handpiece drive / control unit instructions for use.

Troubleshooting with pairing problems

> Remove any metallic objects located between the foot control and handpiece drive / control unit.
> Change the position of the foot control.
> Eliminate any sources of interference (e.g. brush motors, mobile telephones, radios, WLAN, ...)
> Use the stick to press the reset button on the foot control and try pairing again.

If the pairing problem cannot be remedied using the steps described above, the unit will need to be inspected by an authorized Brasseler service partner.



Follow your local and national laws, directives, standards and guidelines for cleaning and disinfection.



> Wear protective clothing, safety glasses, face mask and gloves.



Cleaning agents and disinfectants

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
> Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic. Manual cleaning agent: “LUMINOX®” (Alconox), disinfectant: “CaviWipes™” (Metrex)
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.

> Use disinfectants which have been tested and found effective by the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).

> The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Send worn or damaged medical devices and/or medical devices with material changes to an authorized Brasseler service partner.



> Clean the medical device immediately after every treatment.
> Wipe the entire surface of the medical device with disinfectant.
Manual cleaning agent: “LUMINOX®” (Alconox), disinfectant: “CaviWipes™” (Metrex)



> Ensure that no fluids enter the medical device.



> The charger must not be connected.



Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.



> Do not place the medical device in liquid disinfectant or in an ultrasonic bath.
> Do not immerse the medical device in water or clean them under running water.

> Lightly wipe all external surfaces of the medical device with a soft, lint-free cloth moistened with a neutral detergent for medical devices. Clean all surfaces for 1 to 3 minutes, at least until all visible soil is removed.
> Remove the detergent from all surfaces using a lint-free cloth moistened with distilled water, deionized water, or demineralized water.



Evidence of the medical device's basic suitability for effective manual cleaning was provided by an independent test laboratory using the cleaning agent “LUMINOX®” (Alconox).

> Brasseler recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection (intermediate level) was provided by an independent test laboratory using the disinfectant “CaviWipes™” (Metrex).

> The medical device is not approved for automated processing in a washer-disinfector and sterilization.



> Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any medical devices that are still soiled.

7. Servicing

Periodic inspection
Regular periodic inspection of the function and safety of the medical device is necessary and should be carried out at least once every three years, unless shorter intervals are prescribed by law. The periodic inspection covers the complete medical device and must only be performed by an authorized service Partner.

Repairs and returns
In the event of operating malfunctions immediately contact an authorized Brasseler service partner.
Repairs and maintenance work must only be undertaken by an authorized Brasseler service partner.

> Ensure that the medical device has been completely processed before returning it.

> Always return equipment in the original packaging!

8. Brasseler Accessories and spare parts



Use only original Brasseler accessories and spare parts or accessories approved by Brasseler.
Supplier: Brasseler

5028513U0 HPX Charger

9. Technical data

Foot control	HPX-Foot Control
Battery type:	Li-ion
Runtime:	approx. 2 months
Standby:	automatically if not actuated
Charging time:	approx. 3 h
Rated voltage:	3.7 V
Rated capacity:	680 mAh
Dimensions (WxDxH):	117 x 117 x 38 mm
Weight:	190 g

Foot control	HPX-Foot Control
Frequency band:	2.4 GHz ISM band (2.402 – 2.480 GHz)
Transmitting power:	3 dBm
Modulation:	GFSK
Channels:	40 channels with 2 MHz spacing

Ambient conditions

Temperature during storage and transport:	-20°C to +60°C (-4°F to +140°F)
Humidity for storage and transport:	8% to 80% (relative), non-condensing
Temperature in operation:	+10°C to +35°C (+50°F to +95°F)
Humidity in operation:	15% to 80% (relative), non-condensing

Classification according to Paragraph 6 of the General Specifications for the Safety of Medical Electrical Equipment according to IEC 60601-1/ANSI/AAMI ES 60601-1



Charger: Class II medical electrical equipment (protective earth conductor used for functional earth connection only!)



The medical device is protected against vertically falling drops of water (IPX1 as per IEC 60529).

Pollution level:	2
Overvoltage category:	II
Altitude:	up to 3,000 m above sea level

10. Data on electromagnetic compatibility according to IEC/EN 60601-1-2



Operating environment and EMC warning notes

This medical device is neither life-sustaining nor coupled to the patient. It is suitable for operation both in domestic healthcare and in facilities used for medical purposes except rooms/areas, in which EMC interference of high-intensity may occur. The customer and/or the user should assure that this medical device is set up and used in an environment of the specified type and/or in accordance with the specifications of the manufacturer. This medical device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.

No special precautions are necessary to maintain the basic safety and essential performance of this medical device.



Essential performance

This medical device has no critical functions and therefore does not have any essential performance features.

RF communication equipment
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to the medical device. Otherwise, degradation of the performance of this medical device could result.

Brasseler guarantees the compliance of the device with the EMC requirements only when used with original Brasseler accessories and spare parts. The use of accessories and spare parts not approved by Brasseler can lead to an increased emission of electromagnetic interference or to a reduced resistance against electromagnetic interference.

Use of this medical device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this medical device and the other equipment should be observed to verify that they are operating normally.

The medical device is not intended for use in the vicinity of HF surgical devices.

Results of the electromagnetic tests

Requirement	Class / Test Level*	
Electromagnetic emissions		
Mains terminal disturbance voltage (Conducted Emissions) CISPR 11/EN 55011 [150 kHz – 30 MHz]	Group 1 Class B	
Electromagnetic radiation disturbance (Radiated Emissions) CISPR 11/EN 55011 [30 MHz – 1000 MHz]	Group 1 Class B	
Harmonic distortion IEC/EN 61000-3-2	Class A	
Voltage fluctuations and flicker IEC/EN 61000-3-3	–	
Immunity to electromagnetic interference		
Electrostatic discharge (ESD) IEC/EN 61000-4-2	Contact discharge: ±2 kV, ±4 kV, ±6 kV, ±8 kV Air discharge: ±2 kV, ±4 kV, ±8 kV, ±15 kV	
Radiated RF electromagnetic fields IEC/EN 61000-4-3 [80 MHz – 2.7 GHz]	10 V/m	
Proximity fields from RF wireless communications equipment IEC/EN 61000-4-3	710 / 745 / 780 / 5240 / 5500 / 5785 MHz	9 V/m
	385 MHz	27 V/m
	450 / 810 / 870 / 930 / 1720 / 1845 / 1970 / 2450 MHz	28 V/m

Results of the electromagnetic tests

Electrical fast transients / bursts IEC/EN 61000-4-4	Mains supply: ±2 kV		
Surges IEC/EN 61000-4-5	±1 kV L – N	±2 kV L – PE	±2 kV L – PE
Conducted disturbances induced by RF fields IEC/EN 61000-4-6	3 V 6 V in ISM bands and in amateur radio bands		
Power frequency magnetic fields IEC/EN 61000-4-8	30 A/m		
Voltage dips, short interruptions and voltage variations IEC/EN 61000-4-11	0% for 0.5 cycle at 45° steps from 0°-315° 0% for 1 cycle 70% for 25/30 cycles 0% for 250/300 cycles		
Proximity magnetic fields IEC/EN 61000-4-39	30 kHz	8 A/m	
	134.2 kHz	65 A/m	
	13.56 MHz	7.5 A/m	

* There are no deviations or simplifications to IEC/EN 60601-1-2.

11. Disposal



Ensure that the parts are not contaminated on disposal.



Follow your local and national laws, directives, standards and guidelines for disposal.

- Medical device
- Waste electrical equipment
- Packaging

Explanation of warranty terms

This Brasseler medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantees faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for Use have been followed.

As the manufacturer, Brasseler is liable for material or manufacturing defects within a warranty period of 24 months from thedate of purchase. Accessories and consumables (stick) are excluded from the warranty.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by Brasseler.

Claims under warranty accompanied by proof of purchase must be sent to Brasseler or to an authorized service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

24 months warranty

Authorized Brasseler service partners

Brasseler U.S.A Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419, USA
800.841.4522

Manufactured For:
Brasseler U.S.A Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419, USA
800.841.4522

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