

# STORZ

## KARL STORZ—ENDOSKOPE

en **Instructions for use**  
**UNIDRIVE Select**



02-2022

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## Table of Contents

<b>1</b>	<b>General information</b>	<b>5</b>
1.1	Read the instructions for use	5
1.2	Read the instructions for use of compatible products	5
1.3	Scope	5
1.4	General signs and symbols	5
1.5	Description of warning messages	6
1.6	Abbreviations	6
<b>2</b>	<b>Normal use</b>	<b>7</b>
2.1	Intended use	7
2.2	Indications	7
2.3	Contraindications	7
2.4	Target user populations	7
2.5	Patient groups	7
2.6	Intended conditions of use	7
<b>3</b>	<b>Safety and warning</b>	<b>8</b>
3.1	Serious incidents	8
3.2	Correct handling and product testing	8
3.3	Product not clean	8
3.4	Combination with other components	8
3.5	Risk of explosion and fire	9
3.6	Dangers from electrical current	9
3.7	Damage due to ingress of liquid in electrical components	10
3.8	Electromagnetic interference	10
3.9	Failure of products	11
3.10	Observing ambient conditions	11
3.11	Functionality of the touch screen	11
<b>4</b>	<b>Product description</b>	<b>12</b>
4.1	Description of operation	12
4.2	Product overview	12
4.3	Possible combinations	13
4.4	Technical data	14
4.5	Symbols employed	17
4.5.1	Symbols on the packaging	17
4.5.2	Symbols on the product	18
4.5.3	Symbols on the type plate	19
4.5.4	Symbols on the user interface	19
4.6	Ambient conditions	20
<b>5</b>	<b>Preparation</b>	<b>21</b>
5.1	Unpacking the product	21
5.2	Setting up the product	21
5.3	Connecting the product	21
5.4	Putting the product into operation	23
5.5	Putting the pump into operation	25
<b>6</b>	<b>Application</b>	<b>28</b>
6.1	Selecting the handpiece	28

6.1.1	High-speed micro motor .....	28
6.1.2	DrillCut-X II-35 .....	29
6.1.3	INTRA motor .....	31
6.1.4	Micro ear burr .....	32
6.1.5	Perforator .....	32
6.2	Setting the speed .....	33
6.3	Changing the direction of rotation .....	34
6.4	Selecting the motor connection .....	34
6.5	Setting the irrigation flow .....	35
6.6	Operating the footswitch .....	36
6.7	Settings .....	37
6.7.1	Device information .....	37
6.7.2	Setting the language .....	37
6.7.3	Setting the brightness and volume .....	38
6.7.4	Calling up the event log .....	39
6.7.5	Setting the pedal control .....	39
6.7.6	Setting the motor stop behavior .....	40
6.7.7	Service .....	40
6.8	Switching off the product .....	41
<b>7</b>	<b>Maintenance, servicing, repairs, and disposal .....</b>	<b>42</b>
7.1	Maintaining the product .....	42
7.1.1	Maintenance .....	42
7.2	Changing a fuse .....	42
7.3	Safety inspection in accordance with IEC 62353 .....	44
7.3.1	Visual inspection .....	44
7.3.2	Electric measurements .....	44
7.3.3	Functional test .....	44
7.4	Repairing the product .....	44
7.5	Disposing of the product .....	45
<b>8</b>	<b>Accessories and spare parts .....</b>	<b>46</b>
8.1	Accessories .....	46
8.2	Spare parts .....	53
<b>9</b>	<b>Electromagnetic compatibility .....</b>	<b>54</b>
9.1	General notes on the operating environment .....	54
9.2	Accessories and cables .....	54
9.3	Table 1 – Compliance level for immunity tests .....	54
9.4	Table 2 – Test levels for proximity fields from HF wireless communications equipment .....	56
9.5	Table 3 – Test levels for radiated and conducted immunity tests .....	57
9.6	Table 4 – Emission class and group .....	58
9.7	Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product .....	58
<b>10</b>	<b>Errors and messages .....</b>	<b>60</b>
10.1	Troubleshooting .....	60
10.2	Software messages .....	60
<b>11</b>	<b>Overview of mitigating warnings .....</b>	<b>61</b>
<b>12</b>	<b>Subsidiaries .....</b>	<b>62</b>



# 1 General information

## 1.1 Read the instructions for use

If the instructions for use are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions carefully and follow all the safety notes and warnings. The reprocessing instructions can be downloaded from [www.karlstorz.com/ifu](http://www.karlstorz.com/ifu) by entering the item number.
- ▶ Keep the instructions for use and reprocessing instructions in a safe place.

## 1.2 Read the instructions for use of compatible products

If the instructions for use of compatible products are not followed, patients, users, and third parties may be injured or the product may be damaged.

- ▶ Read the instructions for use of the compatible products carefully and follow all the safety notes and warnings.
- ▶ Read the reprocessing instructions of the compatible products carefully and follow all the safety notes and warnings.

## 1.3 Scope

This instruction manual is valid for:

Product name	Item number
UNIDRIVE Select	UM600

## 1.4 General signs and symbols

The signs and symbols used in this document have the following meaning:

### Practical tip

-  This sign refers to useful and important information.

### Actions to be performed

Action to be carried out by several steps:

- ✓ Prerequisite that must be met before carrying out an action.
- 1. Step 1
  - ⇒ Interim result of an action
- 2. Step 2
  - ⇒ Result of a completed action

Actions in safety notes or in the case of a single step:

- ▶ Step 1

### Lists

- 1. Numbered list
  - Unnumbered list, 1st level

- Unnumbered list, 2nd level

## 1.5 Description of warning messages

To prevent any injury to persons or damage to property, the warnings and safety notes in the instructions for use must be observed. The warnings use the following levels of danger:

### **⚠ WARNING**

#### **WARNING**

Designates a possible imminent risk. If this is not avoided, it could lead to death or serious injuries.

### **⚠ CAUTION**

#### **CAUTION**

Designates a possible imminent risk. If this is not avoided, it could lead to minor injuries.

### **NOTICE**

#### **NOTICE**

Designates a possibly harmful situation. If this is not avoided, the products could be damaged.

## 1.6 Abbreviations

Abbreviation	Explanation
CT	Computed tomography
ENT	Ears, nose and throat medicine
MRT	Magnetic resonance tomograph
NEURO	Neurosurgery
RFID	Radio frequency identification
SPINE	Vertebral column
OMFS	Oral and maxillofacial surgery
CNS	Central nervous system

## 2 Normal use

### 2.1 Intended use

Motor control units are used for electronic regulation and control of motors during surgical operations. Motor control units do not come into contact with the body.

### 2.2 Indications

The motor control unit is suitable for all applied parts which, in order to be used successfully, require the energy provided as per the "Technical data" section of the relevant instructions for use.

### 2.3 Contraindications

The medical devices must not be used for procedures in direct contact with the central nervous system (CNS) and central cardiovascular system. Beyond that, there are no contraindications for use of the medical devices directly associated with the medical devices.

### 2.4 Target user populations

The medical device may only be used by doctors and medical assistants with a relevant specialist qualification.

### 2.5 Patient groups

There are no restrictions in terms of patient groups for this product.

### 2.6 Intended conditions of use

The product may only be used in hospitals and doctors' offices in suitable ambient conditions, see chapter *Ambient conditions* [p. 20].

Condition	Operation
Frequency of use	One or more times a day
Length of use	Several minutes to several hours a day
Place of installation	Positioning on a level, vibration-free surface
Mobility	<ul style="list-style-type: none"> <li>– Can be moved if placed on a cart.</li> <li>– Can be swiveled if installed on ceiling supply units.</li> </ul>

### 3 Safety and warning

#### **⚠ WARNING**

##### **Danger due to non-observance of warnings and safety notes**

This chapter contains warnings and safety notes structured according to hazards and risks.

- ▶ 1. Carefully read and observe all warnings and safety notes.
- ▶ 2. Follow the instructions.

#### 3.1 Serious incidents

A 'serious incident' includes incidents which, directly or indirectly, had, could have had or could have any of the following consequences:

- Death of a patient, user, or another person
- Temporary or permanent serious deterioration in the medical condition of a patient, user, or another person
- A serious threat to public health
- ▶ The manufacturer and appropriate authority must be notified of all serious incidents.

#### 3.2 Correct handling and product testing

If the product is not handled correctly, patients, users, and third parties may be injured.

- ▶ Only persons with the necessary medical qualification and who are acquainted with the application of the product may work with it.
- ▶ Check that the product is suitable for the procedure prior to use.
- ▶ Check the correct configuration of the product after every software update.
- ▶ Check the product for the following properties, for example, before and after every use:
  - Completeness
  - Good working order
  - Correct assembly of the components
  - Functionality
- ▶ Do not continue to use damaged products.
- ▶ Dispose of the product properly.

#### 3.3 Product not clean

The product is not clean when delivered. The use of products that have not been cleaned poses a risk of infection for patients, users, and third parties.

- ▶ Reprocess the product in line with the reprocessing instructions before initial use and every subsequent use.

#### 3.4 Combination with other components

The use of unauthorized devices and components or unauthorized changes to the product can result in injuries.

Additional devices connected to medical electrical equipment must comply with the relevant IEC or ISO standards. Furthermore, all configurations must comply with the requirements for medical electrical systems. If additional devices are connected to medical electrical equipment, a medical system is configured that must satisfy the requirements for medical electrical

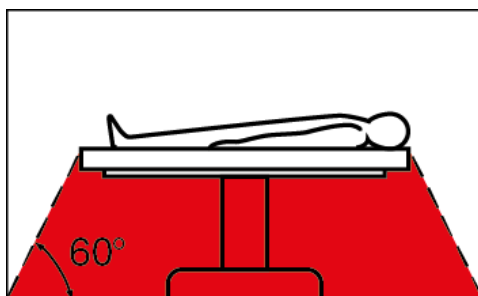
systems. Local regulations take precedence over IEC and ISO standards. If you have any questions, please contact your local KARL STORZ representative or technical customer support.

- ▶ Only combine the product with devices and components that are approved for combined use by the manufacturer.
- ▶ Only use devices and components that have standardized interfaces and do not breach the intended use of the product.
- ▶ Connect only devices that comply with IEC 60601 to signal inputs and signal outputs.
- ▶ Observe the instruction manuals and interface specifications of the devices and components used in combination.
- ▶ Comply with national and local regulations.
- ▶ Only make changes to the product if these changes are approved by KARL STORZ.

### 3.5 Risk of explosion and fire

The product can generate sparks, which cause combustible or flammable gases and liquids to ignite or explode. This may cause injuries to patients, users, and third parties.

- ▶ When using explosive narcotic gases: Operate the product outside of the hazard zone.



- ▶ Do not use the product in the presence of flammable anesthetics.
- ▶ The product must not be operated in oxygenated environments.
- ▶ Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

### 3.6 Dangers from electrical current

An improper power supply may cause an electric shock and injure patients, users, or third parties. All electrical installations of the operating room in which the device is connected and used must meet the applicable IEC standards.

- ▶ Use either the power cord supplied by KARL STORZ or a power cord which has the same properties and which bears a national mark of conformity.
- ▶ The product may only be operated with the line voltage stated on the rating plate.
- ▶ Position the product appropriately so that the power cord can be unplugged at any time. The product is only voltage-free when the mains plug has been disconnected.
- ▶ The product's ground line should be installed by a qualified electrician.
- ▶ Ensure potential equalization according to the applicable national rules and regulations.
- ▶ To ensure reliable protective earth grounding, connect the product to a properly installed socket that is approved for use in the operation room.
- ▶ Connect the product to a power supply with protective conductor.

In the case of electrical products, individual components or the product itself may be live. Live parts can cause electric shocks in the event of contact and injure patients, users, and third parties.

- ▶ Do not open the product.
- ▶ Have servicing carried out by KARL STORZ or a company authorized by KARL STORZ. Failure to do so will void the guarantee.
- ▶ Do not touch the output jacks of the product and the patient at the same time during use
- ▶ Always pull out the mains plug before carrying out any cleaning and maintenance work.

During operations, explosive anesthetic gases are used. If sparks occur, this may trigger explosions.

- ▶ Only connect or disconnect the power plug to or from the power supply outside explosive atmospheres.

### **3.7 Damage due to ingress of liquid in electrical components**

In the case of electrical products, individual components or the product itself may be live. Liquid ingress into an electrical product may result in a short circuit or an unintentional transfer of current. The product is damaged as a result and patients, users and third parties may be injured.

- ▶ Do not store liquids near the product or on the product.
- ▶ If liquid has entered the product, pull out the plug and allow the product to dry completely.

### **3.8 Electromagnetic interference**

Medical electrical products are subject to special precautions regarding electromagnetic compatibility and must be installed and commissioned according to the tables on electromagnetic compatibility. If other products (e.g. for MRT, CT, diathermy, electrocautery, or RFID) emit electromagnetic radiation, the function of the product may be impaired. High-frequency communication equipment can affect electrical medical products and impair their performance.

- ▶ Do not use the product in the vicinity of a magnetic resonance tomograph (MRT).
- ▶ Do not use the product next to or together with other devices. If such use is required, monitor the product and the other devices, and follow the relevant instructions for use in the event of malfunctions.
- ▶ Portable RF communications equipment including peripheral devices (e.g., antenna cables and external antennas) should be used no closer than 30 cm from the product, including cables specified by the manufacturer.
- ▶ Observe the information on electromagnetic compatibility, see chapter *Electromagnetic compatibility* [p. 54].
- ▶ In case of uncertainties, seek expert advice from KARL STORZ.
- ▶ Before use, a clinical/biomedical engineer or an EMC specialist should carry out an ad-hoc test of the electromagnetic radiation.

The use of accessories and cables other than those specified in the instruction manual may result in increased emissions or decreased immunity of the product. When using other accessories and cables, the operator is responsible for checking compliance with IEC 60601-1-2 for this particular product.

- ▶ To prevent increased electromagnetic emissions or reduced electromagnetic immunity of the product, only use accessories, transducers, and cables recommended or supplied by the manufacturer.

### **3.9 Failure of products**

The product may fail during use.

- ▶ Have a replacement product ready for each application or plan for an alternative surgical technique.

### **3.10 Observing ambient conditions**

If the device is stored, transported, operated or reprocessed under unsuitable conditions, patients, users or third parties may be injured and the device can be damaged.

- ▶ Observe the ambient conditions listed in the instructions for use and reprocessing.

### **3.11 Functionality of the touch screen**

If the functionality of the touch screen is limited, the product cannot be used correctly. Patients, users, and third parties may be injured.

- ▶ Do not use the product if the touch screen is defective.
- ▶ Do not tap the touch screen in several places at the same time.

## 4 Product description

### 4.1 Description of operation

The KARL STORZ motor system UNIDRIVE Select is universally applicable in the ENT, NEURO and SPINE application areas due to the use of separate brushless high-performance electronic motors or brushless high-performance electronic motors integrated in the handpiece.

All settings and functions can be controlled via the integrated touch screen. The selectable settings and functions appear as "plain text" on the display. Device information, for example, can be displayed by simply activating the relevant menu field. Troubleshooting in the OR is easier since any faults that may occur, a motor fault for example, are displayed automatically.

Two motors can be connected simultaneously via two connections, e.g. two drill handpieces.

The motor system is characterized by the following features:

- Automatic detection of connected motors
- Infinitely adjustable speed range
- 2 motor outputs
- Preselectable max. speed
- Constant high motor power over the entire speed range
- Processor-controlled speed and motor torque
- Modular coolant and irrigation pump (ENDOMAT SELECT UP220) with homogenous irrigation efficiency over the entire irrigation power range
- Optimized user control via touchscreen
- Easily and clearly readable operating elements with color screen
- Pump can be controlled via footswitch
- 2 footswitch inputs
- Wired and wireless footswitch

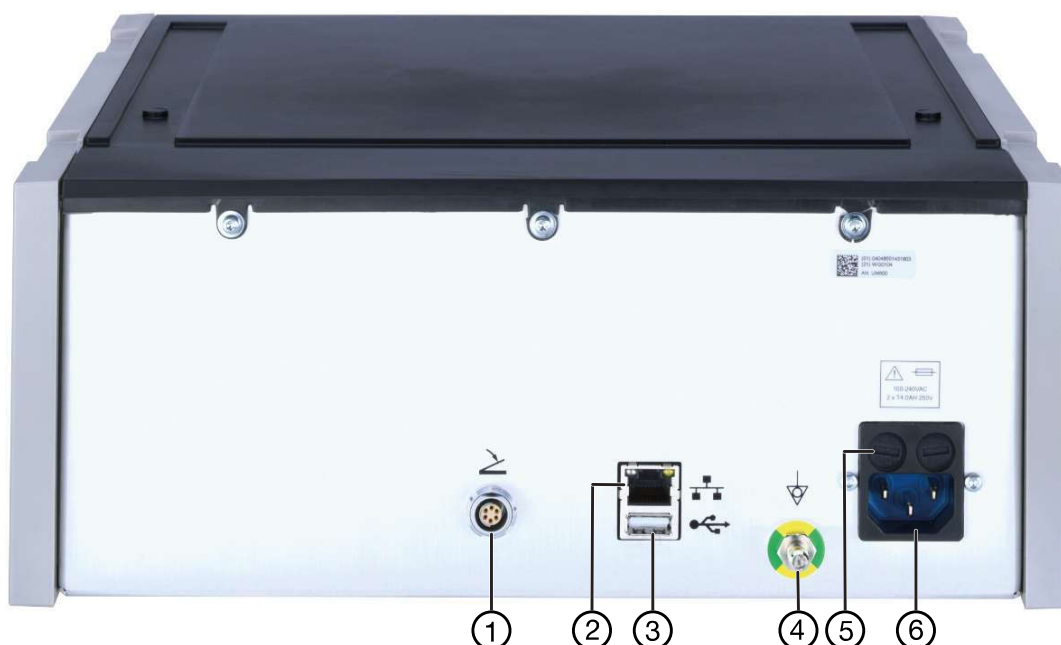
### 4.2 Product overview



UNIDRIVE Select – front view



- |   |                 |   |  |
|---|-----------------|---|--|
| 1 | Standby button  | 3 | Connection sockets for motor and handpiece |
| 2 | TFT touchscreen | 4 | Connection socket for footswitch           |



UNIDRIVE Select – rear view

- |   |   |   |                                  |
|---|---|---|----------------------------------|
| 1 | Connection socket for footswitch                                    | 4 | Potential equalization connector |
| 2 | Ethernet interface (KARL STORZ HIVE) for service and ENDOMAT SELECT | 5 | Line fuse holder                 |
| 3 | USB service interface   | 6 | Power socket                     |

## 4.3 Possible combinations

It is recommended that the suitability of the products for the intended procedure be checked prior to use. Please note that the products listed here may not yet be available in all countries due to differences in approval requirements.

The product can be combined with the following components:

Product name	Item number
Perforator handpiece	362640
High-speed micro motor, small	20363033
High-speed micro motor, large	20362033
INTRA micro motor 80k	20261033
Two-pedal footswitch, one-stage	UF201
Two-pedal footswitch, one-stage, wireless	UF201W
DRILLCUT-X® II spine handpiece	28712050
DrillCut-X II shaver handpiece with shaver blades and sinus burr	40712050, 40712055 412xx, 413xx 413xx

Product name	Item number
DrillCut-X II-35 shaver handpiece with shaver blades and sinus burr	40712035, 40712535 412xx, 413xx 413xx, 41335x
Micro ear burr	460000
ENDOMAT SELECT with patch cable	UP220 WO10275

## 4.4 Technical data

UNIDRIVE Select	
Operating voltage (AC)	100 – 240 V
Operating frequency	50/60 Hz
Mains fuse	2 x T 4.0 AH 250 V, IEC 127 format
Power consumption	200 VA
Electrical protection class	I
Applied part type according to IEC 60601-1	BF
Degree of protection acc. to IEC 60259	IPX1 (protection from dripping water)
Dimensions (L x H x W)	380 x 125 x 305 mm
Weight	4.3 kg
Operating mode (in connection with instrument)	Intermittent duty

INTRA drill handpiece	
Minimum speed	2,000 rpm ( $\pm 10\%$ )
Maximum speed	80,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	80,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

High-Speed Drill 80k	
Minimum speed	2,000 rpm ( $\pm 10\%$ )
Maximum speed	80,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	80,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

<b>High-speed micro motor, large</b>	
Minimum speed	2,000 rpm ( $\pm 10\%$ )
Maximum speed	80,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	80,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

<b>Perforator handpiece</b>	
Minimum speed	200 rpm ( $\pm 10\%$ )
Maximum speed	1,250 rpm ( $\pm 10\%$ )
Start-up maximum speed	1,250 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

<b>Micro ear burr</b>	
Minimum speed	2,000 rpm ( $\pm 10\%$ )
Maximum speed	12,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	12,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

<b>DrillCut-X II – shaver</b>	
Minimum speed	300 rpm ( $\pm 10\%$ )
Maximum speed	7,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	7,000 rpm ( $\pm 10\%$ )
Rotation mode	Oscillation

<b>DrillCut-X II – sinus burr 12k</b>	
Minimum speed	300 rpm ( $\pm 10\%$ )
Maximum speed	12,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	12,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

<b>DrillCut-X II-35 – shaver</b>	
Minimum speed	1,500 rpm ( $\pm 10\%$ )
Maximum speed	10,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	10,000 rpm ( $\pm 10\%$ )
Rotation mode	Oscillation

DrillCut-X II-35 – sinus burr 12k	
Minimum speed	1,500 rpm ( $\pm 10\%$ )
Maximum speed	12,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	12,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation

DrillCut-X II-35 – sinus burr 35k	
Minimum speed	1,500 rpm ( $\pm 10\%$ )
Maximum speed	35,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	35,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation














DrillCut-X II Spine	
Minimum speed	300 rpm ( $\pm 10\%$ )
Maximum speed	12,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	12,000 rpm ( $\pm 10\%$ )
Rotation mode	Rotation




Saws	
Minimum speed	1,000 rpm ( $\pm 10\%$ )
Maximum speed 1	20,000 rpm ( $\pm 10\%$ )
Maximum speed 2	15,000 rpm ( $\pm 10\%$ )
Start-up maximum speed 1	20,000 rpm ( $\pm 10\%$ )
Start-up maximum speed 2	15,000 rpm ( $\pm 10\%$ )
Rotation mode	Oscillation

Dermatomes	
Minimum speed	1,000 rpm ( $\pm 10\%$ )
Maximum speed	8,000 rpm ( $\pm 10\%$ )
Start-up maximum speed	8,000 rpm ( $\pm 10\%$ )
Rotation mode	Oscillation






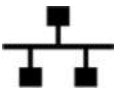



## 4.5 Symbols employed

### 4.5.1 Symbols on the packaging



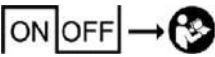



Symbol	Meaning
	Manufacturer
	Date of manufacture
	Medical device
	Article no.
	Serial number
	Number of products in the product packaging
	Unique Device Identifier
	Consult the printed or electronic instructions for use
	Note for the user to consult the instructions for use for important cautionary information such as warnings and precautions.
	Fragile, handle with care
	Keep dry
	Temperature limit
	Humidity limit

Symbol	Meaning
	Air pressure limit
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body.  The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.







#### 4.5.2 Symbols on the product







Symbol	Meaning
	Follow the instructions for use. The color may differ on the product. The symbol is black/white on the packaging label.
	Ready/standby button
	Applied part type BF
	Connection socket, e.g., for footswitch
	Potential equalization connector
	Ethernet
	USB
	Dangerous voltage Danger of an electric shock!
	Fuse

### 4.5.3 Symbols on the type plate

Symbol	Meaning
	Manufacturer
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	Periodic intermittent operation, see instructions for use
	Prevention of pollution by electronic devices
	Separate collection of electrical and electronic devices. Do not dispose of in household refuse.
	CE marking With this marking, the manufacturer declares the conformity of the product with the applicable EU directives. A code number after the CE mark indicates the responsible notified body.  The EU directives relevant to the product can be found in the EU Declaration of Conformity, which can be requested from KARL STORZ.

### 4.5.4 Symbols on the user interface

Symbol	Meaning
	Forward mode
	Reverse mode
	Oscillation
	Footswitch
	Settings
	Cancel

Symbol	Meaning
	Confirm
	Browse back
	Browse up
	Browse down
	Increase value
	Decrease value

## 4.6 Ambient conditions

Storage and transport conditions	
Temperature	-15 °C ... +60 °C (5 °F ... 140°F)
Relative humidity (non-condensing)	5 – 85 %
Air pressure	600 – 1,080 hPa
Average life cycle	5 years

Conditions of use	
Temperature	10 °C ... 40 °C (50 °F...104 °F)
Relative humidity	30 – 75 %
Air pressure	700 – 1,080 hPa
Max. operating altitude	3,000 m



## 5 Preparation

### 5.1 Unpacking the product

1. Carefully remove the product and accessories from the packaging.
2. Check the delivery for missing items and any possible damage.
3. In the case of damage, hidden defects, and short deliveries, document their nature and extent and contact the manufacturer or supplier immediately.
4. Keep packaging for further transport.

### 5.2 Setting up the product

#### **⚠ WARNING**

##### **Overheating! Risk of fire!**

Insufficient ventilation can cause an internal build-up of heat, resulting in a safety shut-down. If the product overheats, there is a risk of fire. Patients, users, and third parties may be injured.

- ▶ Ensure that there is sufficient air circulation.
- ▶ Keep air inlets and outlets free.

#### **⚠ CAUTION**

##### **Breakable glass! Risk of injury!**

The glass of the screen will break if the product is dropped or sustains a significant impact. Patients, users or third parties can injure themselves on broken glass.

- ▶ Do not touch broken glass.
- ▶ Do not touch the glass parts of the product.
- ▶ Remove small glass parts from the product.
- ▶ Have the glass replaced by qualified service personnel.

This product and connected components may only be used in medical rooms with electrical installations that conform to applicable national regulations.

1. Set the product down on a horizontal, flat surface or a video cart.
2. Install the product out of reach of patients.

### 5.3 Connecting the product

1. Connect the potential equipotential cable.



2. Connect the power cord. Push the power plug fully into the power socket.



⇒ The standby button lights up white.

3. Connect the Ethernet cable for combination with ENDOMAT SELECT (UP220).



4. Connect the footswitch cable to the front or rear of the device. To do this, align the red dot on the cable with the red dot on the footswitch socket.



5. Connect the application instrument cables to the motor outputs. To do this, align the red dot on the cable with the red dot on the relevant socket.



6. To avoid damaging the cables, pull on the plug when removing the cables.

## 5.4 Putting the product into operation

- ✓ The footswitch is connected.
- ✓ An application instrument is connected.
- ✓ The ENDOMAT SELECT (UP220) is connected.

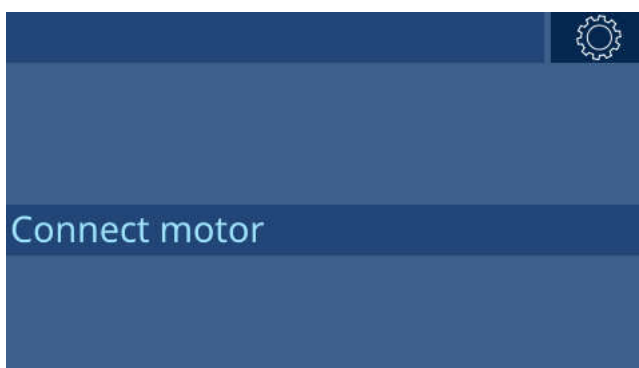
1. Press the standby button to switch the device to ready mode.



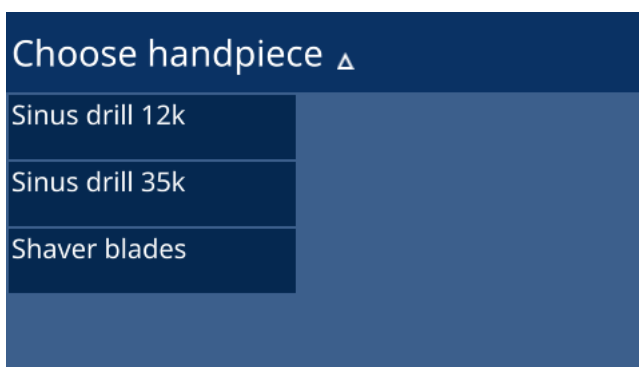
- ⇒ The standby button lights up green; after 40 to 50 seconds a signal sounds and the following start screen appears:



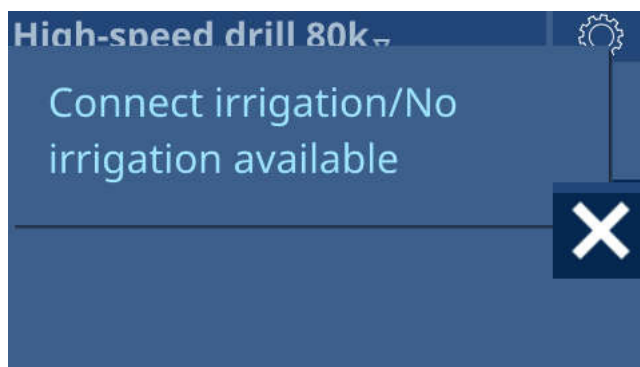
- ⇒ If no application instrument or motor is connected, the following start screen appears:



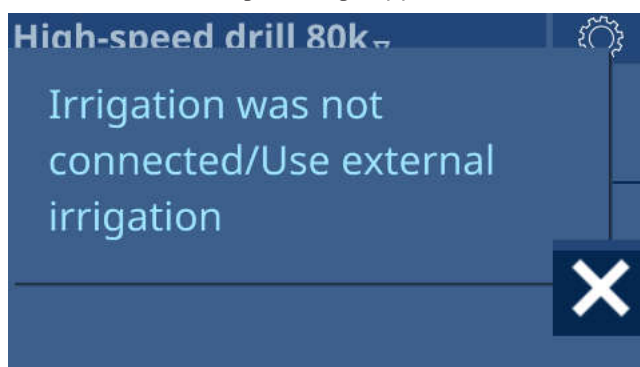
- ⇒ If an application instrument/motor is connected, a screen appears prompting you to select the handpiece. For the DrillCut-X II-35, for example, this appears:



2. Tap the **Arrow** to expand the handpiece selection.
3. Select the desired handpiece.  
⇒ The following message appears:



4. Put the ENDOMAT SELECT (UP220) into operation, see chapter *Putting the pump into operation* [p. 25].
5. Tap the **Arrow** symbol again to collapse the handpiece selection.  
⇒ The selected handpiece appears as a presetting when the handpiece selection is expanded again.
6. If a KARL STORZ pump is not being used, close the message.  
⇒ The following message appears:



7. Put the pump used into operation.
8. Change the language, see chapter *Setting the language* [p. 37].

## 5.5 Putting the pump into operation

### **⚠ WARNING**

#### **Non-sterile product! Risk of infection!**

Cartridges and tubes are not supplied sterile. The use of non-sterile products poses a risk of infection for patients, users, and third parties.

- ▶ Inspect the product for visible contamination before use.
- ▶ Reprocess the product before initial use and before and after all subsequent applications. Use validated methods.
- ▶ Do not use contaminated products.

**⚠ WARNING****Disposable products! Risk of infection!**

The reprocessing of disposable products can lead to infections in patients, users and third parties as well as damage to the product.

- ▶ Never reprocess disposable products.
- ▶ Dispose of disposable products in accordance with the applicable regulations.

**⚠ WARNING****Expiry date passed! Risk of infection!**

- ▶ Check the expiry date.
- ▶ Check the packaging for damage.
- ▶ Never use products that have passed the expired expiry date or have damaged or accidentally opened packaging but dispose of them properly.

- ✓ The UNIDRIVE SELECT is switched on and connected to the ENDOMAT SELECT (UP220).

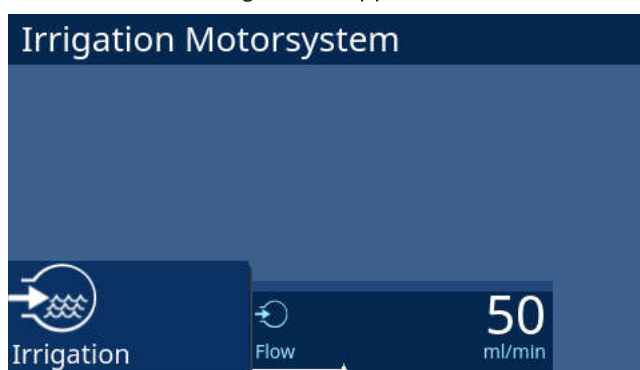
1. Install the tubing set on the ENDOMAT SELECT (UP220). Make sure that the pump tubes are not crushed.



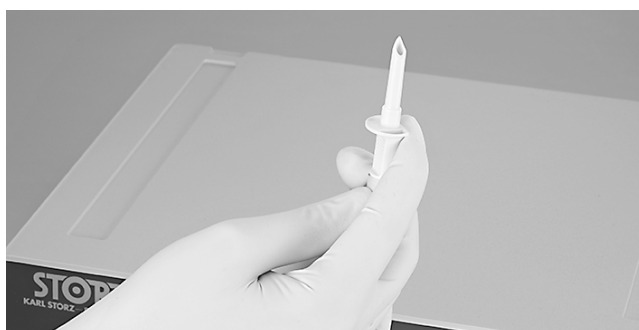
2. Turn the pump lever of the tubing set counterclockwise.



⇒ The following screen appears on the ENDOMAT SELECT:



3. Connect the tubing ends with the irrigation bag (puncture needle) or with the irrigation connector on the instrument (LUER lock).



4. To remove the tubing set, turn the pump lever clockwise to the 9 o'clock position.

## 6 Application

### 6.1 Selecting the handpiece

In the following, selected examples are used to illustrate how handpieces are selected. Other handpieces can be chosen accordingly.

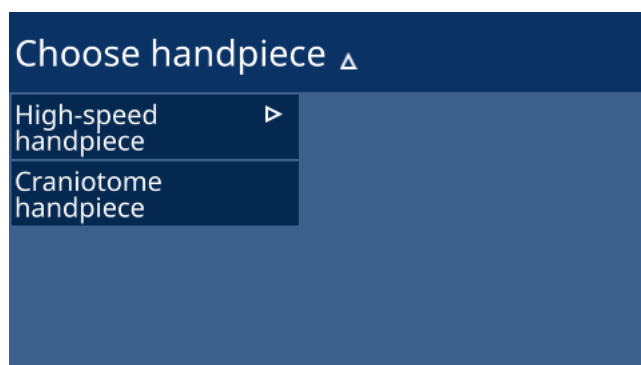
#### 6.1.1 High-speed micro motor

1. Connect the motor, see chapter *Connecting the product* [p. 21].

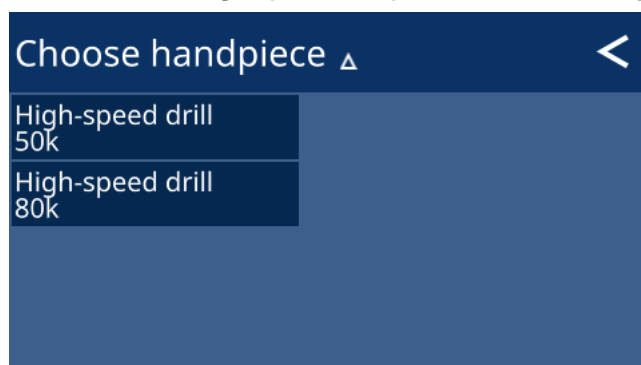
⇒ The following screen appears:



2. Tap on the **Arrow** to expand the handpiece selection.



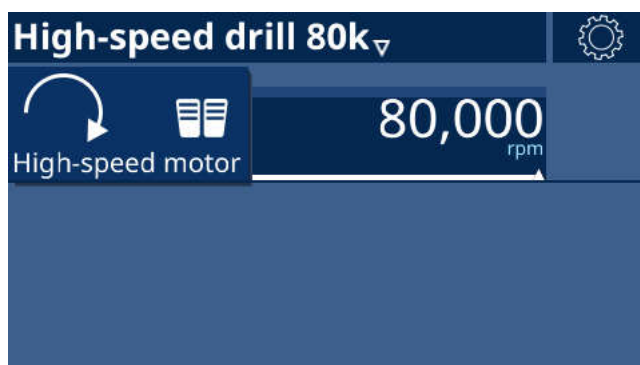
3. Select the **High-speed handpiece** to call up the high-speed burr selection.





4. Select the desired burr, e.g. **High-speed burr 80 k**.

⇒ The following screen appears:



5. Set the speed, see chapter *Setting the speed* [p. 33].

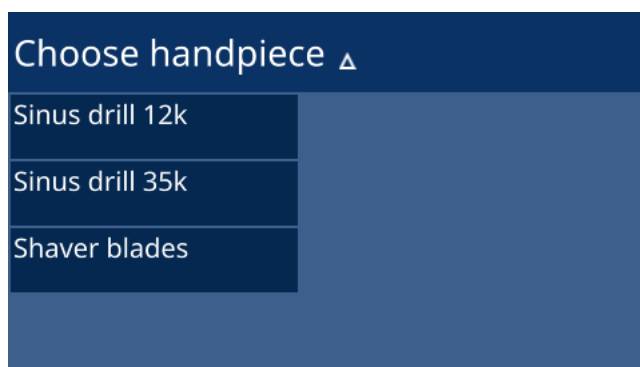
### 6.1.2 DrillCut-X II-35

1. Connect the motor, see chapter *Connecting the product* [p. 21].

⇒ The following screen appears:

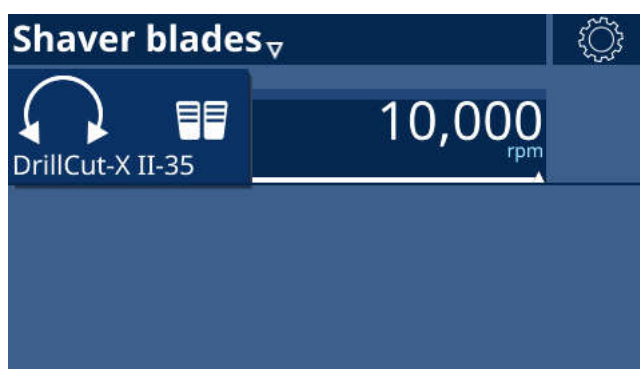


2. Tap on the **Arrow** to expand the handpiece selection.



3. Select the desired handpiece.

⇒ The following screens appear:

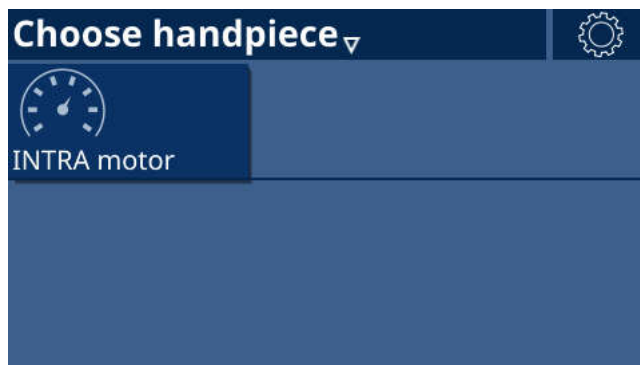


4. Set the speed, see chapter *Setting the speed* [p. 33].

### 6.1.3 INTRA motor

1. Connect the motor, see chapter *Connecting the product* [p. 21].

⇒ The following screen appears:



2. Tap on the **Arrow** to expand the handpiece selection.

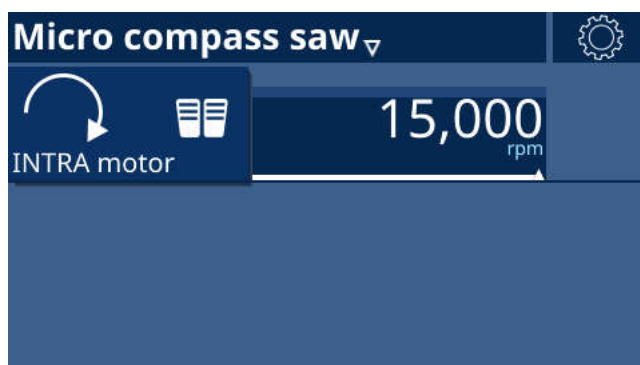


3. Select the **Micro saws** to call up the saw selection.



4. Select the desired saw, e.g. **Micro compass saw**.

⇒ The following screen appears:

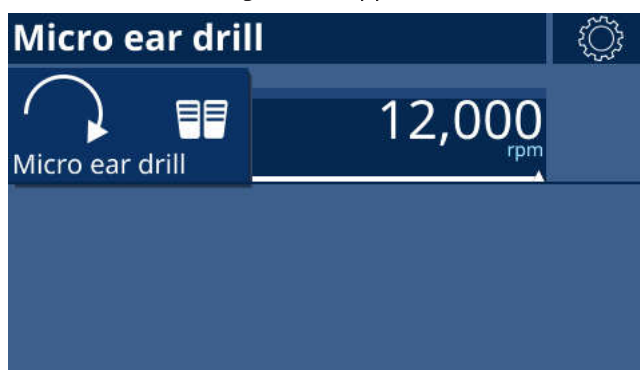


5. Set the speed, see chapter *Setting the speed* [p. 33].

#### 6.1.4 Micro ear burr

1. Connect the motor, see chapter *Connecting the product* [p. 21].

⇒ The following screen appears:

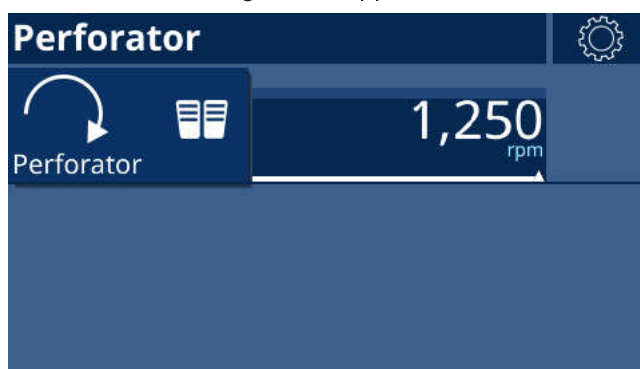


2. Set the speed, see chapter *Setting the speed* [p. 33].

#### 6.1.5 Perforator

1. Connect the motor, see chapter *Connecting the product* [p. 21].

⇒ The following screen appears:

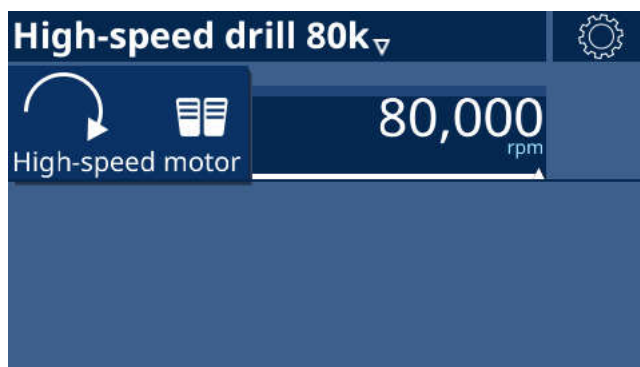


2. Set the speed, see chapter *Setting the speed* [p. 33].

## 6.2 Setting the speed

1. Select the handpiece, e.g., **High-speed burr 80k**, see chapter *Selecting the handpiece* [p. 28].

⇒ The handpiece screen appears with the maximum speed value:



2. Tap the speed value.

⇒ The **Minus** button appears:



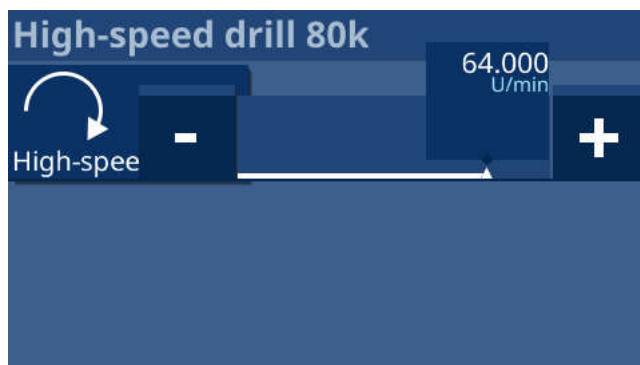
3. Tap the **Minus** button to reduce the speed value.

⇒ The **Plus** button appears:



4. Set the desired speed value using the buttons.

- Alternatively, hold the speed value down and use the slider to set the speed value.

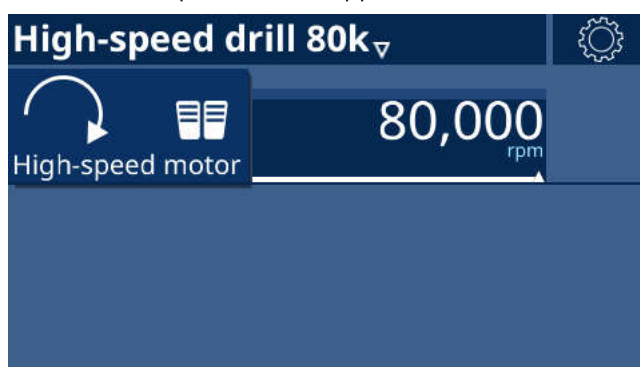


- Release the slider.  
⇒ The set speed value appears on the screen after a few seconds.



## 6.3 Changing the direction of rotation

- Select the handpiece, e.g. **High-speed burr 80k**, see chapter *Selecting the handpiece* [p. 28].
- The handpiece screen appears:

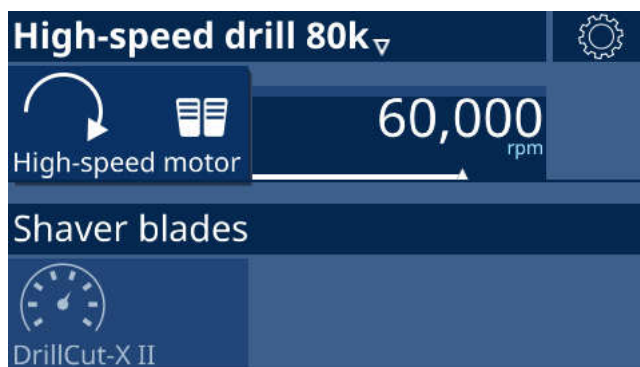


- Tap on the **Forward** button to change the direction of rotation.
- Alternatively, press the footswitch button briefly, see chapter *Operating the footswitch* [p. 36].

## 6.4 Selecting the motor connection

Two application instruments operated within various speed ranges can be connected up to the device. You can switch between the motor connections during application.

1. Two connecting application instruments, see chapter *Connecting the product* [p. 21].
2. Select the first handpiece, e.g. **High-speed burr 80k**, see chapter *Selecting the handpiece* [p. 28].
  - ⇒ The speed setting of the selected handpiece appears. The second handpiece is shown below.



3. Tap on the button of the second handpiece.
  - ⇒ The second motor connection is active.
  - ⇒ The speed setting of the second handpiece appears.
4. Alternatively, press the button on the footswitch for longer than 2 seconds to switch between the two motor connectors, see chapter *Operating the footswitch* [p. 36].

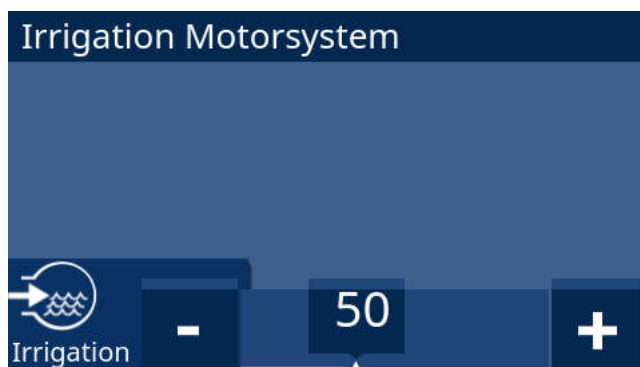
## 6.5 Setting the irrigation flow

### ⚠ WARNING

#### Insufficient irrigation! Risk of injury!

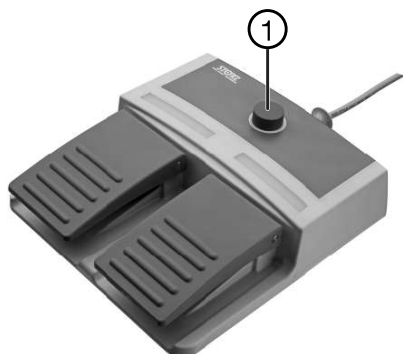
When rotary instruments are used, the instruments may smear, clog or move erratically if not irrigated sufficiently. As a result, increased heat may be generated, causing injury to patients, users or third parties.

- ▶ Please ensure sufficient irrigation.
  - ✓ The pump has been connected and put into operation.
1. Tap on the irrigation flow value on the ENDOMAT SELECT screen.
    - ⇒ The value appears as a slide bar:



2. Move the slide bar to set the desired value.
3. Alternatively, set the irrigation flow using the footswitch, see chapter *Operating the footswitch* [p. 36].

## 6.6 Operating the footswitch



*Two-pedal footswitch, wired*



*Two-pedal footswitch, wireless*

1. Press the left pedal for longer than 2 seconds.  
⇒ The irrigation flow starts with the preset value.
2. Release the left pedal.  
⇒ The irrigation flow stops.
3. Press the left pedal briefly.  
⇒ The irrigation flow is either increased or reduced, depending on the setting see chapter *Setting the pedal control* [p. 39].
4. Press the right pedal.  
⇒ This speed varies depending on the pedal position.  
⇒ The handpiece is started and the pump runs with the defined irrigation flow rate.

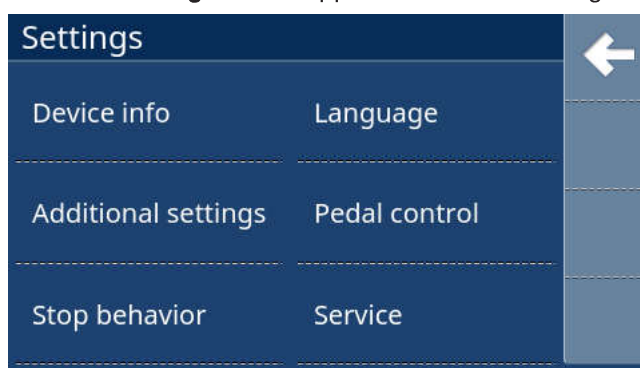




5. To switch between shaver and sinus burr mode during a DrillCut, press the left and right pedals simultaneously.
6. To change the rotation direction of a burr, press the button (1) briefly.
7. Press the button (1) for longer than 2 seconds to switch between the two motor connections.

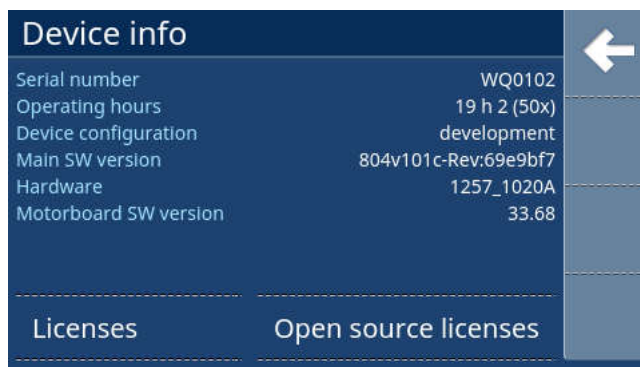
## 6.7 Settings

1. Tap on the **Settings** button on the top right of the touchscreen.  
⇒ The **Settings** screen appears with the following sub-menus:



### 6.7.1 Device information

1. In the **Settings** screen, tap on the **Device info** sub-menu.  
⇒ The **Device info** screen appears:

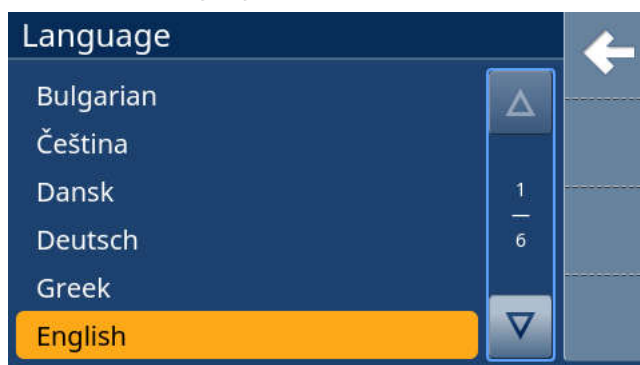


2. Browse back through the screen with the **Arrow**.  
⇒ The **Settings** screen appears.

### 6.7.2 Setting the language

The language is set to English as the default.

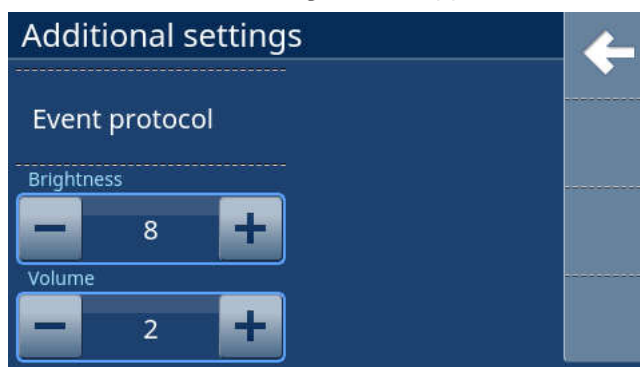
1. In the **Settings** screen, tap on the **Language** sub-menu.  
⇒ The **Language** screen appears:



2. Tap on the language you want to use.  
⇒ The language is saved.
3. Browse back through the screen with the **Arrow**.  
⇒ The **Settings** screen appears.

### 6.7.3 Setting the brightness and volume

1. In the **Settings** screen, tap on the Further settings sub-menu.  
⇒ The **Further settings** screen appears:

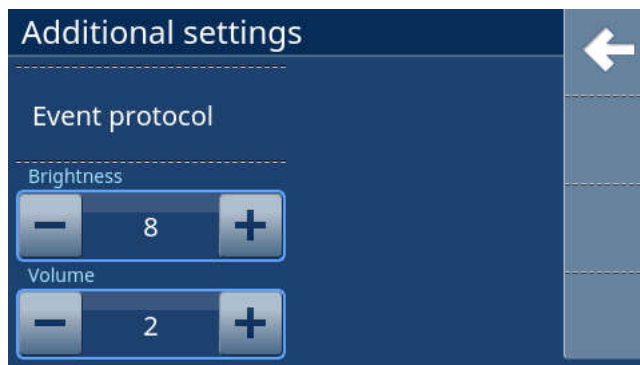


2. Adjust the **Brightness** and the **Volume** with the **Plus** and **Minus** buttons.
3. Browse back through the screen with the **Arrow**.  
⇒ The **Settings** screen appears.

### 6.7.4 Calling up the event log

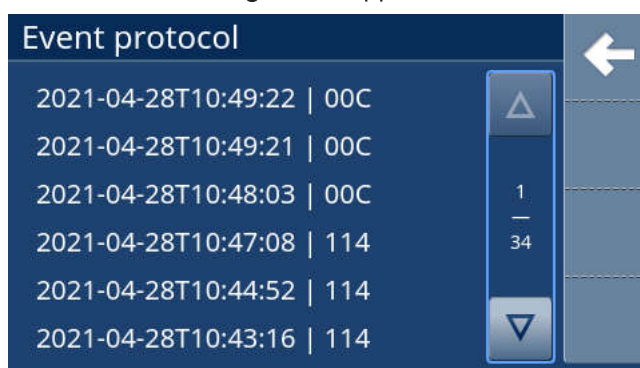
1. In the **Setting** screen, tap on the **Further settings** sub-menu.

⇒ The **Further settings** screen appears:

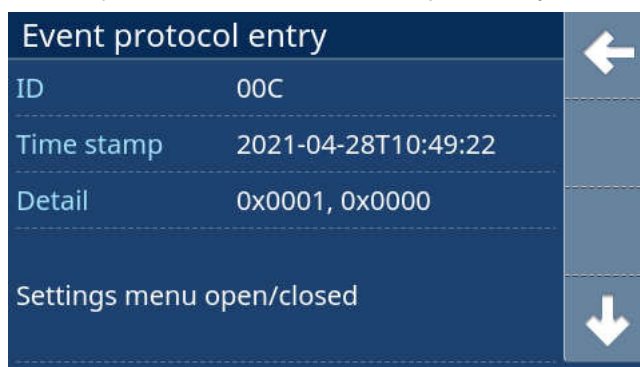


2. Tap on the **Event log** sub-menu.

⇒ The **Event log** screen appears:



3. Tap on the desired line to call up the entry on the event.



### 6.7.5 Setting the pedal control

The pedal control determines how the set irrigation flow behaves when the left pedal is pressed briefly.

1. In the **Settings** screen, tap on the **Pedal control** sub-menu.

⇒ The **Pedal control** screen appears:



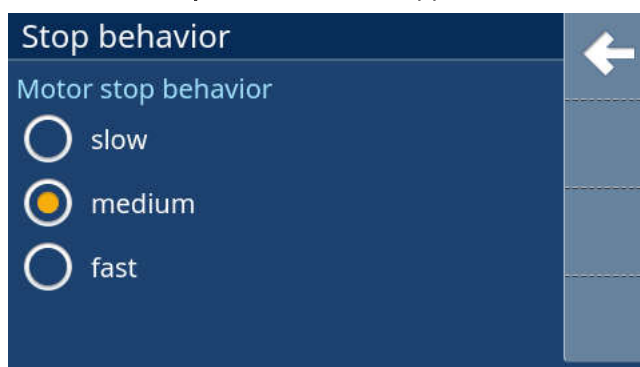
2. Set the pedal control as follows:

- **Up:** The value is increased by 10 ml/min up to the maximum value and starts again with the lowest setting 10 ml/min.
- **Down:** The value is reduced by 10 ml/min down to the lowest value and starts again with the highest setting.

### 6.7.6 Setting the motor stop behavior

1. In the **Settings** screen, tap on the **Stop behavior** sub-menu.

⇒ The **Stop behavior** screen appears:



2. Set the stop behavior of the motor.
  3. Browse back through the screen with the **Arrow**.
- ⇒ The **Settings** screen appears.

### 6.7.7 Service

The Service area is password-protected and can only be accessed by the KARL STORZ technical customer service or authorized persons.

## 6.8 Switching off the product

1. Switch off the product with the stand-by button.



## 7 Maintenance, servicing, repairs, and disposal

### 7.1 Maintaining the product

If they are not described in more detail here, maintenance activities may only be performed by KARL STORZ or by a company authorized by KARL STORZ.

#### 7.1.1 Maintenance

The following maintenance intervals are recommended:

Interval	Activity	To be performed by
annually	Safety test	KARL STORZ service technicians

### 7.2 Changing a fuse

#### **⚠ WARNING**

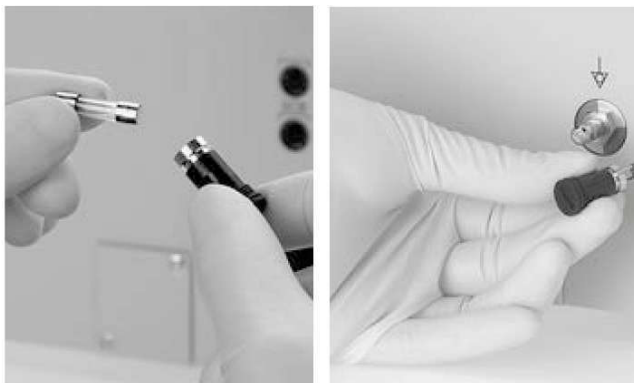
**Undesired current flow! Risk of injury!**

Live parts of the equipment can cause severe injuries due to electric shock.

- ▶ Do not open the housing.
  - ▶ Make sure that the connection to the power supply is disconnected.
  - ▶ Request a KARL STORZ service technician for service work.
- ✓ The product is switched off.
  - ✓ The power cord is disconnected from the product.
1. Remove the screw inserts on the power fuse holder with a screwdriver.



2. Remove the defective fuse.



3. Insert the new fuse. Only use fuses with the same fuse ratings, see chapter *Technical data* [p. 14].
4. Introduce the screw inserts into the power fuse holder again.
5. Connect the power supply again.



6. Switch on the product and check that it is working correctly.



## 7.3 Safety inspection in accordance with IEC 62353

### **⚠ WARNING**

#### **Risk of injury due to product deficiencies!**

Patients, users, and third parties may be injured as a result of deficiencies with the product and accessories.

- ▶ Shut down the product.
- ▶ Have the deficiencies repaired by persons authorized by KARL STORZ.

Regardless of the national accident prevention regulations and testing intervals for medical devices, for this device safety checks must be performed as repeat inspections according to IEC 62353 and recorded by a qualified electrician at least once a year. Detailed specifications regarding the scope and execution of the safety inspection can be found in the service manual.

### 7.3.1 Visual inspection

1. Check the product and accessories for any mechanical damage.
2. Check labels for readability.

### 7.3.2 Electric measurements

**i** Limit values for electrical measurements can be found in the current IEC 62353.

1. Measure the protective ground resistance.
2. Measure the earth leakage current.
3. Measure the touch current.
4. Measure the patient leakage current.

### 7.3.3 Functional test

- ▶ Check the following components:
  - Power switch
  - Handpiece
  - Pump
- ▶ Check the following functions:
  - Footswitch detection
  - Handpiece detection
  - Change in the direction of rotation
  - Reading out of system information
- ▶ Document the results of the safety test.

## 7.4 Repairing the product

Repair work may only be performed by KARL STORZ or by a company authorized by KARL STORZ. The interventions described in this instruction manual are exempt from this rule.

- ▶ Please contact your local KARL STORZ subsidiary or authorized dealer (see the list of subsidiaries).

Contaminated devices may not be shipped. To prevent contact infections and airborne infections, products must first be decontaminated. KARL STORZ reserves the right to send back contaminated products.



## **7.5 Disposing of the product**

The product meets the requirements of the Directive on Waste Electrical and Electronic Equipment (WEEE).

Within the scope of application of this directive, KARL STORZ SE & Co. KG is responsible for the proper disposal of this product.

1. The product must be disposed of in accordance with the applicable national laws and regulations at a suitable collection point for the reprocessing of electrical and electronic equipment.
2. Contact KARL STORZ SE & Co. KG, a KARL STORZ branch or an authorized dealer to find out the address of the collection point in your area.

## 8 Accessories and spare parts

### 8.1 Accessories

#### Cable

Item	Order no.
Power cord, length 300 cm	400A
Power cord, US version, 200 cm	400B
Potential equipotential cable, 10 m	20010170
Potential equipotential cable, 5 m	20010270
Potential equalization cable, 200 cm	20010370
Potential equalization cable, 150 cm	20010570
Potential equipotential cable, 1 m	20010670
Ethernet cable, (OR1) patch cable, CAT6a, length 2.0 m, UL-listed	WO10275

#### Footswitch

Article	Order no.
Two-pedal footswitch, one-stage	UF201
Two-pedal footswitch, one-stage, wireless, comprising: footswitch, receiver, power supply unit	UF201W

#### Motors

Article	Order no.
Perforator handpiece	362640
Micro ear burr, 12,000 rpm	460000
INTRA micro motor 80k	20261033
High-speed micro motor, large	20362033
High-speed micro motor, small	20363033
DrillCut-X II-35	40712035
DrillCut-X II-35 N	40712535
DrillCut-X II	40712050
DrillCut-X II N	40712055

**Craniotome attachments in connection with high-speed handpiece (362645)**

Article	Order no.
Craniotome attachment, short, for use with KARL STORZ high-speed handpiece 362645	362646
Craniotome attachment, medium, for use with KARL STORZ high-speed handpiece 362645	362647
Craniotome attachment, long, for use with KARL STORZ high-speed handpiece 362645	362648

**High-speed handpieces in connection with high-speed micro motors (20362033, 20363033)**

Article	Order no.
High-speed handpiece, 70 mm, angled, 80,000 rpm	362681
High-speed handpiece, 95 mm, angled, 80,000 rpm	362682
High-speed handpiece, 125 mm, angled, 80,000 rpm	362683
High-speed handpiece, 150 mm, angled, 80,000 rpm,	362684
High-speed handpiece, 70 mm, angled, 80,000 rpm, with integrated irrigation	362680
High-speed handpiece, 70 mm, straight, 80,000 rpm, with integrated irrigation	362645
High-speed handpiece, super long, 80,000 rpm	362685

**INTRA handpieces in connection with INTRA micro motor 80k (20261033)**

Article	Order no.
INTRA drill handpiece, angled 80,000 rpm, length 70 mm	262570
INTRA drill handpiece, angled, 80,000 rpm, length 125 mm	262572
INTRA drill handpiece, straight, 80,000 rpm, length 70 mm	262571

**High-speed burr, in connection with high-speed handpieces (362680, 362681, 362645)**

Article	Order no.
High-speed diamond burr, Ø 0.6 mm, 70 mm, 50,000 rpm	340206
High-speed diamond burr, Ø 0.8 mm, 70 mm, 50,000 rpm	340208
High-speed diamond burr, Ø 1.0 mm, 70 mm, 50,000 rpm	340210
High-speed diamond burr, Ø 1.4 mm, 70 mm, 50,000 rpm	340214
High-speed diamond burr, Ø 1.8 mm, 70 mm, 50,000 rpm	340218
High-speed diamond burr, Ø 2.3 mm, 70 mm, 50,000 rpm	340223
High-speed diamond burr, Ø 2.7 mm, 70 mm, 50,000 rpm	340227
High-speed diamond burr, Ø 3.1 mm, 70 mm, 50,000 rpm	340231

Article	Order no.
High-speed diamond burr, Ø 3.5 mm, 70 mm, 50,000 rpm	340235
High-speed diamond burr, Ø 4.0 mm, 70 mm, 50,000 rpm	340240
High-speed diamond burr, Ø 5.0 mm, 70 mm, 50,000 rpm	340250
Tungsten carbide burr, Ø 0.5 mm, 70 mm, 50,000 rpm	340805
Tungsten carbide burr, Ø 0.8 mm, 70 mm, 50,000 rpm	340808
Tungsten carbide burr, Ø 1.0 mm, 70 mm, 50,000 rpm	340810
Tungsten carbide burr, Ø 1.4 mm, 70 mm, 50,000 rpm	340814
Tungsten carbide burr, Ø 1.8 mm, 70 mm, 50,000 rpm	340818
Tungsten carbide burr, Ø 2.3 mm, 70 mm, 50,000 rpm	340823
Tungsten carbide burr, Ø 2.7 mm, 70 mm, 50,000 rpm	340827
Tungsten carbide burr, Ø 3.1 mm, 70 mm, 50,000 rpm	340831
Tungsten carbide burr, Ø 3.5 mm, 70 mm, 50,000 rpm	340835
Tungsten carbide burr, Ø 4.0 mm, 70 mm, 50,000 rpm	340840
Tungsten carbide burr, Ø 5.0 mm, 70 mm, 50,000 rpm	340850
Tungsten carbide burr, Ø 6.0 mm, 70 mm, 50,000 rpm	340860
Tungsten carbide burr, Ø 7.0 mm, 70 mm, 50,000 rpm	340870
High-speed standard burr, Ø 0.8 mm, 70 mm, 50,000 rpm	340108
High-speed standard burr, Ø 1.0 mm, 70 mm, 50,000 rpm	340110
High-speed standard burr, Ø 1.4 mm, 70 mm, 50,000 rpm	340114
High-speed standard burr, Ø 1.8 mm, 70 mm, 50,000 rpm	340118
High-speed standard burr, Ø 2.3 mm, 70 mm, 50,000 rpm	340123
High-speed standard burr, Ø 2.7 mm, 70 mm, 50,000 rpm	340127
High-speed standard burr, Ø 3.1 mm, 70 mm, 50,000 rpm	340131
High-speed standard burr, Ø 3.5 mm, 70 mm, 50,000 rpm	340135
High-speed standard burr, Ø 4.0 mm, 70 mm, 50,000 rpm	340140
High-speed standard burr, Ø 5.0 mm, 70 mm, 50,000 rpm	340150
High-speed standard burr, Ø 6.0 mm, 70 mm, 50,000 rpm	340160
High-speed standard burr, Ø 7.0 mm, 70 mm, 50,000 rpm	340170
High-speed diamond burr, rough, Ø 2.3 mm, 70 mm, 50,000 rpm	340323
High-speed diamond burr, rough, Ø 2.7 mm, 70 mm, 50,000 rpm	340327
High-speed diamond burr, rough, Ø 3.1 mm, 70 mm, 50,000 rpm	340331
High-speed diamond burr, rough, Ø 3.5 mm, 70 mm, 50,000 rpm	340335
High-speed diamond burr, rough, Ø 4.0 mm, 70 mm, 50,000 rpm	340340
High-speed diamond burr, rough, Ø 5.0 mm, 70 mm, 50,000 rpm	340350
High-speed diamond burr, rough, Ø 6.0 mm, 70 mm, 50,000 rpm	340360

**High-speed burr, in connection with high-speed handpieces (362680, 362681, 362645)**

Article	Order no.
High-speed diamond burr, Ø 1.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360210ES
High-speed diamond burr, Ø 2.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360220ES
High-speed diamond burr, Ø 2.5 mm, 70 mm, 80,000 rpm, single-use product, sterile	360225ES
High-speed diamond burr, Ø 3.1 mm, 70 mm, 80,000 rpm, single-use product, sterile	360231ES
High-speed diamond burr, Ø 4.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360240ES
High-speed diamond burr, Ø 5.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360250ES
High-speed diamond burr, rough, Ø 2.3 mm, 70 mm, 80,000 rpm, single-use product, sterile	360323ES
High-speed diamond burr, rough, Ø 3.1 mm, 70 mm, 80,000 rpm, single-use product, sterile	360331ES
High-speed diamond burr, rough, Ø 4.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360340ES
High-speed standard burr, Ø 2.3 mm, 70 mm, 80,000 rpm, single-use product, sterile	360123ES
High-speed standard burr, Ø 3.1 mm, 70 mm, 80,000 rpm, single-use product, sterile	360131ES
High-speed standard burr, Ø 4.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360140ES
High-speed standard burr, Ø 5.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360150ES
High-speed standard burr, Ø 6.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360160ES
High-speed standard burr, Ø 7.0 mm, 70 mm, 80,000 rpm, single-use product, sterile	360170ES

**High-speed burr, in connection with high-speed handpiece (362682)**

Article	Order no.
High-speed diamond burr, Ø 1.0 mm, 95 mm, 80,000 rpm, single-use product, sterile	360210S
High-speed diamond burr, Ø 2.3 mm, 95 mm, 80,000 rpm, single-use product, sterile	360223S
High-speed diamond burr, Ø 3.1 mm, 95 mm, 80,000 rpm, single-use product, sterile	360231S
High-speed diamond burr, rough, Ø 4.0 mm, 95 mm, 80,000 rpm, single-use product, sterile	360340S
High-speed diamond burr, rough, Ø 5.0 mm, 95 mm, 80,000 rpm, single-use product, sterile	360350S

Article	Order no.
High-speed standard burr, Ø 2.3 mm, 95 mm, 80,000 rpm, single-use product, sterile	360123S
High-speed standard burr, Ø 3.1 mm, 95 mm, 80,000 rpm, single-use product, sterile	360131S
High-speed standard burr, Ø 4.0 mm, 95 mm, 80,000 rpm, single-use product, sterile	360140S
High-speed standard burr, Ø 5.0 mm, 95 mm, 80,000 rpm, single-use product, sterile	360150S

**High-speed burr, in connection with high-speed handpiece (362683)**

Article	Order no.
High-speed standard burr, Ø 2.3 mm, 125 mm, 80,000 rpm, single-use product, sterile	360123M
High-speed standard burr, Ø 3.1 mm, 125 mm, 80,000 rpm, single-use product, sterile	360131M
High-speed standard burr, Ø 4.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360140M
High-speed standard burr, Ø 5.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360150M
High-speed standard burr, Ø 6.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360160M
High-speed diamond burr, Ø 1.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360210M
High-speed diamond burr, Ø 2.3 mm, 125 mm, 80,000 rpm, single-use product, sterile	360223M
High-speed diamond burr, Ø 3.1 mm, 125 mm, 80,000 rpm, single-use product, sterile	360231M
High-speed diamond burr, Ø 4.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360240M
High-speed diamond burr, rough, Ø 3.1 mm, 125 mm, 80,000 rpm, single-use product, sterile	360331M
High-speed diamond burr, rough, Ø 4.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360340M
High-speed diamond burr, rough, Ø 5.0 mm, 125 mm, 80,000 rpm, single-use product, sterile	360350M
High-speed diamond burr, extra rough, Ø 4.7 mm, 125 mm, 80,000 rpm, single-use product, sterile	360347M

**High-speed burr, in connection with high-speed handpiece (362684)**

Article	Order no.
High-speed diamond burr, Ø 1.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360210L
High-speed diamond burr, Ø 1.8 mm, 150 mm, 80,000 rpm, single-use product, sterile	360218L
High-speed diamond burr, Ø 3.1 mm, 150 mm, 80,000 rpm, single-use product, sterile	360231L
High-speed diamond burr, Ø 4.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360240L
High-speed diamond burr, rough, Ø 3.1 mm, 150 mm, 80,000 rpm, single-use product, sterile	360331L
High-speed diamond burr, rough, Ø 4.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360340L
High-speed diamond burr, rough, Ø 5.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360350L
High-speed standard burr, Ø 3.1 mm, 150 mm, 80,000 rpm, single-use product, sterile	360131L
High-speed standard burr, Ø 4.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360140L
High-speed standard burr, Ø 5.0 mm, 150 mm, 80,000 rpm, single-use product, sterile	360150L

**Craniotome burr, in connection with high-speed handpiece (362645) and craniotome attachments**

Article	Order no.
High-speed craniotome burr, short, 10 mm, 80,000 rpm, single-use product, sterile, in combination with craniotome attachment (362646)	362640S
High-speed craniotome burr, medium, 15 mm, 80,000 rpm, single-use product, sterile, in combination with craniotome attachment (362647)	362640M
High-speed craniotome burr, long, 25 mm, 80,000 rpm, single-use product, sterile, in combination with craniotome attachment (362648)	362640L

**Micro ear burr in combination with micro ear burr (460000)**

Article	Order no.
Tungsten carbide micro ear burr, Ø 0.5 mm, reusable, sterile, 12,000 rpm	460805
Tungsten carbide micro ear burr, Ø 0.6 mm, reusable, sterile, 12,000 rpm	460806
Tungsten carbide micro ear burr, Ø 0.7 mm, reusable, sterile, 12,000 rpm	460807
Tungsten carbide micro ear burr, Ø 0.8 mm, reusable, sterile, 12,000 rpm	460808
Tungsten carbide micro ear burr, Ø 1.0 mm, reusable, sterile, 12,000 rpm	460810
Tungsten carbide micro ear burr, Ø 1.4 mm, reusable, sterile, 12,000 rpm	460814
Tungsten carbide micro ear burr, Ø 1.8 mm, reusable, sterile, 12,000 rpm	460818
Tungsten carbide micro ear burr, Ø 2.3 mm, reusable, sterile, 12,000 rpm	460823
Diamond micro ear burr, Ø 0.6 mm, reusable, sterile, 12,000 rpm	460206
Diamond micro ear burr, Ø 0.7 mm, reusable, sterile, 12,000 rpm	460207
Diamond micro ear burr, Ø 0.8 mm, reusable, sterile, 12,000 rpm	460208
Diamond micro ear burr, Ø 1.0 mm, reusable, sterile, 12,000 rpm	460210
Diamond micro ear burr, Ø 1.2 mm, reusable, sterile, 12,000 rpm	460212
Diamond micro ear burr, Ø 1.4 mm, reusable, sterile, 12,000 rpm	460214
Diamond micro ear burr, Ø 1.8 mm, reusable, sterile, 12,000 rpm	460218
Diamond micro ear burr, Ø 2.3 mm, reusable, sterile, 12,000 rpm	460223
Diamond micro ear burr, Ø 0.35 mm, reusable, sterile, 12,000 rpm	460203

**Accessories in combination with DrillCut-X II (40712050), DrillCut-X II N (40712055), DrillCut-X II-35 (40712035) and DrillCut-X II-35 N (40712535)**

Article	Order no.
Shaver blades: (applied parts), reusable or disposable (sterile), pack of 5. <ul style="list-style-type: none"> <li>– Straight</li> <li>– Curved</li> <li>– Curved without serrated jaws</li> <li>– Single serrated</li> <li>– Double serrated</li> </ul>	Article number, see catalog
Sinus burr (applied parts), disposable (sterile): <ul style="list-style-type: none"> <li>– Oblong</li> <li>– Round burr</li> </ul>	Article number, see catalog



Article	Order no.
<ul style="list-style-type: none"> <li>– Diamond head 15° curved</li> <li>– 40° curved</li> <li>– 55° curved</li> </ul>	

## 8.2 Spare parts

Article	Order no.
Mains fuse, 100 – 240 V, T 4.0 AH 250 V AC, IEC 127 format	2027690
Perforator Motor, without cable	362641
Perforator connecting cable for connection to the perforator motor 362641	362642
High-speed micro motor without cable	20362133
Cable for high-speed micro motor, large	20362233
High-speed micro motor without cable	20363133
Cable for high-speed micro motor, small	20363233
INTRA motor 80k, without cable	20261133
INTRA Connecting Cable	20261233

## 9 Electromagnetic compatibility

### 9.1 General notes on the operating environment

The product is suitable for use in professional healthcare settings. Professional healthcare facilities include physician offices, dental offices, limited care facilities, freestanding surgical centers, freestanding birth centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgical rooms, outside the HF-shielded room of an ME system for MRT).

- i** The emission characteristics of this product make it suitable for use in professional healthcare facilities as well as in a residential environment (CISPR 11 Class B). This product offers adequate protection to radio communication service. In the rare event of interference to the radio transmission operation, the user might need to take mitigation measures, such as relocating or re-orienting the product.

### 9.2 Accessories and cables

Accessories and cables for EMC compliance				
Type	Shield	Length [m]	Ferrite	Use
High-performance EC micro motor, DrillCut-X II handpiece with connecting cable	Yes	3	No	Energy transfer to motor
Footswitch with connecting cable	Yes	3	No	Equipment control
Wireless footswitch including receiving unit	Yes	–	No	Equipment control
Power cord	No	3	No	Connection of equipment to AC mains
OR1 Patch Cable	Yes	2	No	Service, Connectivity to other KARL STORZ equipment

### 9.3 Table 1 – Compliance level for immunity tests

#### Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	Floors should be made of wood, concrete, or covered with ceramic tiles. If floors are covered with synthetic material, the relative humidity must be at least 30%.
Electrical fast transients/bursts acc. to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	± 2 kV for power lines ± 1 kV for input and output lines 100 kHz repetition	The power supply quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	± 1 kV voltage outer conductor – outer conductor ± 2 kV voltage outer conductor – ground	The power supply quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations acc. to IEC 61000-4-11	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u> 100% for 250/300 cycles	<u>Voltage dip:</u> Dip to 0% for 1 cycle at 0° phase angle Dip to 70% for 25/30 cycles at 0° phase angle Dropout to 0% for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° phase angles <u>Voltage interruption:</u> 100% for 250/300 cycles	The power supply quality should be that of a typical commercial or hospital environment. If the user of the product requires continued operation in the event of interruptions to the power supply network, it is recommended that the product be operated with an uninterruptible power supply or a battery.
Magnetic field at the power frequency (50/60 Hz) acc. to IEC 61000-4-8	30 A/m at 50 Hz / 60 Hz	30 A/m at 50 Hz / 60 Hz	If image distortion occurs, it may be necessary to install the product further from sources of electromagnetic fields or to install magnetic shielding. Before the product is installed, the electromagnetic field should be measured to ensure that it is sufficiently low.
Immunity test acc. to IEC 61000-4-3 for radiated, ra-	3 V/m 80 MHz to 2.7 GHz * Refer to Table 2 for wireless proximity RF field test levels	3 V/m 80 MHz to 2.7 GHz	

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
radio-frequency electromagnetic fields			
Immunity to conducted disturbances, induced by radio-frequency fields acc. to IEC 61000-4-6	3 V <sub>rms</sub> on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V <sub>rms</sub> in ISM band	3 V <sub>rms</sub> on 150 kHz to 80 MHz 1 kHz 80% AM modulation 6 V <sub>rms</sub> in ISM band	

#### 9.4 Table 2 – Test levels for proximity fields from HF wireless communications equipment


Test frequency MHz	Frequency band MHz	Radio service	Modulation	Immunity test level V/m	Compliance level V/m
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	27	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine wave	28	28
710	704 – 787	LTE band 13 and 17	Pulse modulation 217 Hz	9	9
745					
780					
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE band 5	Pulse modulation 18 Hz	28	28
870					
930					
1720	1700 – 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28	28
1845					
1970					
2450	2400 – 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9	9
5500					
5785					

## 9.5 Table 3 – Test levels for radiated and conducted immunity tests

### Guidelines and manufacturer's declaration – electromagnetic immunity

The product is intended for use in the electromagnetic environment specified below. The user of the product should make sure that it is used in such an environment.

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Conducted HF disturbances acc. to IEC 61000-4-6	3 V <sub>rms</sub> 150 kHz to 80 MHz	3 V <sub>rms</sub>	Portable and mobile HF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distances:  $d = 1.2 \sqrt{P}$  Where P is the rated power of the transmitter in watts [W] according to the information provided by the transmitter manufacturer and d is the recommended separation distance in meters [m].  Field strengths from fixed HF transmitters as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup> .  $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz  $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz  Interferences may occur in the vicinity of equipment marked with the following symbol:
Radiated HF disturbances acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Interference immunity tests	EN/IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
			
<p>Note: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.</p> <p><sup>a</sup> Field strengths from fixed transmitters, e.g., base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the device is used exceeds the above compliance levels, the device should be monitored to ensure proper function. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.</p> <p><sup>b</sup> Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

## 9.6 Table 4 – Emission class and group

### Guidelines and manufacturer's declaration – electromagnetic emissions

The product is intended for use in such an environment as specified below. The customer or user of the device should ensure that it is used in such an environment.

Interference emission measurements	Conformity	Electromagnetic environment – Guidelines
RF emissions according to CISPR 11	Group 1	The product uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference affecting nearby electronic equipment.
RF emissions according to CISPR 11	Class B	The product is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions acc. to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions acc. to IEC 61000-3-3	Compliant	

## 9.7 Table 5 – Recommended separation distances between portable and mobile HF communications devices and the product


The device is intended for use in an electromagnetic environment in which HF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications device.

Rated power of the transmitter [W]	Separation distance d [m] according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose maximum rated power is not listed in the table above, the recommended separation distance d in meters (m) can be estimated using the equation from the respective column, whereby P is the maximum rated power of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorptions and reflections of buildings, objects, and people.

-  The product was tested for compatibility with HF surgical devices in accordance with IEC 60601-2-2 Appendix BB.

## 10 Errors and messages

### 10.1 Troubleshooting

Fault	Possible causes	Actions
Application instrument not functional	Power supply failure	► Check power supply
Product failed		► Contact Service
Power switch lamp does not light up	Power supply failure	► Check power supply
	Defective fuse	► Changing a fuse
	Power switch lamp defective	► Contact Service
Power switch lamp lights up: – No rotation – No reaction when footswitch is pressed – No reaction when tapping on the touch screen – Speed cannot be regulated	Faulty motor control electronics	► Contact Service
	Connection to motor interrupted	
	Faulty handpiece	► Connect another handpiece
	Handpiece blocked or jammed	► Clean handpiece
Tubing set connectors do not fit in the pump	Tubing set installed incorrectly	► Check the connection side (upper and lower connectors are different sizes)
	Connectors secured incorrectly to the tube	► Replace tubing set
No irrigation fluid	Irrigation bag empty	► Use new irrigation liquid bag
	Tubing clamp impedes flow	► Loosen tubing clamp
	Kinked tubing	► Change run of tubing
	Irrigation bottle not ventilated	► Ventilate the irrigation bottle
	Pump deactivated	► Activate pump






### 10.2 Software messages

Message	Possible causes	Actions
Motor not supported	Motor cannot be used with available license	–
Motor defective	Connector problems	► Contact Service
Product defective	Motorboard defective	► Contact Service
Footswitch defective	Pedal defective	► Contact Service
	Pedal cannot be calibrated	



## 11 Overview of mitigating warnings

The original English warning text is as follows:

 WARNING	<p>To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.</p>
 WARNING	<p>Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.</p>
 WARNING	<p>Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.</p>
 WARNING	<p>Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.</p>
 WARNING	<p>No modification of this equipment is allowed.</p>

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