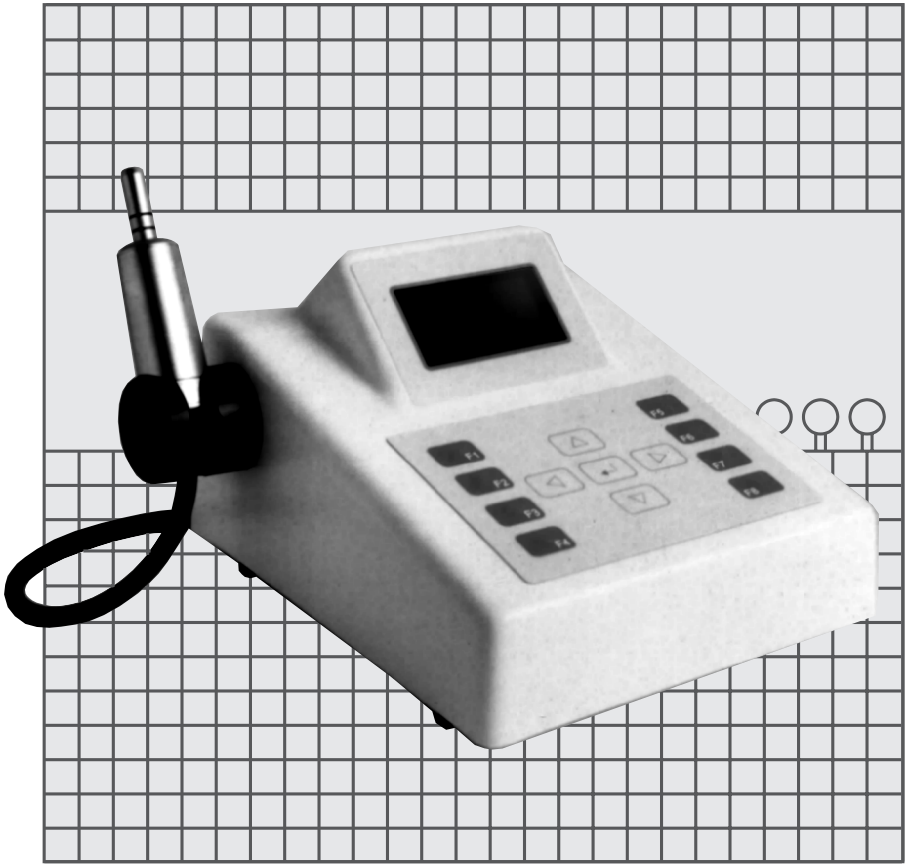
phytron®

EndoStepper®

Operating Instructions and User's Manual



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EndoStepper®

Operating Instructions

and User's Manual

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The EndoStepper System is a class II medical device according to IEC-601.
Read this operating instructions carefully before using the system!
This will help to prevent injury from persons and damage from the device.

1 Overview

1.1 Intended Use

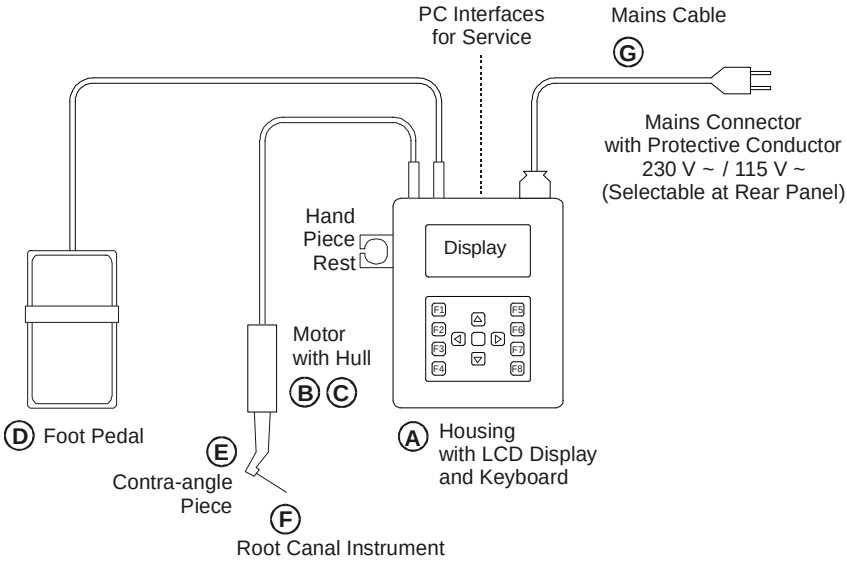
The EndoStepper system is a dental drive system to be used by dentists only.

Its intended use is to drive dental drills and files for root canal preparation, and other dental treatment procedures.

1.2 Short Description

The EndoStepper is a novel drill drive best suited for preparing root canals in dental surgery. The drive offers a well controlled torque characteristic, which is selected for each drill instrument and stored in a special memory. This yields a far reduced risk of breaking the drill as compared to conventional systems.

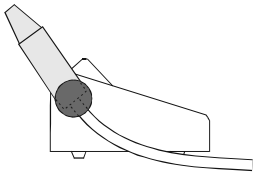
The EndoStepper system consists of the following components, which can be ordered separately:

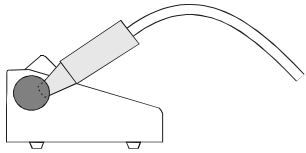


A Controller in a console type housing with LCD display, keyboard and hand piece rest
B Drive unit (motor) with connector matching to the console housing
C Motor protective cover (hull)
D Foot pedal with connector matching to the console housing
E Contra-angle piece (commercially available)
F Root canal instruments (commercially available)
G Mains cable

The EndoStepper system supports the treating dentist in an optimum way. It offers a wide range of operating safety. All necessary data and parameters, e.g. the selected instrument type, are shown in the LCD display.

The **multi function hand piece rest** mounted on the housing's side represents a safe place of deposit for the drive unit while changing the drills and periods in which it is not used.

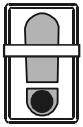
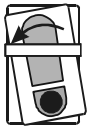
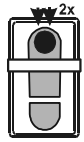
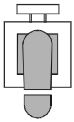
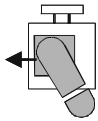
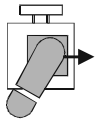
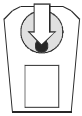
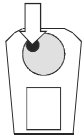
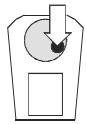
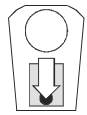




The openings of the hand piece rest have been designed to offer a well suited place of deposit for every position of the drive unit.

You may deposit the complete hand piece, or only the angle piece with the drill instrument or the drive motor alone with or without the protective case.

The **foot pedal** unit is used to select the different operating modes of the drill. With the foot pedal you can also select the next drill type parameters after changing the drill. Please refer to chapter 4.3 and 4.5 to see how to change the drill parameters.

Type FAL-S Foot Pedal			
			
Press foot plate down with heel	Push toe left	Push toe right	Tip toe once or twice
Type FAL Foot Pedal			
			
Press foot plate down	Press down and push foot plate left	Press down and push foot plate right	Press the bow once or twice
Type MF 1 Foot Pedal			
			
Press the round plate down	Press the round plate at the upper left	Press the round plate at the lower right	Press the black button one or two times

The EndoStepper is preset to the type FAL-S or FAL foot pedal. If you want to connect a type MF1 foot pedal, the type of foot pedal has to be changed by menu (see chapter 4).

2 The EndoStepper Operating Principle

The EndoStepper system uses a stepper motor to drive the drill.

A stepper motor is a special motor type, which makes 1600 steps of 0.225° each during one turn. While the user observes a smooth motion, the motor performs a lot of single steps.

The special advantage of a stepper motor is the limitation of its torque. The motor torque depends strongly on the current with which the motor is operated. This characteristic is used in the EndoStepper system to provide unique and reproducible torque values for driving the root canal instruments.

Therefore the system drives each instrument type with a special operation mode. This enables the user to handle the instrument in a safe manner. The dentist has to select only the correct instrument type.

Now the EndoStepper system automatically knows which parameters have to be used. This special feature reduces the risk of an instrument fracture to a very high degree of safety.

With the EndoStepper system you can select the following operating modes:

- The EndoStepper drills to enlarge the root canal and to remove left-over tissues.
- The EndoStepper moves back and forth in the EndoTwisting mode, if the root canal instrument is squeezed. With this procedure the drill can easily be freed.
- It is also possible to drive the drill with a counter-clockwise rotation.

Further functions can be selected by means of the function keys (ref. chapter 4.6)

3 Turning the EndoStepper into Operation

3.1 Unpacking the Device

A special designed packaging protects the EndoStepper parts during shipping. Please keep this packaging to ensure a safe transport in case of any return.

In case of any warranty repair the device has to be sent back in the original packaging. Otherwise any warranty is void.

Please open the packaging with care to avoid any damage to the device.

Please check the completeness of the goods delivered guided by the parts list as declared in the delivery-note.

Do also check all parts of the system for visible damages caused by improper transport.

Please immediately contact your carrier in case of any shipping damage. He is the person in charge to take and regulate the damage!

Do not use any damaged part of the system!
Hidden risks may arise from parts having a visible damage!

If you intend to send back the system or any part of it, please perform first a careful disinfection. Also auxiliary parts, e.g. the foot pedal or any cable, have to be disinfected properly before delivery.

The sender has to certify with his signature on the delivery-note that all parts have been successfully disinfected. Any additional effort to perform the disinfection at the arrival would be charged to the sender.

3.2 A Quick Function Test

After having unpacked the EndoStepper system, you should perform a first short function test of the system:

- First check the correct mains voltage selection. You can read the selected mains voltage in a small window at the rear plate of the desk housing (above the mains connector). The settings can be changed as described in chapter 7.4.

  If operated with wrong mains voltage selection, the device will be destroyed.

- Connect the foot pedal with the connector labeled **Foot Switch** at the back side of the device. Fasten the coupling ring at the socket to assure a safe connection.
- Connect the drive unit (motor) with the plug labeled **Motor** at the back of the device. Fasten the coupling ring at the socket to assure a safe connection.

  The motor cable must only plugged-in or plugged-off when the EndoStepper motor stands still!

  For the first system test, the protective covering, the contra-angle and the root canal instrument need not to be mounted.
- Connect the EndoStepper with the mains supply by means of the mains cable.
- Switch on the EndoStepper. The mains switch is located at the back side of the device.
- The following start up message should appear on the LCD-display:

S.E.T. EndoStepper1
Phytron-Elektronik^{R}
Copyright Phytron-Elektronik
Ser.NR. XXXXXXXX
for Program Update
press <F4> and <F8>

- If after switching on a window "Check contra-angle calibration" is displayed:
  A torque correction value has already been set. Repeat calibration if you are not sure that the correction value is suitable for the actual contra-angle.
- After a short delay time the system switches to the selection menu. The first drill type in the manufacturer's data area is selected. You can cancel the delay time by means of the key ↵.

  The display text will be set to English language by default. If an other language appears, you can select English as follows:

  Press the key labeled ◁ to switch to the left menu column. Move the marker to "S" by means of the arrow keys.

  Now you are in the setup menu. In the right column you see a list of several languages. Change to this column by pressing ▷. Move the marker by means of the cursor keys ▽ or △ to English. Now press the key ↵ to confirm the setting.

  The display language is now English. This setting will be saved. If you switch on the EndoStepper the next time, English language will be used automatically.

  On the top of the setup menu is the item CONTRAST. You can modify the **display contrast** with the keys ◁ and ▷. Now press the key ↵ to confirm the setting. This setting will be saved.

  The menu item FOOT – at the bottom of the setup menu – the unit can be adapted to the foot **pedal type**. Select type FAL or MF1 (refer to page 7) and confirm with ↵ . This setting will be saved.
- Press the direction key labeled ▷. This will select the first drill out of the table. The system is now ready to work with this drill.
- Operate the foot pedal: Press the foot plate down with the heel.

> **In the following, all functions of the foot pedal FAL-S are explained.**
> **For description of the foot pedals FAL and MF: refer to chapter 4.8 and 4.9.**

The motor should now start moving. You can easily see the motion of the small driving pin at the end of the motor's shaft.

If the motor does not turn: please repeat each step of the list above. In chapter 7.8 of this operating instructions you will find additional hints for trouble shooting.

If the drive does not move after all checks have been done, or if e.g. the LCD display, too, stays dark after switching on the device, please contact the service station where you got the device from.

4 Operating Instructions

Before using the EndoStepper for the first time for any treatment read these operating instructions carefully and completely, as well as the operating instructions for the contra-angle you are using and for the root canal instruments.

Please take the possibility to learn the correct and very efficient use of the EndoStepper by visiting training seminars.

Preparing the EndoStepper for treatment:

1. Connect the drive motor and the foot pedal to the console (please refer to chapter 3.2).
2. Slip the protective cover over the motor.
3. Mount the contra-angle and the drill.
4. Switch on the device.
5. Set the display language to English as described in the last chapter. Press the key ↵ .
6. The device will switch automatically to the list of drill manufacturers. Now you can select a drill series out of the list.

   With the F1 key you can always change to the next manufacturer.
   With the F2 key you can always change to the next drill series.

7. After selecting a drill series, the first drill of this series is selected automatically: The system is now ready to use this drill. The drills can be identified by means of their color codes.

Not in any case the smallest drill is automatically selected first after activating a series. Please note the manufacturer's data.

Settings as shown in the display, manufacturer, drill series and drill color have to coincide in any case!

8. You can now start several operation modes by means of the foot pedal:

Drill in the preferential sense of rotation of the selected drill

Press foot plate down with the heel.
If the drive is blocked, you will feel a smooth vibration of the drive unit.

Clearing the drill

Push toe to the right.
The drive will now perform an oscillating motion, during which the drill rotates alternating clockwise and counter-clockwise (EndoTwisting). As soon as the drill is free again, move back the foot to the start position and press the heel down.

By means of the two screws, located on the side of the foot pedal type FAL, it is possible to adjust the strength of moving the foot plate.

Counter-clockwise rotation of the drill

Push toe to the left.
The drill will twist exactly one time and then start to rotate in the opposite direction compared to its preferential direction.

Besides of the drill functions described above, you can also start some menu functions by foot pedal, see tables in chapter 4.8 to 4.9.

To change from drill function ↔ to menu function: Tip **twice** with toe.

Selecting a new drill type without using the keyboard

A new drill type can be selected with only using the foot pedal. To do this, you have to change to the menu mode:

Tip toe **twice**

Now the operation mode has been changed. This is indicated on the display by an inverted color scheme (white on black). You can now select a new drill type by moving the marking down in the list:

Press foot plate down with the heel.

To select a drill type located above the current position in the list, simply go to the end of the list and press down the heel once again. The marking will go to the first entry in the list.

If the marking is highlighted on the desired drill type, this is automatically selected.

If you want to continue the treatment, you simply have to switch back to the drill mode:

Tip toe **twice.** Now you can again drill as described above.

Before using the EndoStepper for any treatment, get acquainted with the functions of the system. This will assure that you use the system safely and reliably!

Read carefully all warning notes summarized in chapter 9 before you start using the EndoStepper system.

4.1 Keyboard

With the keyboard you can select drill manufacturers, several drill series, one special drill out of a series and special operation modes. The single keys have the following meaning:

 down	Scrolling down in a menu (highlighted selection key) or scrolling down within the drill table
 up	Scrolling up in a menu (highlighted selection key) or scrolling up within the drill table
 right	Changing from menu area to table area
 left	Changing from table area back to the menu area
 enter	Confirmation or selection of a sub-menu

4.2 Menu Structure

After switching on the EndoStepper there will be a start-up message on the LCD display. It shows type, manufacturer and serial number of the device. During this period a software update can be started. Software packages for the extension of instruments data can be purchased from your system supplier. Please refer with this to the instructions delivered with any extension software package.

You should only start the update function if you have got a software package suited for your EndoStepper device.

You can abbreviate the start-up message display by pressing the enter key ↵.

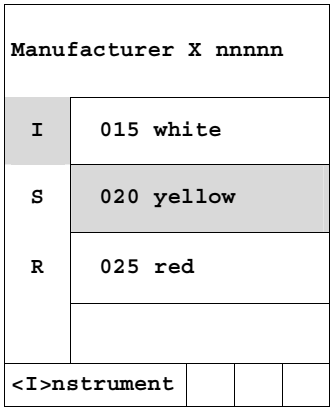
Now the menu control will be activated. A selection window will be shown. The display language will be English by default. To select an other display language please refer to chapter 3.2.

Left column:
Menu Selection Keys

Instrument

Series

Return to the main menu



Headline:
Manufacturer and drill series

Right Column: drill list

The current selection is shown inverted.

Here: **020 yellow**

Field to the lower left: Some information text to the currently active function, here: **I** --> **<I>**nstrument

Field to the lower right: Here is shown whether any hot key function has been activated. Please refer to chapter 4.6.

The marking can be moved by means of the direction keys.

Pressing the key ▷, you can switch to the right display column. By pressing the key ◁, you can switch back to the left column. Move the highlighted marking to the desired drill manufacturer by means of the keys ▽ or △. The selection has now to be confirmed by pressing the ↵ key.

You can always switch to the next manufacturer with F1.

Now the sub-menu **S** is active. Here are the drill series tables offered by the selected manufacturer. Move the highlighted marking to the desired drill series and confirm with ↵.

Now the next menu level has been reached, where the different drills of this series are shown. If a manufacturer has only one drill series, the drill table is already reached with the first step.

You can always switch to the next series with F2.

Move the highlighted marking with the direction keys until the desired drill is highlighted. Now this drill is selected. The drill manufacturer will be stored. If you switch off and on the EndoStepper, this manufacturer will be automatically selected again.

If the last entry in the drill table has been reached, the selection mark will jump to the first entry in the table, if you press the down key ▽ again.

4.3 Foot Pedal Functions: Normal Operation

After a drill type has been selected, the EndoStepper system is ready for operation and treatment. With the foot pedal you can now start the following functions:

	**Drilling** using the drill's preferred direction
	**Clearing the drill (EndoTwisting)**, if the drive has been blocked
	Once twisting and then motion **against the preferential direction of rotation**

4.4 Recommendations for Special Types of Instruments

Lightspeed Instruments

If a Lightspeed instrument blocks during normal operation:

Do not start a twisting motion. Let the root canal instrument be mounted in the contra-angle and try to pull the instrument out of the root canal with a slowly turning motion of the contra-angle.

Refer to the instructions of the instrument‘s manufacturer!

4.5 Selecting a Drill Type by Foot Pedal

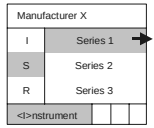
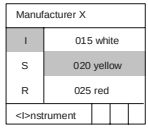
Even without using the keyboard you can easily select another drill. with the next larger diameter. Switch to the selection mode by means of the foot pedal.

	Tip toe **twice**	Switching to the selection mode **The drill motion is now disabled!**

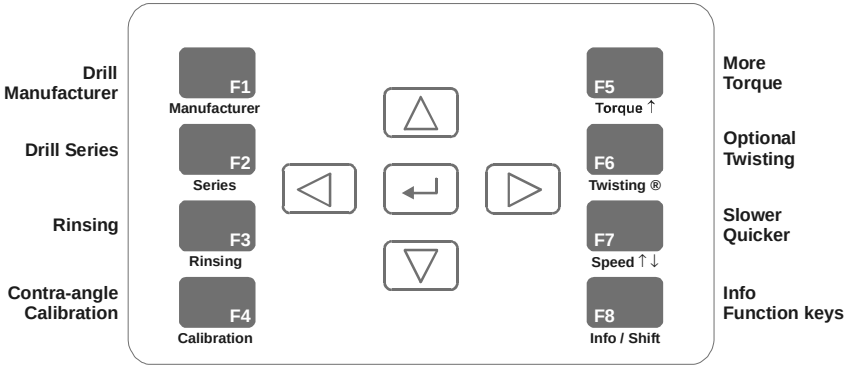
On the LCD display you will now see the drill tables. The information text line is shown in an inverted representation (light characters on a dark background).

Manufacturer X				
I	015 white			
S	020 yellow			
R	025 red			
<I>nstrument				

In the selection mode you can perform the following commands by foot pedal:

	Push toe to the right.	Change from the menu area to the table area in the right window of the display	
	Tip toe once	Step into a sub-menu	
	Press foot plate down by heel.	Menu-Area: Scroll down the menu to the next selection character. Drill table: Scroll one drill type down.	
	Push toe to the left.	Change from the table area to the menu area in the left window of the display	
	Tip toe **twice**.	Select the drill mode again Now the informational text line is no longer shown inverted!	

4.6 Function Keys



Remark:

This keyboard configuration is valid for all units with the actual program version 02H (since June, 2000), even if there is no print "Manufacturer" etc. on the keyboard.

In the case of older program versions not all of the function keys are occupied.

With the special function keys, several functions can be directly selected.
When you press key F8, the list of the special function keys will be shown:

Special Function Key F1 – MANUFACTURER

The selected manufacturer is displayed. When you press F1 again, the next manufacturer is selected. Automatically the first series of this manufacturer is selected, and the top instrument of this series is selected as well.

Special Function Key F2 – SERIES

With F2 you can select the next series of the actual manufacturer (if there is more than one series). Automatically the top instrument of the list is selected.

If a manufacturer had not been selected before, a message window "Manufacturer ?" is displayed now. Press F1 and select a manufacturer.

Special Function Key F3 – RINSING

When you press key F3 the drill turns back about 1 sec. Then it stops for about 0.25 secs, and continues to turn for 1 sec, stops again, and so on.

This procedure is continued as long as the foot pedal is pressed down.

Only use RINSING as last rinsing procedure after end of the root canal preparation.

All other foot pedal operation modes are disabled during the **RINSING** function.

Rinsing OFF: Press Key F3.

Special Function Key F4 – Contra-angle CALIBRATION

The motor torque does not act directly onto the root canal instrument. Mechanical losses in the contra-angle will reduce the actual torque. This will especially happen if you use old contra-angles, which have gears suffering from abrasion.

The EndoStepper system allows to determine the actual efficiency of an contra-angle and to correct the torque delivered by the system. The same function should be used to calibrate a new contra-angle.

The efficiency has to calibrated after each change of the contra-angle!

To calibrate a contra-angle with the EndoStepper system, please proceed as follows:

1. Stick the contra angle on the drive unit, insert the drill.
2. Press special function key F4 and check whether the drill is turning.
3. With the keys ▷ and ◁ you can select the limit point, where the motor just starts turning.
4. Press the key F4 to confirm the setting and to exit the calibration mode.

If a contra-angle can be calibrated that way, it is suitable for the EndoStepper system.

Do not use contra-angles with a reduction gear!

Only 1:1 contra-angles are permitted for use with the EndoStepper!

The calibration data of the contra-angle are stored.

If a contra-angle calibration value is stored, a message window "**Check contra-angle calibration**" is displayed when you switch on the device.

Press ↵ to acknowledge the message. If you wish to use another contra-angle as before, you should calibrate again.

Special function key F5 – TORQUE INCREASE

The TORQUE INCREASE function can only be switched on for appropriate instruments. If the function is not appropriate, this will be indicated on the display. The function, however, continues to remain active. Therefore it will be carried out after selecting an appropriate instrument.

By pressing the function key F5 again, TORQUE INCREASE will be switched off.

Dependend on the type of instrument used, the TORQUE INCREASE functions are different:

1. Torque increase up to the instrument's break limit

By pressing the key F5 the motor torque will be increased up to the instrument's break limit. The torque is – depending on the type of instrument – increased up to 25%. The risk of instrument fracture is higher in this operation mode, especially if the instrument has unknown hidden damages.

The display will show the warning message **TORQUE > BREAK LIMIT**.

The danger of instrument fracture is increased compared to normal operation.

TORQUE INCREASE should only be used, if the dentist decides the treatment situation justifies this risk.

2. Expert mode

With some types of instruments, after pressing F5 the display shows **EXPERT MODE**. This function is admitted for tapered instruments. These instruments must only be used for widening root channels which are already opened. In this case only the thicker part of the instrument has contact to the root channel's wall. The instrument's tip is not stressed. Therefore, in the expert mode these instruments are operated with higher torque.

In the EXPERT MODE the danger of instrument fracture is increased compared to normal operation.

Use the instruments according to the manufacturer's recommendations.

Special Function Key F6 – OPTIONAL TWISTING

With F6 you can activate additional twisting functions for appropriate instruments.

As soon as the function OPTIONAL TWISTING is switched on, the display shows a window: TWISTING. The foot pedal functions have changed:

	Press heel down	The instrument is "twisted into the root channel".
	Push toe right	The instrument rotates once 360° in opposite direction. Next the motor is switched off.
	Push toe left	The drill will twist exactly one time and then start to rotate in the opposite direction compared to its preferential direction. Remark: Same function as without pressing F6

1. Depending on the type of instrument, different rotation angles and torques are preset..
2. OPTIONAL TWISTING can only be activated for instruments which are permitted for this function. If the function is not permitted this will be shown in the display for short time: F6 not possible.
3. The OPTIONAL TWISTING function remains switched on. With another instrument, permitted for this function, OPTIONAL TWISTING can be used.
4. During using the OPTIONAL TWISTING:
   TORQUE INCREASE (F5) is active.
   SLOWER/QUICKER (F7) does not work .
5. The OPTIONAL TWISTING function remains active until F6 is pressed again.

Special Function Key F7 – SLOWER/QUICKER

1. By pressing F7, the speed will be decreased by 45%, the drill moves slower.
2. When you press F7 again, the speed will be increased by 25%, the drill moves quicker.
3. This function remains active until you press F7 again.

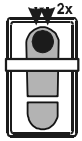
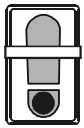
The speed increase function can only be switched on for appropriate instruments. In case of the function not being appropriate, this will be indicated on the display. The function, however, continues to remain active. Therefore it will be carried out after selecting another type of appropriate instrument.

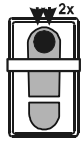
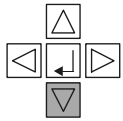
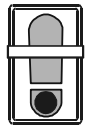
Special Function Key F8 – INFO

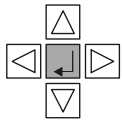
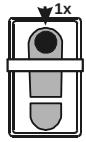
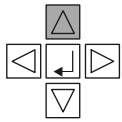
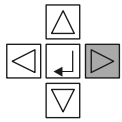
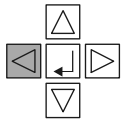
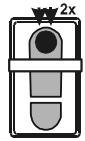
To show the list of special function keys, key F8 can always be pressed. By pressing F8 again, the screen shown before will be displayed again.

Future EndoStepper program versions will provide an additional SHIFT function. That means, when pressing F8 a second time (=SHIFT), a new window with additional functions will be shown. This SHIFT function is not yet active in the actual program version.

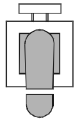
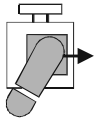
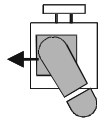
4.7 Table: Use of Foot Pedal FAL-S or Keyboard

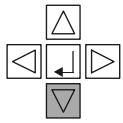
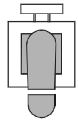
Mode	Using the type FAL-S foot pedal		
Change the operation mode	Tip toe twice. 		
Drill mode	Press heel down.  Drill	Push toe right.  Twist	Push toe left.  Drill with inverse direction (after one cycle of twisting)

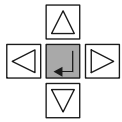
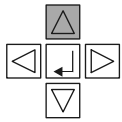
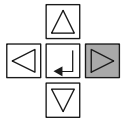
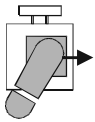
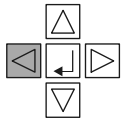
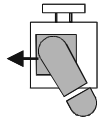
Mode	Function	Keyboard	Foot pedal
Mode selection	Mode selection of foot pedal Drill mode >>> Selection mode		Tip toe twice. 
Selection mode	Scroll the marking in the menu down		Press heel down 

Mode	Function	Keyboard	Foot pedal
Selection mode	Confirmation of selection		Tip toe once 
Selection mode	Scroll up the marking in the drill table		Not available with the foot pedal.
Selection mode	Move the marking to the right onto the table area		Push toe right. 
Selection mode	Move the marking to the left onto the menu area		Push toe left. 
Mode change	Mode selection of foot pedal Selection mode >>> Drill mode		Tip toe twice 

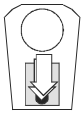
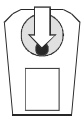
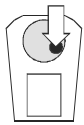
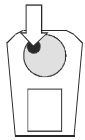
4.8 Table: Use of Foot Pedal FAL or Keyboard

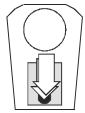
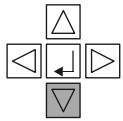
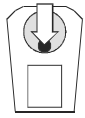
Mode	Using the type FAL foot pedal		
Change the operation mode	Press bow twice  Mode change		
Drill mode	Press foot plate down  Drill	Press down and push right  Twist	Press down and push left  Drill with inverse direction (after one cycle of twisting)

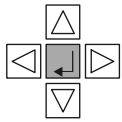
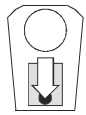
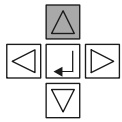
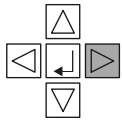
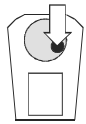
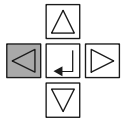
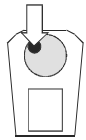
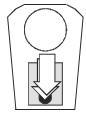
Mode	Function	Keyboard	Foot pedal
Mode selection	Mode selection of foot pedal Drill mode >>> Selection mode		Press bow twice 
Selection mode	Scroll the marking in the menu down		Press foot plate down 

Mode	Function	Keyboard	Foot pedal
Selection mode	Confirmation of selection		Press bow once 
Selection mode	Scroll up the marking in the drill table		Not available with the foot pedal.
Selection mode	Move the marking to the right onto the table area		Press down and push right 
Selection mode	Move the marking to the left onto the menu area		Press down and push left 
Mode change	Mode selection of foot pedal Selection mode >>> Drill mode		Press bow twice 

4.9 Table: Use of Foot Pedal MF1 or Keyboard

Mode	Using the type MF1 foot pedal		
Change the operation mode	Press black the button twice  Mode change		
Drill mode	Press round plate down  Drill	Press round plate at the lower right  Twist	Press round plate at the upper left  Drill with inverse direction (after one cycle of twisting)

Mode	Function	Keyboard	Foot pedal
Mode selection	Mode selection of foot pedal Drill mode >>> Selection mode		Press black button twice  Mode Change
Selection mode	Scroll the marking in the menu down		Press round plate 

Mode	Function	Keyboard	Foot pedal
Selection mode	Confirmation of selection		Press the black button once 
Selection mode	Scroll up the marking in the drill table		Not available with the foot pedal.
Selection mode	Move the marking to the right onto the table area		Press round plate to the lower right 
Selection mode	Move the marking to the left onto the menu area		Press round plate to the upper left 
Mode change	Mode selection of foot pedal Selection mode > Drill mode		Press black button two times  Mode change

5 Maintenance and Cleaning

5.1 Maintenance Instructions

Maintenance of the EndoStepper unit

The EndoStepper system is free of maintenance needs except cleaning, disinfection or sterilization procedures as described herein. The control electronics is ready to use without of any maintenance requirements.

Maintenance of the EndoStepper Software

If you want to extend or correct the instrument parameters stored in your EndoStepper system, you can perform a software update by means of a special PC software delivered by the manufacturer of the EndoStepper.

To start the software update, you have to connect the interface **RS** at the rear side of the EndoStepper to the serial interface COM1 or COM2 of your PC. Please use a serial links cable (accessory, can be ordered).

Insert the delivered floppy disk or CD-ROM into the appropriate drive of your PC and proceed as instructed in the documentation delivered with the software update.

After the update procedure you have to disconnect the serial cable!
During treatment with the EndoStepper no additional cables must be inserted to the unit!

5.2 Cleaning and Disinfection

The EndoStepper system has to be disinfected before using it for the first time, and after any use or any other possible contact to biological hazardous material.

Motor cover and housing (parts accessible from above):

We recommend to use commercially available disinfectant spray on ethanol/water basis, for example FD 322 (manufacturer: Dürr Dental).

The removable motor cover can also be sterilized in a vaporized autoclave up to temperatures of 134 °C.

Drive unit (motor with cable): Only wipe disinfection permitted!

5.3 Waste Disposal and Recycling

The EndoStepper system consists of electronic components, plastics and metal parts. All parts of the system may be disposed as usual electronic waste.

It should be a matter of course that only completely disinfected parts should become accessible to other persons.

6 Accessories

6.1 EndoStepper Accessories

The EndoStepper system may only be used with accessories as permitted by the manufacturer!

The following accessories may also be separately ordered as spare parts:

EndoStepper drive (Motor and cable)

EndoStepper protective cover

Mains supply cable

PC interface cable (optional)

Foot pedal

6.2 Recommended Accessories

Contra-Angles

The EndoStepper system may be used with all contra-angles commercially available according to the standard ISO 3964, with a 1:1 internal gear ratio[1]

All 1:1 contra-angles are suited for use with the EndoStepper, which fit to the protective cover delivered with the EndoStepper, and which can be calibrated with the efficiency calibration procedure.

Do not use reduction contra-angles with the EndoStepper!

If a contra-angle calibration value is stored, a message window "**Check contra-angle calibration**" is displayed when you switch on the device (refer to chapter 4.6).

Root Canal Instruments

The recommended root canal instruments are those displayed in the drill tables of the EndoStepper LCD display.

[1]The list of available accessories is shown as valid at time of printing. Please contact your local distributor to get the manufacturer‘s documentation of commercially available accessories.

7 Technical Data

7.1 Classification of the System Parts

The EndoStepper system is an active, electrical driven medical device according to

class IIa as defined in the European standards EN 60601.

The EndoStepper drive unit is a **type B application device** as defined in the European standard EN60601. The housing of the drive is normally not connected to the protective ground level of the mains connection.

The console type housing fulfills the **IP40** protection level (splashproof).

The EndoStepper system has been designed to be operated in an **intermittent short time operation mode**. The maximum operating interval is 5 min with an off-time of at least 10 min (device switched on, but motor not running).

Product Label

The product label contains the following data:

Type	EndoStepper 1
Supply voltage	230/115 V~ / 50 – 60 Hz
Current consumption	0.2 A at 230 V~ 0.4 A at 115 V~
Acceptable On-time	I. 5 min / 10 min
Protection level	IP 40
Stock no.	Phytron-ID: 200xxxx
Manufacturer	Phytron-Elektronik GmbH

CE-Marking with code of the competent body, which supervises the manufacturer's quality management system according to the EN 46001 European standard.

Serial number of each unit coded as barcode and plain text

7.2 Dimensions and Weights

Console housing	Dimensions Weight	WxHxD = 190x150x225 mm about 2 kg
Foot pedal	Dimensions/Weight Length of cable	Depending on type about 2.7 m
Drive motor	Dimensions (without shaft) Length of cable Weight	Ø25 x 70 mm about 2 m about 165 g
Protective Cover	Dimensions (Motor with cover) Weigth (Protective cover)	about Ø30 x 75 mm 39.5 g

7.3 Ambient Conditions

The EndoStepper system has been designed for use in the dental consultation rooms with the following ambient conditions:

Ambient temperature:	+10 °C to +40 °C
Humidity of air:	20% to 75% relative humidity
Air pressure:	860 hPa to 1060 hPa

Operating the system with other ambient parameters may cause malfunction.

7.4 Mains Connection

The EndoStepper system can be supplied with 115 V or 230 V nominal mains voltage. Only mains supplies with a protective earth connection are admissible for the device.

Check whether the mains supply voltage setting as shown in the small window above the mains connector (rear side of the console housing) corresponds with your local supply voltage.

Using the EndoStepper with wrong mains supply voltage setting will cause damage to the device!

If necessary, you can easily change the mains supply voltage setting:

1. Remove the cover of the mains supply module on the rear side of the console housing. Insert a small screw driver into the little gap and lift the cover.
   Disconnect the mains supply cable before any manipulation at the mains supply module!

2. Plug out the red colored fuse holder.
3. Exchange the fuses and insert new ones according to the table with the fuse values on the back cover of the console housing.
4. Turn the fuse holder and insert it again. Replace the cover. Now the new supply voltage setting is shown in the small window above the connector.

Mains supply voltage:	230 V~ or 115 V~ single phase, selectable, with protective earth connection
Frequency:	50 to 60 Hz
Current consumption:	approx. 0.2 A at 230 V~ approx. 0.4 A at 115 V~
Protection class:	I
Mains fusecc:	with 230 V~ supply voltage: T 0.5 A / 250 V, 5x20 mm glass housing, switching characteristics 1500 A, acc. to IEC 127-2/V resp. EN 60127-2/V with 115 V~ supply voltage: T 1 A / 440 V, 6.3 mm x 32 mm glass housing, switching characteristics 1000 A, acc. to UL E67006

7.5 Drive Motor Characteristics

Type:	2-phase stepper motor
Step resolution:	200 steps per revolution The stepper motor of the EndoStepper system is operated in the 1/8-ministep mode, this equals 1600 steps / rev.
Motor supply voltage:	maximum 45 $V_{=}$
Motor current:	maximum 1.5 A_{peak} (this equals approx. 1.1 $A_{r.m.s.}$ per phase)
Motor control:	constant current control, chopped
Chopper frequency:	45 to 90 kHz
Speed:	maximum 6000 rpm
Torque:	maximum 3.5 Ncm

7.6 Electromagnetic Compatibility

The EndoStepper system fully complies with the requirements of the EMC standard for medical equipment as defined in the standard EN 60601-1-2.

Please note that the EMC compliance is only given if only accessories (e.g. apex locator systems) are used which have been approved and recommended by the EndoStepper manufacturer!

The use of the EndoStepper system for treatment of patients having an implanted pacemaker is strongly not recommended.

If the EndoStepper should have EMC disturbances at most adverse locations, you should care for more distance to devices with strong perturbing radiation or you should switch off these devices.

7.7 Error Messages

In case of malfunction an error message is displayed on the LCD-display.

7.7.1 No Motor Connected

If the EndoStepper is switched on without any motor connected, the following error message is displayed:

Program Stop
Error
or
Motor not connected

Switch off the device and connect the motor. Now you can again switch on the device.

The error message only disappears after the EndoStepper has been switched off and on again.

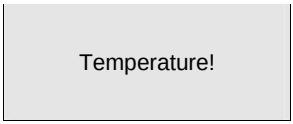
If the error message continues to appear even if the motor is connected, please contact the next service station.

If during operation the motor is disconnected **– only permitted during motor stand-still –** no error message is shown. The system only checks the motor connection during the start-up phase after switching on.

7.7.2 Overtemperature

After longer periods of operation, the drive motor may become hot. The EndoStepper will issue a warning sound, if the motor temperature reaches approx. 41 °C. But the motor will continue operation. A dental treatment may therefore be safely finished.

If – due to any misuse – the motor temperature will rise above approx. 55 °C, the motor will be switched off. The system will display a warning message as:



This message disappears, if the motor temperature goes below 50 °C again. Now you can continue the treatment.

If you intend to continue the treatment immediately after a temperature caused cutoff, you can exchange the drive motor by a new one.

Warning!
Do not operate the foot pedal while exchanging the drive motor.

7.7.3 Error Message ERROR XX

If an error message similar to the following picture is displayed, please contact your nearest service agency. The figure behind the string “Error" will give valuable information for the service personnel about the cause of trouble, so please note this figure.

7.8 Troubleshooting

The EndoStepper may be only opened or repaired by personnel qualified and specially trained by the unit‘s manufacturer!

The following list will help the user to solve the more probable problems by himself. If any malfunction in the system cannot be solved according to these recommendations, please contact your nearest service agency.

If the LCD display gets not enlightened:

- Is the mains connector plugged in?
  Before inserting the mains connector, please switch off the device!
- Mains switch set to "**I**" (= ON)?
- Is the mains outlet powered, to which the device has been connected? If you are not sure, try to operate any other electrical device from this outlet (e.g. some lamp).
- Are mains voltage and fuses of the correct value?
- Is any of both (!) fuses in the mains connection module defective?

If the drive motor and/or drill does not rotate:

- Has the motor cable been connected to the console housing?
  Before you insert the cable, please switch off the device.
- Is the contra-angle defective or has it to high internal friction?
  See chapter 4.6 – contra-angle calibration

If the unit has other malfunctions:

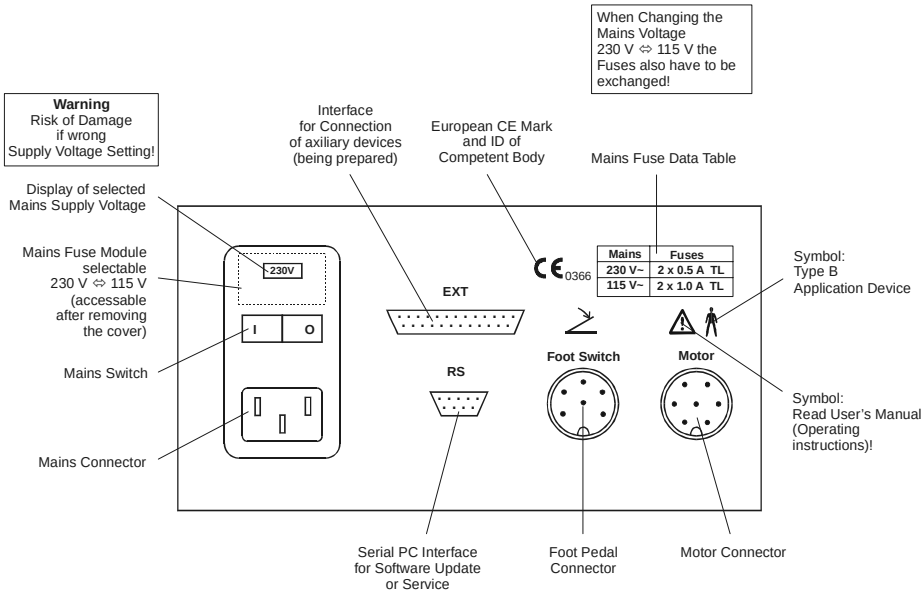
The EndoStepper fulfills the EMC standards for medical devices, but in spite of this, EMC disturbances could arise at most adverse locations.

In this case you should care for more distance to devices with strong perturbing radiation or you should switch off these devices.

7.9 Explanation of Symbols

~	Alternating Current
=	Direct Current
	Read User's Manual / Operating Instructions
	Type B Application Device
	Foot Pedal
	Protection Earth
CE 0366	CE marking with code of the competent body, which supervises the quality management system of the manufacturer acc. to the EN 46001 European standard

7.10 Rear Panel View



7.11 Displaying the Software Version

After switching on the device, a start message including type, manufacturer and serial number is displayed.

As long as the start message is displayed, the software revision code can inquired:

Press both function keys F2 and F6 coincidently.

This display function is for service purpose only.

8 Certificate of Conformity

Declaration of Conformity

We, the manufacturer, hereby certify, that the following product:

Description:	**Dental drive system EndoStepper®**
Type:	**EndoStepper® 1**
Serial numbers:	all above **098120100020**
Classification:	**IIa**

is in conformity with the following European directives:

MDD 93/42EEC of June, 14th 1993 (Medical Device Directive), Appendix II

The following harmonized standards have been applied:

EN 60601-1	Medical Electrical Equipment Part 1: General Requirements for Safety
EN 60601-1-2	Medical Electrical Equipment Part 1: General Requirements for Safety 2nd Collateral Standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-4	Medical Electrical Equipment Part 1: General Requirements for Safety 4th Collateral Standard: Programmable electrical medical systems

Appendix I of the Directive 93/42/EEC for Medical Devices

Gröbenzell, November, 27th, 2002

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9 Warning Notes / Safety Recommendations

Read the following instructions carefully and completely before using the EndoStepper for the first time treating a patient:

- **These operating instructions and**
- **the special operating instructions delivered by the manufacturers of the contra-angle and the root canal instruments you are using.**

Please note, that using the EndoStepper is strongly not recommended in the environment of humans having a pacemaker implanted.

9.1 Safety Precaution against General Risks

The EndoStepper system is an electrical medical device of class IIa according to EN 60601. The device may cause the risk of an electrical shock in case of malfunction.

The following precautions have to be obeyed in any case:

9.1.1 Visible Inspection

Anytime you turn the device into operation, all parts of it should be inspected for any visible damage.

If any part is damaged, e.g. if any cable has been crushed or parts of the housing have been cracked, the device must not be operated!

Please assure before using the device that all accessories are of a type which have been approved by the manufacturer.

Use only new root canal instruments with the EndoStepper system. Root canal instruments already used for manual treatment may have hidden defects or deformations.

Pay attention to the instructions for use of the instrument manufacturers. Note the recommendations of the manufacturers, how often each drill may be used.

9.1.2 Periodical Disinfection

The EndoStepper system is not specially treated and **not disinfected** before delivery.

The user is responsible to disinfect the EndoStepper system before using it for the first time and later periodically according to his disinfection plan.

See chapter 5.2.

Parts of the EndoStepper system may get into direct contact with the patient treated or may be contaminated with e.g. spittle or blood. The disinfecting procedure has therefore also to be extended to parts which get into contact only occasionally.

9.1.3 Operating the Device only with Acceptable Ambient Conditions

The EndoStepper system must not be operated in inadmissible positions and inadmissible environmental conditions.

The control electronics of the EndoStepper system has been built into a console housing. The housing may only be operated standing flat on a plane surface.

Do not hinder the heat transfer from the device to the ambient area.

Do not deposit anything on the EndoStepper housing!

Please note the recommendations for appropriate use given in this manual.

The parts of the system must not be exposed to any shock. The device has to be used only if it stands on a safe place, and if the cables are also in a safe position. There is a risk due to system parts which fall inadvertently down!

9.1.4 Careful Handling of Root Canal Instruments

If root canal instruments are mounted at the drive unit of the EndoStepper, the risk of being injured by these instruments is increased.

There is a risk of catching dangerous infections by contaminated instruments. Please store the instruments and the drive unit only in a safe place, where the risk of accidental contacts is minimized.

The root canal instruments should be put into the hand piece rest mounted to the console housing, if the root canal treatment is interrupted.

Respect the proper safety regulations during the treatment. Root canal instruments turning with high speed may throw away contaminated material like liquid drops also over a larger distance!

9.2 Risks Due to Unintended Use

Unintended use can lead to malfunction of the system and to the possibility that risks can emerge from the system, or that the root canal treatment cannot be performed with the required quality.

Unacceptable operating conditions, misuse and ignoring protective precautions have to be avoided in any case!

The motor cable must only be plugged-in or plugged-off when the motor stands still.

9.2.1 Risk Due to Contamination of System Parts

Missing or insufficient disinfection after working with the EndoStepper or after storing it in a microbiological contaminated area will bear the risk of infections!

Before performing any disinfection: Deposit the system parts only in a safe place! Preferably use the hand piece rest mounted at the console housing.

After using the EndoStepper disinfection measures have to be undertaken!

The removable protective cover of the drive unit can also be sterilized by means of a vaporized autoclave at temperatures up to 134 °C.

9.2.2 Risk Due to Unacceptable Permanent Use

The EndoStepper has been designed to be used intermittent. An operation period of up to 5 minutes should be followed by a rest period of 10 minutes with the device being switched on, but not operating.

If these values are exceeded, the drive motor will have a slow temperature increase up to unacceptable temperatures. The dentist will feel that the motor gets warmer, and he can decide whether to continue the treatment or not.

If the maximum permissible temperature of about 41 °C has been reached, the unit will issue a **warning sound**, but will not switch off. So a treatment can be continued and finished in a safe manner. Nevertheless, contacting the patient's skin with the motor protective cover motor should be avoided.

If the temperature is increased – due to improper use of the device – to about 55 °C, the motor is switched off. The following error message will be displayed:

Temperature !

This message disappears again, if the motor's temperature is reduced below about 50 °C. Now you can continue working with the system.

If a longer treatment has to be continued and you have a spare motor, you can exchange the motor.

Warning!
Change the motor only at standstill.
Do not press the foot pedal, while exchanging the motor.

9.2.3 Risk of Use with Unacceptable Ambient Conditions

The EndoStepper has been designed to be used with ambient conditions as described in chapter 7.3. Please notice the recommendations as described in chapter 9.1.3.

Do not use the device with other ambient conditions, especially with unacceptable humidity, excessive ambient temperatures or with direct heat radiation.

9.2.4 Risks Due to Overload of the Device

In the case of overload, e.g. with unstable mains supply voltages under the nominal tolerances, or with an unacceptable duty cycle or unacceptable ambient temperature, a built-in temperature protection will trigger and de-activate the complete device.

Before again using the device, it has to be switched off.

After a proper delay time the device can be switched on again.

9.2.5 Mechanical Risks Emerging from the Device

Risk due to loose cables: People and things may be caught by the cables!

Risk of injury, if things could drop on patients or other people.

Risk due to the acute root canal instruments: You have to lay down the drive unit only at a safe place, even if you interrupt the treatment only for a short period!

Always put the drive unit into the hand piece rest at the console housing!

9.2.6 Risks Due to Operating Errors

Using a root canal instrument with wrong parameter settings may result in drill breaking.

Check before any operation whether the display information coincides with the used instrument.

Use only the parameter settings for the designated instrument type, and do not use other parameter settings with any root canal instrument!

Do not change the direction of rotation, if the instrument is in the root canal!

9.2.7 Risk Due to Tilting the Root Canal Instrument

When using the EndoStepper there is a risk of accidentally tilting the root canal instrument, which is easier done as compared with e.g. purely manual treatment.

Risk of permanent locking the root canal instrument in the root canal, if a tilted drill is used!

9.2.8 Risk Due to Line Fault

If the mains supply has any fault, the EndoStepper drive will stop immediately. You cannot continue the treatment of the patient.

After the mains supply voltage has returned:

Check the parameters setting, before you continue the treatment!

9.2.9 Risk due to Damage to System Parts

Do not use the EndoStepper system, if any part has any visible damage!

Drill breaking as a consequence of material fatigue due to alternate bending cannot be avoided by the system. Notice the recommendations of the instrument manufacturer.

9.2.10 Risk of Use with Wrong Mains Supply Voltage

Pay attention to the correct supply voltage selection. If you change the mains voltage setting, you have to exchange the mains fuses, too. Please refer to chapter 7.4 for details.

The EndoStepper device will be destroyed if operated with wrong mains voltage selection!

9.2.11 Risk of Using Improper Accessories

Use the EndoStepper only with accessories which have been approved by the manufacturer!

You must not use angle pieces with a built-in reduction gear!

Risk of drill breaking if using drills with wrong selection of parameters!

Risk of drill breaking if using inadequate angle pieces!

Risk of drill breaking if the calibration is not done properly!

Check all parameters and settings again if you change the angle piece or the root canal instrument!

9.2.12 Risk of Dangerous Voltage or Malfunction due to Material Fatigue

Use the EndoStepper system only within the designed lifetime of the device. Any visible damage at the system or parts of it, e.g. mechanical abrasion, should lead you to the conclusion that the device should no longer be operated.

Perform a visible inspection before turning the device into operation!

9.2.13 Risk of Misuse of Keyboard or Foot Pedal Commands

Be careful not to press a key or the foot pedal by accident! Other things deposited on the keyboard might trigger commands accidentally.

Risk of self-instructed motion!

Please note the signal sound produced by the EndoStepper every time you make any parameter changes by means of the keyboard or the foot pedal!

Risk of unnoticed parameter change!

9.2.14 Risk of not admissible Parameter Changes

Check every entry done by auxiliary staff, if you as the responsible dentist do not perform the entry by yourself!

Misunderstandable, unclear or wrong understood instructions may result in wrong parameter selection and therefore may increase the risk of a drill breaking!

9.2.15 Risks Due to Missing or Wrong Instruction Manuals

Use the EndoStepper only after having read the operating instructions belonging to the special device!

The manufacturer reserves the right to modify the system without prior notice. Each unit may be operated only according to the operating instructions and user‘s manual delivered with the device. Always keep the operating instructions of the EndoStepper, the contra-angle and the root canal instruments ready to hand.

9.2.16 Risk Due to Changes of the Accessories

Use accessories as root canal instruments and angle pieces only if you are sure that the parts are approved for use with the EndoStepper!

Angle pieces with reduction gears must not be used with the EndoStepper!

Use only angle pieces, which can be calibrated.

Changing instruments or angel pieces accidentally may cause an instrument break!

Use new instrument types only if the appropriate software is installed in the EndoStepper (refer to the documentation delivered with the update disk or CD-ROM).

9.3 The Risk of Drill Breaking

The EndoStepper system offers a formerly unknown high degree of safety in using the root canal instruments. This is valid even in the case of curved root canals. Root canal treatment is therefore possible also in cases which have not been treated in the past.

The root canal instruments are very delicate tools, which have to be handled with care. Mechanical fatigue may result in a hidden but permanent damage. This may result in a later drill breaking.

Using the EndoStepper system reduces the risk of drill breaking in a way not known in earlier times. But there will be a small, but non neglectable risk of breaking even if the treatment is done with very great care. But this is also the fact, if the treatment is done with a manual way of treatment.

The risk of drill breaking results mostly from smaller damages of the instruments, which are not obvious:

A Material Defects of the Root Canal Instruments

According to the state of art in instrument manufacturing, the instruments may contain hidden material defects. At these flaws of pre-damaged crystal structure the material has no longer the designed stability. Such a damage cannot be detected with reasonable effort.

B Non-appropriate Use of Root Canal Instruments

Handling the root canal instruments you should always be aware of the fact, that no mechanical stress may work onto the instruments. This is valid during storage, cleaning and sterilization and during operation. If parts of the instruments are locally overcharged, the stability of the instruments may be reduced in a way which is not visible!

C Using the Instruments in Excess

Using the root canal instruments to prepare curved root canals will expose the instruments to a stress due to alternate bending. This can result in breaking if the instrument is not used according to the manufacturer's recommendations.

D Using the Wrong Drill Selection or Wrong Accessories

Use instruments only with the correct parameter selection as displayed at the device. Check the selection before using an instrument. Only in this way you can avoid operating an instrument with the wrong parameters.

Operate the device only with the licensed contra-angles with a 1:1 gear ratio. You must not use contra-angles with a reduction gear! Please pay attention to repeat any correction for friction, if you change the angle piece or you switch the device off and on again!

10 The EndoStepper Software Versions

The EndoStepper software has been always adapted to the actual requirements, for example to new drill types. Therefore different software versions are in use.

After switching on the EndoStepper you can inquire the software version. Press F2 and F6 together while the start window is visible. Now a window with some system information is shown: Series no., BIOS version, LOADER version, total system version GesSys, system version System. The service technician needs these information to check your system.

The version information in the item **GesSys** is important for the customer, too:

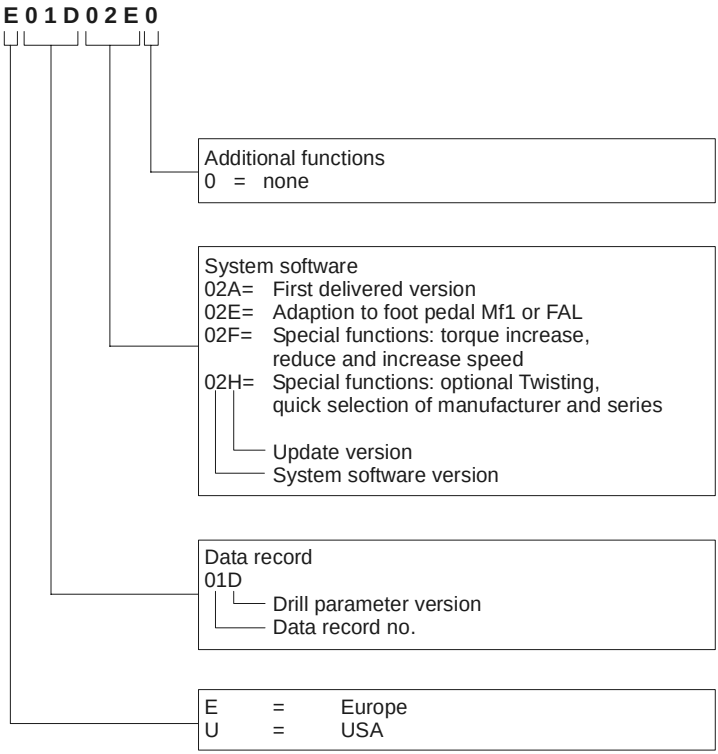
GesSys = total system (see fig. below)

The first character describes the sales region, for ex. Europe or USA.

The following number (01) is the number of the drill data record. The drill parameters were enlarged several times, the character (D) shows the actual drill parameter version.

The actual EndoStepper software edition is 02. There are several versions of this software which offer additional functions.

Further information about additional functions of your software update you'll find in the leaflet delivered with the clearing code.



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