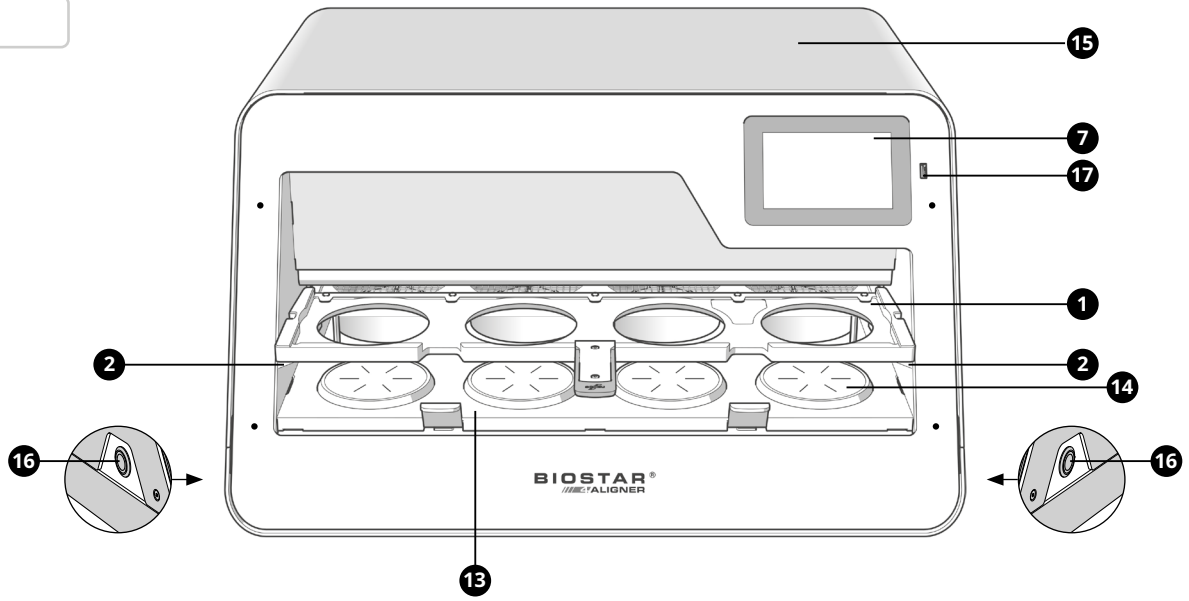


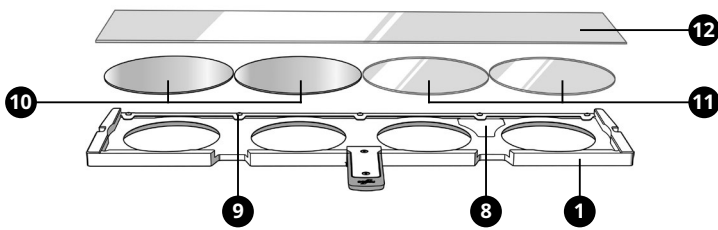


**BIOSTAR**® Operating instructions  
**ALIGNER**

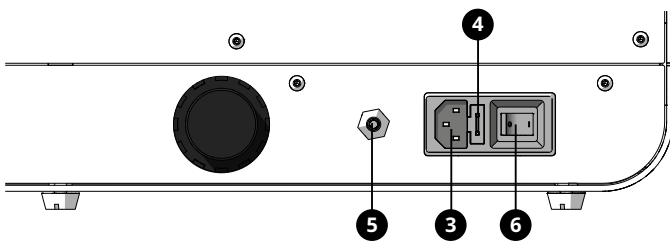
**Fig. 1**



**Fig. 2**



**Fig. 3**



POS	NAME
1	Foil tray
2	Foil tray support
3	Power socket
4	Fuse
5	Air hose connection
6	On/off switch
7	Display
8	Contrast background for barcode
9	Clips for foils
10	Space holder
11	Round foils
12	Strip
13	Model tray
14	Model support plate
15	Top of the device
16	Safety switch
17	USB port

# Safety instructions

Carefully read the operating instructions and important information before commissioning and connecting the device, ensuring that all requirements are met.

- Inspect the device for damage before commissioning. If any damage is found, it must not be operated.
- Always supervise the device when it is switched on.
- We recommend using original SCHEU-DENTAL foils in the size 114 × 499 mm. Optionally, round foils with a diameter of 125 mm can also be used.
- Keep the device out of reach of children!
- Avoid any contact with liquids in order to protect the device against electric shock.
- Heaters reach high temperatures.
- Do not operate the device close to highly flammable materials.
- The device may only be operated using its handles so as to avoid the risk of burns.
- The device may only be transported when it has cooled down.
- When transporting the device, ensure that it is carried by two people from underneath. Weights must not be placed on top of the device under any circumstances.
- The device may only be operated by one person!
- Safe operation of the device can only be ensured using the original SCHEU-DENTAL foils and spare parts.
- Any kind of service work must always be performed by service technicians instructed by SCHEU-DENTAL or at the SCHEU-DENTAL premises. Any conversion or modification of the device will compromise product safety and void warranty and guarantee claims.
- Never open the device without authorisation. Caution: risk of injury!
- Never carry out repairs yourself, without consulting a specialist or following the instructions in this manual!

To prevent electrical overloads, overheating or potential damage to your electrical system, please take the following precautions:

- Check your power supply: ensure that your electrical system can handle the requirements of this device. Consult a qualified electrician if you are unsure.
- Avoid overloading the power supply: do not operate multiple high-power devices such as this one on the same circuit so as to prevent electrical tripping or damage to your electrical system.
- Use a suitable power source: only connect this device to a compatible power source with the required voltage and current rating.

The installation of the power supply for the connection of our devices must be carried out in accordance with international regulations and the regulations derived from them. Our devices are built according to VDE (German Association for Electrical, Electronic & Information Technologies) protection class I and must be connected to a socket with protective conductor.

## Installation

Only use the power and air connections provided. Also ensure that the compressed air supply has a maintenance unit, is free of oil residues and moisture and has a working pressure of at least 4.0 bar, a pressure vessel of at least 12 l and a compressor capacity of 140 l/min. The device can be operated with 230 V, 115 V, 100 V AC with 50 or 60 Hz. The maximum power consumption is 1450 W. Connect to a socket with at least 16 A to which no other device is connected.

### 1. Aufstellung des Gerätes

Place the device on a level, stable surface. Avoid placing it near steam jet and sandblasting equipment or in locations with high levels of plaster or dust, as this may cause contamination. Do not position the device with its rear side directly against a wall, so that the warm exhaust air can circulate and the compressed air supply is not blocked. The device must not be placed in a draught or directly under an air conditioning unit, as this will interfere with the heating control system. The foil tray **1** must rest on the support rails **2** when not in use.

### 2. Mains connection

Connect the BIOSTAR® 4-Aligner to the power supply by plugging the power cable provided into the power socket **3** on the back of the device. To replace the fuses, use a small screwdriver to pull the drawer out of the mains socket **3** and remove the fuse compartment **4**. The fuse compartment contains a spare fuse. A **T15A fuse (REF 3030.935)** is used.

### 3. Compressed air connection

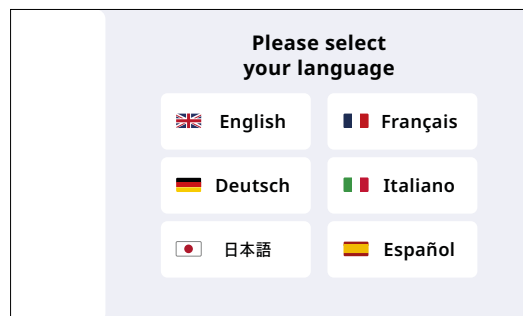
A 20 bar air hose with filter element **5** is connected to the device. Connect the BIOSTAR® 4-Aligner to the air hose (DN 7.2 / 6 mm inner tube diameter) provided and your compressed air supply. The operating pressure for the device is factory set to 4.0 bar/58 psi. The pressure is continuously shown on the display.

## 4. Switching on the device

The device is switched on using the on/off switch ⑥ on the back. The SCHEU logo is displayed for 10 seconds, followed by the current firmware version above the logo and then the start dialogue for using the device.

## 5. Initial settings

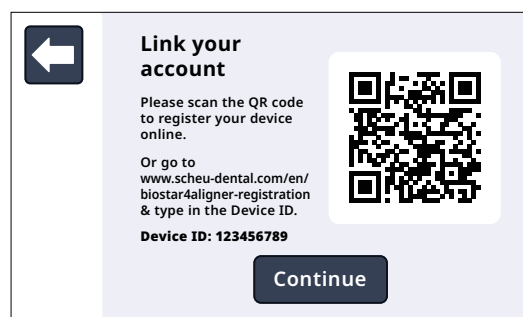
After switching on the device for the first time, you can set the language, date format, time format, device registration/account linking (see point 6), pressure unit, temperature unit and screen contrast to suit your personal requirements. These settings can also be accessed and changed later via the SETTINGS menu (⚙️).



## 6. Link device with SCHEU-DENTAL account

To use the BIOSTAR® 4-Aligner, you need to register your device first. Follow the instructions on the display. After registration you can link the device to your account using the unique device ID.

You can now enter the information required for registration. A five-digit password will then be displayed on the website. This password must be entered manually on the device and the device must be restarted. Then the device is ready for use. If you encounter any problems with online activation, please contact SCHEU-DENTAL.



# Using the device

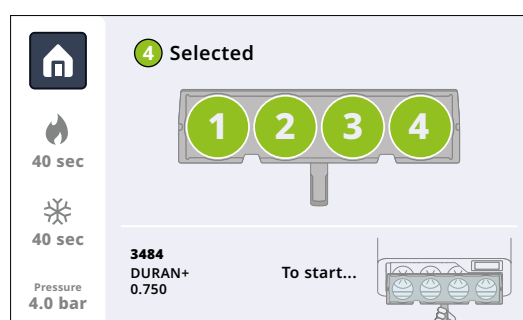
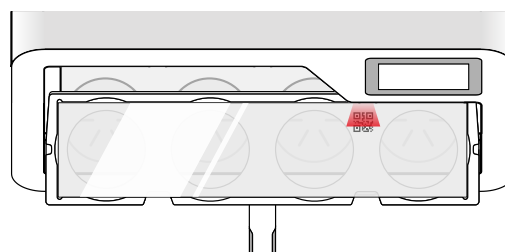
The following paragraphs describe the use of a strip or, optionally, a round foil from SCHEU-DENTAL (Ø 125 mm). Please note that the BIOSTAR® 4-Aligner was designed for processing the strips and is the most effective method of processing. Round foils from SCHEU-DENTAL can also be used.

## SCHEU-DENTAL strips

### 1a. Use of SCHEU-DENTAL strips

The strips must be scanned by the device in order to load the heating and cooling parameters. First, place the foil with the DataMatrix code over the white sticker ⑧ and under all five clips ⑨ in the foil holder ①. Then insert the foil holder so that the scanner reads the barcode on the foil. A beep will sound and the heating and cooling times will be loaded on the display ⑦. All four heater positions are active. To deactivate individual heaters, select the position number of the respective heater by tapping on it.

Place the foil below the scanner



## Round foils (Ø 125 mm)

### 1b. Processing round SCHEU-DENTAL foils

There are **3 options** for loading the parameters of a round foil:

- A.** Place the round SCHEU-DENTAL foil under the scanner.
- B.** Type in the 4-digit REF number for SCHEU-DENTAL foils. To do this, the round foil must be marked.
- C.** Enter the heating and cooling parameters manually. After entering the values, all heater positions are active. Here you can also deactivate individual heaters by tapping on the respective heater position.

#### Please note:

If heater positions are deselected, you must work with placeholder foils and fill the deselected positions with foils in the foil tray. For example, use the supplied DURAN® 1.0 mm foil for this purpose.

## 2. Heating

The heating process starts automatically when the foil tray is pushed completely into the device. Acoustic signals indicate the end of the heating process (+5 seconds to 0 seconds = beeps; if the thermoforming process is triggered by the safety buttons during this time, an error message may appear. Please confirm this with 'Continue'). If no further processing takes place within 5 seconds of the end of the heating process, the process is cancelled because the foil has cooled down too much for a good impression.

## 3. Preparing the models

Before the end of the heating process, the models must be placed as centrally as possible on the model support plates **14** of the model tray at the active heater positions. As soon as the display confirms that the heating process is complete, carefully push the model tray back to the end position **13** so that the models do not slip on the model support plate.

## 4. Lowering pressure chambers

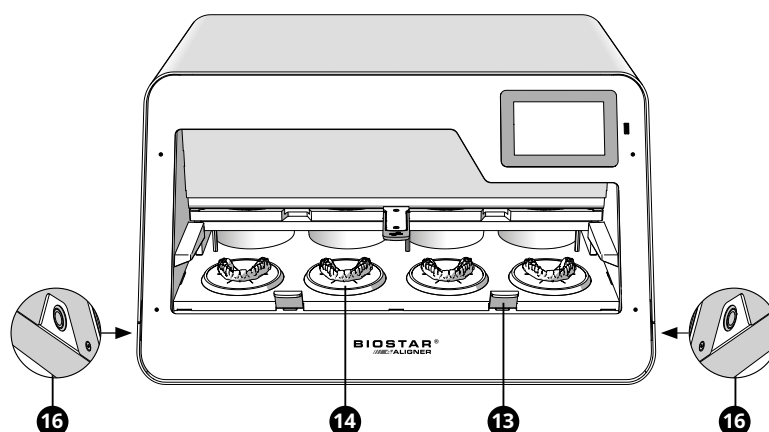
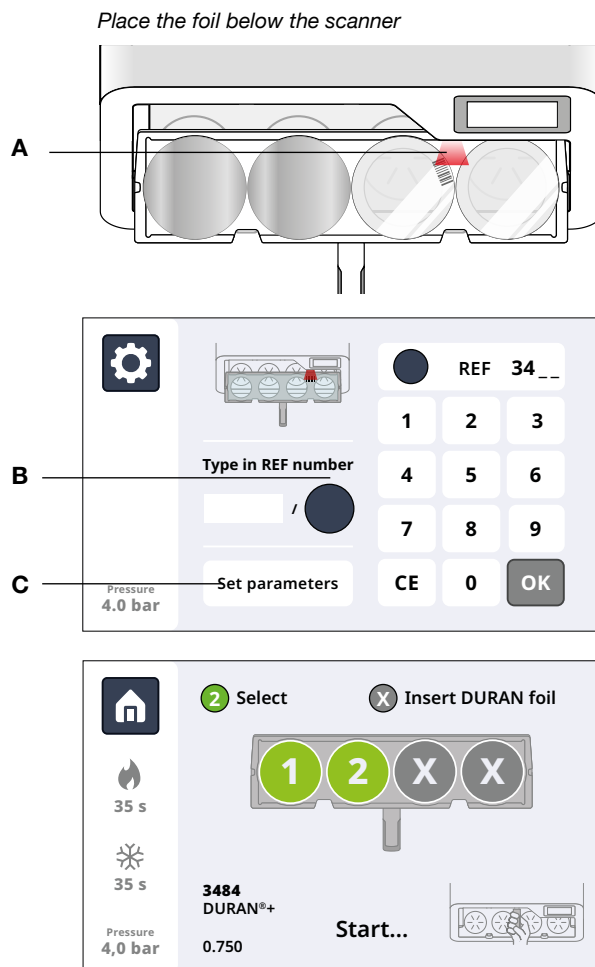
The pressure chambers are lowered automatically using the right and left safety buttons. When the corresponding instruction is displayed, press and hold both safety buttons **16** on the sides of the device simultaneously. Once the pressure chambers have been lowered and the display confirms this, the safety buttons can be released.

## 5. Ventilating, cooling down and venting

The pressure chambers are automatically filled with compressed air after lowering. The cooling time begins with a countdown on the display. Once cooling is complete, the pressure chambers are vented. Wait until the pressure chambers have risen.

## 6. Taking out foil and models

Pull the model tray **13** towards you by the handles and remove the foil and models from the foil tray. The device is now ready for the next thermoforming process.



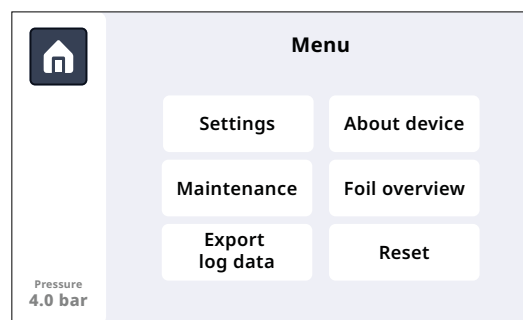
# Device settings

## Settings in menu

The settings menu in the display is accessed by pressing the settings icon. Many device settings can be changed in this menu.

## Settings

These settings include language, date, time, pressure, temperature and brightness. They were already configured during installation.



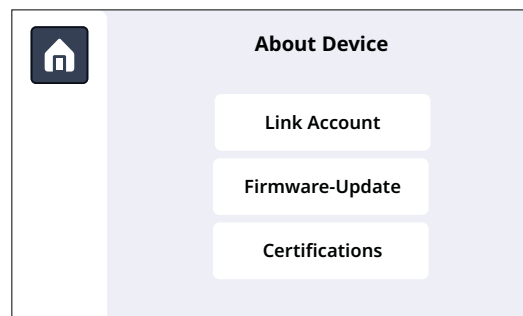
## About Device

In the device information, you will find information about account linking, firmware updates and certificates for the device.

### 1. Link account:

Here you can deregister your registered device connected to your SCHEU-DENTAL account.

### 2. Firmware update:



BIOSTAR® 4-Aligner

### Important information about installation/firmware update

#### 1. Device registration

Please ensure that the BIOSTAR® 4-Aligner has been registered on our website ([www.scheu-dental.com/en/device-registration](http://www.scheu-dental.com/en/device-registration)) before performing the firmware update. This is necessary to ensure smooth operation of the device.

#### 2. Use of suitable USB sticks

Please only use flat USB sticks (see Fig. 1), as other USB stick formats do not guarantee secure contact, which may interfere with the update or cause the device to not recognise the update file for installation.



Fig. 1:  
Example of a flat USB stick.

#### 3. Downloading and preparing the update

- Download the firmware update from the BIOSTAR® 4-Aligner product page at [www.scheu-dental.com](http://www.scheu-dental.com). Unzip the file and transfer the data it contains to the USB stick.
- After copying, you will find the 'MOS' directory on the USB stick, which contains the required update file.

#### 4. Installing the update

- Insert the USB stick into the BIOSTAR® 4-Aligner. ⚙️
- To install the update, navigate to the following path in the device menu: Settings (⚙️) » Device Info » Firmware Update » Select Update » Install
- The update will start and be installed. The process may take 20 minutes or longer. Please do not remove the USB stick before the update is complete.
- Once the update has been successfully completed, a message will appear on the device display.
- Then restart the device to activate the firmware update.

If the screen turns black after installing the firmware update, please contact SCHEU-DENTAL.

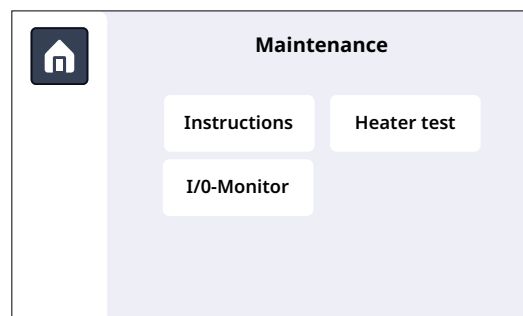
### 3. Certifications:

Scan the QR code shown to view the current certificates for the BIOSTAR® 4-Aligner.

## Maintenance

**IMPORTANT SAFETY NOTICE:** Before carrying out any maintenance, please ensure that the device is completely **turned off** and unplugged from its power source. Failure to do so may result in serious injury, electric shock or damage to the device.

1. Instructions: Scan the QR code shown, which will take you to the BIOSTAR® 4-Aligner product page. Here you will find detailed maintenance instructions.
2. Heater test: Follow the instructions on the display to test the heater function.  
**Restart the device after the test is complete.**
3. I/O-Monitor: Here you can see a control view of all current status values and test the functions of the sensors. You also have the option of viewing the performance of the heaters and testing the fan, the LED display of the safety buttons and the signal transmitter.



## Foil overview

Here is a list of compatible SCHEU-DENTAL foils for the BIOSTAR® 4-Aligner.

## Export log data

Every successful thermoforming process is logged in the device. The following key data is stored: date, time, mode, foil type, unique foil ID, heating and cooling time. To export the log data to a USB stick, insert a **formatted** USB stick into the port **17** next to the display and follow the menu steps. **Then restart the device.**

## Reset

In this menu, you can reset the above device settings and disconnect the device from your SCHEU-DENTAL account.

# Error codes

Error	Description	Possible cause	Solution
<b>Error 001</b>	Pressure too low.	<ol style="list-style-type: none"> <li>The compressor is switched off</li> <li>The output pressure of the compressor is set too low</li> </ol>	<ol style="list-style-type: none"> <li>Switch on the compressor</li> <li>Increase the pressure in the supply network to at least 4.0 bar/58 psi and ensure that the supply line has a diameter of 6 mm. 140 l/min should be guaranteed!</li> </ol>
<b>Error 002</b>	Heater(s) (X) is/are not in operation. You can continue to operate the device without the position of the defective heater(s).	<ol style="list-style-type: none"> <li>Damaged heater (X)</li> <li>Heater test failed</li> </ol>	<ol style="list-style-type: none"> <li>Perform the heater test in the <b>'Maintenance'</b> menu and replace the heater if necessary. The thermocouple may not be working (visual inspection of the heater).</li> <li>Perform the heater test again in the maintenance menu. Perform a visual inspection.</li> </ol>
<b>Error 003</b>	The process is cancelled by pressing the STOP button.	The STOP button was pressed by the user.	The STOP button was pressed by you for a specific reason. Restart the process.
<b>Error 004</b>	Pushing the model support plate back was performed too early	The model tray plate was pushed back too early (before the heating time had elapsed / before the 5 seconds were up).	Make sure that the model support plate is moved at the right time.
<b>Error 005</b>	Process cancelled because the end position (bottom) of the traverse (pressure chamber position) could not be reached.	<ol style="list-style-type: none"> <li>There is an obstacle, the sensor is not switching. Has the model slipped?</li> <li>The safety buttons are not being pressed long enough.</li> </ol>	<ol style="list-style-type: none"> <li>Clear the path of the traverse (pressure chambers).</li> <li>Keep the safety buttons pressed until the message <b>'Release buttons'</b> is displayed.</li> </ol>
<b>Error 006</b>	Timeout	<ol style="list-style-type: none"> <li>The model support plates were not moved from the front position to the rear position early enough</li> <li>After reaching the rear model support plate position, the safety buttons were not pressed early enough to lower the traverse (pressure chambers).</li> <li>An obstacle is preventing the model support plates from reaching their end position.</li> </ol>	<ol style="list-style-type: none"> <li>The foil material has cooled down too much. The quality of the impression has not been achieved. Please restart the process with a new foil.</li> <li>Hold down the safety buttons until the message 'Release buttons' is displayed. Please restart the process with a new foil.</li> <li>Remove the obstacle so that the model support plate can reach the rear end position and the sensor function is ensured. Please restart the process with a new foil.</li> </ol>
<b>Error 007</b>	CMOS battery voltage is low	The battery voltage is below 2.8 V.	Replace CR2032 button cell battery (REM probably deleted). Please contact SCHEU-DENTAL Service.
<b>Error 008</b>	Used strip	The QR code on the strip has already been used.	Use a new strip
<b>Error 009</b>	Invalid strip	The QR code on the strip does not comply with the specifications.	Use a strip with a valid specification.
<b>Error 010</b>	SD card error	The SD card could not be read	Replace the SD card. Please contact SCHEU-DENTAL Service.
<b>Error 011</b>	USB port error	<ol style="list-style-type: none"> <li>USB stick not suitable</li> <li>USB stick defective or full</li> </ol>	<ol style="list-style-type: none"> <li>Use a USB key</li> <li>The USB stick must be formatted in FAT 32</li> </ol>
<b>Error 012</b>	Safety buttons pressed	The safety buttons are 'pressed' – even though they should not be pressed.	Do not press the safety buttons unnecessarily – check that the buttons move freely and are not jammed!
<b>Error 013</b>	Model support plates not in end position during the heater test	During the heater test, the model support plate was moved and the end sensor is not active.	Restart the heater test and follow the instructions.
<b>Error 014</b>	The sensors do not detect the foil tray (left and/or right).	When heating the foil, the sensors on the foil tray are not active. The foil tray may have been moved.	Do not move the foil tray once it has been inserted for heating.
<b>Error 015</b>	Internal diagnosis code (not visible on the user interface)	Internal system process information	No action required; used for service and analysis purposes only
<b>Error 016</b>	After heating, whilst the model support plate is being pushed back (not yet at the end position), the sensors on the foil tray no longer detect the tray.	Sensors on foil tray not active. The foil tray has been moved or the guide plate is broken.	Check whether the magnets are present on the left and right sides of the foil tray and whether the sensors are switching -> I/O monitor under Maintenance. "Foil Left / Foil Right" 1=active / 0=inactive Guide plate may need replacing.
<b>Error 017</b>	The rear end position of the model support plate is not being held.	The model support plate was brought to the end position, but then lost the end position. The platform may have been pulled forwards again, or the spring-loaded pressure pieces are not providing enough support.	Check whether the model support plate is running smoothly. The sensor can be tested in the I/O monitor under Maintenance. "Switch Back" 1=active / 0=inactive The spring-loaded pressure pieces may need replacing.
<b>Error 018</b>	The sensors do not detect the foil tray (left and/or right) – within 5 seconds of heating, when the model support plate is pushed back to the end position.	Sensors on foil tray not active. Foil tray moved or guide plate broken.	Check whether the magnets are present on the left and right sides of the foil tray and whether the sensors are switching -> I/O monitor under Maintenance. "Foil Left / Foil Right" 1=active / 0=inactive Guide plate may need replacing.
<b>Error 019</b>	The model support plates are not in their end position whilst the safety buttons are pressed and the pressure chambers are moving downwards.	The model support plate was brought to the end position, but then lost the end position. The platform may have been pulled forwards again, or the spring-loaded pressure pieces are not providing enough support.	Check whether the model support plate is running smoothly. The sensor can be tested in the I/O monitor under Maintenance. "Switch Back" 1=active / 0=inactive The spring-loaded pressure pieces may need replacing.

Do you have a problem with the device that is not listed here? Please feel free to contact the SCHEU-DENTAL team.

# Warranty

## **GB** Warranty terms and conditions for SCHEU-DENTAL GmbH devices

SCHEU-DENTAL GmbH does not provide warranties for:

- repair services carried out by the purchaser or unauthorised personnel
- damage caused by inappropriate handling or operation
- failure to comply with the operation, cleaning and maintenance regulations
- inappropriate connection or incorrect installation
- force majeure or any other influences beyond the control of SCHEU-DENTAL
- any modifications to the devices
- the use of spare parts from other manufacturers
- signs of wear due to age that do not affect the main functions of the devices
- improper handling as a result of using foils that do not originate from SCHEU-DENTAL.

Claiming warranty services does not result in the warranty period being extended or restarted. If you make an unjustified claim to customer service, you will be invoiced for the costs incurred.

**GB** Our foils have been tested and approved regarding cell biology in accordance with the international standards ISO 10993 and ISO 7405.



## EU - Declaration of Conformity

Name and address of manufacturer:

SCHEU-DENTAL GmbH  
Am Burgberg 20  
58642 Iserlohn  
Telefon: 02374 / 9288-0  
Telefax: 02374 / 9288-90

This is to certify that this machine:

**Machine for applications in the dental Pressure Moulding Technique**

Typ:  
**BIOSTAR®**  
**///E-ALIGNER**

**Art.-No 3030.1**

**Technical Information:**

<b>Voltage</b>	<b>95 - 230 V 50/60 Hz</b>
<b>Power</b>	<b>max. 1450 W</b>
<b>Working Pressure</b>	<b>4 bar / 58 psi</b>
<b>W x H x D</b>	<b>62 x 34 x 55 cm</b>
<b>Gross / Net Weight</b>	<b>62 kg / 56 kg</b>

is in accordance with the following guide line:

**Low Voltage Guide Line 2014 / 35 / EU**  
**EMV Guide Line 2014 / 30 / EU**  
**RoHS Guide Line 2011 / 65 / EU**  
**Machinery Directive 2006 / 42 / EC**

Testing according to

**DIN VDE 0411-1 / EN 61010-1 / IEC 61010-1**

This Declaration of Conformity is valid until recalled.

Iserlohn, 16.04.2024

Andreas Faber  
Quality Manager / Regulatory Affairs  
Person Responsible for Regulatory Compliance (PRRC)

E-BIOSTAR\_4-Aligner\_rev\_0\_16\_24

SCHEU-DENTAL GmbH Am Burgberg 20 Postfach 7562 phone 02374 9288-0 Geschäftsführer: CEO Albert Sterkenburg HRB Iserlohn 2371  
www.scheu-dental.com 58642 Iserlohn 58613 Iserlohn fax 02374 9288-90 CFO Rüdiger Schmidt WEEE-Reg.-Nr: DE 52399144



**SCHEU-DENTAL GmbH**

www.scheu-dental.com

phone +49 2374 9288-0

fax +49 2374 9288-90

Am Burgberg 20

58642 Iserlohn · Deutschland