























Safety instructions

Carefully read the operation and safety instructions before commissioning and connecting the device, ensuring that all requirements are met.

- Inspect the machine for damage before commissioning. If any damage is found, it shall not be operated.
- Always supervise the machine when it is switched on.
- Please use original SCHEU-DENTAL strips of 114x499mm!
- Keep the device out of reach of children!
- Avoid any contact with liquids in order to protect the device against electric shock.
- Infrared heaters reach high temperatures during operation.
- Do not operate the device close to highly flammable materials.
- Ensure to operate the device only using its handles to avoid the risk of burns.
- The device shall only be transported when it has cooled down.
- Make sure that the heater is not exposed to any load during transport.
- Safe operation of the device can only be ensured using the original SCHEU-DENTAL spare parts.
- Any kind of service operation shall always be performed by service technicians instructed by SCHEU-DENTAL or at the SCHEU-DENTAL facilities. Any conversion or modification of the device compromises product safety and leads to the expiration of warranty and guarantee claims.
- Never open the device without authorization. Caution: Risk of injury!
- Never carry out repairs yourself, without consulting a specialist or following the instruction in this manual!

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

- Check your electrical capacity: ensure that your electrical circuit can handle the current requirements of this device. Consult with a qualified electrician if you are unsure.
- Avoid overloading circuits: do not use multiple high-power devices on the same circuit as this device to prevent electrical tripping or damage to your electrical infrastructure.
- Use the appropriate power source: always connect this device to a compatible power source with the required voltage age rating.

The installation of power supply for the connection of our equipment shall be carried out in accordance with international regulations and the regulations derived thereof. Our equipment is built according to VDE (German Association for Electrical Engineering, Electronics and Information Technology), protection class I and shall be connected to a socket with protective conductor.

Installation

Ensure to use solely the original power and air connections provided with the delivery. Make also sure that the compressed air supply is completely free from oil residues and humidity and has a minimum feed pressure of 4.0 bar and flow rate of 5.0 CFM, 140 l/min . The device operates on 230V, 115V, 100V AC with 50 or 60Hz. The maximum power input is 1450 W. Plug into an outlet of at least 16A without an other appliance connected.

1. Positioning device

Place the device on a flat surface not close to steam jet and sand blasting units or places with high plaster and dust exposure. Make sure that hot air can exit the device on the back, do not place the device directly against a wall. The foil tray **1** should rest on the support rails **2** when not used. Placing the foil tray on top of the device might damage the surface.

2. Mains connection

Connect the BIOSTAR[®] 4-Aligner device to the power supply by plugging the power cable provided with the machine into the power socket on the back of the device. A single fuse is built in the main socket protecting the electrical parts from overvoltage. In order to exchange the fuses, press the small clip underneath the power socket and remove the fuse box (3). A spare fuse is stored in the fuse box. The fuse **T15A (REF 3030.935)** is used.

3. Compressed air connection

A 20 bar air hose with filter element \bigcirc (DN 7.2 / 6 mm inner tube diameter) is connected to the device. Connect the BIOSTAR[®] 4-Aligner device to the provided (DN 7.2 / 6 mm inner tube diameter) air hose and your compressed air system. The operating pressure is set at the factory to 4.0 bar/58 psi. This pressure guarantees best thermoforming results and is being continuously indicated on the display; it shall not be modified. In case a reduction should be required, you can adjust the pressure using the pressure regulator \bigcirc on the back of the device. The pressure regulator is unlocked by pulling and can then be turned (- \checkmark +). After adjusting, the pressure regulator should be locked again by pressing it in. In case pressure is increased, exceeding 5 bar/72 psi (which does not correspond to our recommendation), the safety valve starts to operate, which is indicated by a loud venting noise.

4. Switching on the device

The device is switched on using the on/off switch 🕜 on the back. A startup screen with Scheu logo is shown for approx. 10 sec, before the standard dialogue appears.

5. First-time-use settings

After powering on the device for the first time, you can customize the language selection, date format, time format, pressure definition, temperature scale and screen contrast to your personal needs. These settings are also accessible from the SETTINGS menu.



6. Link device with SCHEU-DENTAL account

To use the BIOSTAR® 4-Aligner device, you need to register at www.scheu-dental. com/en/biostar4aligner-registration. After registration you can link the device to your account using the unique Device ID. Once the first-time-use settings have been made, a QR code is displayed. You can also display the QR-Code by accessing the SETTINGS menu. It is recommended to scan the code with a mobile phone to access the landing page. (Alternatively, you can simply type in the URL next to the QR code on a computer.)

You can now enter the necessary entries for registration. Once these have been finalised, a five-digit activation code on the website is shown. This code must be entered manually on the device. Once the code has been entered, the device is ready for use. If you have trouble with the online activation, please contact SCHEU-DENTAL.

Link your account Please scan the QR code to register your device online. Or go to www.scheu-dental.com/en/ biostar4aligner-registration & type in the Device ID. Device ID: 123456789 Continue Device ID: 123456789 Please enter the Activation code: <u>Enter</u> mastercode Enter

Using The Device

Before using the device determine how many models you want to make and what foil you want to use. The following paragraphs describe how to use a SCHEU-DENTAL strip foil or a round foil (Ø 125 mm). Please note that the best results can only be achieved with the original SCHEU-DENTAL foils.

SCHEU-DENTAL strip foil

1. Load parameters for strip foil

To pressure form four aligners at the same time, only strip foils from SCHEU-DENTAL can be used. These foils need to be scanned by the device to load the heating and cooling parameters. Place the foil first in the foil tray **①** with the datamatrix code above the white sticker (9) and beneath the clamps (10). Then slide in the foil tray until the scanner reads the barcode on the foil. You will hear a beep sound, and the heating and cooling times are loaded on the screen (8). After which the foil tray 1 should be pushed in completely.

2. Selecting heaters

With original SCHEU-DENTAL strips four heater positions are selected by default. To deselect a position, click on it. --- Go to 3. Heating

Place the foil below the scanner



Round foil (Ø 125 mm)

1. Load parameters for round foil

There are **3 options** to load the parameters of a round foil:

A. Place the round SCHEU-DENTAL foil under the scanner

- ${\bf B}.$ Type in 4 digit REF number for SCHEU-DENTAL foils
- $\ensuremath{\textbf{C}}.$ Fill in heating and cooling parameters manually



Place the foil below the scanner





2. Selecting heaters

With round foils (\emptyset 125 mm) only two heater positions can be used. Standard are the two right heater positions selected. To change a postition, first deselect before selecting a new position. If no heater is selected, place the DURAN 1.0 foil (that is included in the packaging) (1) on the position that is not selected in the foil tray (1).

3. Heating

The heating process will automatically start when you slide in the foil tray fully to the back in the device. Acoustic signals indicate the end of the heating process (+5 sec to 0 sec = beeps). If no action is followed up within 5 seconds after the end of the heating process, the operation will be aborted, since the foil has cooled down too much to make a good impression. You will be asked to restart the operation with a new foil.

4. Preparing the models

Before the end of the heating process the dental models 2 should be placed on the platforms 1 of the model tray where no DURAN 1.0 foil is placed. When the screen confirms that the heating process has finished, slide the model tray 3 with dental models backward.

5. Lowering pressure chambers

A safety feature has been built in to automatically lower the pressure chambers. When indicated on the screen, press and hold the two safety buttons 🕡 on each side of the device simultaniously. When the pressure chambers are down and the screen confirms this, the safety buttons can be released.

6. Pressurising, cooling & depressurising

After the pressure chambers have been lowered, they are filled with air automatically. The cooling time starts with a count down clock on the screen. Once the cooling has been finished, the pressure chambers are depressurized. Wait for the pressure chambers to be in the top position. Then the device is ready for the foil and dental models to be taken out.

7. Taking out foil & dental models

Pull the model tray 12 towards you by the handles and remove the foil and dental models from the foil tray. Take off the foil tray and place it on the support rails (2). The device is now ready for the next pressure moulding process.



Device Settings

Settings in screen menu

To enter the settings menu on the screen the settings icon must be pressed. In this menu many device settings can be changed:

Settings

These settings include the language selection, date format, time format, pressure definition, temperature scale and screen contrast. They have already been configured during installation.

About device

Information about the certifications of the BIOSTAR 4-Aligner device can be found here, as well as the menu to link the device to a SCHEU-DENTAL account, and the option to update the firmware of the device (see also Chapter Firmware).

Maintenance

User maintenance procedures are explained in the Maintenance chapter of this instruction manual. The maintenance menu on the device provides direct links to all user maintenance procedures in this manual.

Foil overview

The compatible foils from SCHEU-DENTAL for the BIOSTAR® 4-Aligner device are listed here.

Export log data

Each successful thermoforming process is logged onto the device. The following key data is saved: date, time, foil type, unique foil ID, active heater positions, heating time and errors. To export the log data to a USB-stick, place a USB-stick in the slot **(P)** next to the screen and follow the menu steps. Then switch the equipment off and on again.

Reset

In this menu the above settings of the device can be reset, and there is the option to unlink the device from the SCHEU-DENTAL account.

Maintenance

IMPORTANT SAFETY NOTICE: before performing 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, electrical shock, or damage to the machine.

1. Replacing the heater (Fig. 5, 6 and 7)

Make sure that the back of the device is accessible, and that the model plate 🔞 is in the fully backward position.

1. Remove the back panel 20 by unscrewing the hex socket screws, 2. Take off the heater protector 21 by also unscrewing six hex socket screws, 3. Unscrew the two heater wires 24 from the ceramic terminal block 25 4. Detach the circulair part glass of the heater 22 from the clips 23 and take out, 5. Position and fasten a new heater onto the clips.

To check if the heaters are working properly, perform the heater test and follow the instructions on the screen.

2. Replacing the thermocouple (Fig. 8 and 9)

Follow step 1 till 4 from Replacing the heater. Unscrew the two screws holding the small bracket ③ which clamps the thermocouple tube ③ in place inside the reflector. Unplug the damaged thermocouple adapter ③ . Plug-in the new thermocouple, position and fasten the thermocouple adapters and small bracket. Finally, place the heater back and perform a heater test in the 'Maintenance' menu.

3. Replacing an O-ring (Fig. 4)

If the device gives an error that the pressure cannot build up, check if the O-ring 23 at the bottom of the pressure chambers 27 is in place and in tact.

4. Removing stuck foil from heater protector

Always use the recommended heating time for the selected foil. If the foil gets too hot during heating it might bend and touch the heater protector. Remove the back panel and heater protector (see 1. Replacing the heater) to be able the clean this part.

5. Cleaning the device

The BIOSTAR[®] 4-Aligner device is generally maintenance-free. Ensure however to control the air tube with the filter element for any kind of debris or moisture. The filter element can be exchanged if necessary. The four model platforms (1) can be cleaned by means of air nozzle or steam jet (if

Â	Ме	Menu	
	Settings	About device	
	Maintenance	Foil overview	
	Export log data	Reset	
Pressure 4.0 bar			

needed the platforms can be taken out by turning counter-clockwise). Ensure that the reflective surfaces of the reflectors 23 are always clean for optimum heating results. Use a non-aggressive cleaning agent to clean the housing parts 16 of the device.

Firmware

1. Download the firmware

Go to www.scheu-dental.com/en/download.

2. Upload the firmware on an empty USB-stick

3. Select and install the firmware

In the 'About device' menu the new firmware version can be installed. Select the new firmware version from the USB-stick and click on Start update. After installing the device will restart itself.

Troubleshooting

Problem	Probable reason	Solution
The foils are partially burned or too soft.	You entered a wrong code or heating time for the foil.	Ensure to observe the batch specifications given in the product labelling.
Pressure moulding results are not satisfying.	You entered a wrong code or heating time for the foil. The inlet pressure is too low.	Ensure to observe the batch specifications given in the product labelling. Ensure that the inlet pressure is set to 4.0 bar (58 PSI).
No pressure build-up.	The O-ring is not sealing the foil. No foil or DURAN 1.0 foil is present in the foil tray.	Check if the O-ring is in place and in tact. Place the foil or metal disc correctly in the foil tray, not protruding the dedicated recess.
Heating process won't start.	The foil tray and/or model plate are not in correct position.	To start heating, pull the model tray forward, and slide in the foil tray all the way to the back of the device.
Pressure chambers do not reach bottom position.	An obstruction is detected. Safety buttons are not pressed long enough.	Clear the path of the pressure chambers.
One of the heaters is not warming up.	Faulty heater.	Perform the heater test in the Maintenance menu and replace the heater if necessary.
Heater is turned on. An error is shown that the heater is not working.	Faulty thermocouple.	Perform the heater test. If the heater is turned on, but no temperature change is registered, then replace the thermocouple.
Cycle is aborted.	You have waited too long to move model plate backward or to press safety buttons.	Follow the instructions on the screen and release the safety buttons when instructed.

Error codes

Error	Probable reason	Solution
Error 001 Pressure too low.	1. Compressor is turned off.	Turn on compressor.
	2. Compressor output pressure is set too low.	Increase the inlet pressure to 3.5 bar (50,8 PSI) minimum.
	3. Pressure control valve on the Biostar 4-Aligner is too low.	Increase the inlet pressure to 3.5 bar (50,8 PSI) minimum.
Error 002 One or more heaters are not working. You can continue operating the machine without the position of the broken heater(s).	1. Faulty heater	Perform the heater test in the 'Maintenance' menu and replace the heater if necessary.
	2. Unsuccessful heater test	Rerun the heater test in the maintenance menu. Perform a visual check to see if the heater is working.
Error 003 Cycle aborted by pressing STOP button.	The STOP button was pressed by the user.	Restart the the process with a new foil.
Error 004 Cycle aborted because of faulty heater(s).	During the heating process the device could not detect heat at one or more positions.	Perform the heater test in the 'Maintenance' menu and replace the heater if necessary.
Error 005 Cycle aborted because the end position has not been reached.	1. An obstruction is detected.	Clear the path of the pressure chambers.
	2. Safety buttons are not pressed long enough.	Hold safety buttons until the message 'Release buttons' appear.
Error 006	1. Thermocouple is not connected.	Plug in thermocouple correctly.
One or more thermocouples do not give a signal.	2. Thermocouple is faulty and doesn't give a signal.	Replace thermocouple.
Error 007 Short circuit in thermocouple cable.	A damaged cable or incorrect placement of the thermocouple.	Please check if the thermocouple is installed correctly and that the cables are not damaged.
Error 008 Operation time out.	The model plate did not reach the back position in time.	The foil material has cooled down excessively, affecting the quality of the dental impression. Please restart the operation with a new foil.
Error 009 Cannot build pressure in chambers.	1. Compressor doesn't meet the requirements.	1. Check if your compressor has the appropriate requirements.
	2. The foil has a puncture through which air escapes.	2. Use a new foil.
	3. DURAN 1.0 foil is missing in one of the unused positions.	3. If a round foil is used, a metal disc should cover the unused dental positions in the foil tray.
Error 010 The heating operation was stopped before completion.	1. The STOP button was pressed by the user.	
	2. The model plate was pushed forward before the heating cycle was completed.	
	3. The foil tray was pulled back by the user which interrupted the heating cycle.	
	4. The safety buttons were pressed before the heating cycle was completed.	
Error 011 Faulty USB	1. Damaged (or full) USB-stick.	1. Check if the USB-port or USB-stick is physically damaged.
		2. Check the USB-stick functionality on another device.
Error 013 CMOS battery voltage is low.	CMOS battery voltage is low. User settings are lost, and time and date are not showing correctly.	Please contact SCHEU-DENTAL service about replacing the CMOS battery.

Warranty

GB Warranty terms and conditions for the following machines of SCHEU-DENTAL GmbH

The machine you bought has been carefully checked and found to be in perfect condition, meeting highest technical demands. SCHEU-DENTAL GmbH does not provide warranties for:

- repair services effected by the buyer or unauthorised staff
- in case of damages due to inappropriate use or handling
- in case of a failure to comply with the handling, cleaning and maintaining prescriptions
- in case of inappropriate connection or incorrect installation
- in case of force majeure or any other influences beyond the control of SCHEU-DENTAL
- in case of any modifications to the machines
- in case of using spare parts of other manufacturers
- in case of signs of wear due to age, not affecting the main functions of the machines
- in the event of improper handling as a result of using foils that do not originate from SCHEU-DENTAL.

Utilisation of warranties does not extend or restart the standard warranty period. In case of unjustified utilisation of our warranties we reserve to charge a fee for the corresponding services.

GB Our pressure moulding material has been tested and approved in terms of cell biology in compliance with the international standards ISO 10993 and ISO 7405.



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