

Instructions for Use

SAHARA-TSC SAHARA-TSC 115V



Basic notes!


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Please keep the Instructions for Use as a reference for information on your device.

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Nümbrecht, August 2023
SARSTEDT AG & Co. KG

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Table of Contents

Basic notes!	2
1 Safety information	4
2 Explanation of symbols and instructions	4
3 After unpacking	6
4 Scope of delivery	6
5 Indication for use and function	6
6 SAHARA-TSC membrane keypad	7
7 Installation and commissioning	7
7.1 SAHARA-TSC	7
7.2 Protocol printer module	8
8 Standby mode	8
9 Pre-warming of the adaptation compresses	8
9.1 Pre-warming using SAHARA-TSC	8
9.2 Pre-warming using SAHARA-III basic model	9
10 Thawing of cryopreserved leukapheresis products from mobilised donors	10
10.1 Infrared sensor	10
10.2 Thawing	10
11 Error messages and troubleshooting	11
12 SAHARA-TSC service and maintenance	12
12.1 System test	12
12.2 Cleaning	13
13 Decommissioning and disposal	14
14 Servicing and transport	14
15 Technical Data SAHARA-TSC	14
16 Accessories	15
17 Warranty and guarantee	15

Instructions for use SAHARA-TSC

1 Safety information

- Please note the information in the service manual.
- The device may only be operated by trained medical personnel.
- The device may only be installed and operated in areas of professional health care facilities with no strong electromagnetic interference fields. Portable RF communication equipment may affect the device functions and should therefore not be used at a distance less than 30 cm from parts and cables of the device.
Operate the device only with the mains cable supplied. Using a mains cable other than the original cable supplied may lead to a higher electromagnetic emission or reduced electromagnetic immunity of the device and result in a malfunction. This device should not be operated directly beside or stacked with other devices, since this may lead to a malfunction. If this is however necessary, the devices should be observed with respect to their correct operation.
- To prevent the risk of electric shock, the device must only be connected to a mains supply with a protective earth connection.
- Check the device for visible signs of damage before switching on. If you notice any safety relevant damage the device must not be used.
- If the device should be connected to an IT network, the integration of IT devices other than those specified in Chapter 16, changes to the IT network configuration, additional connection or removal of IT devices, and a software update on the IT devices used can lead to risks for patients, operators or third parties that were previously unknown. These risks should be analysed and assessed by the operator.
- To remove leaked liquids do not tilt the device.
- To avoid possible crushing of fingers install and remove the agitation plate only when the device has been turned off.
- If the device has to be opened during cleaning or servicing, it must be turned off and disconnected from the local power supply by unplugging the mains cable since some device parts are under voltage even when the device has been turned off.
- The device must not be used within the patient environment.
- The leukapheresis product within the device must not be connected to the patient.
- During an on-going tempering process the leukapheresis product must not be removed from the device.
- Do not modify this equipment without authorization of the manufacturer.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent national authority in which the user is established.

2 Explanation of symbols and instructions



Follow instructions for use



WARNING

Important information. If ignored a serious or life-threatening injury may occur.



WARNING

Important information. If ignored an electrical shock due to dangerous voltage may occur.



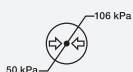
CAUTION

Important information. If ignored a minor injury may occur.



CAUTION

Helpful information on the appropriate use of the device. If ignored an operating error, malfunction or device defect may occur



Permissible pressure range

Instructions for use SAHARA-TSC



Permissible temperature range



Store in a dry place



Article number



Serial number



CE mark



Medical device



Manufacturer



Country of manufacture



Manufacturing date



Unique product identification



Separate collection of electrical and electronic equipment



Alternating current

3 After unpacking

Immediately upon receipt check the packaging and the device for damage and completeness in accordance with chapter 4. If you notice any damage caused during transit then please notify the responsible transport company and the sales agency assigned to your organisation without delay.

Retain the entire packaging in a safe place as evidence for any claim and if required for the return of the device.

4 Scope of delivery

SAHARA-TSC and SAHARA-TSC 115V each consist of:

- the SAHARA-TSC platform including the warming plate
- a warming shell
- the adaptation compress TSC (5 pieces)
- a mains cable
- these instructions for use and
- a service manual



The protocol printer module is not in the scope of delivery of the SAHARA-TSC or SAHARA-TSC 115V respectively. It must be ordered separately (see Section 16). The use of the protocol printer module is necessary if the temperature of the leukapheresis products is to be displayed and documented during the thawing process, or if the system test or occurring errors are to be recorded.

5 Indication for use and function

The dry tempering device SAHARA-TSC allows a fast and temperature-controlled thawing of cryopreserved products from mobilised donors (therein referred to as leukapheresis products). SAHARA-TSC has been successfully tested using cryopreserved leukapheresis products from mobilised donors with volumes ranging from 60 ml to 120 ml.

Immediately prior to the transfusion, the cryo-preserved leukapheresis products are thawed separately between a pre-warmed adaptation compress and an equally pre-warmed aluminium warming shell, employing the "sandwich method". Thus, the temperature of each leukapheresis product bag is measured continuously via an infrared sensor which is placed directly on the surface of the preparation. To achieve an almost homogeneous temperature profile within the leukapheresis product it is permanently agitated. During the thawing process the adaptation compress serves as a passive heat reservoir which cools off whereas the temperature of the warming shell is controlled actively by an electrically heated warming plate. If the infrared sensor detects a free of ice state of the leukapheresis product, a visual and audible signal is output, and the energy supply via the warming plate is reduced to decelerate the further warming of the leukapheresis product.

Functions:

Safe tempering method

- Contamination risks by water-borne pathogens associated with water baths are prevented
- Temperatures of the warming shell and the adaptation compress are controlled to ensure leukapheresis product quality that is at least equal to or even be better than using a water bath
- Standardised thawing process
- Delayed key reaction prevents unintentional aborting of the thawing process.

Simple operation

- No adjustment of tempering times and ambient temperatures required

Blood bag agitation

- Gentle agitation to achieve an almost homogeneous temperature profile within the bag and to prevent damage to the stem cells.

Temperature monitoring

- Measurement of the preparation temperature by means of an infrared sensor.
- Documentation of the recorded preparation temperature by means of a protocol printer.

Instructions for use SAHARA-TSC

- Fast availability of the leukapheresis products due to visual and audible free of ice indication.
- Display of the degree of tempering of the adaptation compresses.

Integrated system test

- Checking the device functions
- Calibration of temperature sensors
- Use of additional measuring equipment is not required

Protocol printer

- Display and documentation of the measured preparation temperature.
- Documentation of errors
- Documentation of the integrated system test

Easy cleaning

- Leaking stem cells from defective bags are collected in the warming shell and cannot reach the interior of the device
- Warming shell, warming plate and adaptation compresses can be taken out of the instrument separately and can easily be cleaned and disinfected.

Hygienic thawing conditions

- Easy to clean and disinfect warming shell which can even be autoclaved prior to thawing the leukapheresis product.

6 SAHARA-TSC membrane keypad

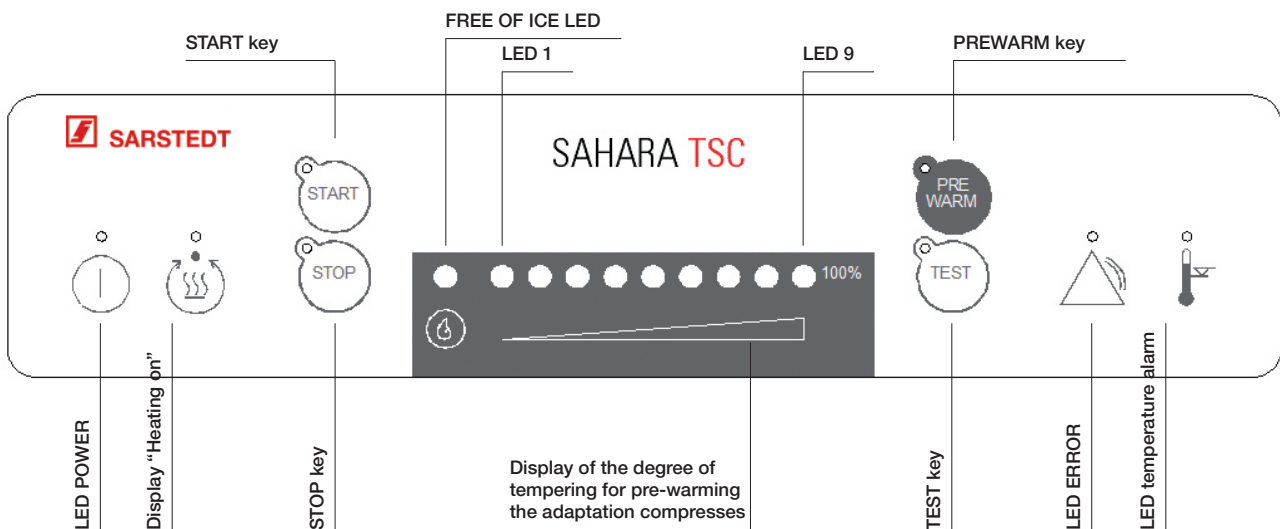


Fig. 1: SAHARA-TSC membrane keypad

7 Installation and commissioning

7.1 SAHARA-TSC

- Install SAHARA-TSC away from sources of heat and humidity. The installation base must be horizontal and should not be exposed to any vibration.
- Connect SAHARA-TSC via the supplied mains cable to the local power supply.

Instructions for use SAHARA-TSC



The device may be connected only to a power supply with protective earth conductor and has to be set up so that the mains plug can be disconnected from the mains supply at any time.

- Connect the warming plate coding plug to the socket at the rear of the agitator mechanism. Locate the four pins on the underside of the warming plate on the agitator mechanism and push to secure into position.
- Set the warming shell onto the warming plate so that the grooves in the shell are on the left side.
- Turn on SAHARA-TSC using the power switch. The system automatically enters the standby mode.



The device functions should be checked via system testing (see chapter 12.1) before initial operation and after maintenance work.


7.2 Protocol printer module

- Turn off SAHARA-TSC at the power switch.
- Insert the mains cable into the power supply connector at the rear of the protocol printer and connect the mains plug to the local power supply.
- Connect the protocol printer to the serial interface at the rear of SAHARA-TSC by means of the data cable.
- Turn on the protocol printer using the power switch at the rear of the device. The protocol printer automatically enters the standby mode.



Please note further information in the separate instructions for use for the protocol printer that are enclosed with the module.

8 Standby mode

After switching on the device, after aborting the pre-warm or thawing process as well as after passing a system test, SAHARA-TSC automatically enters the standby mode. The warming plate is heated to 36 °C and the thawing function is activated. This is indicated by the non-illuminated LED of the  key.

9 Pre-warming of the adaptation compresses

Prior to thawing cryopreserved leukapheresis products, one adaptation compress per leukapheresis product must be pre-warmed to between 37 °C and 40 °C. For pre-warming, the SAHARA-TSC, the SAHARA-III basic model or any other appropriate dry-tempering system can be used.



When using the SAHARA-III basic model or another dry-tempering device for pre-warming, the adaptation compresses must remain within the device for at least 30 minutes to achieve a complete warming throughout. Non-observance of this may cause prolonged thawing times.

9.1 Pre-warming using SAHARA-TSC

- Clean and disinfect the adaptation compresses as described in the package insert.
- Open the system flap and lay the required number of up to 4 adaptation compresses in the warming shell as described in Figure 2. Place the infrared sensor completely on the compress below.

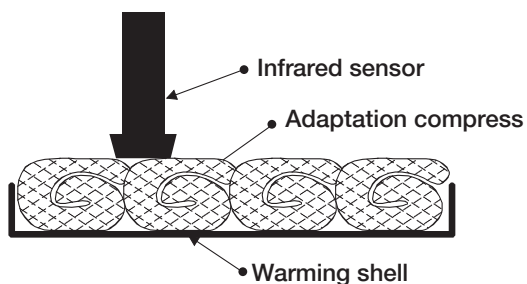








Figure 2: Pre-warming of adaptation compresses in SAHARA-TSC


- Close the system flap and operate the  key. The LED in the  key lights up. This shows the activation of the pre-warm function.
- Start pre-warming by pressing the  key. Approx. 30 seconds after pressing the  key, the blower starts tempering the adaptation compresses on the warming shell by warming the ambient air within the device. Additionally, the adaptation compresses are tempered by the warming plate. The progress of the pre-warming process is indicated by the display of the degree of tempering on the keypad.
- The adaptation compresses must remain within the SAHARA-TSC until the degree of tempering has reached 100 %.



Do not remove the adaptation compresses from the SAHARA-TSC before a 100 % degree of tempering is reached as this could lead to an incomplete warming of the adaptation compresses.

- Immediately before starting the thawing process of the leukapheresis products, abort the pre-warming by pressing the  key.
- Open the system flap and place the adaptation compresses on a heat-insulated bench. Store the adaptation compresses that are not needed immediately in a closed insulated box (see Chapter 16) to prevent them from cooling.
- After the pre-warming, the function for thawing leukapheresis products is automatically activated. This is indicated by the LED in the  key turning off.

9.2 Pre-warming using SAHARA-III basic model


- Clean and disinfect the adaptation compresses as described in the package insert.
- Open the system flap and place the adaptation compresses on the warming plate as described in Chapter 9.1.
- Close the system flap and start the pre-warming process in the 37 °C function by pressing the  key.
- The adaptation compresses must remain in the SAHARA-III basic model for at least 30 minutes.



During the pre-warming process, the warming plate must not be removed from the device.



Do not abort the pre-warming process even if the device indicates a temperature of 37 °C because this could lead to an incomplete warming of the adaptation compresses.

- Open the system flap and remove one adaptation compress for the planned thawing process. Leave the remaining adaptation compresses in the SAHARA-III basic model and close the system flap.
- Upon removing the last adaptation compress from the SAHARA-III basic model, cancel the pre-warming process by pressing the  key.

10 Thawing of cryopreserved leukapheresis products from mobilised donors

10.1 Infrared sensor

The mobile probe that is attached to the arm of the warming plate is an infrared sensor, monitoring a circular area of approximately 7 cm². During thawing the infrared sensor is used to measure the temperature of the leukapheresis product that is placed within this circular area. To achieve a correct temperature measurement there must be no detached labels or loose tubes within the area of the scanned preparation surface.

10.2 Thawing

- Remove the warming shell from the warming plate and put it on a heat-insulated bench.
- Take the storage box containing the leukapheresis product from the deep freezer immediately before the beginning of thawing.
- Carefully take the leukapheresis product out of the storage box.
- Lay the leukapheresis product left-justified on the warming shell so that possibly existing bulges of the preparation will lie within the grooves of the warming shell. The ports must be on the right side (cf. Fig. 3 and 4).
- Completely cover the leukapheresis product with a pre-warmed adaptation compress so that the hole in the adaptation compress is completely over the leukapheresis product (see Fig. 3 and 4).
The leukapheresis product is warmed via the pre-warmed adaptation compress and warming shell.

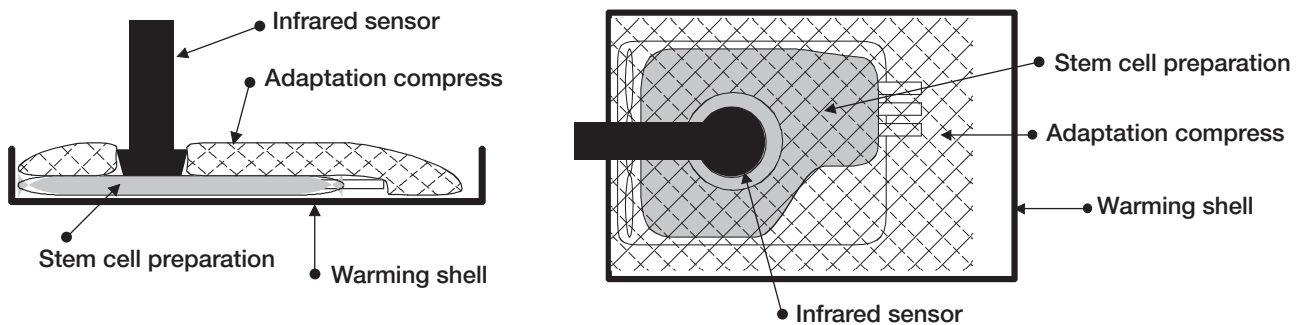


Fig. 3 and 4: Setup of the thawing configuration

- Lay the loaded warming shell on the warming plate. Pass the infrared sensor through the hole in the adaptation compress and place it directly on the leukapheresis product.



Upon locating the infrared sensor, note that the infrared sensor must be completely on the leukapheresis product and may not partly cover the adaptation compress.

- Start the thawing process by pressing the **START** key.
- Leave system flap open and observe the thawing process.
While the adaptation compress cools off during thawing, the temperature of the warming shell is controlled by the heated warming plate. If the module Protocol printer is connected to the SAHARA-TSC the temperature of the leukapheresis product is continuously output via the protocol printer.



During an ongoing tempering process, the warming plate and leukapheresis product must not be removed from the device.

If the frozen leukapheresis product is almost free of ice the FREE OF ICE-LED will start flashing and a recurrent audible signal will sound. The free of ice state is indicated by a permanent illumination of the FREE OF ICE-LED as well as a recurrent audible two-tone signal. Upon detecting the free of ice state, the energy supply to the warming shell is automatically reduced in order to decelerate the further warming of the leukapheresis product.

- As the FREE OF ICE-LED starts flashing, check the viscosity of the leukapheresis product by hand (cf. Fig. 5 and 6).
Terminate the thawing process by pressing the **STOP** key at the desired viscosity or temperature and remove the leukapheresis product from the SAHARA-TSC.

Instructions for use SAHARA-TSC



A control of the leukapheresis product temperature during the thawing process is only possible when using the protocol printer module.

- If possible, the leukapheresis product should be transfused immediately after the thawing process.




Fig. 5 and 6: Sensory and visual check of the preparation viscosity

11 Error messages and troubleshooting

In case of a system failure, the SAHARA-TSC issues an error message by illuminating the ERROR LED and the FREE OF ICE-LED or the LEDs of the degree of tempering. Furthermore, a permanent audible alarm signal sounds. If the module Protocol printer is connected the error will be documented in the printout. After the error message the device is disabled for further use and can only be re-started by turning off and on at the power switch. The device must not be used for the thawing of cryo-preserved leukapheresis products or for the pre-warming of adaptation compresses until the error has been eliminated.



The acoustic signal during an error message can be deactivated for 2 minutes by pressing the  button.

If an error message or a malfunction should arise during the thawing process, the temperature of the leukapheresis product must be measured immediately after its removal from the device with respect to a mistemping. This can be done easily and reliably by means of a calibrated thermometer: Simply fold the bag along its length and place the thermometer in the hollow. If the thermometer reads an unacceptably high temperature the leukapheresis product may become useless for transfusion purposes. Please, in any case, contact the responsible physician!

The following table assists you in identifying the cause of an error and how to remedy it. If more than one measure appears to be suitable in remedying a particular error, then each measure must be implemented one after the other. If the measures listed in the table do not eliminate the error, or error messages other than those listed below are displayed, please notify the after-sales service (see Section 14).



You should initiate a new system test after each measure is carried out. For this, the device must be turned off and then on again a few seconds later at the mains power switch. Please note also the information in Section 12.1.

Display:	Cause:	Measure(s):
ERROR + FREE OF ICE	Infrared sensor soiled or defect	Clean the optics of the infrared sensor with as little glass cleaner as possible and dry it afterwards.
ERROR + LED 1	Wrong or missing coding plug	Turn off SAHARA-TSC at the power switch. Completely insert the coding plug of the warming plate into the socket of the agitator mechanism. Turn on SAHARA-TSC again.

Instructions for use SAHARA-TSC

Display:	Cause:	Measure(s):
ERROR + LED 2 + temperature alarm	Overt tempering possible	<ol style="list-style-type: none"> 1. Check if a leukapheresis product is lying within the scanning area of the infrared sensor. If this is not the case, switch off and on again the SAHARA-TSC. Place a cryo-preserved leukapheresis product under the infrared sensor and start a new tempering process. 2. Check whether the infrared sensor is lying completely on the leukapheresis product and does not partly cover the adaptation compress. The scanned surface of the leukapheresis product must not show any protruding objects (no additional packaging, detached labels etc.). Remove those objects and start a new tempering process.
ERROR + LED 3	Warming plate temperature sensor defect	Make sure that the coding plug of the warming plate is inserted completely into the socket of the agitator mechanism. If necessary, remove the plug and push it in one more time.
ERROR + LED 4	Ambient air temperature sensor defect	Notify the after-sales service.
ERROR + LED 5	Warming shell not removed during system test or blower defect	<ol style="list-style-type: none"> 1. Remove the warming shell from the warming plate during the system test. 2. Cool the device down to room temperature by leaving the system flap open.
ERROR + LED 6 + temperature alarm	Ambient air heating defect (overheating possible)	Notify the after-sales service.
ERROR + LED 7 + temperature alarm	Warming shell not removed during the system test or warming plate heating element defect (overheating possible)	<ol style="list-style-type: none"> 1. Remove the warming shell from the warming plate during the system test. 2. Cool the device down to room temperature by leaving the system flap open. 3. Make sure that the coding plug of the warming plate is inserted completely into the socket of the agitator mechanism. If necessary, remove the plug and push it in one more time.
ERROR + LED 8	No communication with warming plate or ambient air temperature sensor	Make sure that the coding plug of the warming plate is inserted completely into the socket of the agitator mechanism. If necessary, remove the plug and push it in one more time.
ERROR + LED 9	No communication with infrared sensor	Make sure that the coding plug of the warming plate is inserted completely into the socket of the agitator mechanism. If necessary, remove the plug and push it in one more time.

12 SAHARA-TSC service and maintenance

12.1 System test


By means of the integrated system test the device functions including the electromechanical components and temperature sensors are checked in 10 steps.

The user performs the first two testing steps. During these steps, the functionality of the LEDs and agitator mechanism must be ensured via a visual inspection. The further test steps are performed automatically. The conclusion of each test step is indicated by a short audible signal and the illumination of an LED of the degree of tempering display. The system test takes about 30 – 40 minutes.

If a malfunction is observed by the user during the first and second test step then SAHARA-III should be suspended from usage and the after-sales service must be contacted. If a system error is detected during the following test steps, then the system test will be automatically aborted and an error code is displayed in the FREE OF ICE LED or in the LEDs of the degree of tempering display, as well as in the printout of the protocol printer if the corresponding module is connected. An explanation of the different error codes as well as the appropriate measures are given in chapter 11.

Instructions for use SAHARA-TSC

- Turn off SAHARA-TSC at the power switch.
- Remove the warming shell from the warming plate and thoroughly clean the warming plate.
- Locate the infrared sensor on the warming plate.
- Turn on the SAHARA-TSC at the power switch and operate it in standby mode for around 15 minutes.

- Press key .

Step 1:

All LEDs of the membrane keypad are illuminated simultaneously for approx. 5 seconds.

- Check the function of the LEDs.

Step 2:

The agitator mechanism starts a recurrent movement of the warming plate.

- Check if the warming plate repeatedly moves to the front and back.

Step 3 to 10:

Leave system flap closed for further testing.

Test steps 3 to 10 occur automatically.

After a passed system test the SAHARA-TSC automatically enters the standby mode.

- Lift the infrared sensor and place it in the top position.



The device functions should be checked before initial operation and after maintenance work. The device functions must always be checked no later than every 3 months.

12.2 Cleaning

To prepare the SAHARA-TSC for cleaning, the upper housing, the warming shell and the warming plate must first be removed. All the subsystems in the interior are now freely accessible and can easily be cleaned. Furthermore, the upper housing can be cleaned thoroughly at a more suitable site.

For a regular disinfection of the system alcohol-based disinfection agents should be used. However, other disinfectants such as oxygen-based sporicides may be used during unscheduled disinfections.



Always observe the information from the disinfectant manufacturer before cleaning!

- Turn off the device at the power switch and disconnect it from the local power supply system.
- Open the toggle-type fastener on the system's rear panel and lift the back of the upper housing by about 2 cm.
- Move the upper housing forward about 2 cm, lift and remove it.
- Remove the warming shell from the warming plate.
- Pull the warming plate out of its plug-in connection and remove the coding plug from the agitator mechanism. Do not tilt the warming plate by hand!
- Clean the surface by gently rubbing it with sufficient disinfectant. In case of contamination with organic material (blood, secretions etc.) the visible material should first be removed by means of a one-way cloth or cellulose soaked with disinfectant which shall be discarded afterwards. Generally, a disinfection by wiping is to be preferred to a disinfection by spraying because the spraying may endanger the doer and does not have a reliable effect. A disinfection by spraying should only be carried out if the areas to clean cannot be reached by wiping. If need be, the warming shell can also be sterilised in an autoclave. For cleaning the adaptation compresses, please see the enclosed instructions for use.



Keep liquids and objects away from the fan and the agitator mechanism.



Do not use sharp or pointed objects or scouring agents for cleaning SAHARA-TSC.

Instructions for use SAHARA-TSC

13 Decommissioning and disposal

This product has been made from high-quality parts and materials which can be re-used and recycled. Therefore, do not throw the product away with normal household waste at the end of its life. This is indicated by this symbol on the product. For a product return, please contact your distributor or the manufacturer. Help protect the environment by recycling used products.

14 Servicing and transport

If you have questions regarding the device, please contact the manufacturer or the sales agency assigned to your organization. Please always provide the serial number of the device and in case of a device malfunction the corresponding error code and a description of the error.

If the device has to be shipped for repair, servicing or testing, please pack it properly to prevent any transit damage. For this we strongly recommend the use of the original packaging or a transport case authorized by the manufacturer or your sales agency. The manufacturer will assume no responsibility for damage incurring during transport caused by improper packaging. Any carriage charges for the return of the device must be paid by the customer.

The manufacturer reserves the right to make improvements and modifications to the device which lead to a technical enhancement.

15 Technical Data SAHARA-TSC

Dimensions:	WxHxD: 320 mm x 325 mm x 493 mm	
Weight:	14.3 kg	
Rated voltage ($\pm 10\%$):	SAHARA-TSC:	230 V AC
	SAHARA-TSC 115V:	115 V AC
Power supply frequency:	50/60 Hz	
Max. Power consumption:	655 W	
Temperature measurement precision:	Max. $\pm 4\%$ at 37 °C	
Ambient conditions during operation:	+10 °C – +30 °C 30% – 75% relative humidity 790 hPa – 1060 hPa max. 2000 m operating altitude	
Ambient conditions for storage and transport:	-20 °C – +50 °C 500 hPa – 1060 hPa	
Anticipated service life:	10 years (with normal use and provided that the required regular inspections and maintenance are carried out)	
Fuse:	2 x T 4.0 A H 250 V	
Protection class:	I	

Instructions for use SAHARA-TSC

16 Accessories

Article	Article no.
SAHARA-III basic model Pre-warming of adaptation compresses, mains power 230 V	97.8710.500
SAHARA-III basic model 115V Pre-warming of adaptation compresses, mains power 115 V	97.8710.502
Protocol printer module Star Micronics impact printer SP742MD; Documentation of the tempering process, the system test and occurring errors	97.8710.570
Protocol printer paper Spare paper roll for the module Protocol printer	79.8710.575
Ink ribbon for protocol printer SP542MD Spare ink ribbon for the module Protocol printer	79.8710.576
Ink ribbon for protocol printer SP742MD	79.8710.577

17 Warranty and guarantee

In general, the "Delivery and Payment Terms" of SARSTEDT AG & Co. KG. apply. These are noted on the back of the invoice. During the warranty period, repairs on the device must only be carried out by SARSTEDT AG & Co. KG or by persons authorized by SARSTEDT AG & Co. KG. In case of improper handling or repair, this warranty will become null and void. Warranty and liability claims are excluded if they can be traced back to one or several of the following causes:

- Improper use of the device.
- Improper assembly, putting into operation, operation and maintenance of the device.
- Operation of the device with defective safety equipment or incorrectly mounted or non-functioning safety features and protective devices.
- Failure to comply with the information in the instructions for use concerning transportation, storage, assembly, putting into operation, operating, maintenance, setup work and waste disposal.
- Unauthorized modifications to the device.
- Catastrophic failure due to external cause and/or force majeure.
- Improper repair work.

The product guarantee is 12 months, beginning with the date of purchase. This guarantee applies to the replacement or repair of any components which the manufacturer has found to be defect and which have not been modified without authorization, misused, or misapplied. Wearing parts are excluded from the product guarantee. The manufacturer sees himself responsible for the safety, reliability, and effectiveness of the device only when checkups, installation, expansions, readjustments, modifications, and repairs have been conducted by persons authorized by the manufacturer and when the device is being used in full compliance with these instructions for use.

Instructions for use SAHARA-TSC

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BA 129