Instructions for Use

SAHARA-III
SAHARA-III 115 V

CE MD UK CA

SARSTEDT

Basic notes!

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

Technical modifications reserved!

Nümbrecht, May 2023
SARSTEDT AG & Co. KG

Manufacturer and customer service address:	Device data: (to be completed by the customer)
SARSTEDT AG & Co. KG Sarstedtstr. 1 51588 Nümbrecht Germany Phone: +49 (0) 22 93-30 50 Fax: +49 (0) 22 93-305 282 E-Mail: info@sarstedt.com www.sarstedt.com	Type: SAHARA-III Serial No.: Place of installation: Issue date: Inventory No.:

Last modified: May 2023

Table of Contents

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 HF 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.
- Only operate the device with the supplied mains cable. Using a mains cable instead of the original one may lead to a higher electromagnetic emission or reduced electromagnetic interference resistance of the device resulting 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 avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- Before operation examine the device for evidence of damage. 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.
- The device must not be operated within the vicinity of the patient.
- The blood bags or infusion containers within the device must not be in contact with the patient.
- During an on-going tempering process blood bags must not be removed from the device.
- To avoid overheating, prior to starting the tempering process install the module suitable for the items to be tempered as described in Chapter 7 and observe the conditions for using the fast tempering function in Chapter 8.3 for thawing and warming of blood components.
- If the device has to be opened during cleaning or servicing, it must be turned off and disconnected from the local power supply system by unplugging the mains cable since some device parts are under voltage even when the device has been turned off.
- Do not modify this equipment without authorisation 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

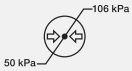
Follow instructions for use

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
	Permissible temperature range
	Store in a dry place
REF	Item number
SN	Serial number
CE	CE mark
MD	Medical device
	Manufacturer
	Country of manufacture
	Manufacturing date
UDI	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-III basic model and SAHARA-III basic model 115V each consist of:

- the SAHARA-III platform incl. warming plate module
- a mains cable
- an instructions for use and a service manual.

SAHARA-III MAXITHERM and SAHARA-III MAXITHERM 115V each consist of:

- the SAHARA-III platform incl. MAXITHERM module
- a mains cable
- an instructions for use and a service manual.

5 Application and function

The variants SAHARA-III basic model and SAHARA-III MAXITHERM enable blood components packed in plastic bags such as frozen plasma, cryopreparations, whole blood or erythrocytes to be thawed or warmed up prior to transfusion. The tempering process is carried out dry, which means without the use of water as the heat transferring agent. Instead of water, heat is transferred from a warming plate to the blood components according to the principle of thermal conduction (SAHARA-III basic model only), and from highly turbulent, heated ambient air according to the principle of forced convection (SAHARA-III basic model and SAHARA-III MAXITHERM). In comparison with SAHARA-III MAXITHERM the SAHARA-III basic model needs less time for blood product tempering. However, the SAHARA-III MAXITHERM has double the loading capacity for blood bags.

Functions:

Safe tempering method

- Contamination risks by water-borne pathogens associated with water baths are prevented
- Actively drying the bag surface provides hygienic conditions surrounding the blood bag
- Temperatures of the warming plate and ambient air are controlled to ensure a blood component quality equal to the quality obtained when applying the water bath method
- Standardised thawing and warming procedure

37 °C function

- Tempering at a constant ambient temperature of 37 °C
- Tempering of different blood components
- Tempering of bags with different filling volumes

Fast tempering function

- Rapid thawing and warming of blood components

Temperature monitoring

- Contactless measurement of the blood component temperature by an infrared sensor
- Fast availability of frozen blood components due to free of ice indication
- Display of blood component temperature from 29 °C to 37 °C in increments of 1 °C
- Documentation by use of a protocol printer available

Blood bag agitation

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

Integrated system testing

- Checking the device functions
- Calibration of temperature sensors
- Additional measuring apparatus not necessary
- Documentation by use of a protocol printer available

Simple operation

- No adjustment of tempering times and ambient temperatures required

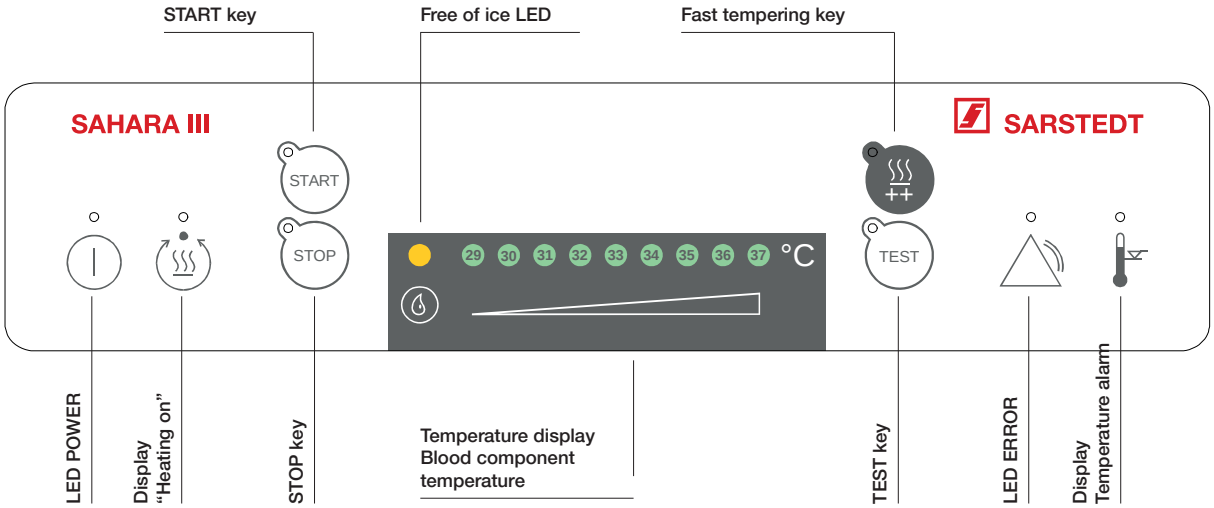
Delayed key reaction

- Delayed button response prevents accidental termination of the heating process

Modular assembly

- Rapid change possible between basic model and MAXITHERM
- Infusion warming as an additional function is available

6 Membrane keypad



7 Commissioning

SAHARA-III is delivered with a separate mains cable for connecting the device power inlet on the left side of the housing to the local power supply system. SAHARA-III should not be connected to power sockets supplying systems which may cause power disorders such as photocopiers, refrigerators, etc. The installation site chosen must be away from sources of heat and humidity. The installation base must be horizontal and should not be exposed to any vibration.

Pressing the power switch on the left side of the housing causes SAHARA-III to switch automatically into standby mode.

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

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

7.1 Warming plate module

The warming plate module consists of an agitation plate which is connected to a coding plug by a flat cable.

- Turn off SAHARA-III at the power switch and open the system flap.
- In case of a built-in agitation plate pull the plate out of its plug-in connection and remove the coding plug from the agitator mechanism. Do not tilt the agitation plate by hand!
- Connect the coding plug “warming plate” to the socket at the rear of the agitator mechanism. Locate the four pins on the underside of the warming plate onto the agitator mechanism and push to secure into position.
- Turn on SAHARA-III at the power switch.

The system automatically enters the standby mode.

7.2 MAXITHERM module

The MAXITHERM module consists of a double tray and a coding plug.

- Turn off SAHARA-III at the power switch and open the system flap.
- In case of a built-in agitation plate pull the plate out of its plug-in connection and remove the coding plug from the agitator mechanism. Do not tilt the agitation plate by hand!
- Connect the coding plug “MAXITHERM” to the socket at the rear of the agitator mechanism. Locate the four pins on the underside of the double plate onto the agitator mechanism and push to secure into position.
- Turn on SAHARA-III at the power switch.

The system automatically enters the standby mode.

7.3 Infusion warmer module

The infusion warmer module consists of a coding plug.

- Turn off SAHARA-III at the power switch and open the system flap.
- In case of a built-in agitation plate pull the plate out of its plug-in connection and remove the coding plug from the agitator mechanism. Do not tilt the agitation plate by hand!
- Connect the coding plug “infusion warmer” to the socket at the rear of the agitator mechanism.
- Turn on SAHARA-III at the power switch.

The system automatically enters the standby mode.

7.4 Protocol printer module

The protocol printer module consists of a document printer incl. data cable and a mains cable. The protocol printer is used to document blood component temperature and any errors which arise as well as to automatically create test reports during system testing.

- Turn off SAHARA-III 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 data cable of the protocol printer module to the serial interface at the rear of SAHARA-III.
- Turn on the protocol printer using the power switch at the rear of the device.

The protocol printer automatically enters the standby mode.

You can obtain further information in the separate instructions for use of the protocol printer. These are enclosed with the module.

8 Thawing and warming of blood components

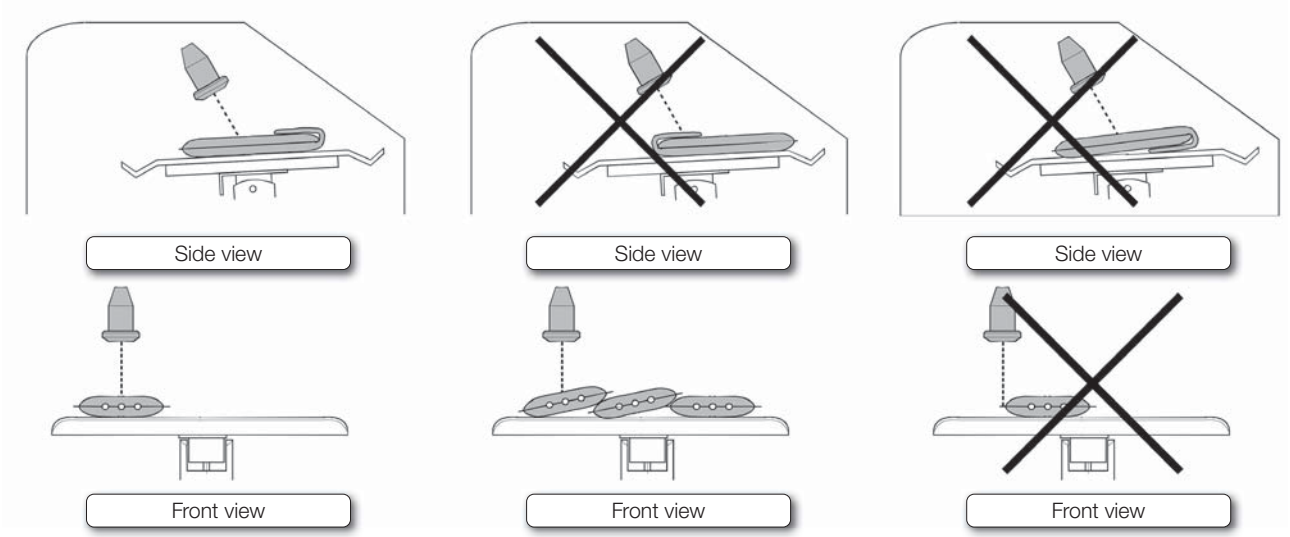
8.1 Infrared sensor

The probe attached on the upper edge of the fan cover is an infrared sensor that monitors a circular area of approximately 7 cm^2 on the left side of the agitation plate. During tempering of blood components the infrared sensor is used for measuring the temperature of the blood component which is placed within the scanning area without coming into contact with the blood bag. To achieve correct temperature measurement all additional wrappings have to be removed from the blood bag (e.g. bonded plastic sheeting) before starting the tempering process and there must be no multiple or detached labels or loose tubes within the area of the scanned blood bag surface. In cases where additional wrappings cannot be removed, measurement of the blood component temperature can only be attained for blood bags with transparent and tight fit wrapping.

8.2 Positioning of blood bags

The variants basic model and MAXITHERM differ in their agitation plates. The agitation plate of the basic model consists of a warming plate which is actively heated. Blood bags are placed on one level. In contrast to this blood bags in the MAXITHERM are placed on a nonwarmed double plate with two different tempering levels. The loading capacity of SAHARA-III for blood bags is therefore doubled.

To achieve optimal tempering times and an accurate measurement of the blood component temperature please bear in mind the following diagrams for the correct positioning of blood bags on the agitation plate:



8.3 Fast tempering function

The fast tempering function enables the SAHARA-III to warm or thaw blood components within a short period of time. Before using the fast tempering function, all of the following three conditions must be fulfilled:

1. All blood components have the same initial temperature
2. Frozen blood components are colder than -20 °C
3. Minimum filling quantity for each blood bag:
   - Frozen blood component WITHOUT additional wrapping: 240 ml / 250 g
   - Frozen blood component WITH additional wrapping: 200 ml / 210 g
   - Liquid blood component: 190 ml / 200 g

If any of the three conditions are not fulfilled, the blood components must be tempered with the 37 °C function (see chapter 8.4).

- If possible remove all additional wrappings and multiple labels from the blood bags (e.g. bonded plastic sheeting) or use blood bags with tight fit and transparent wrapping. This reduces the tempering time and enables a more precise measurement of the blood component temperature.

Blood bags with secondary wrapping or with an uneven surface may lead to extended tempering times.

- Place the blood bags on the agitation plate. Please note the information regarding positioning in chapter 8.2.
- Close the system flap and activate the fast tempering function. To do this, press the button.
- The LED within the key illuminates.
- Press the START button.

If the tempering process is not started within 20 sec, the 37 °C function will be automatically re-activated.

Approx. 30 sec. after pressing the START button, the fan will start warming the blood bags loaded on the agitation plate by warming the ambient air within the device. When used with the warming plate module, the blood bags are also tempered by the warming plate.

During an ongoing tempering process, the agitation plate and blood bags must not be removed from the device.

When reaching the free of ice state the free of ice LED lights up permanently and an audible signal sounds. Starting from 29 °C the blood component temperature is indicated on the temperature display in 1 °C steps. Additionally, starting from a blood component temperature of 34 °C recurrent audible signals sound, with its intensity increasing during the tempering process.

- As soon as the device indicates that the blood bag is free of ice or the blood bag has reached a temperature of 37 °C, terminate the warming process by pressing the STOP button. Remove blood bags.

Pressing the STOP button will automatically deactivate the fast tempering function. The system then automatically enters the standby mode.

If not stopped manually within 90 min, the tempering process will be automatically terminated and a continuous acoustic signal will sound. Afterwards the system will enter standby mode.

8.4 37 °C function

The 37 °C function allows blood components to be thawed or warmed at a constant ambient temperature of 37 °C. The 37 °C function must always be used if at least one of the conditions for the fast tempering function cannot be fulfilled.

To prevent unintentional use of the fast tempering function the 37 °C function is automatically activated after every tempering process. This is indicated by the unlit LED in the button.

- If possible remove all additional wrappings and multiple labels from the blood bags (e.g. bonded plastic sheeting) or use blood bags with tight fit and transparent wrapping. This reduces the tempering time and enables a more precise measurement of the blood component temperature.

Blood bags with secondary wrapping or with an uneven surface may lead to extended tempering times.

- Place the blood bags on the agitation plate. Please note the information regarding positioning in chapter 8.2.
- Close the system flap and press the START button.

Approx. 30 sec. after pressing the START button, the fan will start warming the blood bags loaded on the agitation plate by warming the ambient air within the device. When used with the warming plate module, the blood bags are also tempered by the warming plate.

During an ongoing tempering process, the agitation plate and blood bags must not be removed from the device.

When reaching the free of ice state the free of ice LED lights up permanently and an audible signal sounds. Starting from 29 °C the blood component temperature is indicated on the temperature display in 1 °C steps. Additionally, by reaching a blood component temperature of 37 °C a recurrent audible signal sounds every 5 min.

- As soon as the device indicates that the blood bag is free of ice or the blood bag has reached a temperature of 37 °C, terminate the warming process by pressing the STOP button. Remove blood bags.

If not stopped manually within 90 min, the tempering process will be automatically terminated and a continuous acoustic signal will sound. Afterwards the system will enter standby mode.

9 Infusion warming

The infusion warmer module can be used to heat infusion solutions filled in plastic vessels or glass bottles as well as tubes, instruments, contrast media, etc. to 37 °C.

Always check whether and for how long the items to be tempered can be subjected to a temperature of 37 °C. Only items that do not need to be agitated during warming can be tempered!

- Place the items in the interior of the SAHARA-III.
- Close the system flap and press the START button.

The blower starts tempering the items by warming the ambient air within the device. Starting from 29 °C, the ambient air temperature is indicated on the temperature display in increments of 1 °C.

- Terminate the tempering process by pressing the STOP button. Remove the tempering products.

10 Standby mode

By switching on the device, after termination of the tempering process or after successful conclusion of the system test the SAHARA-III enters the standby mode. The 37 °C function is automatically activated and the LEDs in the POWER and “Heating ON” displays as well as in the STOP button will remain continuously illuminated. In the SAHARA-III basic model, the warming plate is heated up to 36 °C. The fan is turned off.

11 Error messages and troubleshooting

In case of a system failure, the device issues an error message via the **ERROR** LED and the temperature display and a prolonged audible alarm sounds. If the protocol printer module is connected to the SAHARA-III, the error will also be documented on the protocol. After announcing the failure the device is locked from further use and can only be re-started by turning off and on at the power switch. The device must not be used until the error is eliminated.

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

If an error message or a malfunction should arise during operation, then the temperature of the blood components or the tempering items must be measured immediately after removal from the device with respect to a mistempering. In the case of blood components, this can be done easily and reliably by means of a calibrated thermometer: To do this, fold the blood bag along its long side and place the thermometer between the two halves of the blood bag. If the thermometer reads a temperature that is unacceptable, then the blood components may become useless for transfusion purposes. Please contact the responsible physician!

The following table assists you to identify the cause of an error and 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, then please notify the after-sales service (see chapter 14).

You should initiate a new system test after each measure is carried out. To do this, turn the device off at the power switch and switch it on again a few seconds later. Please note the information in chapter 12.1.

Display:	Cause:	Measure(s):
ERROR + free of ice	Infrared sensor soiled or defect	Clean the infrared sensor with as little glass cleaner as possible. Afterwards dry it.
ERROR + 29 °C	Wrong change of coding plug	Turn off SAHARA-III at the power switch. Insert correct coding plug completely into the socket of the agitator mechanism. Turn on SAHARA-III.
ERROR + 30 °C + temperature alarm	Inadmissible temperature range	**Warming plate module and MAXITHERM:** 1. If there is no blood bag within the scanning area of the infrared sensor, displace the blood bags on the agitation plate according to chapter 8.2 and start a new tempering process. 2. Check whether the scanned surface of the blood bag is plain (no additional wrapping, detached labels, or other objects). Remove any objects that may cause a measuring error. **Infusion warmer module:** Check ambient temperatures within SAHARA-III. As required remove tempering items from SAHARA-III.
ERROR + 31 °C	Warming plate temperature sensor defect	Check that the coding plug is pushed completely into the socket of the agitator mechanism. If necessary, loose the plug and push it in one more time.
ERROR + 32 °C	Ambient air temperature sensor defect	Notify after-sales service!
ERROR + 33 °C	Blower defect	Cool the device down to room temperature, with the upper housing removed.
ERROR + 34 °C + temperature alarm	Ambient air heating defect (overheating possible)	Notify after-sales service!
ERROR + 35 °C + temperature alarm	Warming plate heating defect (overheating possible)	Check that the coding plug is pushed completely into the socket of the agitator mechanism. If necessary, loose the plug and push it in one more time.
ERROR + 36 °C	No communication with warming plate or ambient air temperature sensor	Check that the coding plug is pushed completely into the socket of the agitator mechanism. If necessary, loose the plug and push it in one more time.
ERROR + 37 °C	No communication with infrared sensor	Notify after-sales service!

12 Device maintenance

12.1 System testing

By means of the integrated system test the device functions including the electromechanical components and temperature sensors are checked. The user observes the first two testing steps manually. 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 an illumination of a temperature LED. The system test takes about 30 – 40 min for SAHARA-III basic model and about 20 – 30 min for SAHARA-III MAXITHERM.

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 shown on the temperature display. An explanation of the different error codes as well as the appropriate measures are shown in chapter 11.

- Install the warming plate module or the MAXITHERM module (see chapter 7).
- Clean the agitation plate carefully and operate the device for approx. 15 min in the standby mode.
- If necessary, connect the protocol printer module to the device to create a test protocol printout (see chapter 7.4).
- Press the (TEST) button.

All LEDs of the key pad will light up simultaneously for approx. 5 sec.

- Check the operation of the LEDs.

The agitator mechanism starts a recurrent moving of the agitation plate.

- Check the movement of the agitation plate.
- Keep the system flap closed for the following test steps.

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

So that the SAHARA-III is ready for basic cleaning, the upper housing and the agitation plate must first be removed. All the subsystems in the interior are now freely accessible and can be easily 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 disinfection agents like oxygen generating 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.
- Keeping the upper housing at this angle, push it to the front by about 2 cm. Lift and remove it.
- In case of a built-in agitation plate pull the plate out of its plug-in connection and remove the coding plug from the agitator mechanism. Do not tilt the agitation 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, wipe disinfection is preferred to spray disinfection as spray disinfection can put the person carrying out the task at risk and its effect is not reliable. A disinfection by spraying should only be carried out if the areas to clean cannot be reached by wiping.

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

Do not use sharp-edged or pointed objects or abrasive agents for cleaning.

13 Decommissioning and disposal

This product has been made from high-quality parts and materials which can be re-used and recycled. To return this product, please contact your contract partner 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 organisation. Please make a note of the serial number of the device and specify the error in case of a malfunction.

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 authorised 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.

We reserve the right to make improvements and modifications to the device which lead to a technical enhancement.

15 Technical data

Dimensions:	W x H x D: 320 mm x 325 mm x 493 mm	
Weight:	SAHARA-III basic model:	13.7 kg
	SAHARA-III basic model 115V:	13.7 kg
	SAHARA-III MAXITHERM:	13.4 kg
	SAHARA-III MAXITHERM 115V:	13.4 kg
Rated voltage (±10%):	SAHARA-III basic model:	230 V AC
	SAHARA-III basic model 115V:	115 V AC
	SAHARA-III MAXITHERM:	230 V AC
	SAHARA-III MAXITHERM 115V:	115 V AC
Supply frequency:	50/60 Hz	
Max. power consumption:	655 W	
Temperature measurement precision:	Max. ± 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 during storage and transport:		-20 °C – +50 °C
	500 hPa – 1060 hPa	
Anticipated service life:	10 years (in 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	

16 Accessories

Article	Article no.
Paper for protocol printer	79.8710.575
Ink ribbon for protocol printer SP542MD	79.8710.576
Ink ribbon for protocol printer SP742MD	79.8710.577
Stainless steel tray	97.8710.501
Module infusion warmer for SAHARA-III	97.8710.550
Module protocol printer for SAHARA Star Micronics impact printer SP742MD	97.8710.570
Module MAXITHERM for SAHARA-III basic model	97.8710.580
Module warming plate for SAHARA-III MAXITHERM	97.8710.590

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 authorised 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:

- Unintended 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.
- Unauthorised 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 authorisation, 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 authorised by the manufacturer and when the device is being used in full compliance with these instructions for use.

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