Instructions for Use

SAHARA 4

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 4 Serial No.: Place of installation: Issue date: Inventory No.:

Last modified: May 2023

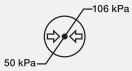
Table of Contents

1 Safety information

- Please note the information in the service manual.
- Due to its heavy weight, the device must be carried by two persons during transport. For this purpose, the device must be lifted from the bottom of the housing.
- Check the device for visible signs of damage before switching on. If you notice any safety relevant damage the device must not be used.
- 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.
- The device must be set up so that the alarm systems of other devices are not affected and it can be easily disconnected from the local power supply system by removing the mains cable
- If the device has to be opened for cleaning, it must be switched off and disconnected from the mains by removing the mains cable.
- To prevent the risk of electric shock, the device must only be connected to a mains supply with a protective earth connection. Furthermore, the device may only be operated with the built-in plastic collection tray and must not be tilted to remove liquids that have leaked out. Liquids or objects must not get into the mixing mechanism.
- The device must not be used within the patient environment.
- The blood products placed into the device must not be connected to patients.
- To avoid burns, do not touch the heating element for ambient air inside the device.
- Only the USB stick and barcode reader supplied or specified in chapter 15 may be connected to the USB interfaces of the device.
- Repairs, maintenance and checks may only be carried out on the device by authorised personnel, companies and facilities with the corresponding expertise and suitable tools and test equipment.
- Protect the device from unauthorised access.
- Do not modify this equipment without authorisation of the manufacturer.
- All serious incidents associated with this product must be reported to the manufacturer and the national authorities where the user is located.

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 4 consists of:

- the SAHARA 4 platform incl. collection tray, warming plate and positioning frame
- a mains cable
- a USB stick

5 Application and function

The SAHARA 4 is a tempering system in which blood products packed in plastic bags can be thawed and warmed prior to transfusion. Tempering is carried out dry, without the use of water as a heat transferring agent, by using a warming plate with 4 separate heating zones according to the principle of thermal conduction and by circulated heated ambient air according to the principle of forced convection.

During tempering SAHARA 4 provides a context-related user guidance via a touch display. The required operating steps and hints are shown in the display.

Functions:

- Safe tempering
- Contamination risks by water-borne pathogens associated with water baths are prevented
- Actively drying the bag surface provides hygienic conditions surrounding the blood product
- Automatic system test during start up of the device
- Over-temperature alarm and cut-out
- Standardised thawing and warming procedure

Tempering function

- Tempering at a constant, preselectable ambient temperature between 37°C and 42°C
- Rapid availability of blood products through automatic recognition of aggregate state and convenient change during the running tempering process
- Visual inspection of the blood products through the transparent cover flap and interior illumination
- Reminder to remove the blood products
- Innovative tilting and pivoting motion of the warming plate to agitate the blood products
- Delayed button response prevents accidental termination of the tempering process

Integrated function test

- Checking the device functions
- Use of additional measuring equipment is not required
- Digital signatured logging via USB stick is possible

Data backup

- Optional storage of the temperature profile and registration data such as user and blood product number for each blood product
- Automatic backup of the stored data on an external memory medium (USB stick)
- Status indicator for external memory medium
- Indicator for the number of saved data records of the current day as well as the non-saved data records
- Quick and easy capture of registration data by means of a barcode reader
- Easy import of the saved data records in common data processing software

Easy operation and cleaning

- Presetting of tempering times is not required
- Intuitive user guidance via the colour touch display
- The device is easy to clean due to the removable warming plate, positioning frame and collection tray

6 Operating and display elements

6.1 Device view

Side view

Back view

1. Stand-by switch
2. Over-temperature alarm indicator
3. Touch display
4. Cover flap
5. Two equivalent USB slots
6. Mains switch and device plug
7. LAN connection*
8. Tension locks
9. Warming plate
10. Positioning frame

* not supported at this time and therefore not connected and blocked

6.2 Touch display

6.2.1 Information in the status bar

37 °C Set target temperature


External memory medium not identified


Internal data storage inactive


External memory medium identified


Internal data storage active


Failure during internal data storage

6.2.2 Icons during standby


Access options menu


Increase target temperature


Decrease target temperature


Start tempering process for frozen blood products


Start tempering process for liquid blood products

Data record indicator:
1. Value: number of saved data records of the current day
2. Value: number of data records not backed up externally

6.2.3 Icons during registration/tempering


Frozen blood product

Blood product is ready to be removed


Terminate tempering process


Register another blood product


Cover flap open


Liquid blood product


Request for placement of a blood product


Aggregate state detection is initialised


Terminate scan step or registration

7 Installation and commissioning

- Place the device on a level, vibration-proof workbench away from sources of heat and humidity.
- Open the cover flap, connect the coding plug to the jack of the warming plate and install the warming plate on the mixing mechanism.
- Connect the device plug at the rear of the device to the local power supply using the mains cable.


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.

- Activate the power switch on the device plug at the rear of the device.
- Switch the device on using the stand-by switch at the front of the device.

Each time the device is switched on, it carries out a system test during which important internal system functions are checked. If all system functions are error-free, the device enters the standby mode and is preheated for a few minutes via the warming plate and fan heater.

The device is ready to use when the following indicator appears in the display:

- During initial operation or after maintenance work, check the system settings (see chap. 9), adjust them if necessary and check the device functions using the function test (see chap. 11.1.1).

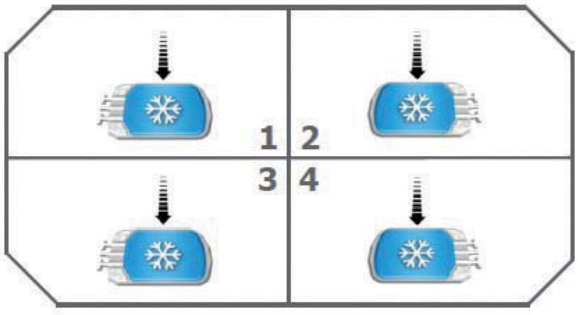
The target temperature can also be adjusted in standby mode with the setting buttons and , unless this has been turned off, in which case the target temperature can be adjusted in the password protected settings.

- To capture the temperature profile data, activate the data storage function (see chap. 9) and insert the USB stick supplied into a free USB slot on the device.
- To capture the registration data, activate the scan function (see chap. 9) and connect a barcode reader recommended by the manufacturer (see chap. 15) to a free USB slot on the device.

8 Thawing and warming of blood products

Observe the following instructions to ensure short warming times and reliable determination of physical state for all blood bags on the warming plate:

- Blood bags should have a surface that is as level as possible and be placed according to the illustration below.
- Remove additional packaging (e.g. sealed plastic film), labels that are not firmly affixed and multiple labels if possible prior to starting the tempering process or use blood product bags with a transparent packaging that is as tight as possible.
- Labels remaining on the blood bags should be on the warming plate.
- Do not place blood products that have already been warmed as these may not be recognised by the device.
- As soon as the device is ready activate the desired tempering process by pressing the or button on the ddisplay, for frozen or liquid components respectively.
- Open the cover flap and place the blood products on the heating zones of the warming plate as shown:



- Close the cover flap.

The tempering process and aggregate state detection for the blood products on the warming plate is started.

- As soon as the device indicates that the blood products on the warming plate are ready to be removed (see chap. 6.2.3) respectively the blood products have reached a temperature of approximate 37° C and the device beeps three times, open the cover flap and remove the blood products from the device.

Longer warming of the blood products may result in protein denaturation. Therefore, a continuous acoustic signal will sound as a reminder to remove the blood products no later than 30 min after the display indicates that the blood products are ready to be removed.

- If required, place new blood products on the warming plate and immediately close the cover flap.

If the cover flap remains open for a longer period of time, blood products already warmed may not be reliably detected by the device after the cover flap is closed.

The tempering process continues automatically.

- If no more blood products should be tempered, the tempering process should be terminated by pressing and holding the button on the display.

8.1 Registration of blood products with activated data storage

The blood products are registered when they are inserted into the device and when they are removed from the device by selecting the corresponding heating zone on the display. In addition to the temperature profile data, registration data such as user and blood product number can optionally be captured via a scan sequence consisting of two scan steps each.

The captured data records for each blood product are stored in the internal memory of the device. After termination of the tempering process, all data records not yet saved are automatically copied to a file on the connected USB stick.

Please ensure in advance that the conditions for data recording are met (see chap. 7).

8.1.1 Registration when placing in the device

- After activating the tempering process via the button or , select the desired heating zone on the display and, if necessary, capture the requested barcodes using the barcode reader.
- Open the cover flap and place the blood product on the selected heating zone of the warming plate.

If a barcode is not available, the relevant scan step can be cancelled by pressing the button in the scan field. In addition, the commenced registration can be cancelled by pressing the button at the bottom right of the display.

- If necessary, register further blood products to be inserted via the button .
- Once all blood products have been placed on the selected heating zones, close the cover flap.

The tempering process as well as the aggregate state detection for the inserted blood products is started automatically.

8.1.2 Registration when removing from the device

- During an ongoing tempering process, select the desired heating zone on the display and open the cover flap.
- Remove the blood product from the device and, if necessary, capture the requested barcodes using the barcode reader.
- If necessary, register further blood products to be removed via the button .
- Once all blood products have been removed from the selected heating zones, close the cover flap.

The tempering process continues automatically.

9 Options menu

Pressing the button takes you to the selection window of the options menu. The options menu allows the device to be individually adapted to the operator's requirements, to activate data storage and to display important system information.

As long as the system settings menu is activated, no automatic heating of the device via the warming plate will occur. It is not possible to access the options menu while the tempering process is ongoing.

The options menu can be controlled using the following buttons:


Selection buttons


Select a menu item or save the setting


Change the selected value


Exit menu item or options menu

When setting the target temperature for the thawing and warming process, observe the recommendations of the blood product manufacturer and the local transfusion guidelines.

System settings

- **Target temperature**
  Adjustable in the range 37 °C - 42 °C
  Factory setting: 37°C
- **Volume**
  - **Key click**
    off, medium, loud
    Factory setting: medium
  - **Notes**
    off, medium, loud
    Factory setting: medium
  - **Alarms**
    medium, loud
    Factory setting: loud
- **Date/time**
- **Language**
  Operating language selection
  Factory setting: English

Data management

- **Data storage**
  Internal storage of the captured data records
  Factory setting: off
- **Scanning**
  Activation or deactivation of the scanning sequence for scanning registration data during the tempering process
  Factory setting: off
- **Data cleanup**
  Internally stored data records which have already been saved externally are deleted after an adjustable period of 3 to 10 days. This period can be modified in increments of 1 day.
  Factory setting: 3
- **Data backup complete**
  All internally stored data records are saved externally to USB stick.

Function testing

Testing the internal system functions

System information

- **SN**
  Device serial number
- **Software version**
  Version of the application software
- **Warming plate software version**
  Version of the warming plate control software
- **Fan heater software version**
  Version of the fan heater control software
- **Last error**
  Last error message of the device

10 Error messages and troubleshooting

If a system error or a malfunction of the device is detected during operation, an error message appears on the display and the device is locked for operation until the next time it is switched on.

If an over-temperature alarm is triggered by the device during operation, the temperature of the blood product should be measured immediately after removal from the device to check for an incorrect temperature. This can easily be done with 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 shows an impermissible temperature, the preparations may be unusable. In any case, consult the responsible doctor!

Some errors that appear in the display can be resolved independently using the following table. If several actions appear appropriate for resolving the error, carry them out in order.

If the actions carried out do not resolve the error or if error messages other than those listed below are displayed, contact technical service (see chap. 13).

Description	Cause	Measure(s)
Communication fan heater sensor	Coding plug detached from fan heater	Switch off device and connect coding plug to fan heater
Communication IR Sensor	Coding plug detached from fan heater	Switch off device and connect coding plug to fan heater
Communication warming plate	Coding plug detached from warming plate	Switch off device and connect coding plug to warming plate
Mixing mechanism blocked	Object in swivelling range of warming plate	Switch off device and remove the object from the swivelling range of the warming plate
Fan heater blocked	Object in fan	Switch off device and remove the object from the fan
Inadmissible ambient temperature	Ambient temperature too low or too high	Switch off device and operate according to the environmental conditions given in chap. 14.
Error of external memory	No access to inserted USB stick	Replace defective USB stick
Data memory full	Maximum number of data records in the database has been reached	No measure required, as the device automatically deletes the longest stored data record and stores the current data record instead.

11 Maintenance

11.1 Preventive checks

The operator must perform the following preventive controls or have these done regularly. After maintenance or repair works the controls below must be done if the safety or functioning of the device could be affected by the service measures.

Test	Proceeding	Test interval
Visual inspection	Check the device for completeness, contamination and safety-relevant damages. Check the device inscriptions for completeness and readability. Check the accompanying documents for availability and completeness.	Every 24 months
Examination of the electrical safety	Measurement of protective earth resistance and leakage currents	Every 24 months
Function test	Execution of the function test (see chap. 11.1.1) Check the position fans according to the service manual	Every 12 months
External calibration	External calibration according to the service manual	Every 12 months

Please use the “Checklist for preventive checks” form within the service manual to document the checks performed.

11.1.1 Function testing

- Clean the warming plate.
- To activate the function test, press the button on the display and select the "Function test" menu item.

Keep the cover flap closed after the cover flap test. To log the function test, insert the supplied USB stick into one of the USB slots of the device.

If a malfunction is detected, the device must be locked from further use and may only be used again for tempering when the error has been resolved.

11.2 Cleaning

- Switch off the mains switch at the rear of the device and disconnect the device from the mains supply by removing the mains cable.
- Open the tension locks at the rear of the device and remove the cover.
- Gently pull the warming plate upwards out of the plug connection and remove the coding plug from the warming plate.
- Use a sufficient quantity of disinfectant and wipe the surface to be cleaned with gentle pressure using a wet cloth. In case of contamination with biological material (blood, secretions etc.), the visible material should absorbed with a disposable cloth or wipe soaked in disinfectant which shall be discarded afterwards.

In principle, wipe disinfection is preferable to spray disinfection as spray disinfection may be hazardous to the person carrying it out and an unreliable effect is achieved. A disinfection by spraying should only be carried out if the areas to clean cannot be reached by wiping.

Alcohol-based disinfectants as an active ingredient can be used for a regular disinfection. Always observe the information from the disinfectant manufacturer before cleaning!

12 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.

13 Servicing and transport

If you have questions regarding the device, please contact the manufacturer or the sales agency assigned to your organisation. 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 needs to be shipped because of a repair, maintenance or tests, please pack this properly to avoid transport damage, also in your interests. If possible, please use the original packaging or a transport container approved by the manufacturer or service partner. The manufacturer will assume no responsibility for damage incurring during transport caused by improper packaging. The customer pays the shipping costs for returning devices.

The manufacturer reserves the right to make changes to the device if these serve the technical progress of the device.

14 Technical data

Dimensions (W x H x D):	574 mm x 348 mm x 554 mm
Weight:	27.3 kg
Rated voltage:	100 – 240 V AC
Supply frequency:	50 – 60 Hz
Max. power consumption:	1000 W
Protection class:	I
Operation type:	continuous operation
Temperature adjustment range	37 °C to 42 °C
Temperature regulation precision	-1.5 °C / +2.5 °C

Infrared sensor precision:	± 3% at a blood bag temperature of 37 °C
Max. load	4 blood bags, each weighing up to 400 g
Fuse data	2 x T 10.0 A H 250V, 20 x 5 mm acc. to IEC / EN 60127-2
Connections:	2 x USB, 1 x LAN*
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 (with normal use and provided that the required regular inspections and maintenance are carried out)

* is not supported at this time and is therefore not connected and blocked

15 Accessories

Article	Article no.
Scanner TOUCH 65 PRO USB Barcode reader with connection for USB	97.8720.440

16 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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