

SAHARA-III

Dry warming of blood components

poz. 3.1



poz. 3.1.2

Safe warming procedure

- The risk of contamination from water-borne pathogens, as can occur with traditional water baths, is avoided
- Active drying of the storage bag surface provides hygienic conditions in the area immediately surrounding the blood product
- The temperatures of the heating plate and circulating air are adjusted so that an equivalent blood product quality can be achieved in comparison with the water bath procedure
- Standardised thawing and heating process
- Delayed key response prevents unintentional interruption of the heating process

poz. 3.1.5

- Pre-settings of heating times and ambient temperatures are not required

Temperature monitoring

- Contactless determination of the blood product temperature using an infrared sensor
- Quick availability of frozen blood products via ice-free identification
- Display of the blood product temperature in the range between 29°C and 37°C in 1°C increments
- Documentation via protocol printer possible

poz. 3.1.8

poz. 3.1.1



Protocol printer module

- Documentation of the progression of the blood product temperature
- Documentation of the system test
- Documentation of the error message in the event of a malfunction

Modular structure

- Rapid switching between the basic model and MAXITHERM
- Additional functions such as infusion heating possible

Heating plate module

- Quick thawing or heating of blood products via additional contact heat

poz. 3.1.2



Infusion heater module

- Heating to 37°C of
 - infusion solutions
 - tubes
 - instruments
 - contrast agents etc.

poz. 3.1.1

poz. 3.1.1



MAXITHERM module

- Expands the capacity of the SAHARA-III to up to 6 storage bags

poz. 3.1.3



Stainless steel collecting tray

- Allows for the collection of plasma leaking from defective storage bags
- Makes it easier to clean the SAHARA-III



Storage bag agitation

- Gentle agitation in order to achieve a homogeneous temperature distribution within the blood products

poz. 3.1.10

Fast thawing function

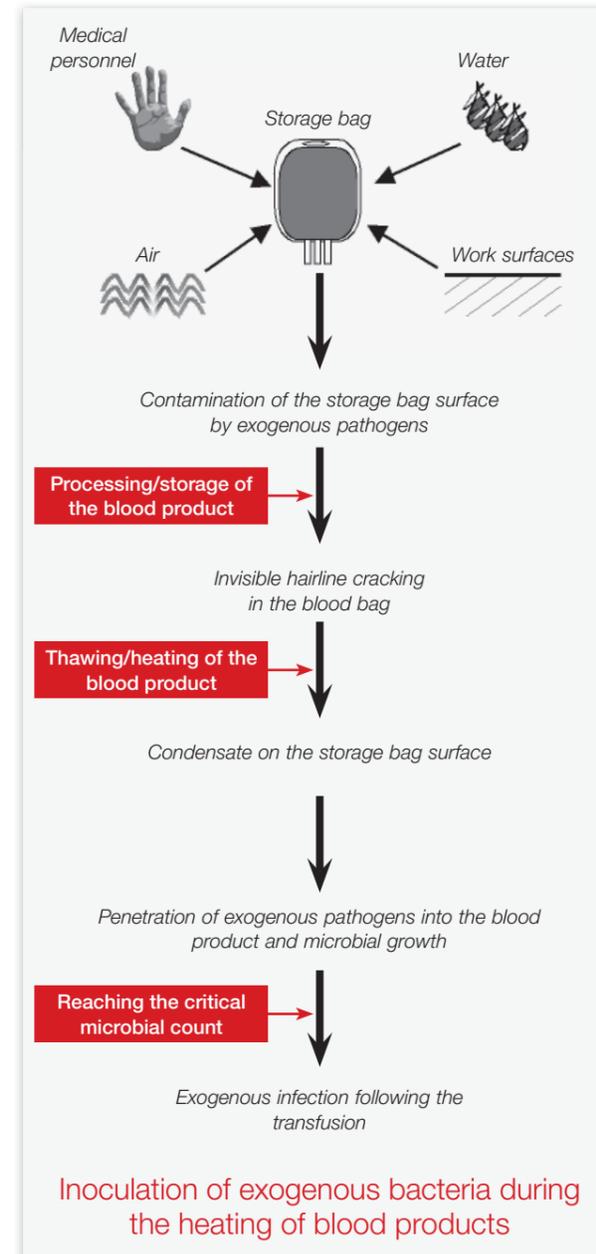
- Quick thawing and heating of blood products

37°C function

- Warming at a constant ambient temperature of 37°C
- Simultaneous warming of different blood products
- Simultaneous warming of storage bags with different filling quantities

Integrated system test

- Inspection of device functions
- Calibration of the temperature sensors
- Use of additional measuring apparatus not required
- Documentation via protocol printer possible



What sources are there for microbial contamination of blood products by exogenous pathogens?

Exogenous bacteria originate from the skin of the blood donor, from water, the air or from elsewhere in the environment, from surfaces or even from the hands of medical personnel. These can be inoculated during the blood collection and during the processing and storage of blood products.

Particularly during the processing and storage of blood products, mechanical influences can cause multiple small tears to form in the bag systems (predominantly in the frozen state), through which micro-organisms can subsequently penetrate into the products. Even when warming blood or blood components, preparations may become contaminated (see diagram), namely when

- the immediate environment of the blood product (e.g. the warming medium) is itself contaminated or
- the outer surface of the blood bag is contaminated with germs.

Various cases of the transfer of Pseudomonas bacteria have been observed during the thawing of previously uncontaminated FFP and cryoprecipitates using water baths.^{4,5}

1. Montag T. et al. **Bakterielle Kontamination von Blutkomponenten** (Bacterial contamination of blood components), Bundesgesundheitsbl. - Gesundheitsforsch. - Gesundheitsschutz 42, 132-142, 1999
2. Sazama K. **Bacteria in Blood for Transfusion**, Arch. Pathol. Lab. Med., 118, 350-365, 1994
3. Puckett A. **Bacterial contamination of blood for transfusion: a study of the growth characteristics of four implicated organisms** Med. Lab. Sci. 43, 252-257, 1986
4. Centers for Disease Control **Follow-up on nosocomial Pseudomonas cepacia infection**, MMWR Morb. Mortal Wkly Rep., 28, 409, 1979
5. Casewell M. W. et al. **Operating theatre water-baths as a cause of Pseudomonas septicaemia**, J. Hosp. Infect., 2, 237-240, 1981

poz. 3.1.2

Follow-up costs

TRANSMED Medizintechnik GmbH & Co. KG guarantees that operating the dry warming systems SAHARA-III basic model and SAHARA-III MAXITHERM will not be associated with any follow-up costs through the use of disposable and consumable items.

Ordering information

Order number	Article name
97.8710.500	SAHARA-III basic model ← poz. 3.1
97.8710.800	SAHARA-III MAXITHERM

Accessories

Order number	Article name
97.8710.501	Stainless steel collecting tray
97.8710.550	Infusion heater module for SAHARA-III ← poz. 3.1.1
97.8710.570	Protocol printer module for SAHARA
79.8710.575	Paper roll protocol printer
79.8710.577	Ink ribbon for the protocol printer SP742MD
97.8710.580	MAXITHERM module for SAHARA-III basic model ← poz. 3.1.3
97.8710.590	Heating plate module for SAHARA-III MAXITHERM

Technical data

Exterior dimensions:	W x H x D: 320 mm x 325 mm x 493 mm	
Weight:	SAHARA-III basic model:	13.7 kg
	SAHARA-III MAXITHERM:	13.4 kg
Nominal voltage (±10%):	SAHARA-III basic model:	230 VAC
	SAHARA-III MAXITHERM:	230 VAC
Max. power consumption:	655 W	

Distributed by:

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export@sarstedt.com
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Dalinis dokumento <20_282_0000_200_saharIII_0319.pdf> vertimas iš anglų kalbos

Poz. 3.1.2

Aktyvus saugojimo maišelio paviršiaus džiūvimas užtikrina higienines sąlygas kraujo produkto zonoje.

Poz. 3.1.5

Standartizuotas atšildymo ir šildymo procesas.

Poz. 3.1.8

Bekontaktis kraujo produkto temperatūros nustatymas naudojant infraraudonųjų spindulių jutiklį.

poz. 3.1.11

Kraujo produkto temperatūros rodymas nuo 29 °C iki 37 °C, 1 °C intervalu.

poz. 3.1.10 Švelnus maišymas, kad būtų pasiektas vienodas temperatūros pasiskirstymas kraujo produktuose.

Poz. 3.1.1

Galimos papildomos funkcijos, pvz., infuzinio tirpalo šildymo funkcija.

Infuzinių tirpalų šildytuvo modulis.



Poz. 3.1.2

Greitas kraujo produktų atšildymas arba pašildymas naudojant papildomą kontaktinę šilumą.

RANSMED Medizintechnik GmbH & Co. KG garantuoja, kad naudojant sauso šildymo sistemas, SAHARA-III bazinis modelis ir SAHARA-III MAXITHERM nebus susiję su jokiais papildomomis išlaidomis dėl vienkartinių ir eksploatacinių medžiagų naudojimo.

Poz. 3.1

SAHARA-III bazinis modelis.

Poz. 3.1.3

Padidina SAHARA-III talpą iki 6 saugojimo maišelių.

MAXITHERM modulis, skirtas SAHARA-III baziniam modeliui.

Dokumentą elektroniniu parašu
pasirašė AKVILĖ, GEGELEVIČIENĖ
Data: 2024-11-21 14:13:44
Paskirtis: Dalinis dokumento
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DIAMEDICA

SAHARA-III

Dry tempering of blood components



SAHARA-III *Safe tempering method*

- Contamination risks by water-borne pathogens associated with water baths are prevented
- Active drying of the bag surface provides hygienic conditions surrounding the blood bag
- **Temperatures of the warming plate and the ambient air are controlled to ensure that the blood products will not be damaged**
- Standardized thawing and warming procedure
- Delayed key reaction prevents unintentional abort of the tempering process

poz. 3.1.7

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 the blood component temperature from 29°C to 37°C in steps of 1°C
- Documentation by means of a protocol printer



poz. 3.1.9



Blood bag agitation

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

Fast tempering function

- Rapid thawing and warming of blood components

37°C function

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

Easy operation

- No adjustment of tempering times and ambient temperatures required

poz. 3.1.12

Module cart

- Allows mobility
- Offers storage space for accessories
- Pull-out worktop

poz. 3.1.12



Integrated system test

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

Module protocol printer

- Documentation of the blood component temperature profile
- Documentation of the system test
- Documentation of error messages in case of a failure

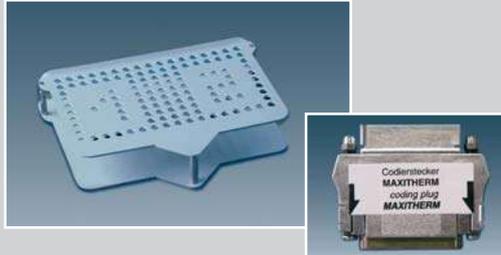


Modular design

- Rapid change between basic model and MAXITHERM possible
- Additional functions such as infusion warming and agitation available

Module MAXITHERM

- Doubles the loading capacity of SAHARA-III up to 6 blood bags with a filling volume of max. 250 ml each

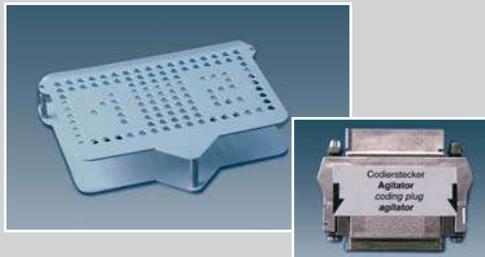


Module warming plate

- Acceleration of the thawing and warming process by extra contact heat

Module agitator

- To be occasionally used for continuous agitation of blood components and infusion solutions packed in plastic bags



Module infusion warmer

Warming to 37°C of items such as

- infusion solutions
- tubes
- instruments
- contrast media etc.

Stainless steel tray

- Collection of plasma and cells leaking from damaged bags
- Facilitates cleaning of SAHARA-III



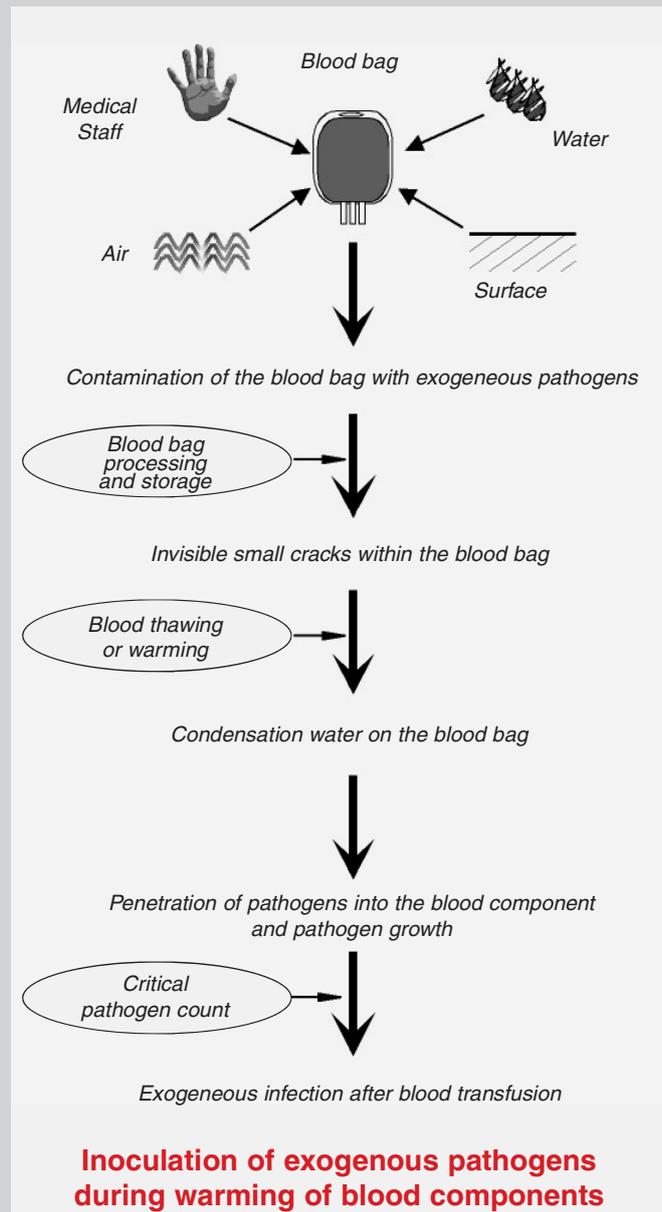
SAHARA-III *The hygienic alternative*

What are the causes for a microbial contamination of blood components by exogenous germs?

Exogenous bacteria originate from the blood donor's skin, from water, air, the blood bag material or the environment, but also from the medical personnel's hands. They can be inoculated during blood collection or during preparation and storage of blood components. While the blood components are processed, mechanical forces may cause small cracks within the bags (mainly within frozen bags). These cracks subsequently allow the invasion of pathogens into the blood component. Contamination may even occur when blood components are warmed (see figure), namely when

- the direct environment of the blood bag to be warmed is highly contaminated, or
- the outer surface of the blood bag to be warmed is populated with pathogens.

Thus, various cases of a transfer of pseudomonades were observed when previously uncontaminated fresh frozen plasma and cryoprecipitates were thawed using water baths.



1. Montag T. et al. **Bakterielle Kontamination von Blutkomponenten**, Bundesgesundheitsbl. - Gesundheitsforsch. - Gesundheitsschutz 42, 132-142, 1999
2. Sazama K. **Bacteria in Blood for Transfusion**, Arch. Pathol. Lab. Med., 118, 350-365, 1994
3. Puckett A. **Bacterial contamination of blood for transfusion: a study of the growth characteristics of four implicated organisms** Med. Lab. Sci. 43, 252-257, 1986

Associated costs

The operation of the dry tempering system SAHARA-III entails no disposable or consumable materials.

Maintenance

Except for safety and functionality checks, the dry tempering system SAHARA-III does not require routine service maintenance.

The testing of the device functions, including calibration of the temperature sensors, is carried out by starting the integrated system test without any additional measuring apparatus.

SAHARA-III

Ordering information

Description:	Order No.:
SAHARA-III basic model (includes module warming plate)	97.8710.500
SAHARA-III basic model 115V (includes module warming plate)	97.8710.502
SAHARA-III MAXITHERM (includes module Maxitherm)	97.8710.800
SAHARA-III MAXITHERM 115V (includes module Maxitherm)	97.8710.802

Accessories

Description:	Order No.:
Stainless steel tray	97.8710.501
Transport case SAHARA-III	97.8710.505
Transport cushion SAHARA-III basic model	97.8710.506
SAHARA module cart for 2 devices, vertical	97.8710.520
SAHARA module cart for 1 device	97.8710.521
SAHARA module cart for 2 devices, horizontal	97.8710.522
Module infusion warmer for SAHARA-III	97.8710.550
Module agitator for SAHARA-III	97.8710.560
Module protocol printer for SAHARA	97.8710.570
Paper for protocol printer	97.8710.575
Ink ribbon for protocol printer	97.8710.576
Module MAXITHERM for SAHARA-III basic model	97.8710.580
Module warming plate for SAHARA-III MAXITHERM	97.8710.590

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 115 V: 13.7 kg SAHARA-III MAXITHERM: 13.4 kg SAHARA-III MAXITHERM 115 V: 13.4 kg
Rated voltage ($\pm 10\%$):	SAHARA-III basic model: 230 V AC SAHARA-III basic model 115 V: 115 V AC SAHARA-III MAXITHERM: 230 V AC SAHARA-III MAXITHERM 115 V: 115 V AC
Frequency:	50 - 60 Hz
Rated power; current consumption:	SAHARA-III basic model: 530 W; 2.3 A SAHARA-III basic model 115 V: 530 W; 4.6 A SAHARA-III MAXITHERM: 400 W; 1.7 A SAHARA-III MAXITHERM 115 V: 400 W; 3.4 A
Accuracy of temperature measurement:	Max. $\pm 4\%$ at 37°C
Ambient conditions:	5 - 30°C max. 85% rel. air humidity
Protection class:	I (acc. to EN 61010-1: 1993, Appendix H)

Distributed by:

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Poz. 3.1.7

Šildymo plokštės ir aplinkos oro temperatūra kontroliuojama taip, kad kraujo produktai nebūtų pažeisti.

Poz. 3.1.9

Greitas užšaldytų kraujo komponentų prieinamumas dėl ledo nebuvimo.

Poz. 3.1.12

Mobilumas.



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Kontaktinė informacija: UAB
DIAMEDICA

Instructions for Use

SAHARA-III

SAHARA-III 115 V



Basic notes!

Copyright:

SARSTEDT AG & Co. KG is the copyright holder of these Instructions for Use. The Instructions for Use are intended only for the operating personnel and for the purchaser of the device. These Instructions for Use may not be reproduced or distributed in whole or in part without the written consent of SARSTEDT AG & Co. KG. Violations can have criminal consequences.

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)
 <p>SARSTEDT AG & Co. KG Sarstedtstr. 1 51588 Nümbrecht Germany</p> <p>Phone: +49 (0) 22 93-30 50 Fax: +49 (0) 22 93-305 282 E-Mail: info@sarstedt.com www.sarstedt.com</p>	<p>Type: SAHARA-III</p> <p>Serial No.: Place of installation: Issue date: Inventory No.:</p>

Last modified:

May 2023

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.

poz. 3.1 ir 3.1.1

poz. 3.1.2

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

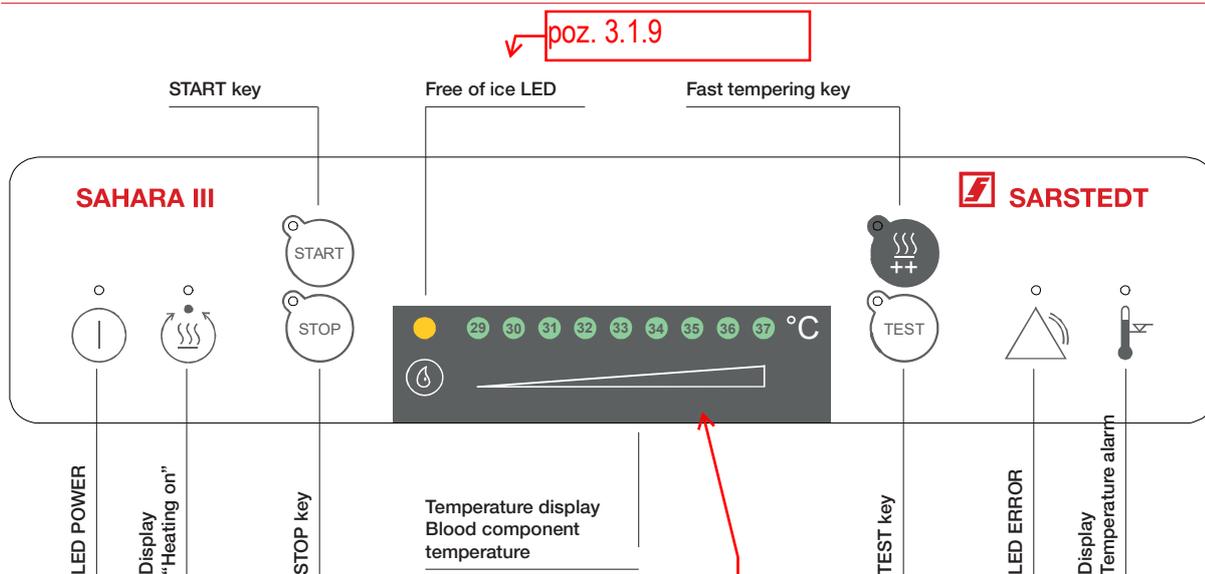
Delayed key reaction

- 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.

Instructions for Use SAHARA-III

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  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.

poz. 3.1.1

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 .

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  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  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  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.

Instructions for Use SAHARA-III



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:	WxHxD: 320 mm x 325 mm x 493 mm	
Weight:	SAHARA-III basic model:	13.7 kg ← poz. 3.1.12
	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 ← poz. 3.1.13
	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 ← poz. 3.1.13	
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	

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Poz. 3.1 ir 3.1.1

SAHARA-III bazinis modelis ir SAHARA-III MAXITHERM sudaro galimybę prieš perpylimą atšildyti arba pašildyti į plastikinius maišelius supakuotus kraujo komponentus, pavyzdžiui, užšaldytą plazmą, kriopreparatus, bendrą kraują arba eritrocitus.

Poz. 3.1.2

Atšildymo procesas vyksta sausuoju būdu.

Poz. 3.1.4

Aktyviai džiovinant maišelio paviršių užtikrinamos higieniškos sąlygos aplink kraujo maišelį.

Poz. 3.1.7

Šildymo plokštelės ir aplinkos oro temperatūra kontroliuojama, kad būtų užtikrinta kraujo komponentų kokybė.

Poz. 3.1.6

Šildymas pastovioje 37 °C aplinkos temperatūroje.

Poz. 3.1.5

Skirtingų kraujo komponentų šildymas.

Poz. 3.1.9

Ledo nebuvimo LED indikatorius.



Poz. 3.1.1

Infuzinio šildytuvo modulis gali būti naudojamas infuziniams tirpalams, supiltiems į plastikines talpyklas ar stiklinius butelius, taip pat mėgintuvėliams, instrumentams, kontrastinėms medžiagoms ir kt., pašildyti iki 37 °C.

Poz. 3.1.12

SAHARA-III bazinis modelis: 13,7 kg

Poz. 3.1.13

SAHARA-III bazinis modelis: 230 V AC

SAHARA-III MAXITHERM 115V: 115 V AC, 50/60 Hz

Dokumentą elektroniniu parašu
pasirašė AKVILĖ, GEGELEVIČIENĖ
Data: 2024-11-21 14:12:10
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Vieta: Vilnius
Kontaktinė informacija: UAB
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