

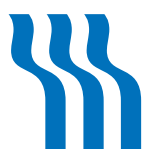
CompoMat G5

Operating Instructions

Software version: 1.01.xx

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Part no.: M67 597 1



**FRESENIUS
KABI**

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2 Important information

2.1 How to use the Operating Instructions

Identification	<p>The document can be identified by the following information on the title page and on the labels, if any:</p> <ul style="list-style-type: none"> – Software version – Edition of the technical document – Part number of the technical document
Page identification	The page identification 1-3, for example, refers to chapter 1, page 3.
Editorial information	The editorial information 6/02.12, for example, refers to: 6. Edition, February 2012.
Changes	<p>Document changes will be released as new editions or supplements. In general, this manual is subject to change without notice.</p> <p>Fresenius Kabi reserves the right to change these Operating Instructions without notice.</p>
Purpose	<p>These Operating Instructions are intended for:</p> <ul style="list-style-type: none"> – first studies – reference purposes
Important instructions on operation	<p>The parameters entered must be verified by the operator, i.e. the operator must check the values entered for correctness.</p> <p>If the verification reveals a deviation between the desired parameters and the parameters displayed on the system, the setting must be corrected before activating the function.</p> <p>The actual values displayed must be compared with the desired values specified!</p>
Importance of the instructions	<p>These Operating Instructions are part of the accompanying documents and an integral part of the system. They include information necessary for the use of the device.</p> <p>The Operating Instructions must be carefully studied before attempting to operate the device.</p> <p>Before the responsible organization may start operating the device, the person responsible for the operation must have been instructed by the manufacturer on how to use the device and must be thoroughly familiar with the contents of the Operating Instructions.</p> <p>The system may only be operated by individuals certificated to have been instructed on the proper operation and handling of the system.</p>
Reproduction	Copying, even of extracts, may only be performed with written authorization.

2.2 Significance of the warnings



Warning

Advises the operator that incorrect operation can result in serious personal injury.



Caution

Advises the operator that incorrect operation may cause damage to the system.

2.3 Significance of the note



Note

Information alerting the operator to the fact that failure to follow the steps as specified may result in the specific function not being executed correctly, not being executed at all, or not producing the desired effect.

2.4 Significance of the tip



Tip

Information providing useful tips for easy handling.

2.5 Intended use

Purpose

The CompoMat G5 is a device for blood banks and transfusion centers, and enables the automatic and reproducible separation of blood components.

The separation of blood components is one of a number of steps within the production process for blood components as a whole.

In the blood component separation process, the CompoMat G5 separates out the centrifuged blood components that are contained within a blood bag system.

CompoMat G5 possesses functionality to open CompoFlow break-off valves in a blood bag system and is thus a Class I Medical product according to Rule 12 of Appendix IX of the EU Medical Devices Directive.

Preparation method	The CompoMat G5 can carry out almost all preparation methods and handle almost all blood bag systems, such as conventional double, triple and quadruple blood bag systems. Components can also be processed in “top & bottom” blood component separation systems.
Bar code scanner	With the optionally-available bar code scanner, data such as donation number, operator and result bar codes can be scanned in.
W-LAN dongle	With the W-LAN dongle – an optionally available peripheral that connects via USB – a connection from CompoMat G5 to CompoMaster Net G5 is established.
Filter holder	With the optionally available filter holder , both hard and soft EK inline filters made by Fresenius can be stored on the device.

2.6 Target group

The device may only be operated and used by trained persons or those possessing the necessary knowledge and experience.

Assembly, extensions, adjustments, modifications or repairs may only be carried out by the manufacturer or persons authorized by him.

2.7 Duties of the responsible organization

The responsible organization assumes the following responsibilities:

- Compliance with the national or local installation, operation, use and maintenance regulations
- Compliance with the accident prevention regulations
- Correct and safe condition of the system
- Permanent availability of the Operating Instructions

2.8 Operator responsibility

The following must be observed when entering parameters:
The parameters entered must be verified by the operator, i.e. the operator must check that the values entered are correct. If the verification reveals a deviation between the desired parameters and the parameters displayed on the system, the setting must be corrected before activating the function.

The actual values displayed must be compared with the desired values specified.

2.9 Disclaimer of liability

The system has been approved for use with the consumables and accessories listed in the Operating Instructions.

Should the responsible organization wish to use other consumables and accessories than those listed in the Operating Instructions, the responsibility to ensure the correct function of the system lies exclusively with the responsible organization. The applicable legal regulations must be complied with (e.g. in Germany the Medical Device Directive, MDD and the MPBetreibV = German regulation for the operation of medical products).

The manufacturer does not assume any responsibility or liability for personal injury or other damage and excludes any warranty for damage to the system resulting from the use of non-approved or unsuitable consumables or accessories.

2.10 Guarantee / warranty

Guarantee

For guarantee refer to the respective sales contracts.

Warranty

The purchaser's warranty rights are governed by the applicable legal regulations.

Proper function of the system is guaranteed for the period specified in the sale contract.

Any use of the system which is not in accordance with its intended use will void any liability and warranty.

The device reflects the latest state of technology and complies with the requirements of IEC 60601-1.

2.11 Warnings

2.11.1 Basic warnings



Caution

CompoMat G5 and CompoMaster Net G5 may only be operated by qualified and specialized personnel.



Caution

The CompoMat G5 may only be opened by qualified and skilled staff.



Caution

Operators are wholly responsible for any processes that they create in CompoMaster Net G5 and which are executed by the CompoMat G5. This applies in particular to possible loss of blood and blood products by incorrect programming. See the User Manual for CompoMaster Net G5 for information about using the CompoMaster Net G5 to program the CompoMat G5.



Caution

Operators are wholly responsible for preparatory tasks, such as storage, centrifuging, transport to the CompoMat G5, suspending on the pins and snapping any possible rated break points, all of which can have a significant influence on the quality of separation of the blood components.

For these reasons, Fresenius Kabi does not provide information in advance concerning the quality of results as regards blood components obtained using CompoMat G5 processes.

Fresenius Kabi only claims that there is a relatively high reproducibility of results for processed blood components within a relatively short preparation time.

Please refer to the relevant literature for specific quality results for blood components processed with the CompoMat G5 in daily practice at a blood bank.

2.11.2 Electrical hazards



Warning

Risk of injury caused by electrical voltage.

When connecting the CompoMat G5 to a mains supply, the local regulations that apply have to be observed.



Warning

Risk of injury caused by electrical voltage.

Improper commissioning and use of the electrical equipment can result in injuries, such as burns and electrical shocks.



Warning

Risk of injury caused by electrical voltage.

When using safety class I devices, the quality of the protective conductor of the installation is of particular importance. It must be taken into consideration that in many countries regulations have been enacted by the national authorities. The rear panel of the CompoMat G5 is provided with a connection for a grounded power cable.



Warning

Risk of injury caused by electrical voltage.

If the power cable needs to be replaced, use only the original power cable listed in the spare parts catalog. If additional equipment, not included in the accessories, is connected to the device, then the permissible leakage currents risk to be exceeded.



Warning

Risk of injury by burning

The devices are not suitable for use with flammable mixtures or nitrous oxide.



Caution

Loss of the preparation when the mains supply is disconnected or there is a power failure.

If there is a loss of power whilst processing a program in the CompoMat G5, all sealing heads/clamps will open and the presses will stop. This may cause a loss of the preparation.

2.11.3 Mechanical hazards



Warning

Risk of injury caused by parts moving autonomously.

To avoid injury, operators must ensure that they position themselves at a sufficient distance from all moving parts of the CompoMat G5 .

Moving parts are:

- Door
 - Upper Press
 - Lower Press
 - Slide
 - Top Press
 - CF-Opener
-
-



Warning

Risk of injury due to crushing.

Keep hands clear of the inside of the CompoMat G5 during operation of the device.

2.11.4 Risk of burning



Warning

Risk of burning by touching the sealing electrodes

- Do not touch the sealing electrodes of heads 1-6 during the sealing process.
 - Do not place any live parts into the heads.
 - Maintain a sufficient distance from the sealing electrodes in the heads.
-

2.11.5 Biological hazards



Warning

Risk of infection by leaking blood bags

It is always possible that donated blood could be infected by germs of contagious diseases. It must always be treated as being potentially infectious.

- Wear surgical or similar gloves when processing blood products.
- Immediately clean and disinfect work surfaces that are contaminated with blood or blood products.

Observe the applicable local laws and regulations for handling of potentially infectious material.



Warning

Risk of infection by leaking tubes

- The operator should not exert any force on tubing, which is currently being sealed.
-

2.12 Addresses

Please address any inquiries to:

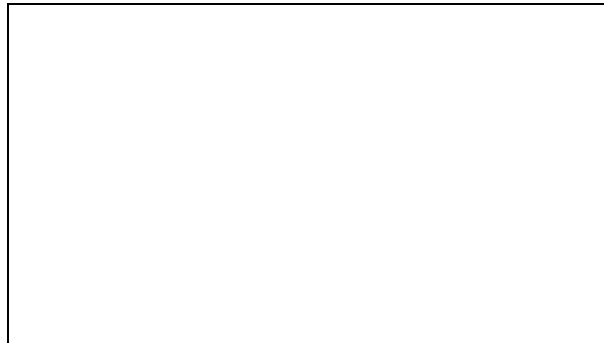
Manufacturer

Fresenius Kabi AG
D-61346 Bad Homburg v.d.H.
Phone: +49 (0)6172 / 608-0

**Service
Central Europe**

Fresenius HemoCare GmbH
Technical Service
Pfungstweide 53
D-61169 Friedberg
Germany
International Service Hotline (8:30 - 17:00)
Phone: +49 (0)6172 608-8469
Fax: +49 (0)6172 608-8539
E-mail: technical_support_medical_device@fresenius-Kabi.com

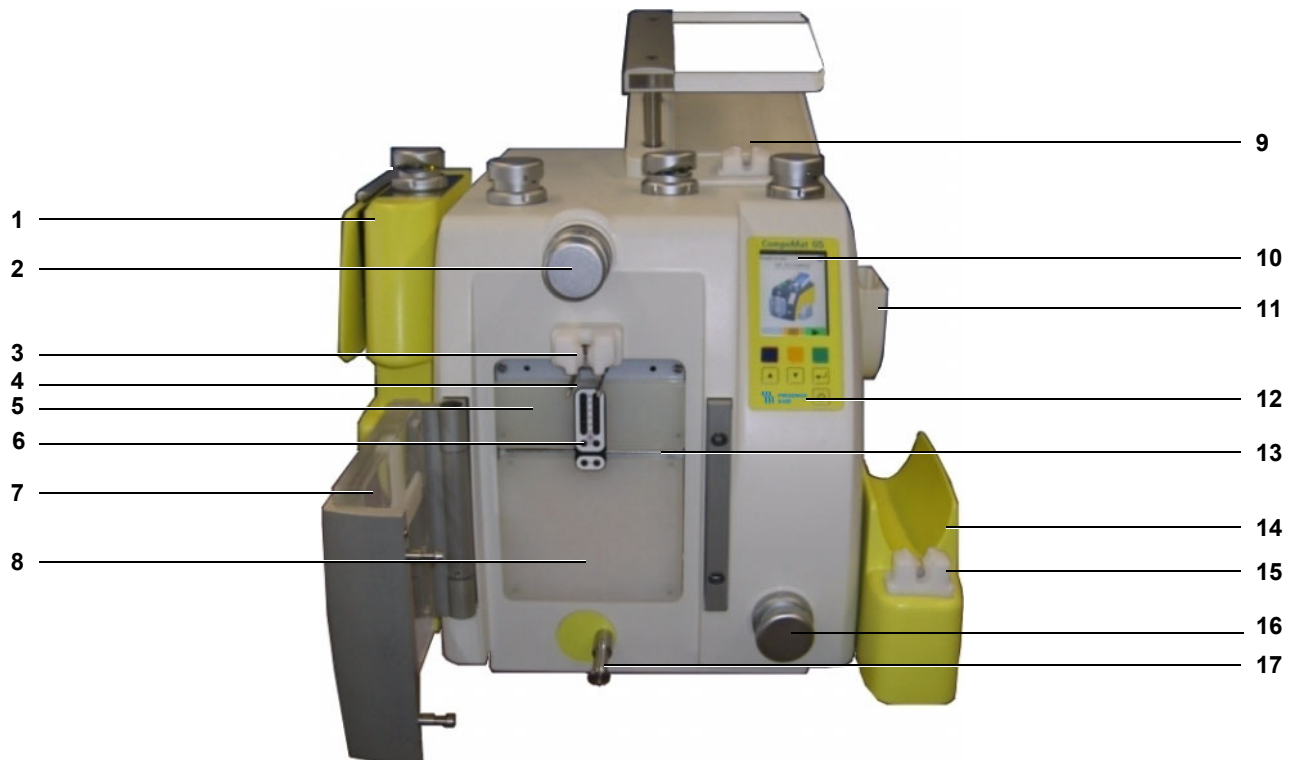
Local service



3 Design

3.1 Views

3.1.1 Front view



- 1 PLS scales (with ventilating function)
(optionally available)
- 2 Head 1 (with clamp and seal function)
- 3 CF-Opener Door
- 4 Press scales on both suspension pins for the collecting bag
- 5 Upper press
- 6 A1 - A8 detectors
For detecting a buffy coat or red blood cells
- 7 Door as pressure plate
- 8 Lower press
- 9 CF-Opener Top
- 10 Color screen
- 11 Filter holder (optionally available)
- 12 Control panel

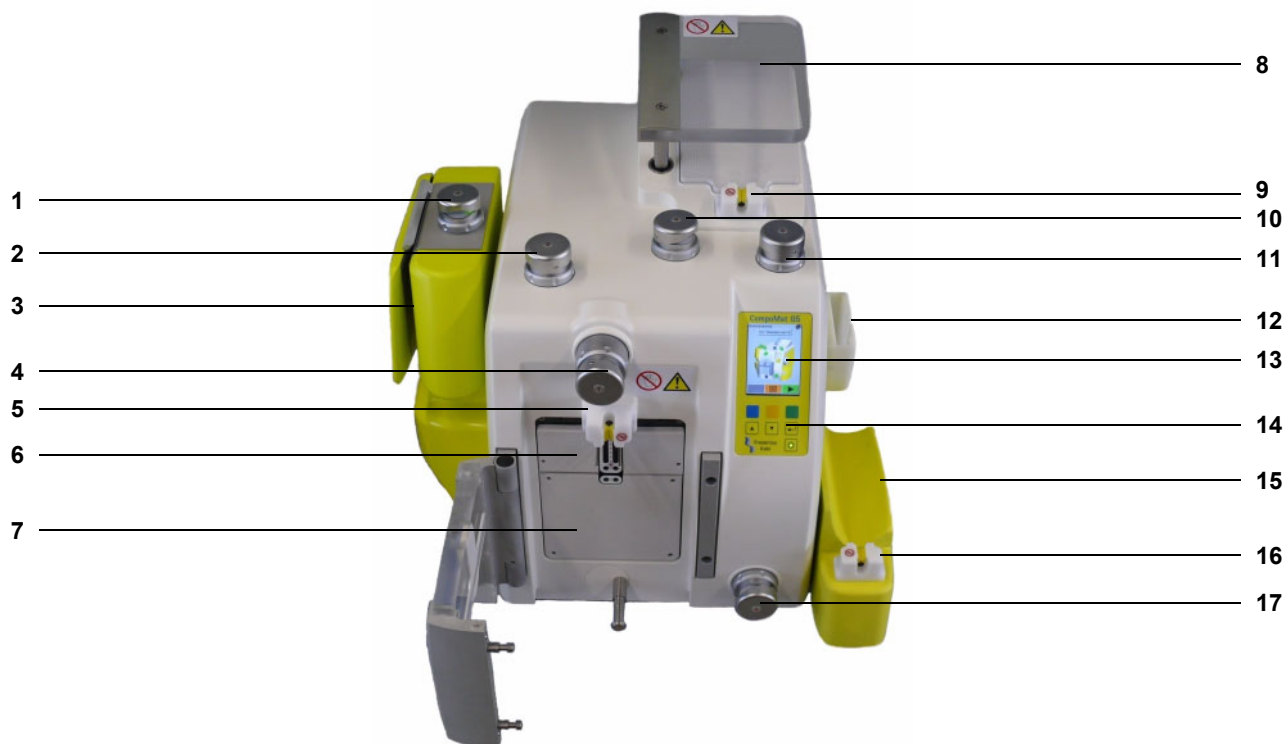
- 13 Slide
- 14 RCC scales (optionally available)
- 15 CF-Opener RCC
- 16 Head 6 (with clamp and seal function)
- 17 Tube guide for Top & Bottom systems

3.1.2 Top view



- 1 Head 3 (with clamp and seal function)
- 2 Head 2 (with clamp and seal function)
- 3 PLS scales (with deaeration function) (optionally available)
- 4 Head 1 (with clamp and seal function)
- 5 Top press for re-pressing storage solution
- 6 Head 4 (with clamp and seal function)
- 7 Head 5 (with clamp and seal function)
- 8 Filter holder (optionally available)

3.1.3 Overall view



- 1 Head 3 (with clamp and seal function)
- 2 Head 2 (with clamp and seal function)
- 3 PLS scales (with deaeration function) (optionally available)
- 4 Head 1 (with clamp and seal function)
- 5 CF-Opener Door
- 6 Upper press with A2-A8 detectors
- 7 Lower press with A1 detector
- 8 Top press for re-pressing storage solution
- 9 CF-Opener Top press
- 10 Head 4 (with clamp and seal function)
- 11 Head 5 (with clamp and seal function)
- 12 Filter holder (optionally available)
- 13 Screen
- 14 Control panel
- 15 RCC scales (optionally available)
- 16 CF-Opener RCC
- 17 Head 6 (with clamp and seal function)

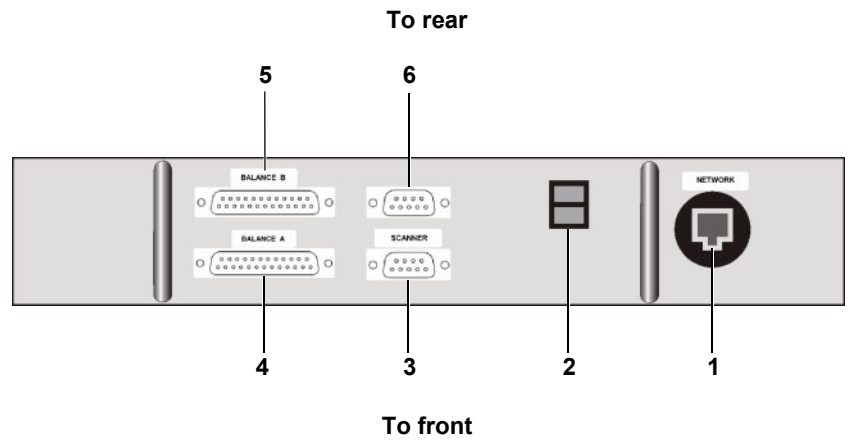
3.1.4 Rear view



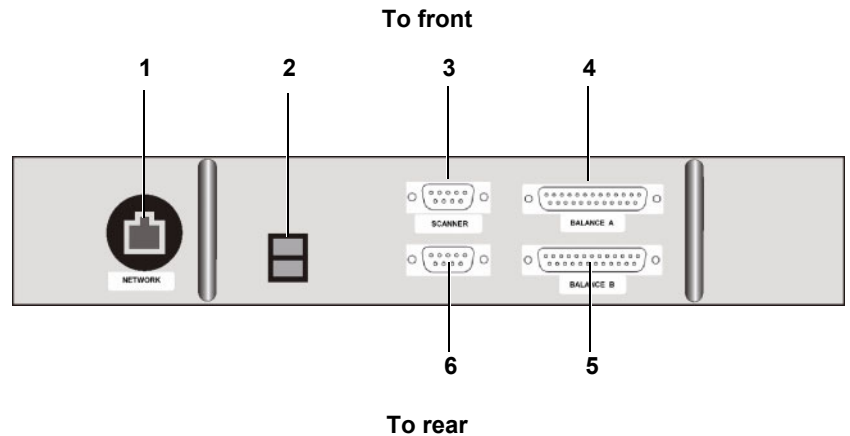
- 1** 2x port **25-pin D-sub**
Front-facing connector: **PLS scales**
Rear-facing connector: **RCC Scale**
- 2** 2x barcode scanner port **9-pin D-sub**
Front-facing connector: **Bar code scanner**
Rear-facing connector: **RFID scanner** (pre-allocated)
- 3** 2x USB port
- 4** LAN port
- 5** Power socket with line fuses (can be accessed externally)
- 6** Main power switch

3.1.5 Connector layout

View: device from rear



View: device with front facing up



1. Network connection (LAN)
2. Two equal-priority USB ports
3. Scanner port
4. Connector for PLS scales
5. Connector for RCC scales
6. RFID scanner (pre-allocated, see following note)

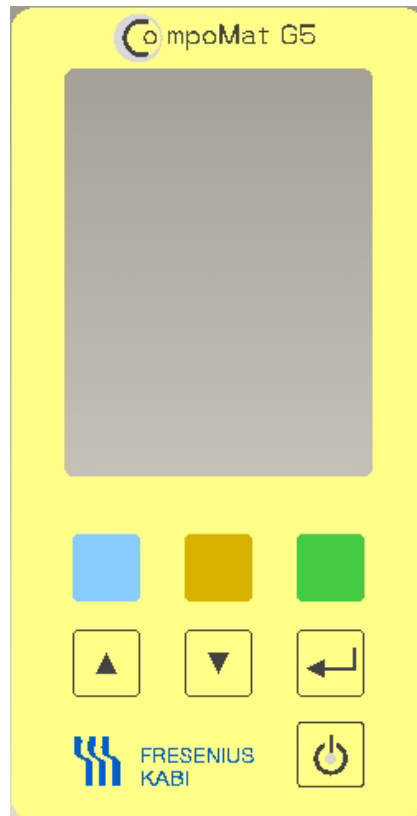


Note

The **RFID Scanner** (6) interface is allocated for future applications. No RFID scanner has been certified and approved as of this time.

3.2 Controls and indicators

3.2.1 Screen with touch pad



Function keys



Blue key:
The key's function will be shown on the screen using an icon.



Yellow key:
The key's function will be shown on the screen using an icon.



Green key:
The key's function will be shown on the screen using an icon.

Menu buttons



Up key;
Used to scroll within lists and to increase numerical values.



Down key;
Used to scroll within lists and to decrease numerical values.




Enter key;
Confirms the chosen numerical value or selected list entry item

Standby key**On/Off key;**

Switches the device **on** or **off** (standby mode)


3.2.2 Soft keys (meaning of icons)**Back**

Goes back to previous screen message.

Activated using the  key (blue).


Cancel

Terminates the current operation.

Activated using the  key (blue).


Stop

Stops the process and returns to the start of the process.

Activated using the  key (blue).

Calibrate stroke

Calibrates the press stroke for the selected press.

Activated using the  key (green).

Forwards

Moves the cursor to the right.

Extend press (cleaning program).

Activated using the  key (green).


Sealing

Starts the manual sealing process on head 2.

Activated using the  key (green).


Check mark (OK)

Acknowledges the note displayed on the screen.

Activated using the  key (green).

Start

Starts or continues the process.


Activated using the  key (green).

Main menu

Opens the main menu.

Activated using the  function key (yellow).

Break

Pauses the current process; press the  key (green) to continue.

Activated using the  function key (yellow).

Calibrate force

Calibrates the press force for the selected press (only for the KD).

Activated using the  function key (yellow).


Skip

Skips the current step.

Activated using the  function key (yellow).


Back



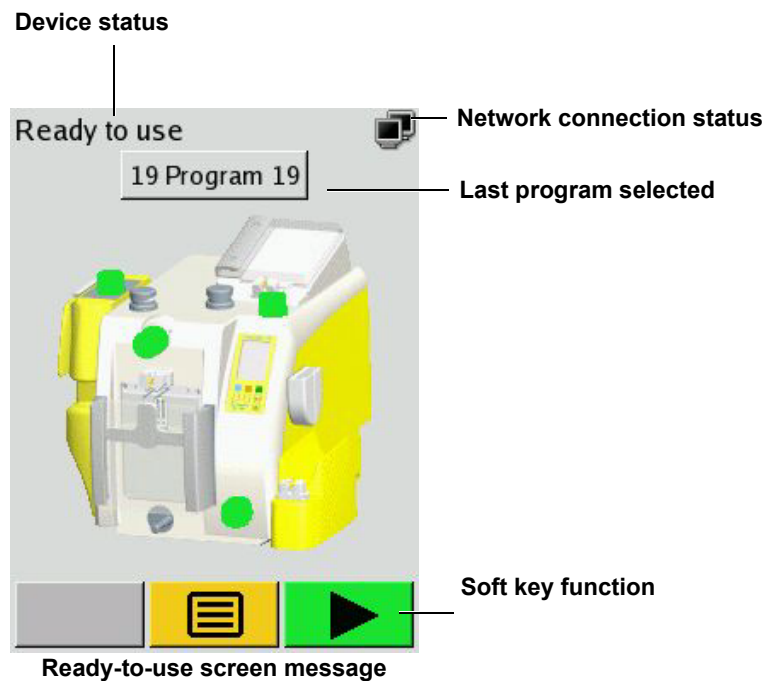
Moves the cursor to the left.
 Retract press (cleaning program).
 Activated using the  function key (yellow).




Zeroing



Zeros the RCC scales (only in **Seal & weighing** menu).
 Activated using the  function key (yellow).

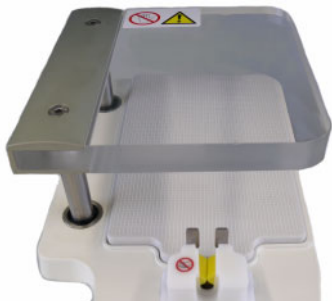
3.2.3 Screen



- The top-left area shows the device status.
- The top-right symbol shows the current network connection status.
 -  = CompoMaster Net G5 connected, process data activated.
 -  = CompoMaster Net G5 not connected.
 -  = CompoMaster Net G5 connected, process data deactivated..
- The highlighted field displays the last program selected.
- The lower area of the screen shows the current soft key functions. The function keys are located at the bottom of the screen (see chapter 3.2.1, page 3-6) and are color-coded.

3.2.4 System components

3.2.4.1 Top Press



The top press serves to feed in storage solutions.

Used together with head 4 and/or head 5, the wedge-shaped top press enables almost air-free re-pressing of the storage solution.

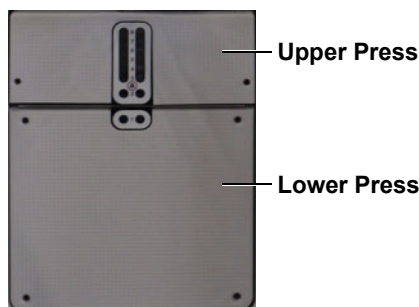
When used in conjunction with EK inline system processing, it thus makes an automatic and virtually air-free filling possible for EK filters.



Tip

The top press is equipped with a pressure sensor that can detect unopened break-off valves.

3.2.4.2 Upper press / lower press



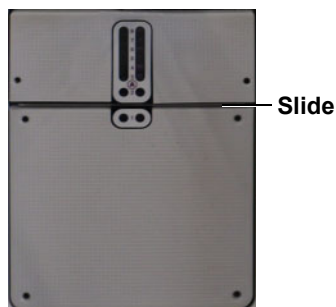
The upper and lower presses serve to press out centrifuged blood products.



Tip

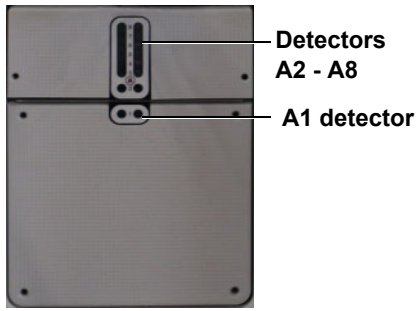
The upper and lower presses are equipped with pressure sensors that can detect unopened break-off valves.

3.2.4.3 Slide



The slide serves as a barrier for the transitional layers.

3.2.4.4 A1 - A8 detectors

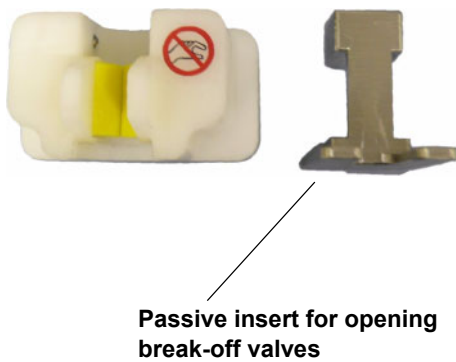


The A1 - A8 detectors in the upper and lower presses serve to record the transition from the plasma phase to buffy coat.

The level recorded is used to control the presses and the slide.

The A1 - A8 detectors ensure an extremely high-precision separation process.

3.2.4.5 CF-Opener attachment and passive insert



The CompoMat G5 is equipped with three CF-Opener attachments (door, top press, RCC).

The CF-Openers serve to open the CompoFlow tube closure system automatically.

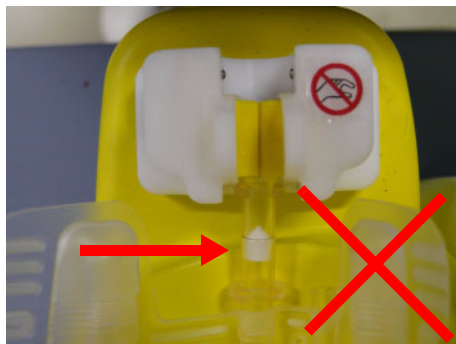
In addition, passive inserts are available for the CF-Opener. The passive insert makes it easier to open a break-off valve.

The spring-loaded yellow jaws on the CF-Opener attachment serve to gauge whether a CompoFlow has been inserted correctly (see figure below).

3.2.4.6 CompoFlow correctly inserted in the CF-Opener attachment



If a CompoFlow has been inserted correctly, then the jaws close perfectly in parallel and no air gap is visible.



Example 1 **Wrongly** inserted CompoFlow:

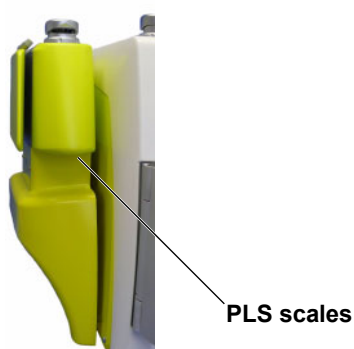
The CompoFlow has been inserted outside the CF-Opener.



Example 2 **Wrongly** inserted CompoFlow:

The CompoFlow has not been inserted as far as the stop position.

3.2.4.7 PLS and RCC scales



Functionality of PLS scales:

1. Automatic and sensor-controlled deaeration of the plasma bag.
2. Sealing the PLS bag with short tube length of 3 cm
3. Automatic weighing of filled PLS bag using auto-tare functionality, which permits the calculation of gross or net weight as desired.



Note

To avoid erroneous calculations, do not touch the PLS scales during the weighing operation (filling or deaeration of the plasma bag). Otherwise, product weights may vary from the values input.

It must be ensured that the PLS scales are not obstructed by the tubing system or other objects. Keep the area under the PLS scales (on the work surface) free of objects at all times.

Fresenius Kabi scales are unsuitable for use when treating patients. The weight displayed must not be utilized in therapeutic or diagnostic applications.



Functionality of RCC scales

The RCC scales serve to establish the RCC weight.



Note

To avoid erroneous calculations, do not touch the RCC scales during the weighing operation. Otherwise, product weights may vary from the values input.

It must be ensured that the RCC scales are not obstructed by the tubing system or other objects. Keep the area under the RCC scales (on the work surface) free of objects at all times.

Fresenius Kabi scales are unsuitable for use when treating patients. The weight displayed must not be utilized in therapeutic or diagnostic applications.

3.2.4.8 Press scales



Suspension pins with weighing

The suspension pins in the press area provide a bag suspension assembly while also measuring the final weight.

To calculate the net weight, a fixed tare can be set for each program.



Note

The operator must ensure that the donation bag is hanging freely during weighing.

3.2.4.9 Head 1...6



Head 1 to head 6 have four functions relevant to the procedure:

- Clamping of tubings
- Sealing of tubings
- Detection of tube status (empty, full)
- Detection of red blood cells



Note

Only use tubing that meets the specifications (see chapter 12.9, page 12-2).

Auto-offset



Tip

A special feature of the head sensors is the automatic off-set based on the plasma currently used.

The sensor measures the value for the current plasma and utilizes the relative change in order to identify red blood cells.

Movable cover as tube clip and insertion aid



Tip

- The movable head cover "signals" the correct insertion of the tubing by a see-sawing motion when the tubing is inserted.
- The tubing is held in place by the special cover molding.
- The free movement of the cover makes it easier to insert larger diameter tubing.

Visual insertion area status indicators



Tip

An LED is located in the insertion area of each of the heads 1...6. This LED shows the head's operating status:

- If the insertion area is lit up, then it is ready-to-use.
- If the insertion area is flashing, then a tube must be inserted for the selected program.

3.2.4.10 Cable routing



To protect cables from pinch damage, feed cabling through the guides as shown (see figure).

3.2.4.11 Line fuses



The line fuses are located behind a cover underneath the power socket. To change the fuses, first disconnect the device from the power supply. The line fuses can be accessed by pulling and folding out the cover.



Note

Only use line fuses that meet the specifications as given in chapter (see **Fuses**, page 12-2).

4 Operation

4.1 Powering on the CompoMat G5

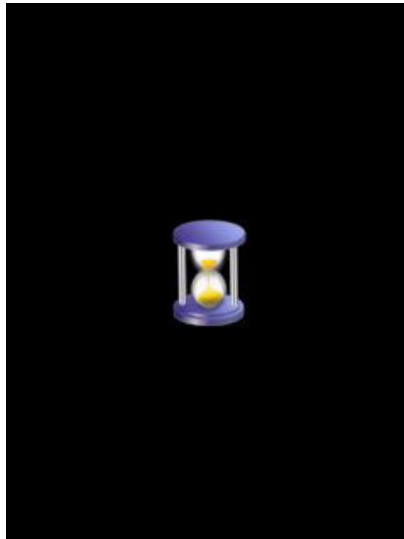


Note

To avoid loss of data, the following power-on order must be observed:

1. Power on CompoMaster PC
 2. Start CompoMaster Net G5
 3. Power on CompoMat G5
-

Once the power supply has been connected up and the main switch activated, the following screen messages appear in sequence:



Booting the PC part 1



Booting the PC part 2



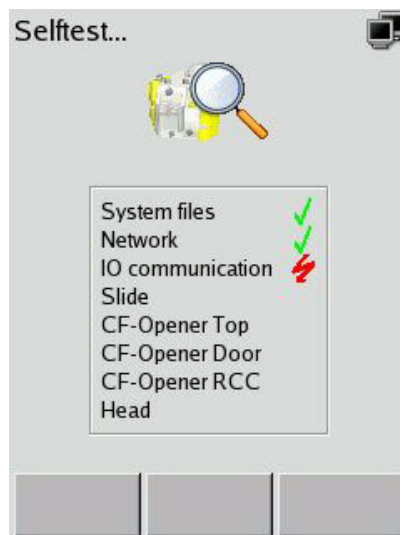
Booting the PC part 3

Cold-starting the device PC takes around 1.5 minutes.

4.2 Self-test

After powering-up, the CompoMat G5 conducts a self-test. The self-test run by the CompoMat G5 has two purposes:

- Checking minimum requirements are met for starting the device
- Identifying available hardware and checking functionality



Self-test part 1



Self-test part 2



Note

The component check made during the self-test cannot guarantee that the components are in perfect working order. It remains possible that certain program steps or functions may develop faults under certain circumstances. The functionality and results of component activity must be monitored at all times by the operator.

4.2.1 Self-test part 1

- **System files**



Possible results for tested component:

- Test passed.



- Test was not passed - system will be stopped.

- **Network**



Possible results for tested component:

- Test passed.



- Test was not passed.

- **IO communication**



Possible results for tested component:

- Test passed.



- Test was not passed - system will be stopped.

- **Slide**



Possible results for tested component:

- Test passed.



- Test was not passed, component unavailable to CompoMat G5.

- **CF-Opener Top**



Possible results for tested component:

- Test passed.



- Test was not passed, component unavailable to CompoMat G5.

● **CF-Opener Door**

Possible results for tested component:



- Test passed.



- Test was not passed, component unavailable to CompoMat G5.

● **CF-Opener RCC**

Possible results for tested component:



- Test passed.



- Test was not passed, component unavailable to CompoMat G5.

● **Head**

Possible results for tested component:



- Test passed.



- Test was not passed - system will be stopped.

4.2.2 Self-test part 2

● **PLS scales**

Possible results for tested component:



- Test passed.



- Component is present, but not calibrated.



- Test was not passed, component unavailable to CompoMat G5.

● **RCC Scale**

Possible results for tested component:



- Test passed.



- Component is present, but not calibrated.



- Test was not passed.

- **Press scales**



Possible results for tested component:

- Test passed.
- Component is present, but not calibrated.
- Test was not passed.

- **Upper Press**



Possible results for tested component:

- Test passed.
- Component is present, but not calibrated.
- Test was not passed.

- **Lower Press**



Possible results for tested component:

- Test passed.
- Component is present, but not calibrated.
- Test was not passed.

- **Top Press**



Possible results for tested component:

- Test passed.
- Component is present, but not calibrated.
- Test was not passed, component unavailable to CompoMat G5.


- **Door**



Possible results for tested component:

- Test passed.
- Test was not passed - system will be stopped.


4.3 Reactivating the CompoMat G5 from the standby mode

As long as the CompoMat G5 has not been disconnected from mains power, the CompoMat G5 can be reactivated by pressing the  key.



Tip

Reactivating the CompoMat G5 from Standby Mode takes only a few seconds.

If the  key is pressed again, then the CompoMat G5 will once again be returned to standby mode.

4.4 Operation of the device

Starting, pausing and stopping CompoMat G5 programs

G5 programs can be started, paused and stopped by operators.



Starting a program always involves the closing of the door!

Aborting a program

Operators may abort running programs at any point in time. This has the effect of stopping all current activities and the program itself will be terminated. The only exceptions to this rule are sealing commands, which are always completed (to avoid leakages). Terminating a program always involves a check of press positions for all presses used, the retraction of the slide, and the opening of the door.

Pausing a program

Operators may pause running programs at any point in time. This has the effect of stopping all current activities. The only exceptions to this rule are sealing commands, which are always completed (to avoid leakages). The operator can continue with program operation in two ways.

- By using the  key (green), the program steps active at the time the program was paused will be continued. The program will be executed normally.
- By using the  key (yellow), the program steps active at the time the program was paused will be skipped. The program will be continued using the subsequent steps.

Selecting a program

A maximum of 50 programs can be created / stored for CompoMat G5 devices. The operator can select a program in two ways:

- Selecting a program via CompoMaster Net G5, if a network connection is available.
See CompoMaster Net G5 User Manual.
- Selecting a program directly from CompoMat G5 (**Ready to use / Main menu / Program selection**).

Password protection for program selection

Direct program selection from CompoMat G5 can be password-protected.



Note

Factory-set password for the **Program selection** menu: **1 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password



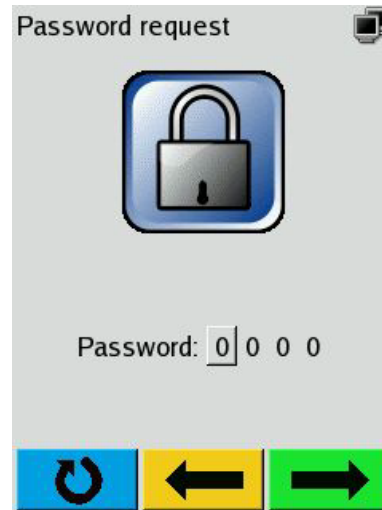
Note

As soon as a CompoMat G5 configuration parameter (e.g. language setting) has been changed in CompoMaster Net G5, the program preset by CompoMaster Net G5 will once again be selected.

4.5 Menu navigation

4.5.1 Entering the password

Password protection can be setup for certain menu items. The entry of a password is explained in the following as an example.



Password request

Use the ▲ or ▼ key to enter the fourth password digit.

Confirm with ■ key (green).

Use the ▲ or ▼ key to enter the third password digit.

Confirm with ■ key (green).

Use the ▲ or ▼ key to enter the second password digit.

Confirm with ■ key (green).

Use the ▲ key or ▼ key to enter the first password digit and accept using ◀ key;

4.5.2 Ready to use

After a successful system test, the device is put into the following state:

- The door is open
- The insertion areas of all program-relevant heads are flashing
- The CompoMat G5 shows the following screen message



The highlighted field displays the last program selected.

Press the  key (green):

the program displayed will be confirmed and executed.



Tip

An LED is located in the insertion area of each head. This LED shows the head's operating status:

- If the insertion area is lit up, then it is ready-to-use.
- If the insertion area is flashing, then a tube must be inserted for the selected program.
- Program-relevant heads are shown in green within the CompoMat G5 screen icon system.



Tip

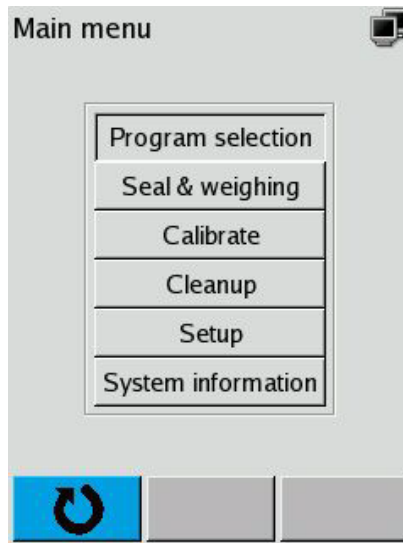
The program will be executed entirely automatically, as long as this is permitted by the program workflow. When the program is finished, all heads and the door will be opened.

or

Press the  key (yellow):

the **Main menu** is displayed (screen message below)

4.5.3 Main menu






Main menu screen message

The following sub-menus can be selected from the **Main menu**:


- Program selection
- Seal & weighing
- Calibrate
- Cleanup
- Setup
- System information

Navigating in the Main menu

Repeatedly press the  key or the  key:
the submenus will be accessed in sequence.
(shown by a 'pressed-in' menu button)

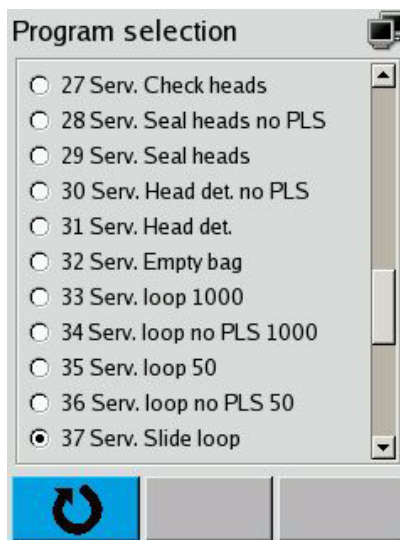
Press the  key:
the selection will be confirmed.

or

Press the  key (blue):
the operator guidance returns to the previous screen message, **Ready to use**.



4.5.3.1 Program selection


The **Program selection** menu is used to select the required program.




The Program selection menu
(example)

Navigating in the Program selection menu

Repeatedly press the  key or the  key:
the program slots will be accessed in sequence (shown by a marked radio button).

Press the  key:
the selection will be confirmed.

or

Press the  key (blue):
the operator guidance returns to the **Main menu**.

Creating, modifying and deleting programs

Creating, modifying and deleting programs is only possible by using the CompoMaster Net G5.

See CompoMaster Net G5 User Manual.

4.5.3.2 Seal & weighing

The CompoMat G5 has a manual sealing and weighing feature. These activities are entirely independent of any programs.



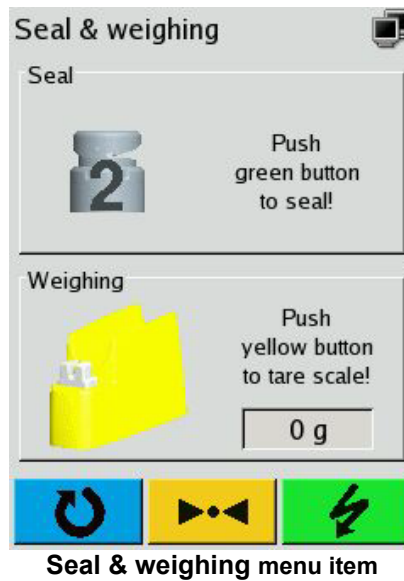
Note

Only the **RCC scales** can be used for manual weighing.



Note

Manual sealing can only be undertaken using **head 2**.



Manual weighing

Press the ■ key (yellow):
the zero (tare) of the scales will be set,
manual weighing can now be carried out.

Information about manual weighing

- It is possible to carry out any number of weighing operations.
- Press the ■ key (blue):
the operator guidance returns to the **Main menu**.

Manual sealing

Place tube in **head 2**,
Press the ■ key (green):
the sealing operation is started.

As soon as the sealing operation is completed, **Head 2** opens automatically and the tube can be taken out.

Information about manual sealing

- It is possible to carry out any number of manual sealing operations.
- Press the ■ key (blue):
the operator guidance returns to the **Main menu**.

4.5.3.3 Calibrate

(see **Press stroke calibration**, page 9-22)

4.5.3.4 Cleanup

(see **Cleaning special device components**, page 6-2)

4.5.3.5 Setup

- **Language selection**

(see **Language selection for the user interface on the CompoMat G5**, page 9-14)

- **Process data**

(see **Activating / deactivating process data**, page 9-15)

- **Software update**




This function may only be carried out by a service technician!

- **Barcode test**

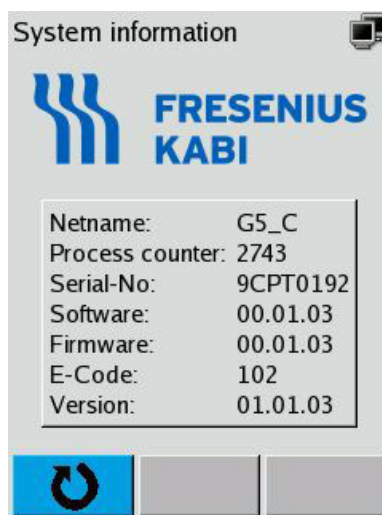
(see **Barcode test**, page 9-17)

4.5.3.6 System information

System information for the CompoMat G5 is accessible via **Ready to use / Main menu / System information**.

Use the  or  keys to access each menu item; confirm the selection with the  key.

The following screen message will be displayed.



System information screen message

4.6 Inserting tubing set components

4.6.0.1 Inserting a tubing into a head



Caution

Wrongly-inserted tubing can lead to poor sealing and/or leakages. Contamination or cross-contamination of blood products.

- It is imperative operators check a sealing result visually.



Keep the length of tubing under moderate tension and insert it into the head with both hands.



The head cover makes a see-sawing motion as the tubing is inserted.



Tip

- The head cover's see-sawing motion is especially useful in helping the insertion of thick tubing.
 - The tubing is held in place at the head by a special molding on the head cover.
-

4.6.0.2 Inserting a bag with CompoFlow into the press



Hang the donation bag on the suspension pins.



As shown in the picture, use both hands to insert the CompoFlow into the CF-Opener:

The large lower ring of the CompoFlow must be inserted beneath the yellow jaws and the small upper ring must be inserted above the yellow jaws, into the molded recess.

The CompoFlow must be inserted into the CF-Opener as far as it will go.



The yellow jaws in the CF-Opener serve to indicate whether the CompoFlow has been inserted correctly.

Where the CompoFlow has been inserted correctly, the jaws close parallel to one another.



Tip

- The CompoFlow system is a system that has been patented by Fresenius Kabi.
- The CompoFlow system reduces the risk of hemolysis.
- The CompoFlow system also prevents the incidence of strain injuries to fingers and forearm, which can occur during the manual opening of standard break-off valves.

4.6.0.3 Breaking of cannula with the aid of the passive insert

A passive insert makes it easier to break traditional cannulas.



Note

On the usage of the passive insert on the RBC scales. The RBC scales must be recalibrated each time after inserting or removing the passive insert.

Inserting a passive insert in the CF-Opener attachment



This requires a form-locking installation of the passive insert in the CF-Opener attachment.



As shown in the picture, insert the break-off valve into the passive insert.



Hold the bag firmly by the tube connector attachment.
Using the passive insert to support the cannula breaking.



Snap off the break-off valve as shown in the picture.

Please also follow the recommendations of the bag manufacturer as explained below.



Tip

If the passive insert is not required, it can be removed without using a tool and attached to the housing side panel of the CompoMat G5 by means of a magnet (see illustration).

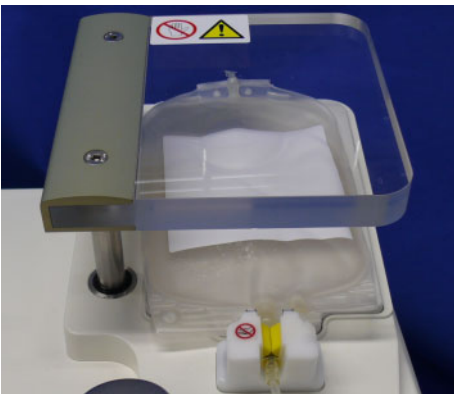
On opening the standard break-off valves it is imperative the information from the bag manufacturer is followed, as there is in principle a risk of hemolysis.

As a rule one standard break-off valve must be broken on both sides such that there is a visible gap of several millimeters underneath the break-off taper to ensure an adequate flow of blood.



Storage of the passive insert.

4.6.0.4 Placing a bag into the top press



As shown in the picture, place the bag into the top press.

Insert the corresponding CompoFlow as shown in (see **Inserting a bag with CompoFlow into the press**, page 4-15



Tip

The top press is constructed so that the bag vent is located at the bag's lowest point. This ensures that no air can enter the filter during filling.

4.6.0.5 Placing a PLS bag into the PLS scales



Note

When inserting the tubing into the head of the plasma deaeration unit, ensure that there are no kinks in the tubing.

Insert the PLS bag as shown in the following pictures.



Insert the PLS bag into the metal bracket on the PLS scales as far as it will go.




4.6.0.6 Placing a RCC collection bag onto the RCC scales



Place the RCC collecting bag onto the RCC scales as shown in the picture.

4.6.0.7 Powering down the CompoMat G5

If the  key is pressed, then the CompoMat G5 will be put in standby mode.



Note

The CompoMat G5 should not be disconnected from mains power during normal operation.

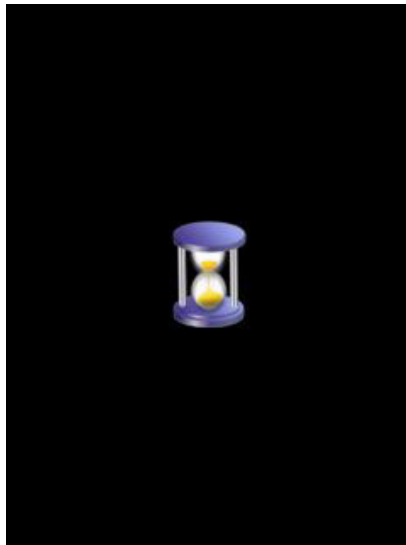


Tip

Reactivating the CompoMat G5 from Standby Mode takes only a few seconds.

4.7 Disconnecting the CompoMat G5 from mains power

The CompoMat G5 shuts down as soon as the CompoMat G5 is disconnected from mains power or powered down using the main power switch.



**Disconnecting the CompoMat G5
from mains power**



Note

Once the CompoMat G5 has been disconnected from mains power, a restart of the CompoMat G5 will take about 1.5 minutes.








Note







Wait at least 10 seconds before powering the unit back on.














5 Alarms




5.1 Definition of visual notifications (with meanings)

	Error / wrong password
	Warning
	Advice
	Question
	Waiting












5.2 List of all visual notifications (with meanings)

















Message	Symbol used	Cause:
Reset EEPROM! Please wait...		<ul style="list-style-type: none"> – The ARM7 firmware has been updated. – The ARM7 EEPROM must be re-initialized.
Procedures updated!		<ul style="list-style-type: none"> – The procedure has been updated. – The CompoMat G5 is in the ready to use state or in the Program selection menu
Head 1 = 55 Head 4 = 52 Head 2 = 56 Head 5 = 53 Head 3 = 57 Head 6 = 55		Result of the head sensor calibration (after ADC calibration).
Det. A1 = 055 Det. A5 = 052 Det. A2 = 056 Det. A6 = 053 Det. A3 = 057 Det. A7 = 055 Det. A4 = 057 Det. A8 = 055		Result of the detector A-calibration.
Please calibrate the Upper Press first!		Cleanup Upper Press has been selected, although this is not calibrated. (see chapter 9.4, page 9-22)
Please calibrate the Lower Press first!		Cleanup Lower Press has been selected, although this is not calibrated. (see chapter 9.4, page 9-22)




Message	Symbol used	Cause:
No connection to CompoMaster Net!		Process data on has been selected, although there is no connection to CompoMaster Net G5. (see chapter 9.3.5.2, page 9-15).
USB stick is not valid!		USB drive cannot be connected (mounted).
Fehler beim Entfernen des USB-Sticks (Error on removing the USB stick)		USB drive cannot be removed (unmounted).
Checksum error.		No update file available or update file has invalid checksum.
Transfer error!		Update file transmission error
SORRY: Bad password! Please check.		Wrong password entered
Calibration failed!		Press calibration error during the self-test
For this action a service stick is required!		An action has been selected that is only allowed to be used by a service engineer.
The actuator must be moved in completely!		Leaving a cleaning function with actuator extended
Init failed!		It was not possible to initialize /install the Trinamic software.
Change program?		The barcode scanned does not match the selected program and in the CompoMaster Net G5 the option “<Start> nach Programmänderung (Start after program change)” is selected.
Kalibriere ADC & Kopfsensoren... (Calibrating ADC & head sensors...)		The ADC must be recalibrated. E.g. after an ARM7 firmware update.
Reset IO board...		Resetting the ARM7 board for an update (triggered by the version check).

Message	Symbol used	Cause:
Erase IO software...		Erasing Arm7 firmware (triggered by the version check).
Install IO software...		Installing ARM7 firmware (triggered by the version check).
Init motor control...		Installing Trinamic procedures (triggered by the version check).

5.3 List of all visual, acoustic notifications (with meanings)

Message	Symbol used	Cause:
Error: Close Door... ERROR-CODE: 0x0555		Problem while closing the door/door obstructed
Error: Open Door... ERROR-CODE: 0x0555		Problem while opening the door/door obstructed
Error: CF-Opener Top is empty!		CF-Opener is empty, no CompoFlow has been inserted
Error: CF-Opener Door is empty!		CF-Opener is empty, no CompoFlow has been inserted
Error: CF-Opener RCC is empty!		CF-Opener is empty, no CompoFlow has been inserted
Error: Seal Head ERROR-CODE: 0x0555		Problem while sealing, head needs cleaning. (see chapter 6.2.2, page 6-3)
Error: Check Head Inspect: 1 3 5		Not enough heads being used (see chapter 4.5.2, page 4-8)
Error: Check Head Remove: 2 4 6		Too many heads being used (see chapter 4.5.2, page 4-8)
Error: Check Head Inspect: 1 4 Remove: 2 3		Too many and not enough heads being used (see chapter 4.5.2, page 4-8)
Calibration-Error: Press Scale ERROR-CODE: 0x0555		Scales are not calibrated. (see chapter I, page 9-11)
Calibration-Error: RCC Scale ERROR-CODE: 0x0555		Scales are not calibrated. (see chapter I, page 9-9)

Message	Symbol used	Cause:
Calibration-Error: PLS scales ERROR-CODE: 0x0555		Scales are not calibrated. (see chapter I, page 9-7)
Ventil an der Toppresse überprüfen! (Check valve on the top press!)		Problem during "top press down with check"; CompoFlow and/or break-off valve not open
Timeout: Top Press!		Press has not moved for at least 10 seconds.
Timeout: Upper Press!		Press has not moved for at least 10 seconds.
Timeout: Lower Press!		Press has not moved for at least 10 seconds.
Timeout: Both Presses!		Presses have not moved for at least 10 seconds.
Head Detector 1 alarm		Red cells detected at head detector 1.
Head Detector 2 alarm		Red cells detected at head detector 2.
Head Detector 3 alarm		Red cells detected at head detector 3.
Head Detector 4 alarm		Red cells detected at head detector 4.
Head Detector 5 alarm		Red cells detected at head detector 5.
Head Detector 6 alarm		Red cells detected at head detector 6.
Error: Pressposition Upper Press		Error in the press position is too large during the verification. Press position must be recalibrated.
Error: Pressposition Lower Press		Error in the press position is too large during the verification. Press position must be recalibrated.
Error: Pressposition Top Press		Error in the press position is too large during the verification. Press position must be recalibrated.
Error: Pressposition Upper Press! Lower Press!		Error in the press position is too large during the verification. Press position must be recalibrated.

Message	Symbol used	Cause:
Error: Pressposition Upper Press! Top Press!		Error in the press position is too large during the verification. Press position must be recalibrated.
Error: Pressposition Lower Press Top Press!		Error in the press position is too large during the verification. Press position must be recalibrated.
Error: Pressposition Upper Press! Lower Press! Top Press!		Error in the press position is too large during the verification. Press position must be recalibrated.

6 Cleaning / disinfection

6.1 Cleaning the surface of the device



Warning

Risk of injury due to crushing.

- Terminate all programs before cleaning.
-



Warning

Risk of injury caused by electrical voltage. Electric shock!

Terminate all programs and disconnect the power plug before cleaning.

Exception:

The device must be ready for operation when cleaning the presses.


Take care to ensure that no liquids enter the device during cleaning. We recommend carrying out a wipe disinfection with a cloth soaked in disinfectant.

- Only switch on the CompoMat G5 once the cleaning agents have evaporated, leaving no residue.
-



Warning

Risk of infection as a result of blood leakage

If it is detected, during the preparation process, that there is a leaking blood bag or blood escaping from a tubing, the preparation procedure must immediately be interrupted by pressing the  (blue; **Stop**) key. Before being restarted, the CompoMat G5 must be cleaned and disinfected according to the disinfection plan provided.



Caution

Damage to the device by cleaning agents getting into the device.

- Do not let cleaning agents drip into the interior of the device.
-



Caution

Damage to surfaces and mechanical components by use of the incorrect cleaning agent

- The CompoMat G5 must never be cleaned using abrasive or corrosive agents.
-



Caution

Damage to surfaces and mechanical components by use of the incorrect cleaning agent

- The CompoMat G5 must never be treated with plastic or lubricant solvents.
-

6.1.1 Cleaning agents

Appropriate cleaning agents for the CompoMat G5

- Alcohol-based fast-acting disinfectant (e. g. Freka[®]-NOL) or equivalent disinfectant with approx. 42% ethanol
- Water and mild detergents

6.2 Cleaning special device components

6.2.1 Cleaning the CF-Opener attachments



Warning

Risk of crushing injury by inadvertent operation of the device.

- Before cleaning the CF-Opener, use the main switch on the rear of the device to disconnect it from mains power.
-

To make cleaning easier, the CF-Opener attachments can be removed.



Use a size 2 Allen wrench (661 526 1) to unscrew the lateral stud screws on both sides.



Pull off CF-Opener attachment.

Clean the CF-Opener attachment with detergent and a lint-free cloth.

Re-install the CF-Opener attachment and tighten the screws.



Note

When securing the screws, the CF-Opener attachment must be in contact with the housing.

6.2.2 Cleaning the heads



Warning

Risk of crushing injury by inadvertent operation of the device.

- Before cleaning the heads, use the main switch on the rear of the device to disconnect it from mains power.

6.2.2.1 Cleaning the surface and the insertion slots

Wipe off the surfaces of the heads and the sealing electrodes with a soft, lint-free cloth.

For suitable cleaning agents, (see chapter 6.1, page 6-1).



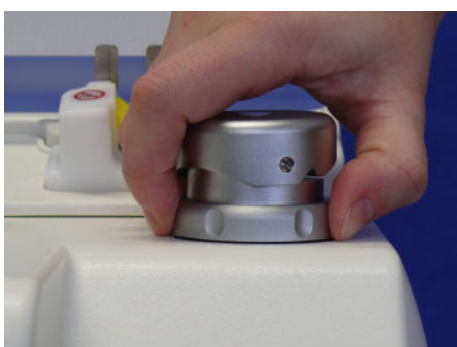
Lift up the head cover.

Clean the tube guide area with a cleaning agent and a cotton swab.



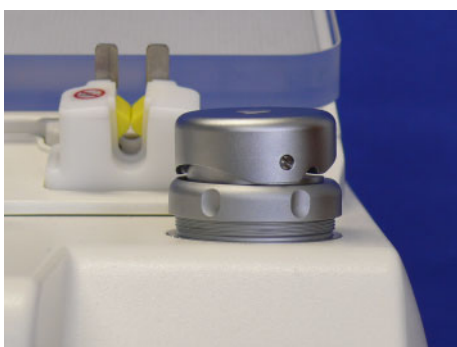
The head may also be cleaned with the help of a cloth. See picture to the left.

6.2.2.2 Cleaning the opened head

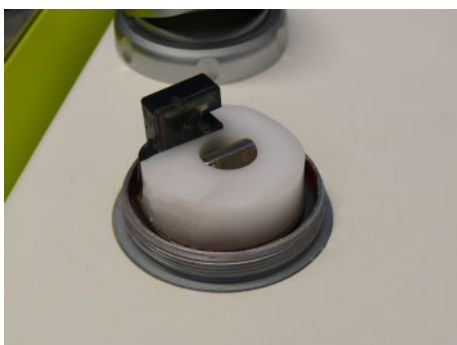


Soiling in the internal compartments of the heads can occur as a result of leakages from bags or tubing. To remove this kind of soiling effectively, it is possible to open any affected head as required (see picture sequence to the left).

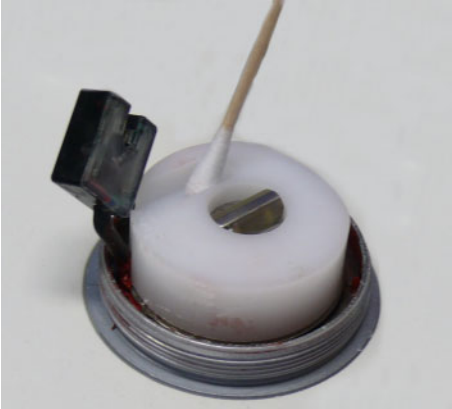
Unscrew the cap nut.



Remove the head cover together with the cap nut.



The interior of the head is now visible.



Carefully prize out the optical fork sensor.

Clean accessible areas with a cleaning agent and a cotton swab.



Where soiling is excessive, it is also possible to remove the plastic cover and spring.

Carry out cleaning with a cleaning agent and a cotton swab.



Note

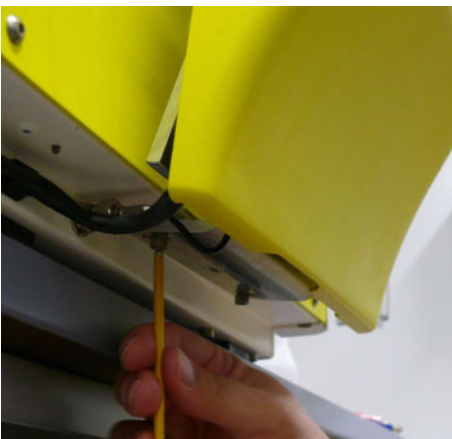
On re-fitting the head components, it must be noted that the union nut is only allowed to be tightened hand-tight.

6.2.3 Cleaning the PLS scales



Tip

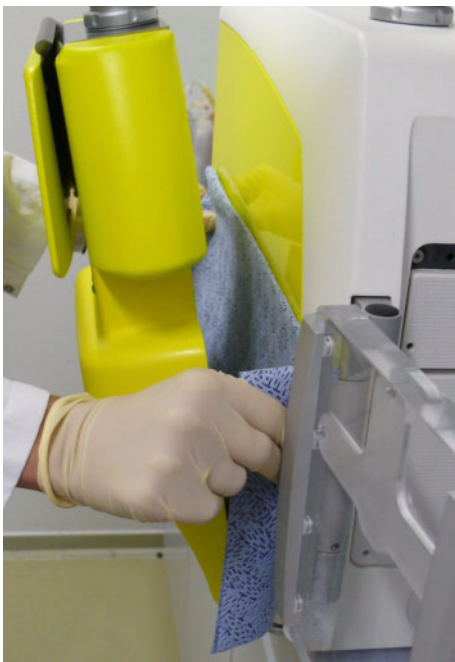
The PLS scales can be folded away for cleaning purposes.



- Place the CompoMat G5 to the border of the table, so that the mounting screws of the PLS scales can be unscrewed.
- Remove the middle fixing screw using a size 3 Allen screwdriver (M67 794 1).
- Unscrew the two outer mounting screws by 2.5 turns (do not remove them).



- Draw the PLS scales as far as possible to the outside and make it fold away.
- Clean the space between CompoMat G5 and PLS scales.



Surface cleaning must only be carried out with detergent and a lint-free cloth. (see **Cleaning agents**, page 6-2.

Return the device to operating condition (after cleaning)

- Return the PLS scales to their original position.
- Tighten all three mounting screws.
- Calibrate the PLS scales. (see chapter 9.3.4, page 9-6)



Note

When installing the PLS scales, it must be ensured that the connecting cables are not touching the scales housing.



Note

Imperatively calibrate the PLS scales to obtain correct measurement results.

6.2.4 Cleaning the RCC scales



Tip

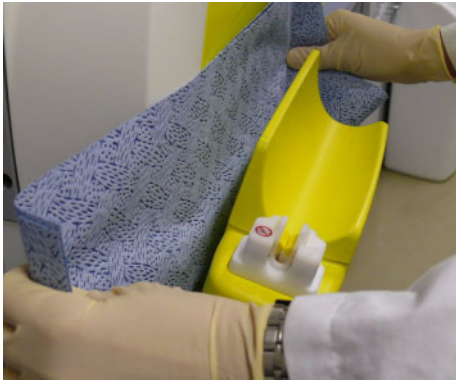
The RCC scales can be folded away for cleaning purposes.



- Place the CompoMat G5 to the border of the table, so that the mounting screws of the RCC scales can be unscrewed.
- Remove the middle fixing screw using a size 3 Allen screwdriver (M67 794 1).
- Unscrew the two outer mounting screws by 2.5 turns (do not remove them).



- Draw the RCC scales as far as possible to the outside and make it fold away.
- Clean the space between CompoMat G5 and RCC scales.



Surface cleaning must only be carried out with detergent and a lint-free cloth. (see **Cleaning agents**, page 6-2).

Return the device to operating condition (after cleaning)

- Return the RCC scales to their original position.
- Tighten all three mounting screws.
- Calibrate the RCC scales. (see chapter 9.3.4, page 9-6)



Note

When installing the RCC scales, it must be ensured that the connecting cables are not touching the scales housing.



Note

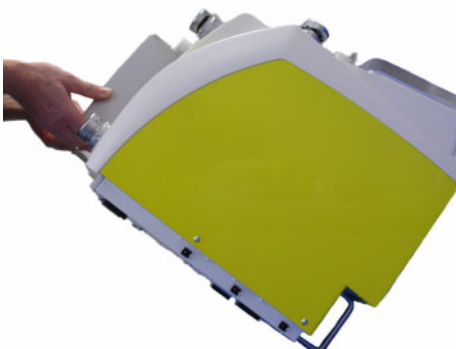
Imperatively calibrate the RCC scales to obtain correct measurement results.

6.2.5 Cleaning the bottom of the CompoMat G5



To clean the bottom of the CompoMat G5, it is possible to position the CompoMat G5 on its rear.
(See the following pictures)

Lift up the CompoMat G5 from its front side.



Pivot the CompoMat G5 over the two frames on the rear of the device.



CompoMat G5, positioned on its rear
Bottom of the CompoMat G5

6.2.6 Password protection for the Cleanup menu



Note

A password can be set for the Cleanup menu (for Upper Press / Lower Press and Slide) (see chapter 4.5.1, page 4-8).

Factory-set password for the **Cleanup** menu: **3 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password

6.2.7 Cleaning the presses

Leakages from bags or tubing can give rise to soiling in the spaces between the presses or the slide and other components. To be able to remove this kind of soiling effectively, it is possible to extend/move the affected press or the slide once the door is open.

6.2.7.1 Cleanup

The **Cleanup** menu (for Upper Press, Lower Press and Slide) can be accessed via:

Ready to use / Main menu / Cleanup.

● **Cleaning the upper press**

Pulling out the suspension pins



The suspension pins can be pulled out to make it easier to clean the upper press and the suspension pins.



Note

The CompoMat G5 must be powered on in order to clean the upper press.



Warning

Risk of crushing injury by inadvertent operation of the device.
Do not activate any keys when cleaning the presses.

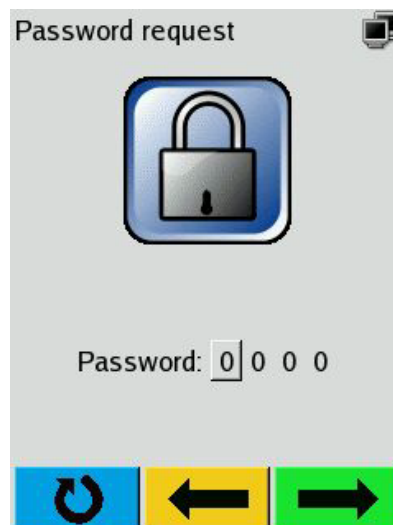


Warning

Risk of injury by electrical voltage by cleaning agent entering the device.
No cleaning agent must enter the device.

Use the controls on the CompoMat G5 to select
Select **Ready to use / Main menu / Cleanup**;

The **Password request** screen message is displayed.





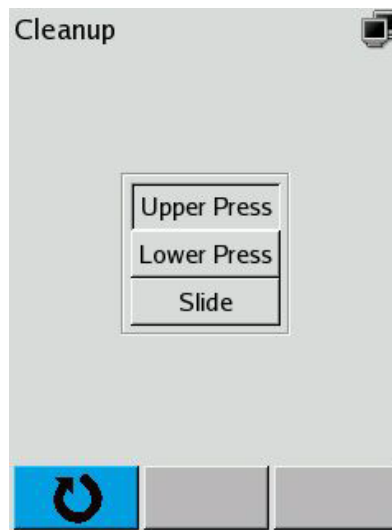
Note




Factory-set password for the **Cleanup** menu: **3 0 0 0**.

Entering the password see (see chapter 4.5.1, page 4-8).

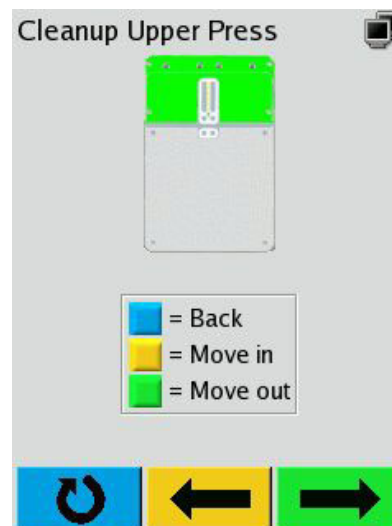
Consult the CompoMaster Net G5 User Manual for information on modifying the password

After the entry of the valid password, the **Cleanup** menu shown below is displayed.




In the **Cleanup** menu, use the  key or the  key to select the **Upper Press** menu item, and confirm with the  key.

The **Cleanup Upper Press** screen message is displayed.



The green-colored upper press indicates that the cleaning program has been selected for the upper press.



 key (blue):

Switches to previous screen message.



Note

The cleaning program can only be exited, if the upper press has been completely retracted.



■ key (yellow);

As long as the ■ key (yellow) is pressed, the upper press continues to move to its initial position.



■ key (green):

As long as the ■ key (green) is pressed, the upper press continues to move to its external position.

As soon as the press has started moving, the screen display will change to that shown below.



Shows the movement of the upper press.

As soon as the press has stopped moving, it can then be cleaned.

Wipe off the press with a soft, lint-free cloth.

For suitable cleaning agents, (see chapter 6.1, page 6-1).

● **Cleaning the lower press**



Note

The CompoMat G5 must be powered on in order to clean the lower press.



Warning

Risk of crushing injury by inadvertent operation of the device.

Do not activate any keys when cleaning the presses.



Warning

Risk of injury by electrical voltage by cleaning agent entering the device.
No cleaning agent must enter the device.

Use the controls on the CompoMat G5 to select
Select **Ready to use / Main menu / Cleanup**;

The **Password request** screen message is displayed.



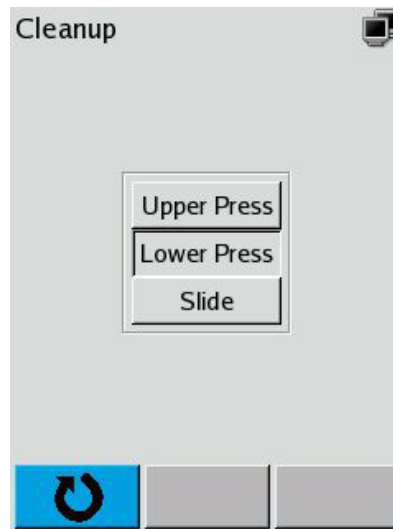
Note




Factory-set password for the Cleanup menu: **3 0 0 0**.

Entering the password see (see chapter 4.5.1, page 4-8).

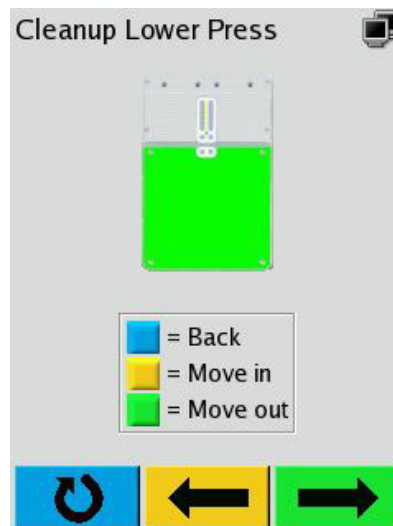
Consult the CompoMaster Net G5 User Manual for information on
modifying the password

After the entry of the valid password, the **Cleanup** menu shown below
is displayed.




In the **Cleanup** menu, use the  key or the  key to select the **Lower Press** menu item, and confirm with the  key.

The **Cleanup Lower Press** screen message is displayed.



The green-colored lower press indicates that the cleaning program has been selected for the lower press.





 key (blue):
Switches to previous screen message.




Note


The cleaning program can only be exited, if the lower press has been completely retracted.



 key (yellow);
As long as the  key (yellow) is pressed, the lower press continues to move to its initial position.



 key (green):

As long as the  key (green) is pressed, the lower press continues to move to its external position.

As soon as the press has started moving, the screen display will change to that shown below.



Shows the movement of the lower press.

As soon as the press has stopped moving, it can then be cleaned.

Wipe off the press with a soft, lint-free cloth.

For suitable cleaning agents, (see chapter 6.1, page 6-1).

● Cleaning the slide



Note

The CompoMat G5 must be powered on in order to clean the slide.



Warning

Risk of injury by crushing by inadvertent operation of the device.

Do not activate any keys when cleaning the slide.



Warning

Risk of injury by electrical voltage by cleaning agent entering the device.

No cleaning agent must enter the device.

Use the controls on the CompoMat G5 to select

Select **Ready to use / Main menu / Cleanup**;

The **Password request** screen message is displayed.



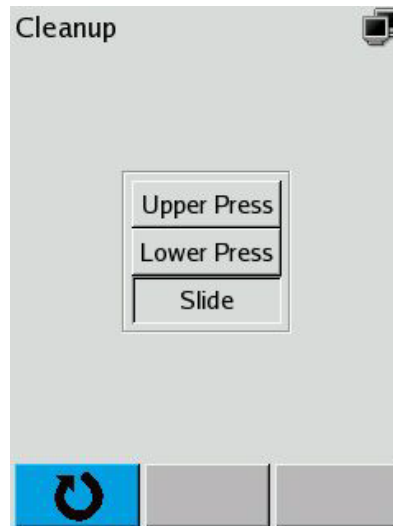
Note



Factory-set password for the Cleanup menu: **3 0 0 0**.

Entering the password see (see chapter 4.5.1, page 4-8).

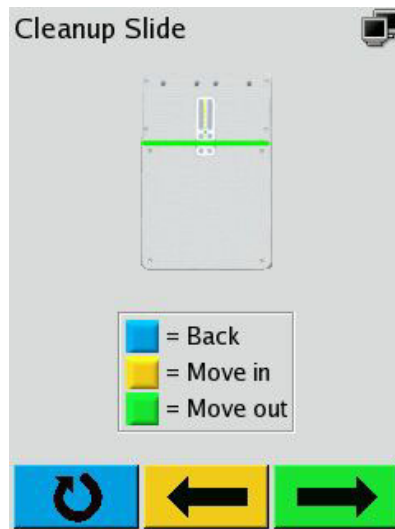
Consult the CompoMaster Net G5 User Manual for information on modifying the password

After the entry of the valid password, the **Cleanup** menu shown below is displayed.




In the **Cleanup** menu, use the  key or the  key to select the **Slide** menu item, and confirm with the  key.

The **Cleanup Slide** screen message is displayed.



The green-colored slide indicates that the cleaning program has been selected for the slide.



 key (blue):


Switches to previous screen message.




Note


The cleaning program can only be exited, if the slide has been completely retracted.




 key (yellow);

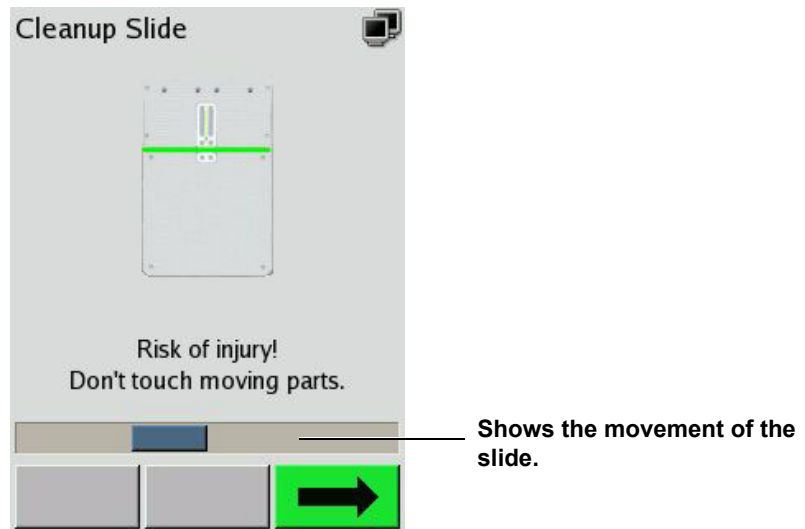
As long as the  key (yellow) is pressed, the slide continues to move to its initial position.



 key (green):

As long as the  key (green) is pressed, the slide continues to move to its external position.

As soon as the slide has started moving, the screen display will change to that shown below.



As soon as the slide has stopped moving, it can then be cleaned.

Wipe off the slide with a soft, lint-free cloth.
For suitable cleaning agents, (see chapter 6.1, page 6-1).

6.2.7.2 A1 - A8 detectors

Wipe off the transparent covers of the A1 - A8 detectors using a soft, lint-free cloth.
For suitable cleaning agents, (see chapter 6.1, page 6-1).

6.3 Cleaning intervals (recommended)

- | | |
|------------------------|--|
| Daily cleaning | The surfaces and the specialized components of the CompoMat G5 should be cleaned daily in accordance with the cleaning guidelines (see chapter 6.1, page 6-1). |
| Weekly cleaning | The covers of the A1 - A8 detectors should be cleaned weekly or as required using a lint-free cloth. |

6.4 Maintenance

- | | |
|---------------------------|--|
| Annual maintenance | The maintenance procedures must be carried out by a trained technician or a Fresenius Kabi service technician. |
|---------------------------|--|

6.5 Start-up after cleaning

Once the surfaces are clean and dry, the device can be used again.

6.6 Disclaimer of warranty and maintenance contract claims


Any damage caused, totally or in part, by these cleaning regulations not being adhered to is excluded from warranty or maintenance contract claims.

6.7 Disinfection



Warning

Risk of infection due to leaking blood.

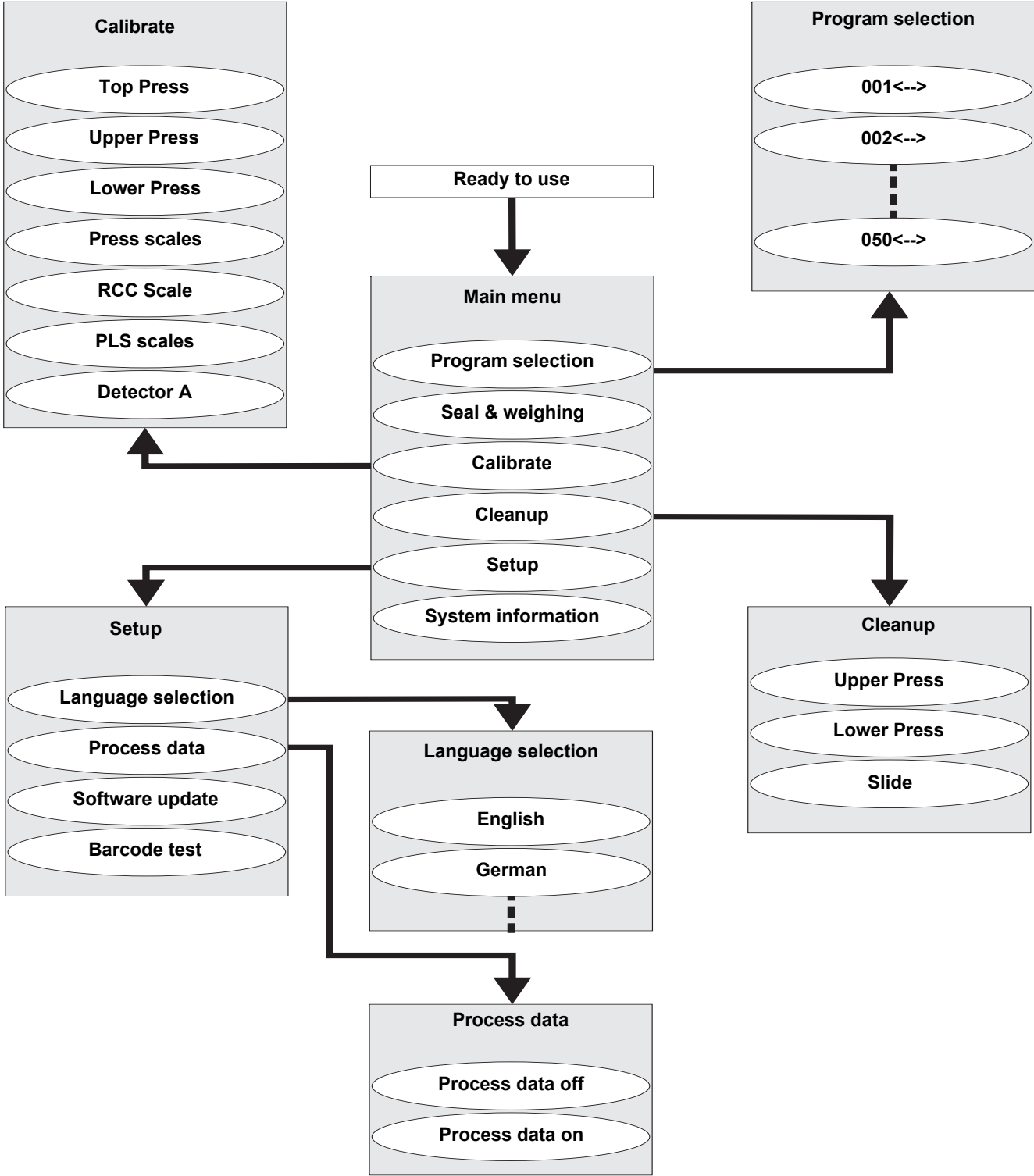
If it is detected, during the preparation process, that there is a leaking blood bag or blood escaping from a tubing, the preparation procedure must immediately be interrupted by pressing the  (blue; **Stop**) key. Disinfect the CompoMat G5 before restarting it.

Appropriate cleaning agents for the CompoMat G5

- Alcohol-based disinfectants (e. g. Freka[®]-NOL)

7 Functional description

7.1 Menu tree (structure of operator guidance)



8 Consumables / accessories / additional equipment

8.1 Basic system CompoMat G5

Product	Part number	Information
EE / COMPOMAT G5	902 550 1	Device without attachment parts
OP COMPOMAT G5 GERMAN	M67 596 1	
OP COMPOMAT G5 ENGLISH	M67 597 1	
ALLEN SCREWDRIVER SIZE 2, ANGLED	661 526 1	For CF-Opener attachment
ALLEN SCREWDRIVER SIZE 3, ANGLED	M67 794 1	For securing the scales

8.2 Accessories

Product	Part number	Information
EE/SCANNER - 9 PINS	902 893 1	
(DENSO) SCANNER HOLDER	M60 814 1	For Denso scanner
NETWORK CABLE 5M (8P8C, straight)	M67 810 1	
WLAN DONGLE	M67 478 1	
WLAN ACCESS POINT	M67 479 1	
LAN HUB ASSY.	M67 481 1	
COMPOFLOW	M67 501 1	3 pcs required per maintenance cycle
500 G CALIBRATION WEIGHT	M63 925 1	
TOOL FOR MANUAL SCREWING	M67 813 1	For tightening the sleeve nuts of the sealing heads

8.3 Additional equipment

Product	Part number	Information
EE / RCC SCALES FOR COMPOMAT G5	902 551 1	
EE / PLS SCALES FOR COMPOMAT G5	902 552 1	
EE / FILTER HOLDER FOR COMPOMAT G5	902 553 1	
PASSIVE INSERT	661 548 1	

9 Installation

9.1 Installation requirements / requirements for initial start-up

9.2 Preface

Instructions for all technicians authorized to commission our systems.

We, as manufacturers, permanently strive to supply products of superior quality.

To live up to this standard, we need your support.

Please commission our systems uniformly using the enclosed "initial start-up report" and enter the values determined in the columns provided.

In general:

Corrections are only required if the measured values are outside the specified tolerances!

9.3 Important information on initial start-up

For initial start-up only	This technical document is only intended for the initial start-up.
Environmental conditions	Variations in temperature during transport may cause condensation leading to water developing on live parts. In the event of major variations in temperature, allow sufficient time for the system to adjust to the ambient temperature before start-up.
Tester's qualification	<p>The initial start-up must be performed by the Technical Service of Fresenius Kabi or a person authorized by them.</p> <p>The initial start-up procedure may only be performed by persons qualified to properly perform the specified checks owing to their educational background and training, and knowledge and experience gained in practice. Furthermore, the persons performing the tests must not be bound by any directives when performing this activity.</p>
Test equipment and accessories	The activities described in this technical document require the availability of the necessary technical measuring equipment and accessories.
Specifications	Observe the information on the specifications.
Precautions	<p>Before turning power on, repair any visible damage.</p> <p>Prior to opening the system and when working on the open system, the following precautions have to be observed:</p>

- Protect the components against ingress of fluids.
- Do not touch live parts.
- All plugs, connections and components may only be disconnected or connected if de-energized.

ESD precautions

When repairing and when replacing spare parts, observe the applicable ESD precautions.

Intervals for Technical Safety Checks (TSC)

The CompoMat G5 is not required to undergo technical safety testing.

Intervals for Technical Measurement Checks (TMC)

The CompoMat G5 is not required to undergo technical measurement testing.

9.3.1 Unpacking the CompoMat G5

Unpacking and setting up

- Remove packaging;
- CompoMat G5 check for any damage;
- CompoMat G5 place on a solid table or laboratory counter;



Tip

Retain the packaging for possible future return shipments.



Caution

Condensation damage to the device.

The CompoMat G5 must have reached ambient temperature before being switched on.



Note

Combined use of the CompoMat G5 and CompoMaster Net G5 requires installation of a private network (see also (see **Network CompoMat G5**, page 9-29)

Scope of delivery for CompoMat G5

- Power supply cable
- Operating Instructions

Connecting up

The rear of the system is equipped with a supply connection with socket for a grounded power cable.

9.3.2 Installing the CompoMat G5



Caution

Damage to the device by improper installation.

The CompoMat G5 may only be installed and calibrated by authorized Fresenius Kabi service personnel or by service technicians certified by Fresenius Kabi.

Electrical installation



Warning

Risk of injury caused by electrical voltage.

When connecting the CompoMat G5 to a mains supply, the local regulations that apply have to be observed.



Warning

Risk of injury caused by electrical voltage.

Improper commissioning and use of the electrical equipment can result in injuries, such as burns and electrical shocks.



Warning

Risk of injury caused by electrical voltage.

When using safety class I devices, the quality of the protective conductor of the installation is of particular importance. It must be taken into consideration that in many countries regulations have been enacted by the national authorities. The rear panel of the CompoMat G5 is provided with a connection for a grounded power cable.



Warning

Risk of injury caused by electrical voltage.

If the power cable needs to be replaced, use only the original power cable listed in the spare parts catalog. If additional equipment, not included in the accessories, is connected to the device, then the permissible leakage currents risk to be exceeded.



Warning

Risk of injury by burning

The devices are not suitable for use with flammable mixtures or nitrous oxide.



Caution

Loss of the preparation and process data when the mains supply is disconnected or there is a power failure.

If there is a loss of power whilst processing a program in the CompoMat G5, all heads will open and the presses will stop. This may cause a loss of the preparation and the process data.

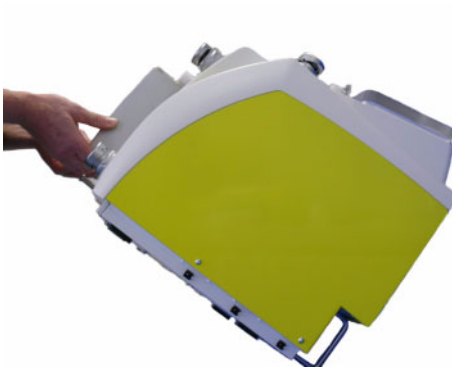
9.3.3 Installing the PLS and RCC scales

9.3.3.1 Tipping the device for easier mounting of PLS and RCC scales



To make it easier to mount the PLS and RCC scales, it is possible to position the CompoMat G5 flat on its rear. (See the following pictures)

Lift up the CompoMat G5 from its front side.



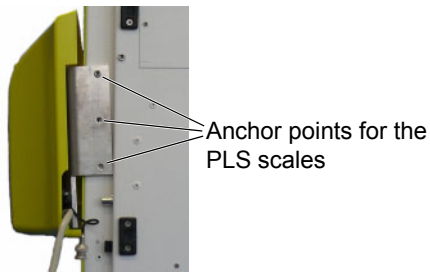
Pivot the CompoMat G5 over the two frames on the rear of the device.



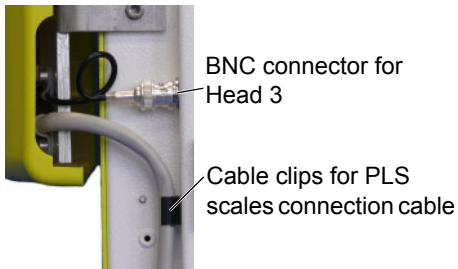
CompoMat G5, positioned on its rear

Bottom of the CompoMat G5

9.3.3.2 Mounting the PLS scales



Place the PLS scales flush with the housing as shown in the picture and tighten the fixing screws using the size 3 Allen screwdriver supplied.



Connect the BNC plug to the BNC port as shown in the picture.

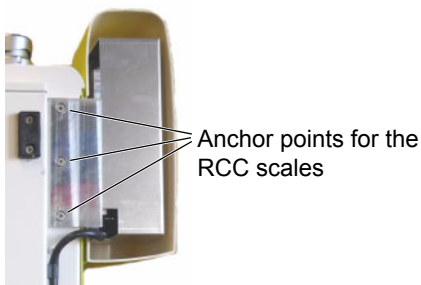
Lay the connection cable as shown in the picture.



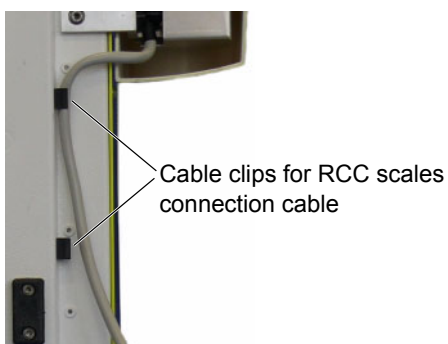
Note

When routing connection cables, it must be ensured that the connecting cables are not touching the scales housing.

9.3.3.3 Mounting the RCC scales



Place the RCC scales flush with the housing as shown in the picture and tighten the fixing screws using the size 3 Allen screwdriver supplied.



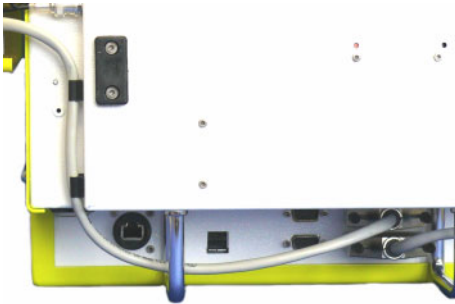
Lay the connection cable as shown in the picture.



Note

When routing connection cables, it must be ensured that the connecting cables are not touching the scales housing.

9.3.3.4 Connecting the PLS and RCC scales to the CompoMat G5



Route the connection cable as shown in the picture.

Insert the plug as shown.

Important:

Cables must be routed through the bracket.

9.3.4 Calibrating the scales



Note

Calibrating the scales is essential to ensure that measurements are accurate.



Note

A 500 g weight is needed to calibrate the scales.
(Also available as an accessory, Art. No. M63 925 1)



Note

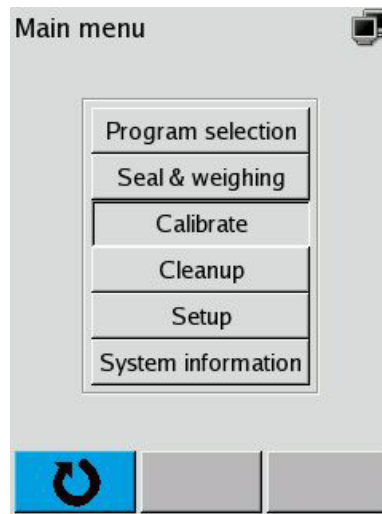
Factory-set password for **Calibrate** menu: **2 0 0 0**.

Entering the password (see chapter 4.5.1, page 4-8)




Consult the CompoMaster Net G5 User Manual for information on modifying the password

- **Accessing the Calibrate menu (starting calibration manually)**

Ready to use / Main menu / Settings / Calibrate.






Main menu

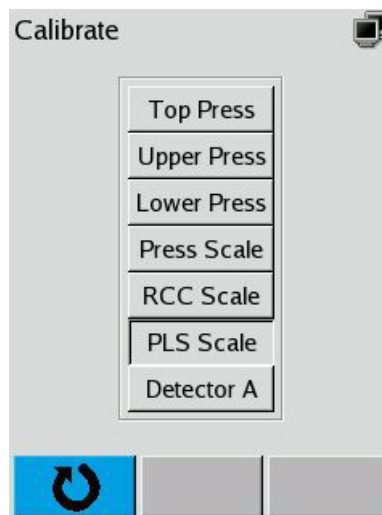
In the **Main menu**, use the  key or the  key to select the **Calibrate** menu item, and confirm with the  key.

The **Calibrate** screen message is displayed (left-hand figure, below).

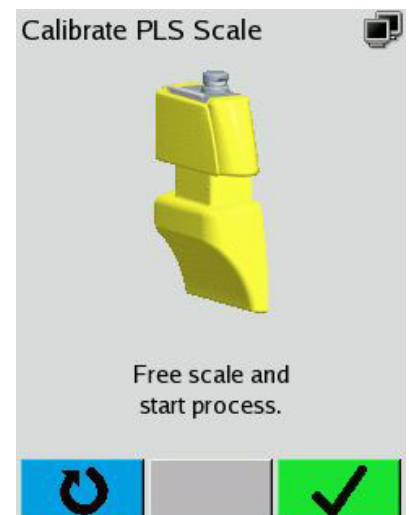
- **PLS scales**

In the **Calibrate** menu, use the  key or the  key to select the **PLS Scale** menu item, and confirm with the  key.

The **Calibrate PLS Scale** screen message is displayed (right-hand figure, bottom).



Calibrate menu



Calibrating the PLS scales

Zero-point calibration, PLS scales

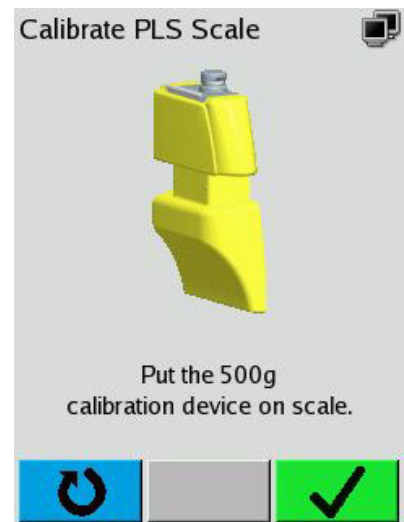
Confirm that the **PLS scales** are unladen.

Press the  key (green):

The following screen message will be displayed (left-hand figure)



Reading the zero point on the PLS scales



Requesting placement of 500 g weight

Calibrating inclination for the PLS scales

Load the scales with 500 g.

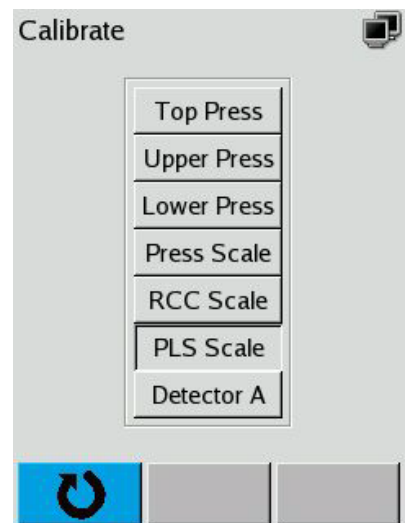
Press the ■ key (green):

The value determined is read in (right-hand figure, top).

After successful calibration the screen message shown below is displayed (left).



Message following successful calibration



Calibrate menu

Press the ■ key (blue):

The **Calibrate menu** is displayed again (right-hand figure, top).

Press the ■ key (blue):

The **Main menu** is displayed.

- **RCC scales**






Note

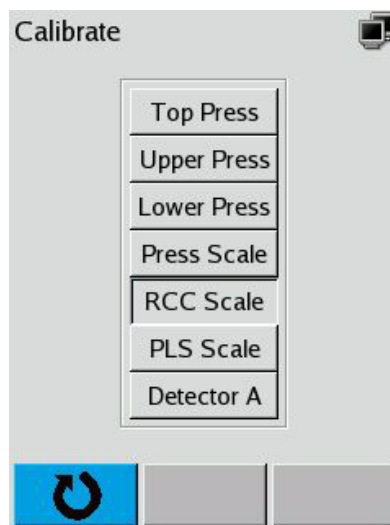
The **Calibrate** menu can be protected with a password (see **Calibrating the scales**, page 9-6).

Entering the password (see chapter 4.5.1, page 4-8).

Starting calibration manually

In the **Calibrate** menu, use the  key or the  key to select the **RCC Scale** menu item, and confirm with the  key.

The **Calibrate RCC Scale** screen message is displayed (right-hand figure, bottom).



Calibrate menu



Calibrating the RCC scales

Zero-point calibration, RCC scales

Confirm that the **RCC scales** are unladen.

Press the  key (green):



Reading the zero point on the RCC scales



Requesting placement of 500 g weight

The zero point is read in (left-hand figure).

Calibrating inclination for the RCC scales

Load the scales with 500 g.

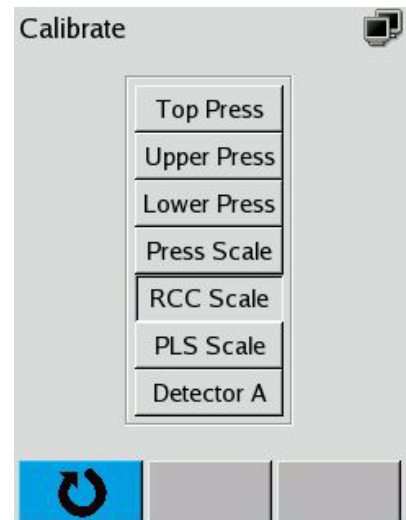
Press the ■ key (green):

The value determined is read in (right-hand figure).

After successful calibration the screen message shown below is displayed.



Message following successful calibration



Calibrate menu

Press the ■ key (blue):

The **Calibrate menu** is displayed again (right-hand figure, bottom).

Press the ■ key (blue):

The **Main menu** is displayed.

● Press scales






Note

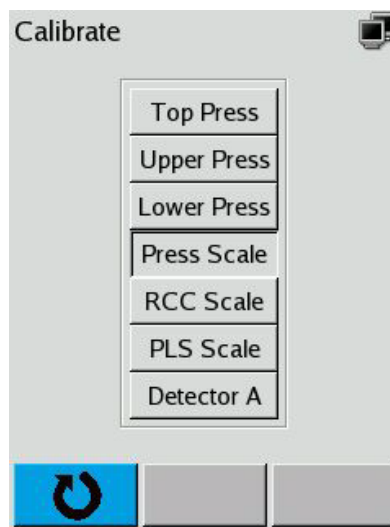
The **Calibrate** menu can be protected with a password (see **Calibrating the scales**, page 9-6).

Entering the password (see chapter 4.5.1, page 4-8).

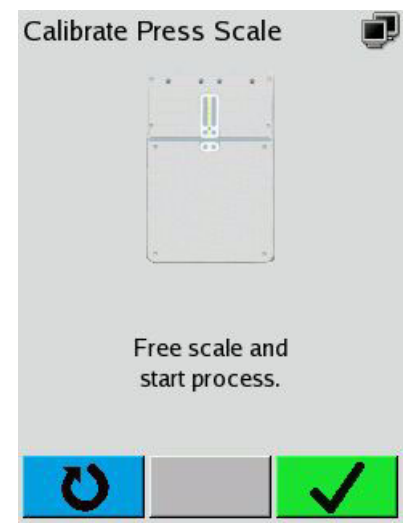
Starting calibration manually

In the **Calibrate** menu, use the  key or the  key to select the **Press Scale** menu item, and confirm with the  key.

The **Calibrate Press Scale** screen message is displayed (right-hand figure).



Calibrate menu



Calibrating the press scales

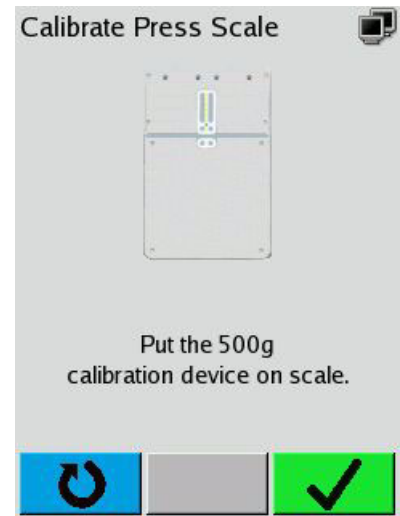
Zero-point calibration, press scales

Confirm that the **press scales** are unladen.

Press the  key (green):



Reading the zero point on the press scales



Requesting attachment of 500 g weight

The zero point is read in (left-hand figure, left).

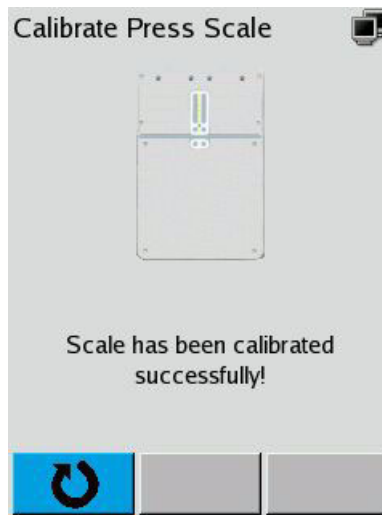
Calibrating inclination for the press scales

Load the scales with 500 g.

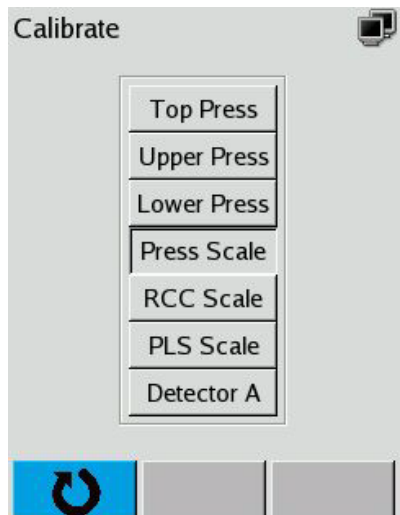
Press the ■ key (green):

The value determined is read in (right-hand figure, top).

After successful calibration the screen message shown below is displayed.



Message following successful calibration



Calibrate menu

Press the ■ key (blue):

The Calibrate menu is displayed again (right-hand figure, top).

Press the ■ key (blue):

The **Main menu** is displayed.

9.3.5 Setup submenu



Note

The **Setup** menu can be protected with a password.

Factory-set password for **Setup** menu: **4 0 0 0**.

Entering the password (see chapter 4.5.1, page 4-8).

Consult the CompoMaster Net G5 User Manual for information on modifying the password.




● Accessing the Setup menu



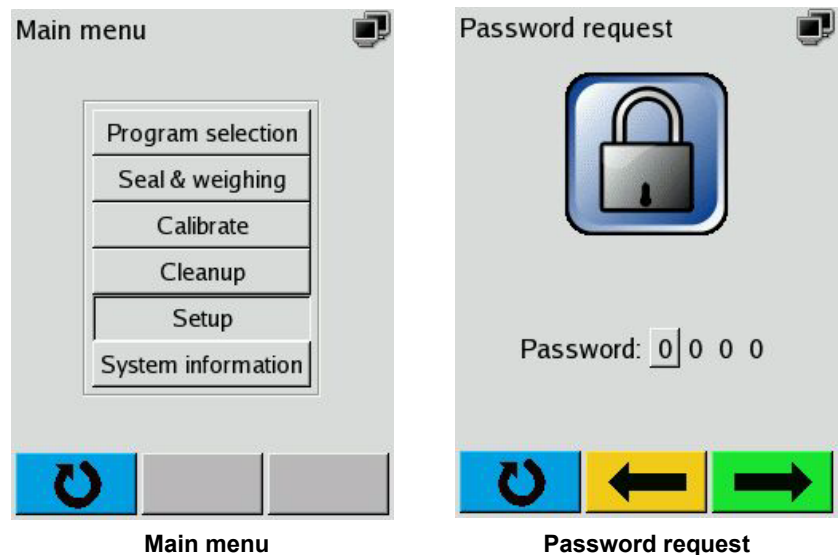
Note

The **Setup** menu can be protected with a password (see **Setup submenu**, page 9-13).

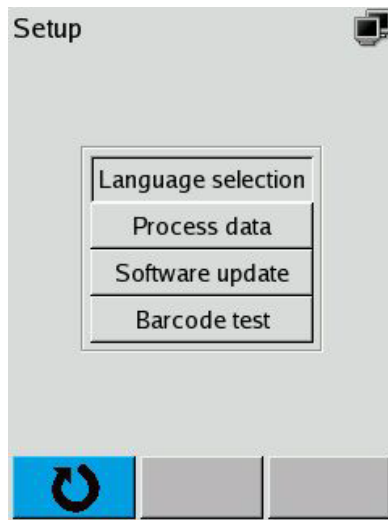
Entering the password (see chapter 4.5.1, page 4-8).

In the **Main menu**, use the  key or the  key to select the **Setup** menu item, and confirm with the  key.

The **Password request** screen message is displayed (right-hand figure)



After the entry of the password the **Setup** screen message is displayed (left-hand figure, below).



Setup menu

9.3.5.1 Language selection for the user interface on the CompoMat G5






Tip

The language for the user interface on the CompoMat G5 can also be selected in CompoMaster Net G5.

See CompoMaster Net G5 User Manual.

The language for the user interface on the CompoMat G5 is selected using

Ready to use / Main menu / Settings / Language selection.

Use the  or  keys to access each menu item; confirm the selection with the  key.

The following screen message will be displayed.




Language selection menu

Selecting the language

Press the  or  key:

the available languages will be accessed in sequence.
(shown by a marked radio button).

Press the  key:

the selection will be confirmed.

or

Press the  key (blue):

the operator guidance returns to the **Main menu**, and the language originally set remains active.

9.3.5.2 Activating / deactivating process data

Ready to use / Main menu / Settings / Process data.

**Note**

The **Setup** menu can be protected with a password (see **Setup submenu**, page 9-13).

Entering the password (see chapter 4.5.1, page 4-8).

General Information

A process data record stores the following data:

- Compomat
 - Name
 - Serial number
- Program data
 - Number
 - Name
- Barcode data
 - Donation number
 - Part number
 - Batch number
 - Operator 1
 - Operator 2
 - Result
 - Centrifuge
 - Additional bar code
 - Dummy barcode
- Process time
 - Date
 - Start time
 - End time
 - Total time
 - Break time
 - Number of breaks
- Weighing data
 - PLS scales
 - Press scales
 - RCC Scale
- Incidences

- Counter
 - Start time
 - Stop time
 - Duration

Local storage of process data

While process data storage is active and no connection to the CompoMaster Net G5 exists, depending on the file size up to 2000 process data records can be stored locally in the device.

Automatic data transmission on restoration of network connectivity

As soon as connectivity to the CompoMaster Net G5 is restored, data will be transferred to the CompoMaster Net G5 automatically.

There are two ways in which process data can be activated / deactivated:

- Activating / deactivating using CompoMaster Net G5
- Activating / deactivating using CompoMat G5

● **Activating / deactivating using CompoMaster Net G5**

See User Manual for CompoMaster Net G5

● **Activating / deactivating using CompoMat G5**




Activating / deactivating process data for the CompoMat G5 is set under **Ready to use / Main menu / Settings / Process data**.



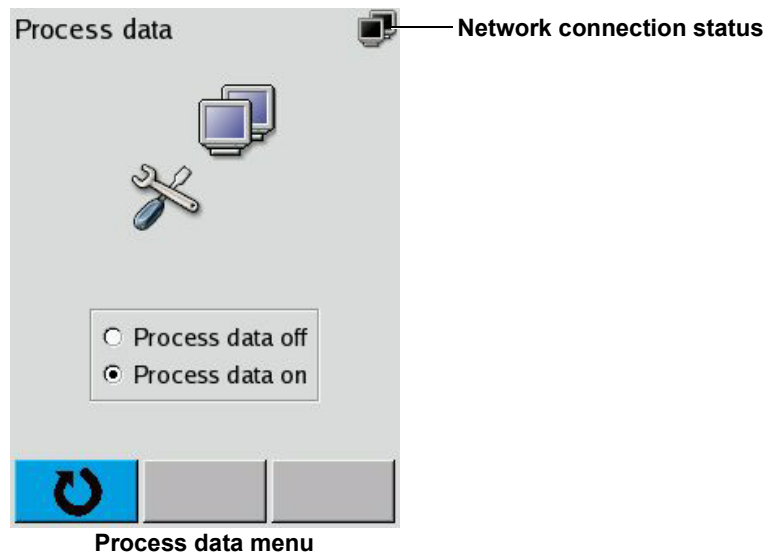
Note

The **Setup** menu can be protected with a password (see **Accessing the Setup menu**, page 9-13).

Entering the password (see chapter 4.5.1, page 4-8).

Use the  or  keys to access each menu item; confirm the selection with the  key.

The following screen message will be displayed.



Network connection status

The top-right symbol shows the current network connection status.



= CompoMaster Net G5 connected, process data activated.



= CompoMaster Net G5 not connected.




= CompoMaster Net G5 connected, process data deactivated..

Selecting process data status

Press the  or  key:

select desired status.
(shown by a marked radio button)

Press the  key:

the selection will be confirmed.

or

Press the  key (blue):

the operator guidance returns to the **Main menu**, and the original setting remains active.

9.3.5.3 Software update

This function may only be carried out by a service technician!

9.3.5.4 Barcode test



Note




The **Setup** menu can be protected with a password (see **Accessing the Setup menu**, page 9-13).

Entering the password (see chapter 4.5.1, page 4-8).

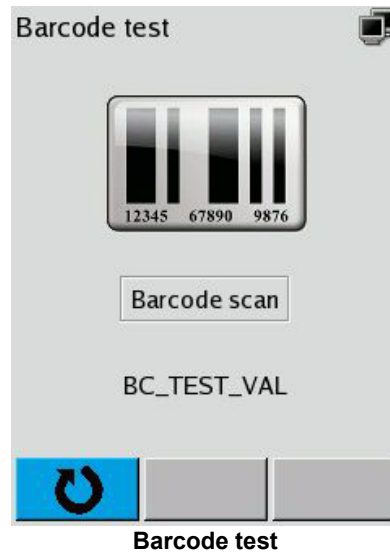
The barcode test function can be used to carry out the following checks:

- Correct functionality of barcode scanner;
- Correct scanning-in of a barcode (displayed as plain text).

The barcode test function can be accessed via **Ready to use / Main menu / Settings / Barcode test**.

Use the  or  keys to access each menu item; confirm the selection with the  key.

The following screen message will be displayed.



Checking barcode functionality



Warning

Risk of injury by overheating.

Skin burn injuries.

- Only scanners supplied by Fresenius Kabi may be connected.
-



Caution

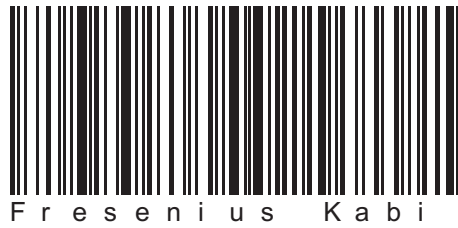
Erroneous data transmission and functional disruption of CompoMat G5.

Loss of preparation, damage to CompoMat G5

- Only scanners supplied by Fresenius Kabi may be connected.
-

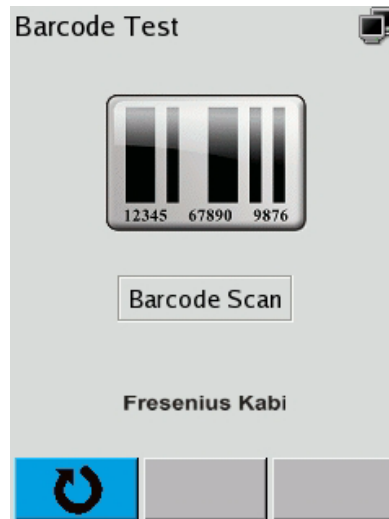
Connect the barcode scanner to the 9-pin D-sub port on the front of the machine.

Scan in the barcode displayed below.



F r e s e n i u s K a b i




Fresenius Kabi will be displayed on the screen (see the following screen message).



Result from the barcode scanned

9.3.6 Displaying system information

System information for the CompoMat G5 is accessible via **Ready to use / Main menu / System information**.


Use the  or  keys to access each menu item; confirm the selection with the  key.

The following screen message will be displayed.



9.3.7 Standby mode

The CompoMat G5 should not be disconnected from mains power during normal operation. This ensures that the CompoMat G5 can be brought back online faster.

If the  key is pressed, then the CompoMat G5 will be put into standby mode.

9.3.8 Powering-down the CompoMat G5 system



Caution

Powering-down the CompoMat G5 may cause a loss of the preparation and the process data.

- The CompoMat G5 must be put into standby mode before powering down the CompoMat G5 system. (see **Standby mode**, page 9-20)

Disconnect the power cable or use the main switch to power down the CompoMat G5.

The CompoMat G5 system will be powered down.

9.3.9 Passwords

Passwords are configured using CompoMaster Net G5 (see CompoMaster Net G5 User Manual)

Passwords can be assigned to the following functions:

Password for the Program selection menu

- **Program selection** menu



Note

Factory-set password for the **Program selection** menu: **1 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password

Password for Calibrate menu

- Calibrating the **top press**
- Calibrating the **upper press**
- Calibrating the **lower press**
- Calibrating the **press scales**
- Calibrating the **RCC scales**
- Calibrating the **PLS scales**
- Calibrating the **A1 - A8 detectors**



Note

Factory-set password for **Calibrate** menu: **2 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password

Password for the Cleanup menu

- Cleaning the **upper press**
- Cleaning the **lower press**
- Cleaning the **slide**



Note

Factory-set password for **Cleanup** menu: **3 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password

Password for the Setup menu

- Language selection
- Process data
- Software update
- Barcode test



Note

Factory-set password for **Setup** menu: **4 0 0 0**.

Consult the CompoMaster Net G5 User Manual for information on modifying the password

9.4 Press stroke calibration

Starting calibration automatically

If the self-test discovers an uncalibrated press position then the calibration procedure will be started automatically by the self-test itself.

Calibration is necessary in the following situations:

- The press positions have not yet been calibrated (initial start-up).
- Significant step loss occurred while a press was moving. (Recognized automatically during the verification process at the end of the program.)
- The press position is unknown on powering up the CompoMat G5 (e.g. caused by the device being switched off while a press was still moving). Recognized automatically during the self-test verification process.
- Significant wear is present on the silicone matting covering the press blocks.
- The calibration of the press position was interrupted.



Note

If a password has been set for the **Calibrate** menu, you will be prompted to enter the password after selecting the **Calibrate** menu item (see chapter 9.3.9, page 9-21).




Entering the password (see chapter 4.5.1, page 4-8).



Note

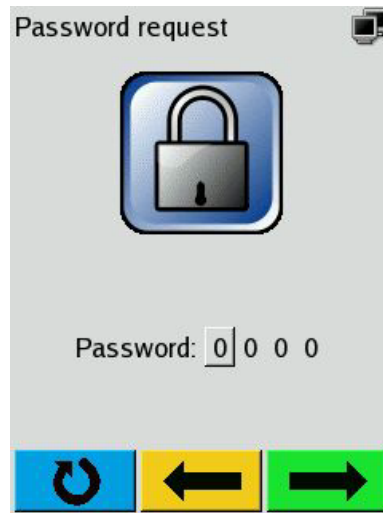
There must be absolutely no load on the presses during the calibration process, and the press area must be free of all foreign objects.

Starting calibration manually

In the **Main menu**, use the  key or the  key to select the **Calibrate** menu item, and confirm with the  key.

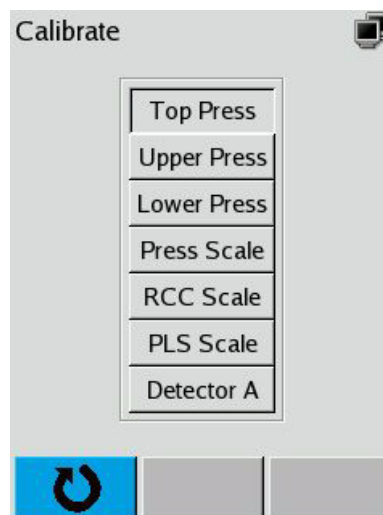
The following **Password request** screen message is displayed.

Entering the password (see chapter 4.5.1, page 4-8).



Password request

After the entry of the password, the following **Calibrate** menu is displayed.

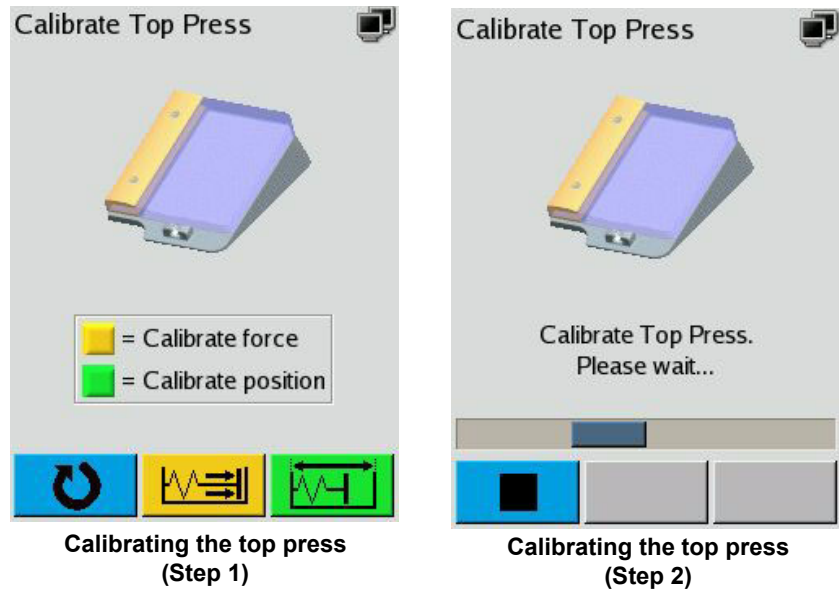


Calibrate menu

9.4.0.1 Press stroke calibration for the top press

In the **Calibrate** menu, use the  key or the  key to select the **Top Press** menu item.

The screen message **Calibrate Top Press** is displayed (left-hand figure, Step 1).



In the **Calibrate Top Press** menu, press the ■ key (green).
 The calibration process will be performed automatically.

The screen message (Step 2) is displayed during the calibration process.

At the end of the calibration process, a screen message is displayed once again (Step 1).

9.4.0.2 Press stroke calibration for the upper press

Starting calibration automatically

If the self-test discovers an uncalibrated press position then the calibration procedure will be started and carried out automatically by the self-test itself.



Note

If a password has been set for the **Calibrate** menu, you will be prompted to enter the password after selecting the **Calibrate** menu item. (see chapter 9.3.9, page 9-21)



Note

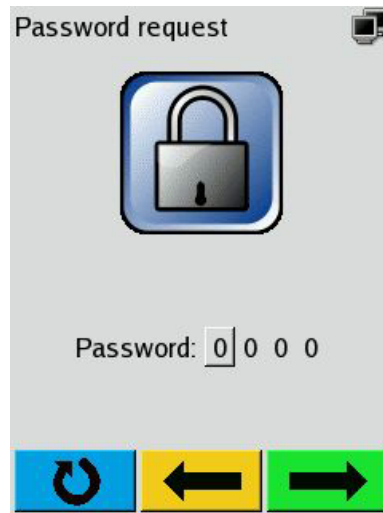
There must be absolutely no load on the presses during the calibration process, and the press area must be free of all foreign objects.

Starting calibration manually

In the **Main menu**, use the ▲ key or the ▼ key to select the **Calibrate** menu item, and confirm with the ▶ key.

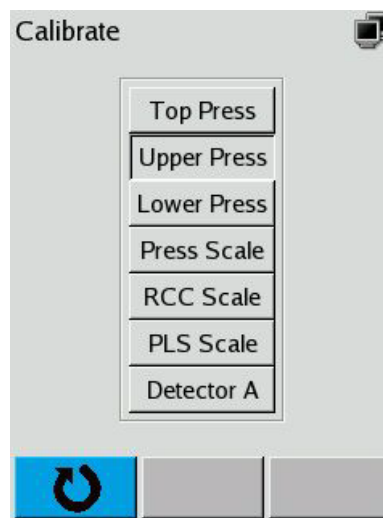
The following **Password request** screen message is displayed.

Entering the password (see chapter 4.5.1, page 4-8).





Password request

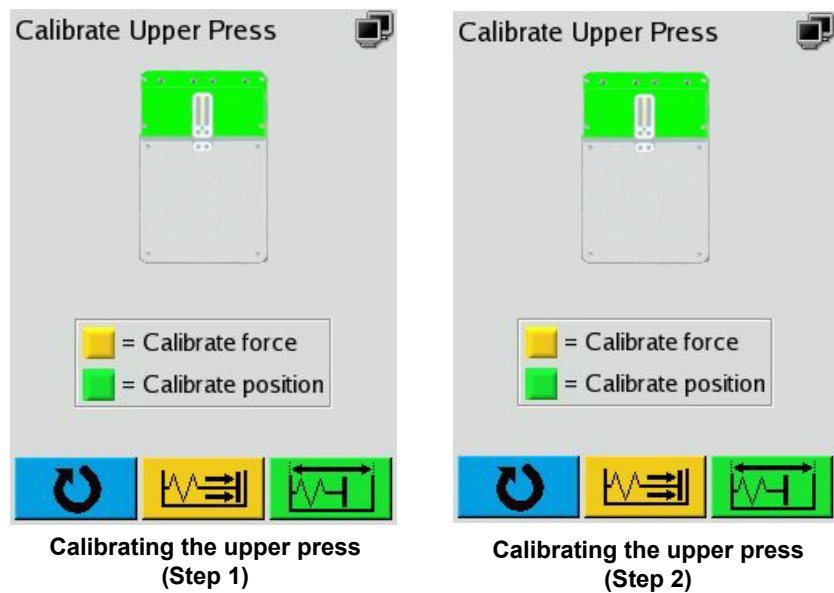
After the entry of the password, the following **Calibrate** menu is displayed.



Calibrate menu

In the **Calibrate** menu, use the  key or the  key to select the **Upper Press** menu item.

The **Calibrate Upper Press** screen message is displayed (left-hand figure, Step 1).



In the **Calibrate Upper Press Menu**, press the **green** key.
 The calibration process will be performed automatically.
 A screen message will be displayed during the calibration process (Step 2).

At the end of the calibration process, a screen message is displayed once again (Step 1).

9.4.0.3 Press stroke calibration for the lower press

Starting calibration automatically

If the self-test discovers an uncalibrated press position then the calibration procedure will be started and carried out automatically by the self-test itself.



Note

If a password has been set for the **Calibrate** menu, you will be prompted to enter the password after selecting the calibration function. (see chapter 9.3.9, page 9-21)



Note

There must be absolutely no load on the presses during the calibration process, and the press area must be free of all foreign objects.

Starting calibration manually

In the **Main menu**, use the **▲** key or the **▼** key to select the **Calibrate** menu item, and confirm with the **◀** key.

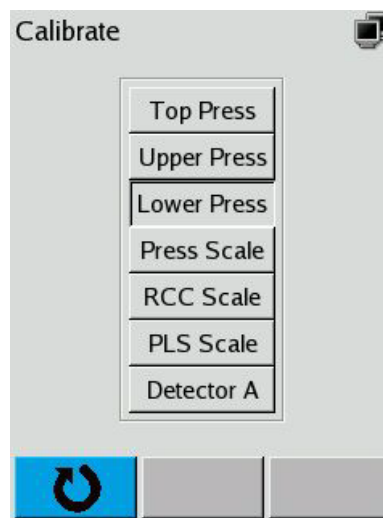
The following **Password request** screen message is displayed.

Entering the password (see chapter 4.5.1, page 4-8).





Password request

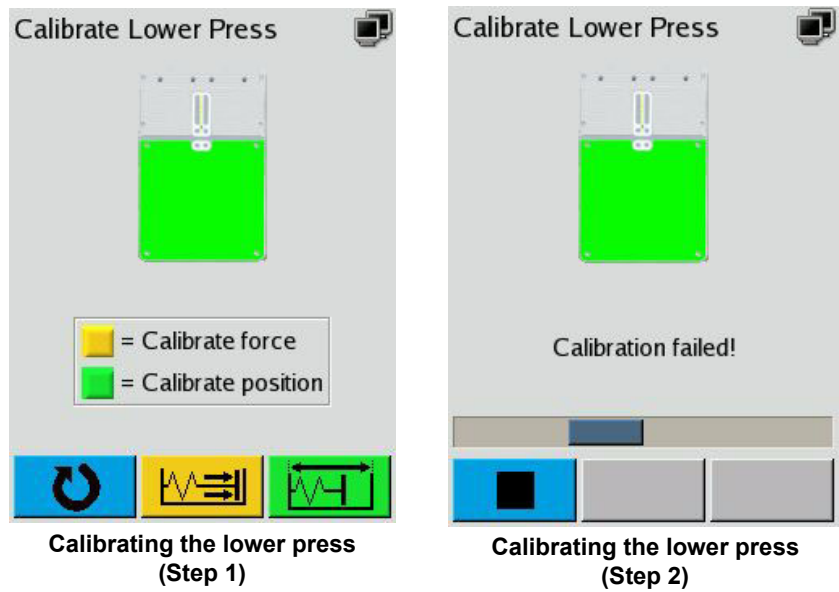
After the entry of the password, the following **Calibrate** menu is displayed.



Calibrate menu

In the **Calibrate** menu, use the  key or the  key to select the **Lower Press** menu item.

The **Calibrate Lower Press** screen message is displayed (left-hand figure, Step 1).



In the **Calibrate Lower Press** menu, press the **green** key.
The calibration process will be performed automatically.
A screen message will be displayed during the calibration process (Step 2).
At the end of the calibration process, a screen message is displayed once again (Step 1).

9.5 Calibrating the press force

Press force calibration can only be carried out by trained personnel.

9.6 Calibrating the A1 - A8 detectors

The calibration of the A1 - A8 detectors can only be carried out by trained personnel.

9.7 Network CompoMat G5

9.7.1 Communication via LAN or WLAN

CompoMat G5 and CompoMaster Net G5 are connected together either via LAN or WLAN within a **private network**.

The following preconditions apply:

- Only one CompoMaster Net G5 (PC) may be present.
- At least one CompoMat G5 must be present.
- A maximum of 100 CompoMat G5 may be present.

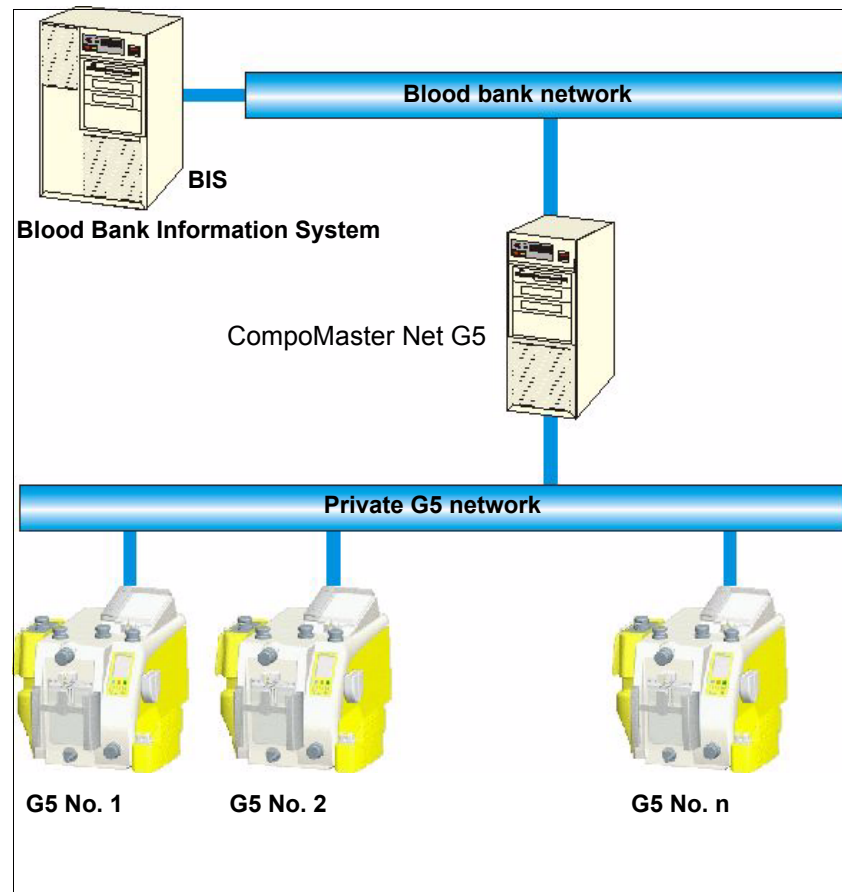
No other devices or PCs may be present in the network. IP address allocation will be handled by CompoMaster Net G5.

A maximum of one network interface may be active at any one time (Ethernet 10Base-T or USB WLAN). If both a LAN network cable and USB WLAN device are available, then priority is given to attempting a wireless network connection.

9.7.2 LAN (Local Area Network)

A LAN consists of the following components:

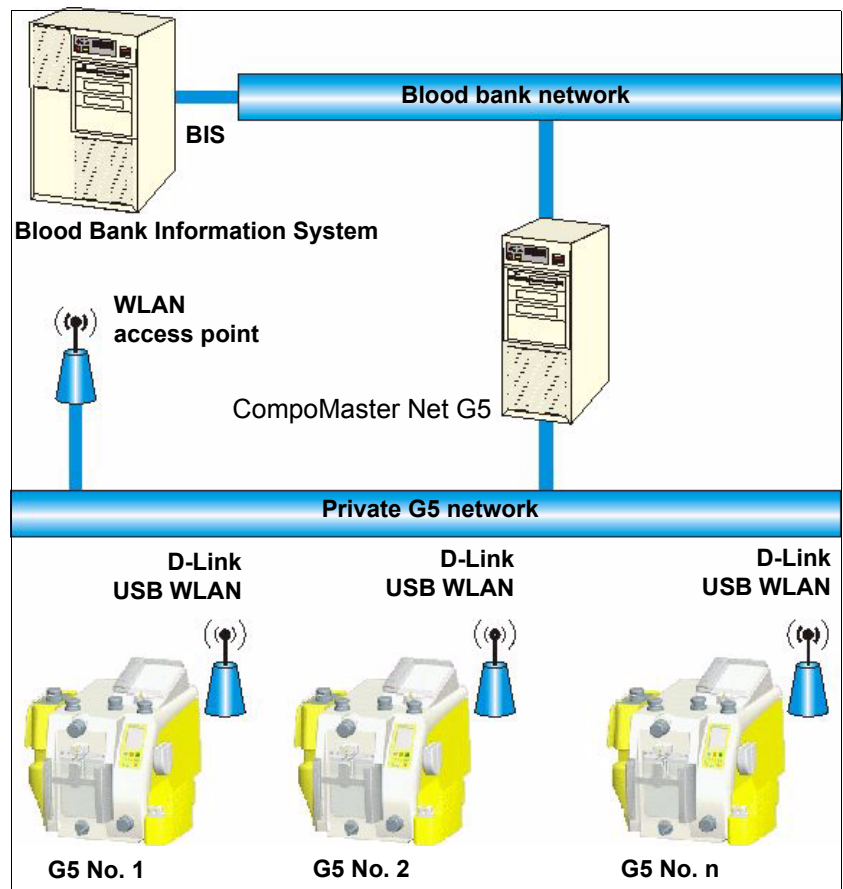
- **A single** application instance of CompoMaster Net G5
- At least one and no more than 100 CompoMat G5
- A private network (Ethernet 10/100Base-T)
- (Blood bank network / BIS)



9.7.3 WLAN (Wireless Local Area Network)

A WLAN consists of the following components:

- **A single** application instance of CompoMaster Net G5
- At least one and no more than 100 CompoMat G5
- A private network (WLAN)
- A WLAN access point
- A maximum of one USB WLAN dongle per CompoMat G5 (D-Link DWL-G122 h/w ver.: C1)
- (Blood bank network / BIS)



9.8 Decommissioning / removal from service / recommissioning

9.8.1 Decommissioning

No especial procedures are required in order to decommission the equipment. We recommend storing the CompoMat G5 in its original packaging.

9.8.2 Removal from service

No especial procedures are required in order to decommission the equipment. We recommend storing the CompoMat G5 in its original packaging.

9.8.3 Recommissioning

To recommission the device, the CompoMat G5 has to be checked in the same way as for an initial start-up. In addition, an electrical safety check must also be carried out.



Caution

Damage to the device by improper recommissioning.

Malfunction

The CompoMat G5 may only be recommissioned by authorized service personnel or by a service technician certified by Fresenius Kabi.

10 Transport / storage

10.1 Transport

10.1.1 Inside buildings



The CompoMat G5 should only ever be lifted by the continuous bottom edge of the base system unit. (see picture).



Caution

The scales can be damaged beyond repair by incorrect transport.

- Never lift the CompoMat G5 by the scales.
-



Caution

The device can be damaged beyond repair by incorrect transport.

- Never lift the CompoMat G5 by the door.
-



10.1.2 Outside buildings

Recommendation

Use the original packaging for the CompoMat G5 to transport the CompoMat G5 outside buildings.



Caution

Disclaimer of liability

Fresenius Kabi is not liable for damages resulting from improper transportation.

10.2 Storage

Recommendation

For storing the CompoMat G5, use its original CompoMat G5 packaging.

10.3 Environmental compatibility / disposal

Only environmentally compatible and recyclable materials have been used for the manufacture of the system and the consumables.

Within the EC member states the device is taken back in accordance with directive 2002/96/EG (WEEE) The locally applicable legal regulations must be observed.

The system and the consumables are generally considered to be contaminated and must therefore be sufficiently disinfected by the responsible organization as specified by the manufacturer.

The respective regulations for the disposal of electronic scrap should be followed for the disposal of electronic boards.

Further information regarding disposal is available on request.

11 Technical Safety Checks / Maintenance

11.1 Important information for the procedure

Checks	<p>This chapter covers maintenance procedures (MA). Performance of the Maintenance Procedures (MA) is recommended by the manufacturer.</p> <p>Tester's qualification</p> <p>The initial start-up must be performed by the Technical Service of Fresenius Kabi or a person authorized by them!</p> <p>The checks may only be performed by persons qualified to properly perform the specified checks owing to their educational background, training, knowledge and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.</p>
Test equipment and accessories	<p>The activities described in this technical document require the availability of the necessary technical measuring equipment and accessories.</p>
Specifications	<p>Observe the information on the specifications.</p>
Precautions	<p>Any visible damage must be repaired prior to turning on power.</p> <p>Prior to opening the device and when working on the open device, the following precautions must be observed:</p> <ul style="list-style-type: none">– Protect the components against ingress of fluids.– Do not touch live parts.– All plugs, connections and components may only be disconnected or connected if de-energized.
ESD precautions	<p>When repairing and when replacing spare parts, observe the applicable ESD precautions.</p>

11.2 Technical safety checks (TSC)



Note

The CompoMat G5 is not required to undergo technical safety testing.

11.3 Technical measurement checks (TMC)



Note

The CompoMat G5 is not required to undergo technical measurement testing.

11.4 Maintenance procedures (MA)

Daily maintenance	Clean the CompoMat G5 after use according to the cleaning instructions. Wipe off the A1 - A8 detector covers using a soft, lint-free cloth.
At least once a week	Check the sealing electrodes for dirt and blackening and clean as necessary. (see Cleaning the heads , page 6-3.
Annual maintenance	Maintenance here relates to checking the sensors and actuators. Checks are carried out without opening the device. We generally recommend to conclude a maintenance agreement to prevent expensive repair work and to ensure an optimum service life of the device.



Warning

Risk of injury caused by electrical voltage, due to modified cable connections, cable routing or electrical parts.

Electric shock!

- Once the CompoMat G5 has been opened, the Electrical Safety Check must be carried out before recommissioning the device.



Caution

Damage to the device by improper recommissioning.

Malfunction

- The CompoMat G5 may only be recommissioned by authorized Fresenius Kabi service personnel or by a service technician certified by Fresenius Kabi.
-

12 Specifications

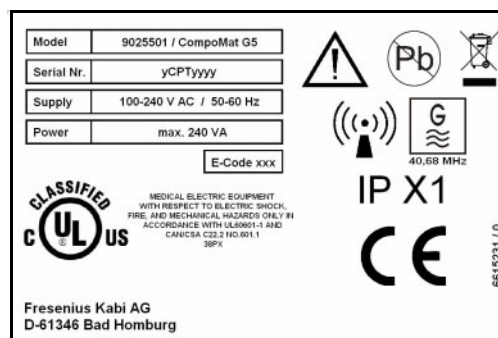
12.1 Dimensions and weight

Dimensions	Height: 45 cm Width: 38 cm Depth: 50 cm
Weight	30 kg without packaging

12.2 Housing

Housing material	Rigid PU foam Steel sheet
-------------------------	------------------------------

12.3 Type label (system identification)



12.4 Electrical safety

Electrical safety (classification according to EN 60601-1, IEC 601-1)

Type of protection against electric shock	Safety class I
Degree of protection against ingress of liquids	Drip-proof (IP X1)
Leakage currents	according to UL / IEC 60601-1

12.5 Electrical supply

Line voltage	100 - 240 V AC, 50 - 60 Hz (The decisive criterion is the line voltage and the operating current specified on the type label of the system.)
Power consumption (max.)	240 VA

12.6 Fuses

Main switch	250 V T 10 A
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12.7 HF seal generator

RF power	140 W peak load 80 W continuous rating
RF frequency	40,68 MHz \pm 10 kHz

12.8 PLS scales, RCC scales, press scales

Measurement range	0 - 600 g
Maximum load:	1,000 g
Breaking load:	> 1,500 g
Measurement time	< 1 second

12.9 Tubing specification

The following tubing is approved for the sealing electrodes:

Exterior diameter:	3,9 mm - 5.4 mm
Wall thickness	max. 0.8 mm
Material	PVC
Tube temperature during processing	15 °C - 35 °C

2.7.



12.10 Network connection

LAN

10Base-T (8P8C) Ethernet or USB


12.11 Guidance and manufacturer's declaration on electromagnetic emissions for all ME devices and ME systems (See 5.2.2.1. c)

12.11.1 Electromagnetic emissions

Guidance and manufacturer's declaration - Electromagnetic emissions		
The CompoMat G5 is intended for use in the electromagnetic environment specified below. The customer or the operator of the CompoMat G5 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The CompoMat G5 uses RF energy only for internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Emission class B	The CompoMat G5 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Emission class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

12.11.2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The CompoMat G5 is intended for use in the electromagnetic environment specified below. The customer or the operator of the CompoMat G5 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electro static discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$< 5 \% U_T$ $(> 95 \% \text{ dip in } U_T)$ for 0.5 cycles $40 \% U_T$ $(60 \% \text{ dip in } U_T)$ for 5 cycles $70 \% U_T$ $(30 \% \text{ dip in } U_T)$ for 25 cycles $< 5 \% U_T$ $(> 95 \% \text{ dip in } U_T)$ for 5 s	$< 5 \% U_T$ $(> 95 \% \text{ dip in } U_T)$ for 0.5 cycles $40 \% U_T$ $(60 \% \text{ dip in } U_T)$ for 5 cycles $70 \% U_T$ $(30 \% \text{ dip in } U_T)$ for 25 cycles $< 5 \% U_T$ $(> 95 \% \text{ dip in } U_T)$ for 5 s	Mains power quality should be that of a typical commercial and hospital environment. If the operator of the CompoMat G5 demands continued function even if power failures occur, it is recommended to ensure supply of the CompoMat G5 from an uninterruptible power system or from a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	$3 V_{\text{rms}}$ 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CompoMat G5, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.17 \sqrt{P}$ for 150 kHz to 80 MHz $d = 0.35 \sqrt{P}$ for 80 MHz to 800 MHz $d = 0.7 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range ^b .  Interference may occur in the vicinity of equipment marked with the following symbol.

Note 1: For 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CompoMat G5 is used exceeds the applicable RF compliance level above, the CompoMat G5 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CompoMat G5.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

12.11.3 Recommended separation distances between portable and mobile RF telecommunication devices and the device

Recommended separation distances between portable and mobile RF telecommunication devices and the CompoMat G5

The CompoMat G5 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the CompoMat G5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CompoMat G5 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.17 \sqrt{P}$	80 MHz to 800 MHz $d = 0.35 \sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7 \sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,70
10	3,70	1,11	2,21
100	11,7	3,50	7,00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: For 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.12 Operating conditions

Operating temperature range	+15 °C to +30 °C
Permissible relative humidity	35 % to 75 %

12.13 Storage conditions

Temperature	-10 °C to +40 °C
Permissible relative humidity	30 % to 75 %

The device should only be stored in a well-ventilated room with little variation in temperature.

12.14 External connection options



Caution

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. UL/IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see UL/IEC 60601-1-1 or clause 16 of the 3rd Ed. of UL/IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible for the system complying with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult the technical service department or your local representative.

LAN	Interface for the exchange of data. Electrically isolated by transformer Port: 8P8C
USB (2 pcs)	Interface for connecting a USB WLAN adapter and for connecting a USB pen drive
Bar code scanner (Front-facing connector)	Interface for connecting a bar code scanner 9-pin D-sub port
RFID scanner (Rear-facing connector)	See following note



Note

This interface is intended for future applications. No RFID scanner has been certified and approved as of this time.

System scales

Connector for PLS scales
Connector for RCC scales
2x 25-pin D-sub port

12.15 Materials used

Only environmentally compatible and recyclable materials have been used for the manufacture of the CompoMat G5. Prior to the disposal of the system, any potential risk of infection must be eliminated by appropriate disinfection. The respective regulations for the disposal of electronic scrap should be followed for the disposal of electronic boards. Storage batteries should be disposed of according to the respective regulations. Further information regarding disposal is available on request.

13 Definitions

13.1 Definitions and terms

CompoFlow	Special tube closure system
CF-Opener	Technical assembly for opening the CompoFlow
Top & Bottom systems	Special bag system, whereby the contents can be pressed out both towards the top and towards the bottom

13.2 Abbreviations

Fig.	Figure
BPS	BridgedPressure Sensor (electronic pressure sensor)
RCC	Red cell concentrate
PLS	Plasma
HF	High frequency
TSC	Technical safety checks
TMC	Technical measurement checks
MA	Maintenance procedures (MA)

13.3 Symbols



Caution: consult accompanying documents. General danger.

IPX1

Protection against ingress of liquids:
Drip-proof (IPX1)



Protective earth terminal



Radiofrequency oscillator

40,68 MHz



On / Off



Keep dry



Storage temperature range



Identification of electric and electronic devices



Fragile, handle with care



Restriction for stack load



Upper level



Transmitter




Keep hands out of machinery



Keep hands out of machinery

13.4 Certificates

13.4.1 EU declaration of conformity

	
EG-Konformitätserklärung <u>EC DECLARATION OF CONFORMITY</u>	
Annex VII of Directive 93/42/EEC Anhang VII der Richtlinie 93/42/EWG	
CompoMat G5 (RCC-Scale and PLS-Scale) (Product name / Produktname)	
9025501, 9025511, 9025521 (Article number / Artikelnummer)	
xCPTxxxx, xRSTxxxx, xPSTxxxx (Serial number / Seriennummer)	
Class / Klasse I	
We / Wir Fresenius Kabi AG D - 61346 Bad Homburg, Germany	
<p>manufacturer of the above products, hereby declare under our sole responsibility that the referenced products comply with all relevant provisions of Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.</p> <p>Hersteller der oben genannten Produkte, erklären hiermit in unserer alleinigen Verantwortung, dass die oben aufgeführten Produkte mit allen relevanten Anforderungen der Direktive 93/42/EWG, geändert durch 2007/47/EG, und deren Umsetzung in nationale Gesetze übereinstimmen. Die Produkte erfüllen die Anforderungen des Anhangs I sowie die Anforderungen der weiteren anwendbaren Standards und normativen Dokumente, wie in der anwendbaren technischen Dokumentation aufgeführt. Alle unterstützenden Dokumente werden in den Räumlichkeiten des Herstellers aufbewahrt.</p>	
Friedberg, 23 March 2010 <small>Place and date of issue/ Ort und Datum der Ausstellung</small>	 i.A. Dieter Fries, Director QA Active Blood Devices <small>Name (printed letters), position and signature of authorized person/ Name (Blockschrift), Position und Unterschrift der autorisierter Person</small>
<small>Valid starting with the original date of the document until product change Gültig ab Ausstellungsdatum bis Produktänderung</small>	

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13.4.2 UL classification

