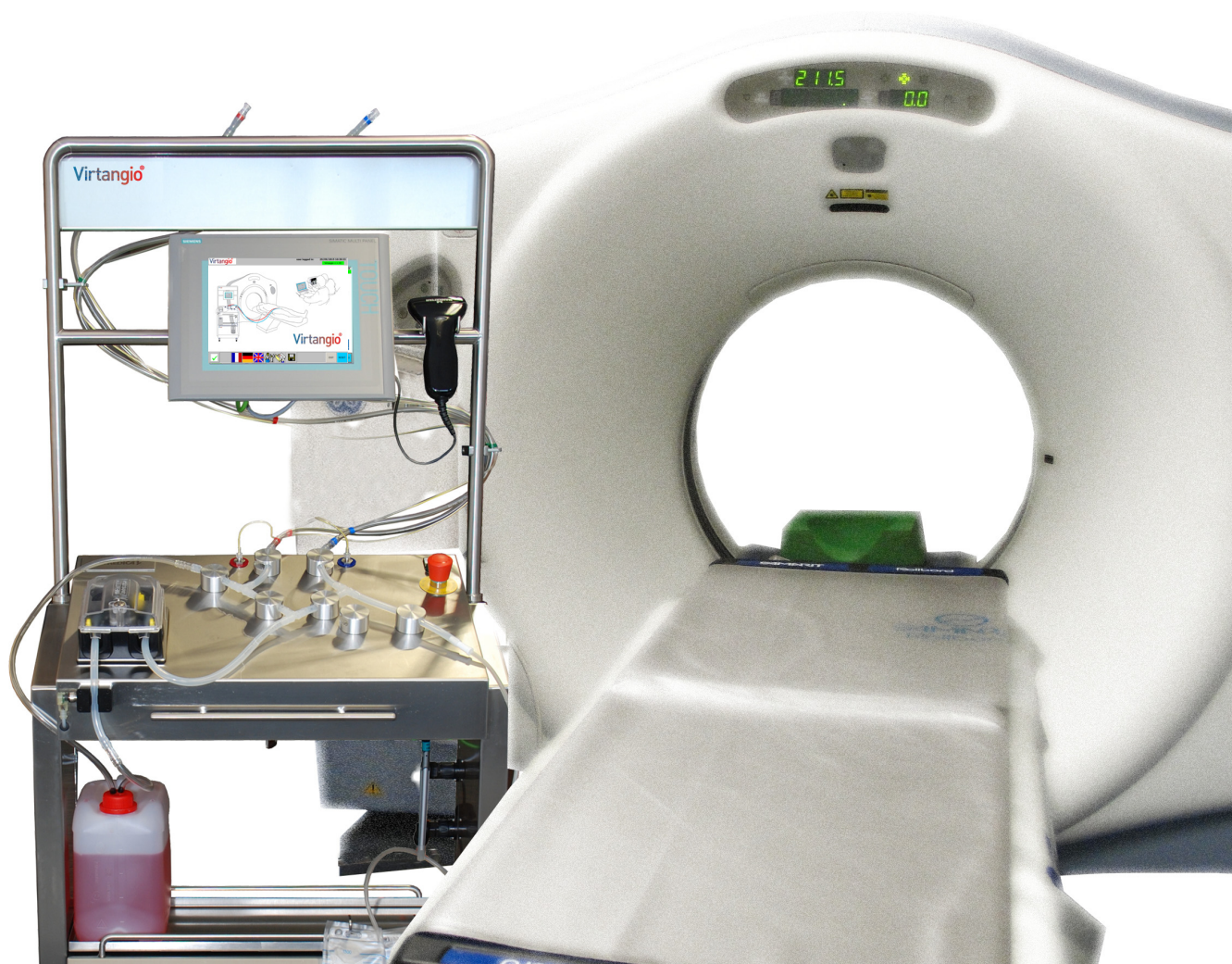


Virtangio®



Instructions for use

Art. No.: S600.1012 Rev.:c

MPMCTA MULTI-PHASE
POST-MORTEM
CT ANGIOGRAPHY

CE

Manufacturer

FUMEDICA AG

Division Postmortem-Angio

Luzernerstrasse 91

5630 Muri, Switzerland

Tel: +41 (0) 56 675 91 00

Fax: +41 (0) 56 675 91 09

E-mail: info@postmortem-angio.ch

Web: www.postmortem-angio.ch

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1 Safety instructions

1.1 Responsibility of operator



- ▲ The device may only be used by qualified staff.
- ▲ Check that the person has read and understood the instructions for use, in particular this section "Safety instructions".
- ▲ Damaged or missing parts should be replaced immediately.
- ▲ The operator is responsible for complying with the applicable accident prevention and safety regulations.

1.2 Intended use



- ▲ The Virtangio machine is used to perform postmortem angiography.
- ▲ The Virtangio machine, and in particular the contrast medium, may only be used on dead bodies.
- ▲ The device must always be operated in accordance with the specified technical data.

1.3 Organisational measures



- ▲ The device may not be put into operation until its functions and the necessary safety precautions have been explained and understood.
- ▲ Always keep the instructions for use ready to hand at the location where the device is in use. Make sure that they are complete and legible at all times.

1.4 Safety awareness at work



- ▲ The device may not be put into operation until its functions and the necessary safety precautions have been explained. Always keep the instructions for use ready to hand at the location where the devices are in use. Make sure that they are complete and legible at all times.
- ▲ Observe safety instructions for connected devices.
- ▲ Make sure you read and observe the instructions for use, in particular these safety instructions.
- ▲ Any changes, including changes in operating behaviour that adversely affect safety, should be immediately reported to the person responsible.
- ▲ If devices are operated with defective housing or defective cables, this may cause danger to life and limb of the operator! For this reason:
 - Any device, cable couplings or connections that are damaged must be replaced immediately.
- ▲ Wear protective gloves and goggles whenever handling the contrast medium.

1.5 Operation with other devices



- ▲ Only use accessories and consumables that have been supplied or recommended by FUMEDICA AG. The use of third-party accessories or consumables may cause the device to malfunction.
 - ▲ Magnetic and electric fields of X-ray apparatus, tomography equipment, radio installations, mobile phones etc. may affect functioning of the device. The Virtangio machine has been specially developed for use in the vicinity of CT scanners. You should nevertheless maintain a sufficient distance.
 - ▲ Portable communication devices, high-frequency radio equipment and devices bearing the  symbol may affect functioning of the device.
-

1.6 Maintenance



- ▲ Risk of electric shock! Do not open device. It does not contain any parts which can be repaired by the user. Servicing may only be carried out by qualified service technicians.
 - ▲ Switch off device before cleaning.
 - ▲ Do not use harsh cleaning products or scouring agents.
 - ▲ Under no circumstances should the device or mains cable be immersed in cleaning liquid.
-

1.7 Guarantee provisions

For your **Virtangio machine** we offer a guarantee covering defects in materials and workmanship for the duration of one year (from date of purchase). This does not include damage caused by a lack of care or improper usage. The guarantee covers replacement of the defective part free of charge. Any liability for consequential damage is excluded here. The guarantee claim does not apply if repair attempts are made by unauthorised or unqualified persons.

In the event of any defect, the device forming the subject of a complaint should be sent in to the nearest FUMEDICA AG agency or to the manufacturer direct. The manufacturer can only guarantee the safety, reliability and good working order of the device if

- assembly work, extensions, resetting, modifications or repairs have been performed by persons authorised by him for this purpose and
- the Virtangio machine and the approved accessories are used according to the manufacturer's instructions.



No further guarantees are offered here. FUMEDICA AG accepts no guarantee for the commercial usability and suitability of the product or product components for any specific purpose.

1.8 Symbols

1.8.1 Symbols used in the manual

The hazard levels have been classified according to ISO 3864. The following overview lists the safety symbols and pictograms used in this manual.



For an imminent risk that may result in serious injury or death.



For a possibly hazardous situation that might result in serious injury or death.



For a possibly hazardous situation that might result in minor injury. May also be used to warn about damage to property.



For general safety instructions as given in this section.



For electrical hazards, warnings or precautionary measures when dealing with electric power.



NOTE: For a possibly hazardous situation that may damage the device or
IMPORTANT: For user instructions and other useful information.



Symbol "Non-ionising electromagnetic radiation".

Information when dealing with devices that emit "non-ionising electromagnetic radiation".



Pump, do not reach into pump when moving

1.8.2 Symbols used on device



Attention: Take note of accompanying documentation!



Class II device

IP42 Degree of housing protection

1.8.3 Symbols used on accessories



Address of manufacturer



Storage temperature



Expiry date



The device should be either disposed of via your local recycling centre according to the relevant national regulations or sent back to FUMEDICA AG Division Postmortem-Angio.



Symbol identifying electrical and electronic equipment.

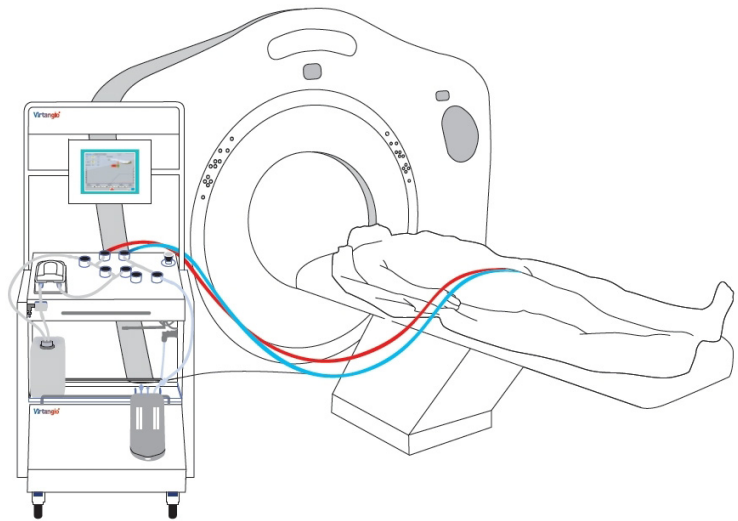
You are obliged to collect the device separately and dispose of it via your local return and collection system.

Failure to effect proper disposal presents a risk to the environment and human health due to the presence of hazardous substances in electrical and electronic equipment.

2 Design and function

2.1 Purpose and function

The **Virtangio® machine** is a contrast filling system which fills the cardiovascular system with a corresponding contrast medium to permit high-resolution postmortem angiography of the entire cardiovascular system to be carried out. The system consists of a perfusion pump controlled by a computer. The computer controls the perfusion volume according to the protocol selected. The pressure parameters are recorded during perfusion, so providing additional information about the vascular system.



The Virtangio machine consists of the device with a touch screen, a perfusion pump and the pneumatic valve system used to fill the venous and arterial lines and a footswitch. The compressed air required is generated by a small built-in compressor. An integrated PLC system controls the process sequence, which is input using the touch screen on the device.

All processes for preparation of the system are only ever controlled via the touch screen.

The button is used to control the final preparation step for complete filling of the tubing set.

The subsequent process steps can be initiated during the CT scan using the remote computer in the shielded part of the CT room.

Data such as the pressure curve during filling of the vascular system is transmitted by the Virtangio machine via WLAN to the remote computer, where it can then be analysed.



2.2 Design

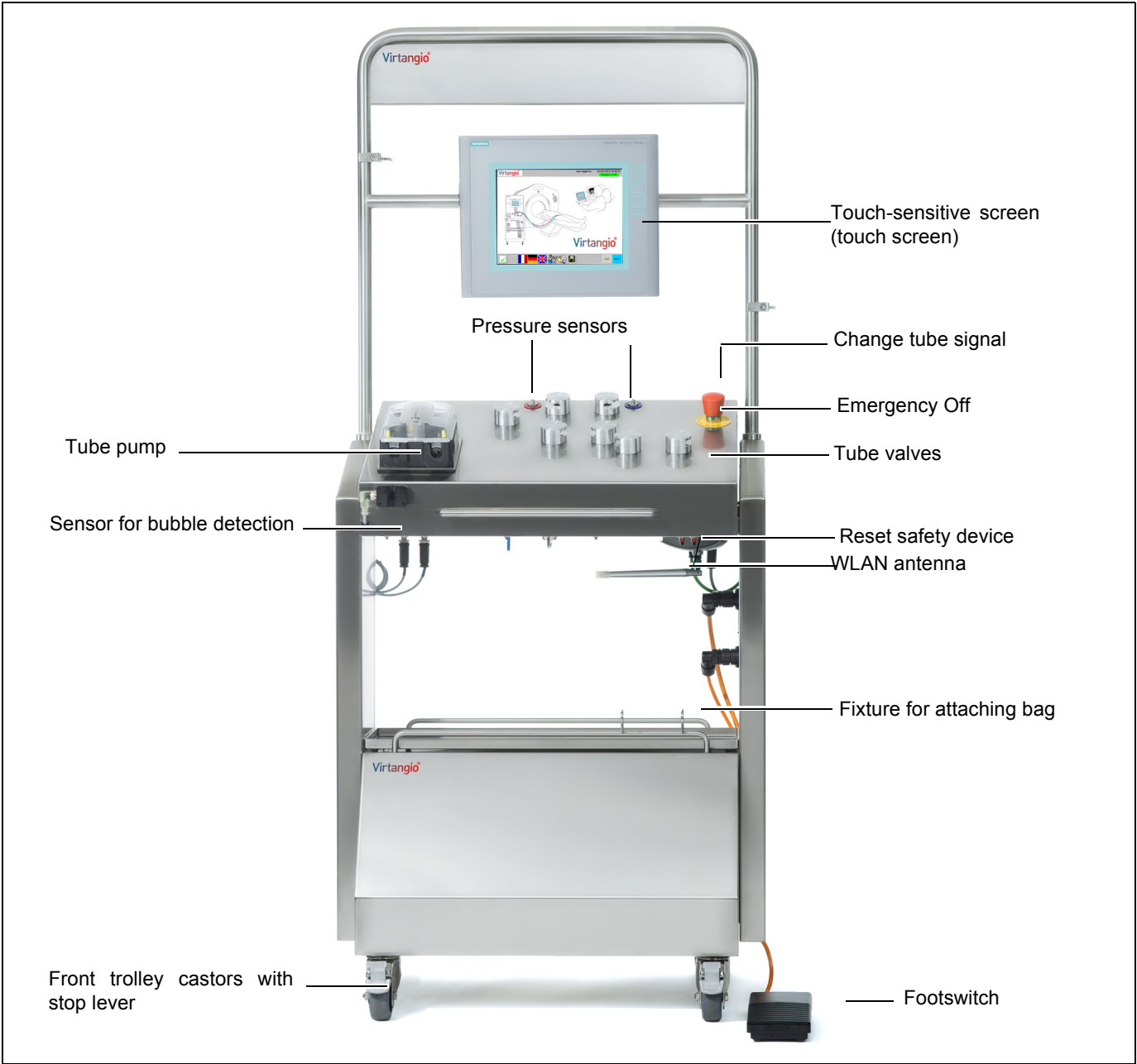


Fig. 2.1 Components of Virtangio machine

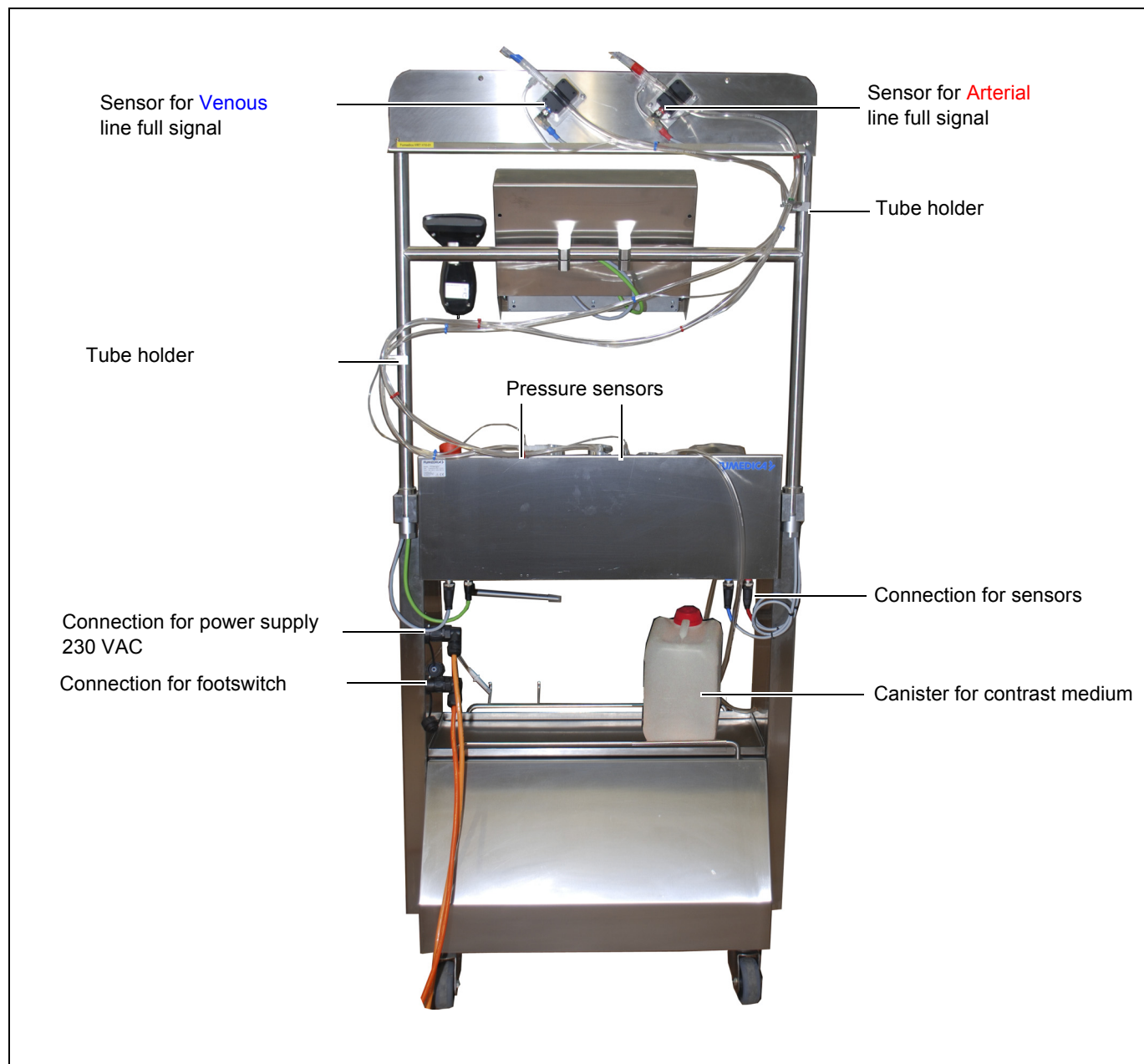


Fig. 2.2 Components of Virtangio machine – rear view

2.3 Function

The following process steps are carried out incl. preparation of the system:

Step A

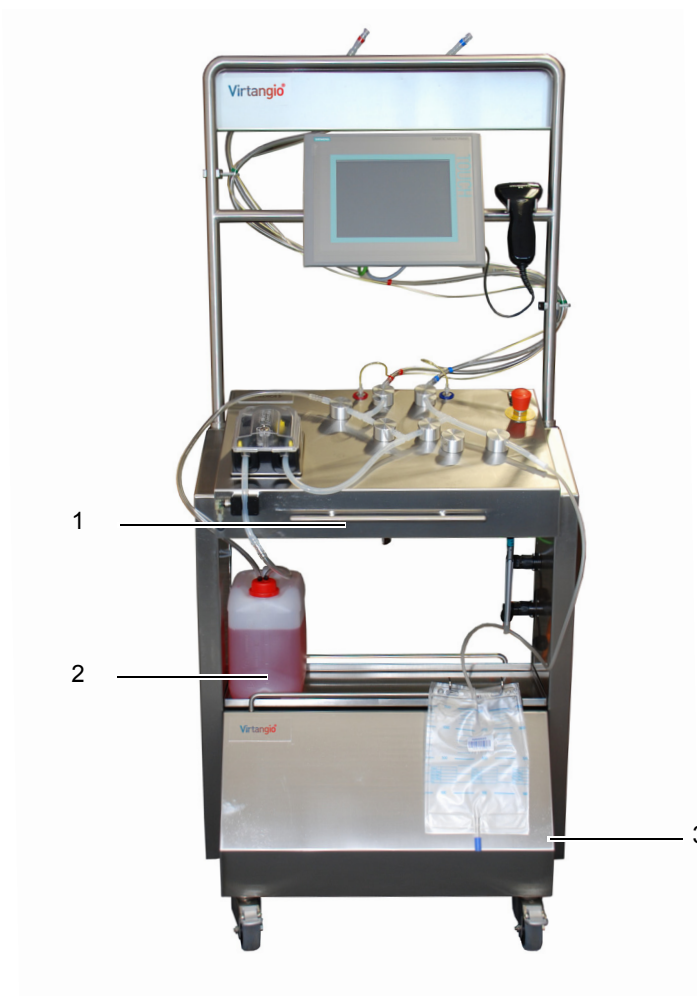
Data input

- Case information
- Body parameters
- Angio parameters

Step B

Preparation

- (1) Insert tubing set
- (2) Connect full supply canister
- (3) Hang up return flow bag

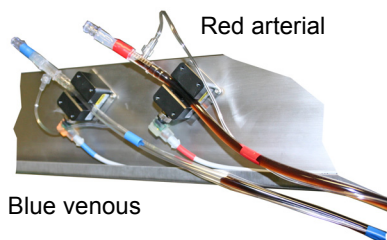


Mixing

After preparation the contents of the container are circulated for the specified period of time, resulting in them being mixed. If the mixing time [min] is smaller than the volume in the container [ml] / 333, the container must be premixed by shaking manually.

The minimum mixing time of 1 minute should always be observed, as otherwise air bubbles may remain in the system. The tubing system is automatically filled at the end of mixing. Mixing should be carried out again after idle periods exceeding one hour.

Pre-filling arterial line



Filling arterial tube system

- Start filling the arterial line. The tube is automatically filled until the sensor is reached. This process is time-monitored. After a malfunction, filling no longer takes place automatically, and the tube has to be filled using the footswitch!

Pre-filling venous line

- Start filling the venous line. The tube is automatically filled until the sensor is reached. This process is time-monitored. After a malfunction filling no longer takes place automatically, and the tube has to be filled using the footswitch!

Connecting arterial line

1. The rest of the tubing is filled with the footswitch in jog mode to prevent any air bubbles forming in the system.
2. The tube is connected to the body and strain-relieved.

Connecting venous line

1. The rest of the tubing is filled with the footswitch in jog mode to prevent any air bubbles in the system.
2. The tube is connected to the body and strain-relieved.

Step C Angio from remote computer

Filling arterial line

1. Start arterial filling and monitoring locally or from remote computer.
2. Pressure is monitored during arterial filling.

Filling venous line

1. Start venous filling and monitoring locally or from remote computer.
2. Pressure is monitored during venous filling.

Circulation

1. Start circulation in arterial system locally or from remote computer.
2. Pressure is monitored and recorded during circulation.
3. Circulation must be stopped manually if air bubbles are present.

2.4 Operation and display elements

The Virtangio machine is operated via the touch screen or the remote computer for process step C. The start screen is displayed when the device is switched on.

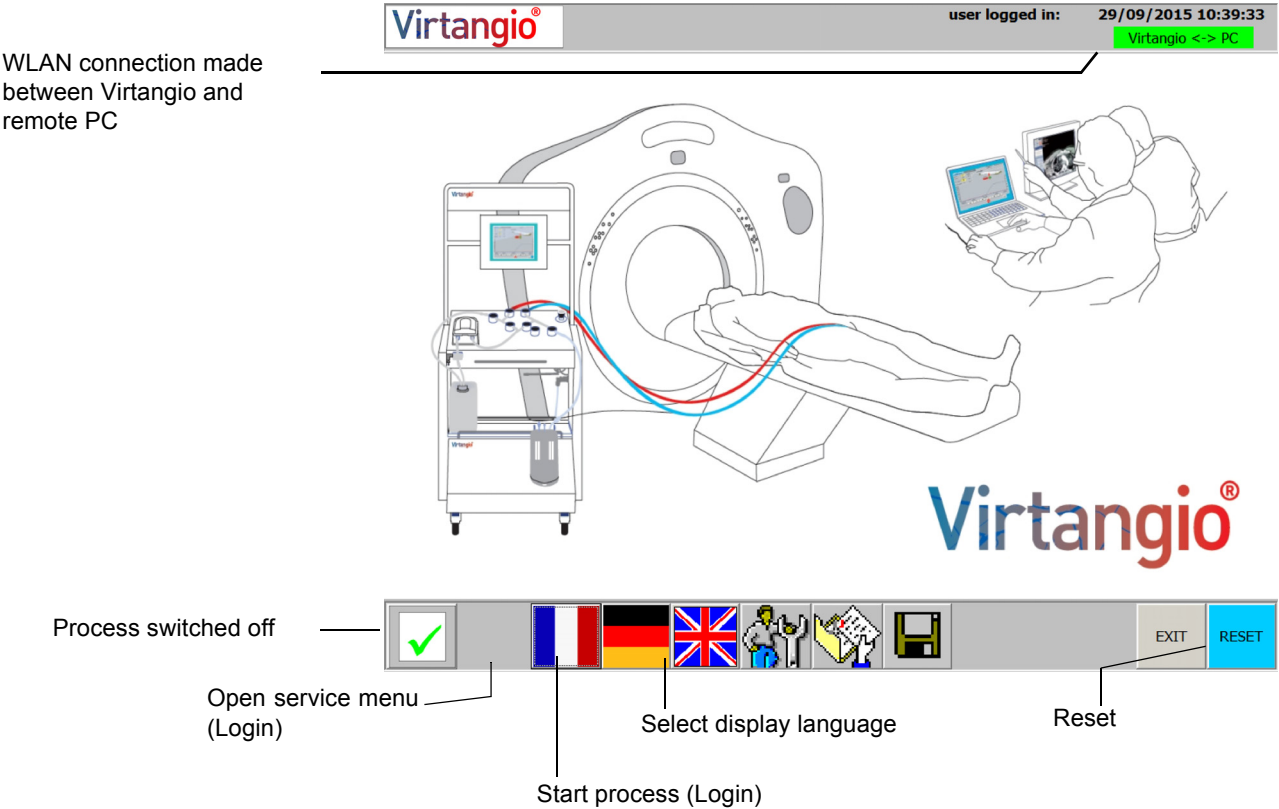
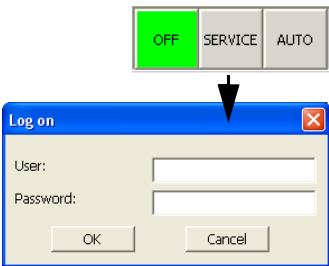


Fig. 2.3 Start screen

2.4.1 Login

Login is used to start the process (Autostart) and open the Service menu.

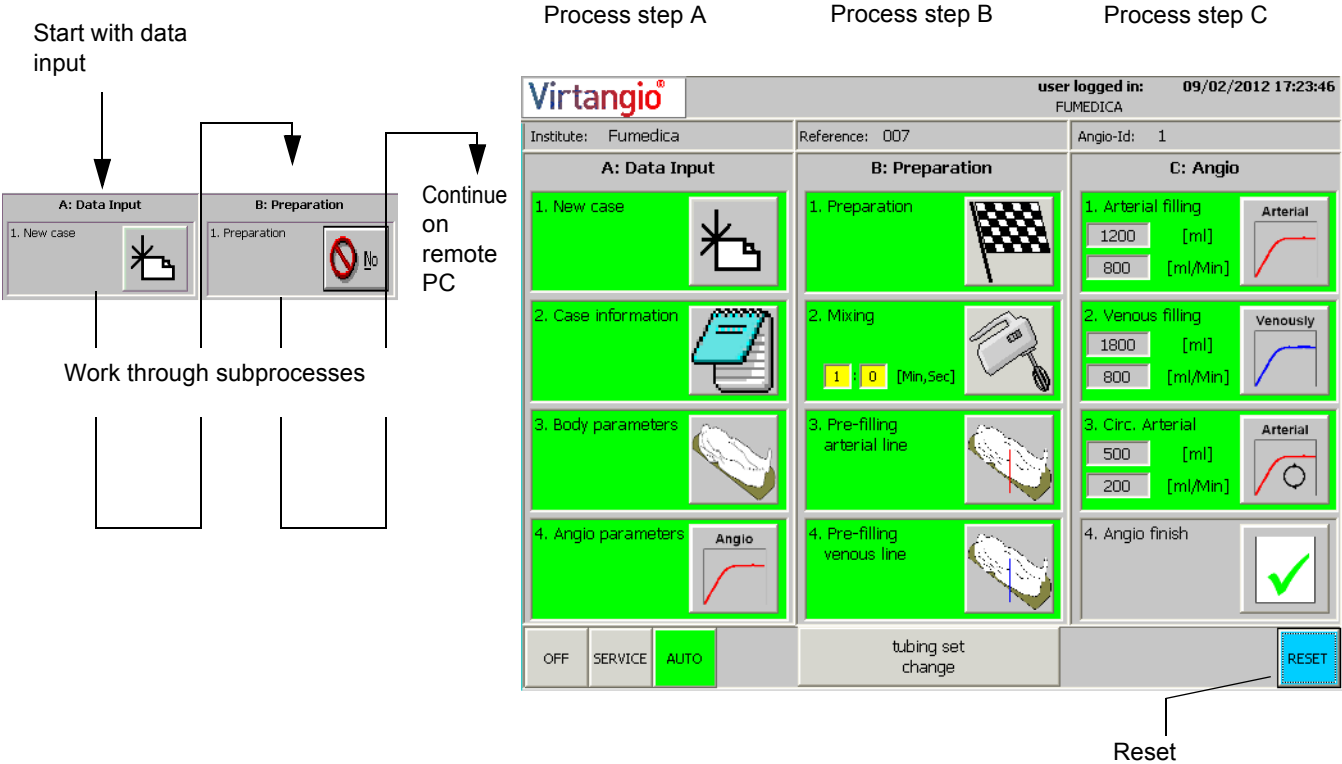


User	Password	Access authorisation
User 1	123	Limited access
User 2	123	Limited access
User 3	123	Limited access
Admin	*****	Full access

Service access only via Admin, see Annex Admin page 29.



The Angio process is started in automatic mode. The process steps A–C and their subprocesses must be executed in the sequence specified in order to access the next process step or subprocess. Processes which have not yet been completed are shown with a grey background, and completed processes marked in green.



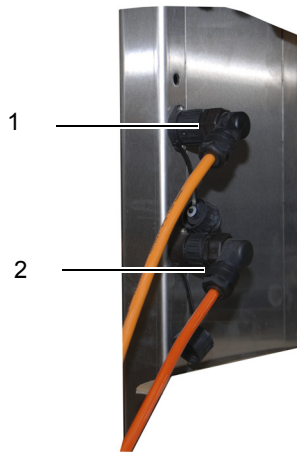
3 Start-up



- ▲ Before the device is put into use, it must be checked that it is in working order and sound condition. In particular, cables and plug connections should be inspected. Damaged parts must be replaced immediately.

3.1 Connect device

Cables are colour-coded so they cannot be connected incorrectly



1. First connect the cable to the footswitch (2) and then the mains cable (1).
2. Connect the mains cable to the corresponding power supply (230 VAC, 50/60 Hz).
3. The device is ready for operation as soon as the touch screen is started.

3.2 Switch on device

The device will switch on as soon as the mains cable is connected to the power supply.

3.2.1 Operation following a power failure

The system saves the latest status and completes the last process step.

3.3 Switch off device and disconnect from power supply

1. End the process using the Off button.
2. Disconnect the mains cable from the power supply.



3.4 Emergency Off

Opens the valve and stops the pump.

4 Operation

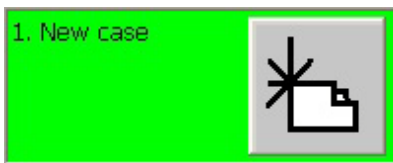
After the device has been switched on, the following steps are carried out to perform angiography:

4.1 Preparation

4.1.1 Step A via touch screen or remote PC

1. New case

- A new case can be started as soon as the device is ready for operation or a case has been completed.



2. Case information

- Institute
- Reference number
- Angio number
- Angio date
- Tubing set barcode (can be switched off by Administrator (see page 37).



Important!

- Special characters such as < > \ / - " etc. cannot be entered in the input fields!
 - Spaces " " and underscore "_" are permitted.
- Use "ENTER" to confirm.

Barcode switched on

Error message if tubing set has been used more than twice.

Go to input field Barcode

Barcode read by hand-held scanner

Press the button to move to the next step.

Barcode switched off

A manufacturer release code is necessary to perform a certain number of angios.

Number of remaining angios. If the number zero is displayed, no angios can be carried out in Auto mode.

3. Body parameters



- Body height
- Body weight
- Age
- Time since onset of death
- Sex
- Body status
- Dead spots (livor mortis)
- Type of storage

Virtangio® user logged in: FUMEDICA 09/02/2012 17:11:56

body parameters

body height in cm:	177
body weight in kg:	66
age (years):	51
time since onset of death days	2
Sex:	male female
body status:	good medium bad
dead spots (livor mortis):	no few many
rigor mortis:	no plastic elastic
type of storage:	cooled uncooled field
	water unknown

✓ Cancel RESET

- Use "ENTER" to confirm entries.

4. Angio parameters



- Artery (filling rate per minute)
- Vein (filling rate per minute)
- Circulation (filling rate per minute)
- Tubing set filling (specified by tubing set)
- Total requirements (total of filling rates selected above)
- Paraffin oil (type of paraffin oil used)
- Angiofil concentration
- Total mix requirement
- Artery connection (to left/right of body or otherwise)
- Vein connection (to left/right of body or otherwise)

Virtangio® user logged in: FUMEDICA 09/02/2012 17:12:48

Angioparameters

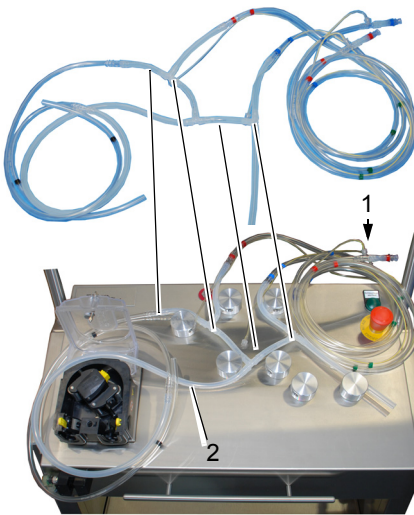
application	[ml/Min]	[ml]	[Min/Sec]
artery:	800.0	1200	1 : 30
vein:	800.0	1800	2 : 15
artery circulation:	200.0	500	2 : 30
tubing set filling:		200	
total requirements:		3700	
paraffin oil:		3478	
Angiofil concentration:	6 %	222	
total mix requirement:		3700	
artery connection:	left right otherwise		
vein connection:	left right otherwise		

✓ Cancel RESET

4.1.2 Step B on device

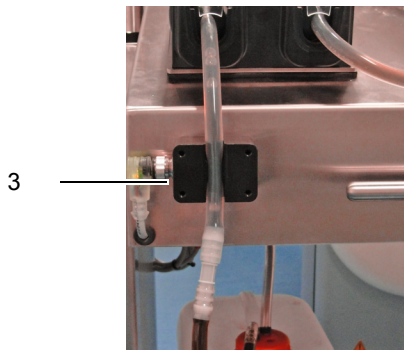


1. To insert the tube in the various pinch valves, the valves first have to be opened. Press **Button 1. Preparation**.
→ Image with fitted tubing set appears. "?" can be used to display additional instruction images.

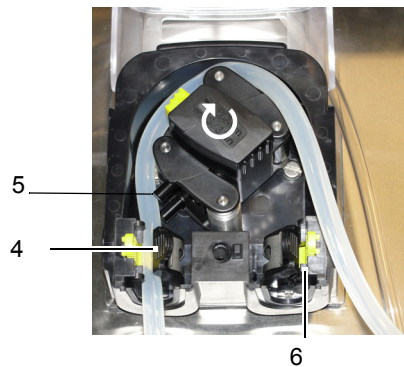


2. Lay the tubing set out on the table as shown in the figure to make it easier to insert. Allow the part of the tubing marked **(1)** in blue/red to fall to the rear of the device.

3. Place the tubing set on the device.

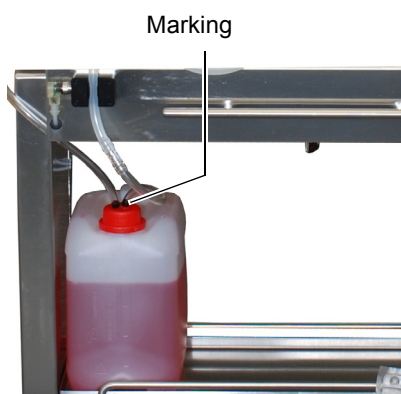


4. First insert the tube **(2)** leading from the canister to the pump into the air bubble sensor **(3)**.



5. Insert the tube **(3)** into the pump. To do so, force open the clamp on the left **(4)** and place the tube into the clamp.
6. Turn the pump head clockwise to feed the tube into the pump head guide **(5)**.
7. Continue to turn the pump head clockwise until the tube is completely inserted.
8. You can now secure the tube in the right-hand clamp **(6)**.
9. Now close the lid of the pump.

10. Now secure the individual sections of tubing in the pinch valves. To do so, you need to apply a little force.



11. Connect both tubes, the pump tube and the mixing tube to the canister.

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Attention!

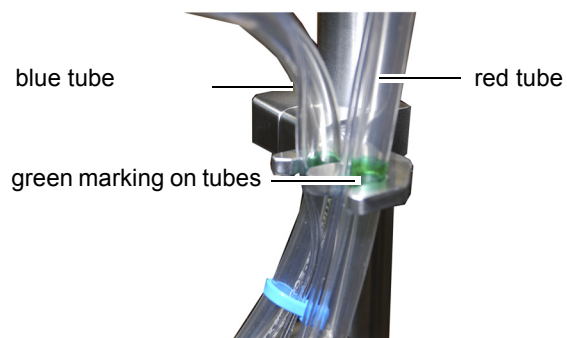
Insert the tubes in the canister so the markings are right next to the lid.

Make sure that the mixing tube is connected as shown in the figure.



12. Connect the collection bag to the tubing set.

13. Place the blue tube in the clamp first, and then the red tube. The green markings on the tubing indicate the clamping position.

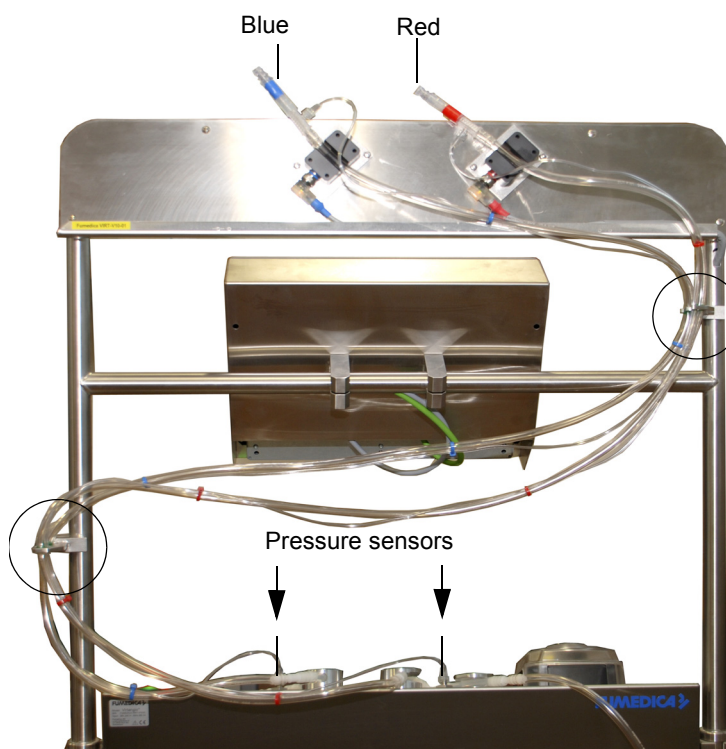


Make sure that the blue tube (venous) is inserted into the holder first and then the red tube (arterial).

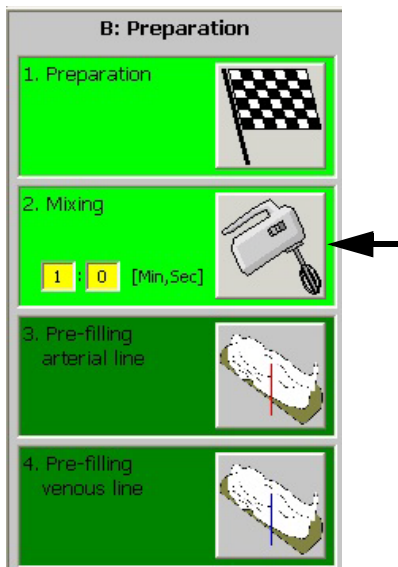
Reason:

In point 17 (filling with footswitch and connection to artery), the arterial filling of the tube must take place first according to the process sequence, meaning it must be taken out of the holder first.

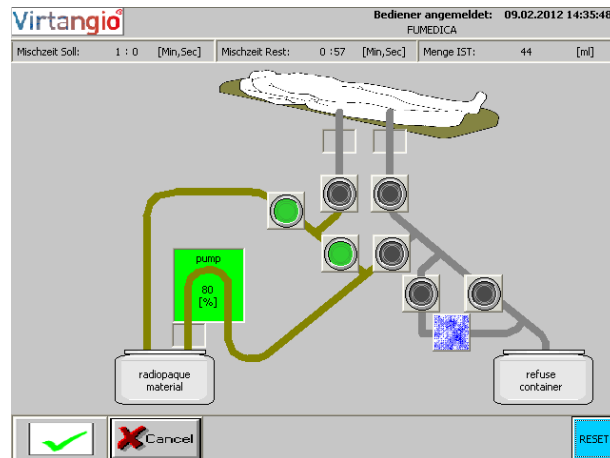
14. Press both tubes firmly into the filling level sensors. Blue on the left and red on the right.



15. Connect the two small tubes to the appropriate pressure sensors.

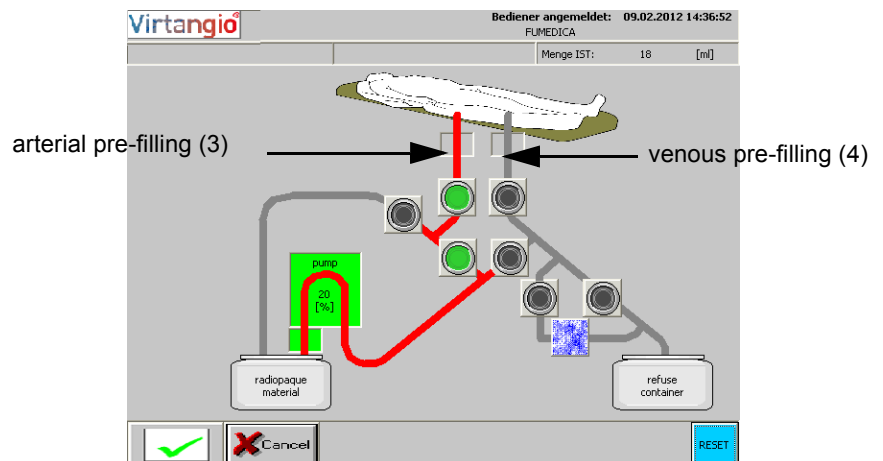


16. Press **Step 2 Mixing**. The tubing is filled and any air bubbles are transported back to the container via the mixing tube.



i

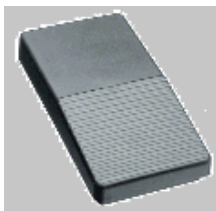
The two tubes are filled up to the filling level sensor. The status of these two steps changes to dark green.



17. Press **Step 3** to activate the footswitch for arterial filling. You can now remove the arterial line from the sensor, fill to the end with the footswitch and then connect to the artery opened on the body.
18. Press the  button to move to the next step.
19. Press **Step 4** to activate the footswitch for venous filling. You can now remove the venous line from the sensor, fill to the end with the footswitch and then connect to the vein opened on the body.

20. Press the  button to move to the next step.

Once both steps have been carried out, the status of **Step 3 and 4** will change to light green.



4.2 Start angiography

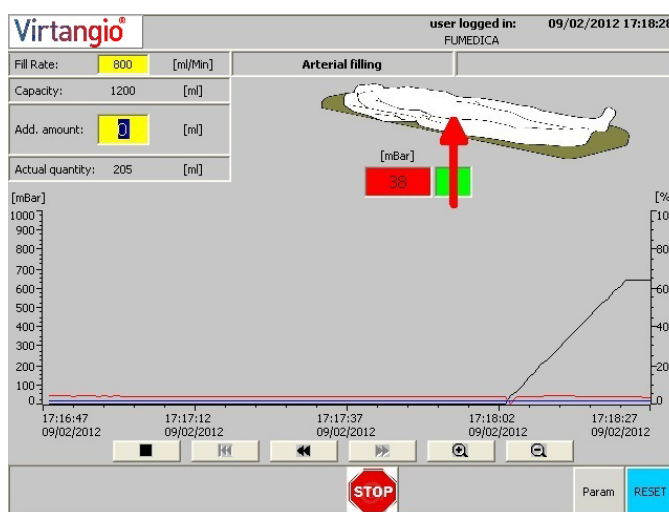
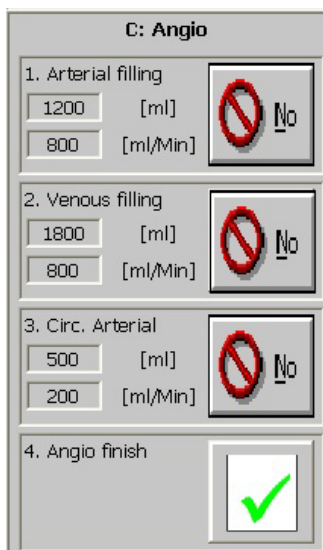
4.2.1 Carry out Step C Angiography

These steps are carried out from the remote computer.

Before starting the CT scan, check the fixings of the tubing:

- Connections must be strain-relieved.
- Tubes must be positioned freely so as to follow the movement of the stretcher.

1. Use the  button to start **Arterial filling 1**. The pressure is recorded and the curve displayed.



2. You can interrupt filling at any time with the  button.
3. Once the filling volume has been attained, the pump will switch off.
4. You can now view the pressure curve for filling again using the appropriate buttons.

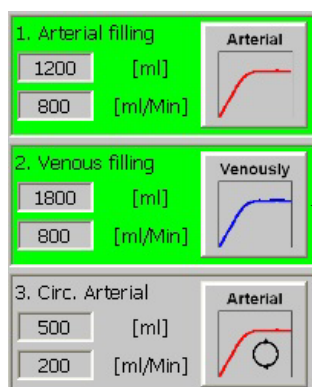


5. Press the  button to move to the next step.

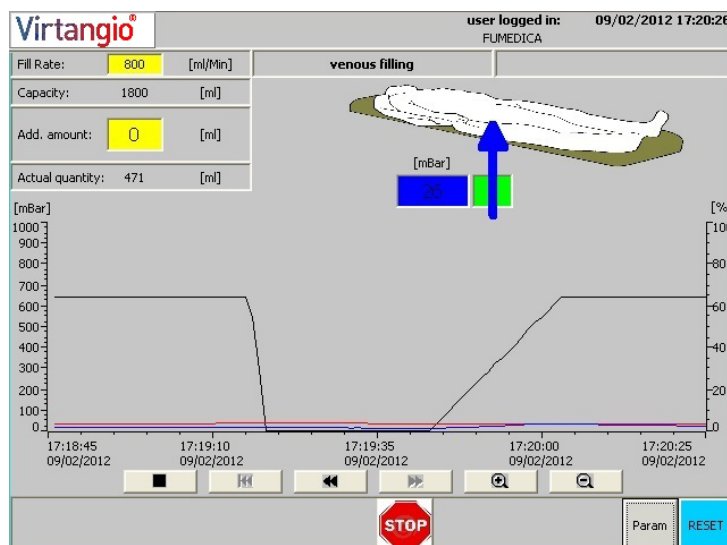
i

If air bubbles are detected during filling, filling stops and an error message is displayed.

→ Press the RESET button and resume filling with the START button.

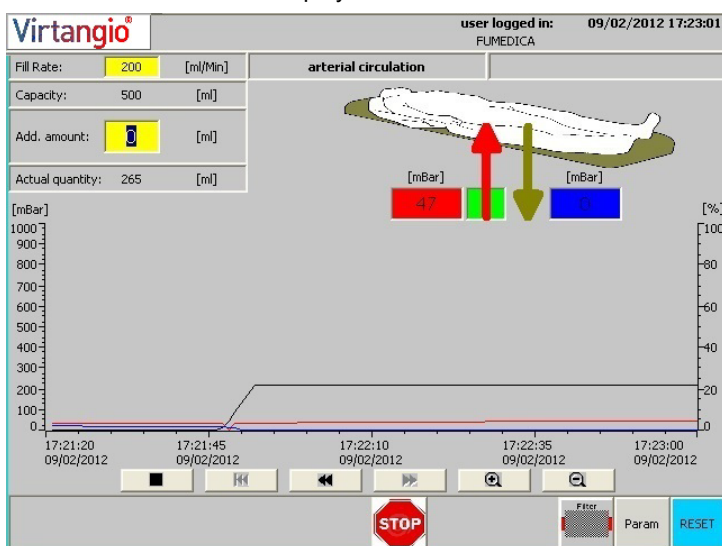
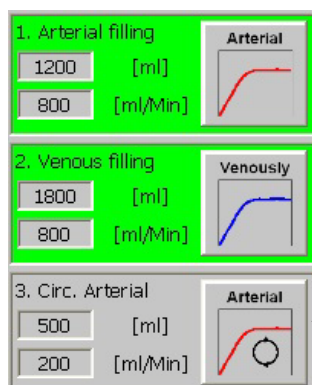


6. Use the  button to start **Venous filling Step 2**.



7. The sequence is the same as for arterial filling from Step 2 onwards.

8. Start **Circulation Step 3** and then the CT scan accordingly. The pressure is recorded and the curve displayed.



9. You can interrupt circulation at any time with the  button.
10. Once the circulation volume has been attained, the pump will switch off.
11. You can now view the pressure curve for filling again using the appropriate buttons.



12. Press **Step 4** to finish angiography and perform a new procedure.



If air bubbles are detected during circulation, only an error message will be displayed: circulation will continue. The process must be stopped manually.

4.3 Finish angiography

To finish angiography or start a new procedure, the tubing set must be removed along with the canister and collection bag.

To do so, proceed as follows:

1. Move the waste bin next to the Virtangio machine.
2. Press the button **"tubing set change"**. The valves then release the tubing.
3. Remove all sections of tubing from the valves and detach both connections from the pressure sensors.
4. Remove the tubing from the pump.
5. You can now dispose of the entire tubing set incl. canister and collection bag in the waste bin.

tubing set
change



1. Now detach the arterial and venous lines from the body.
2. Wrap paper around the ends of the tubing and pass through the frame as shown in the figure. Discard the rest of the tubing set in the waste bin.
3. You can now switch off the Virtangio machine or perform another angiography.

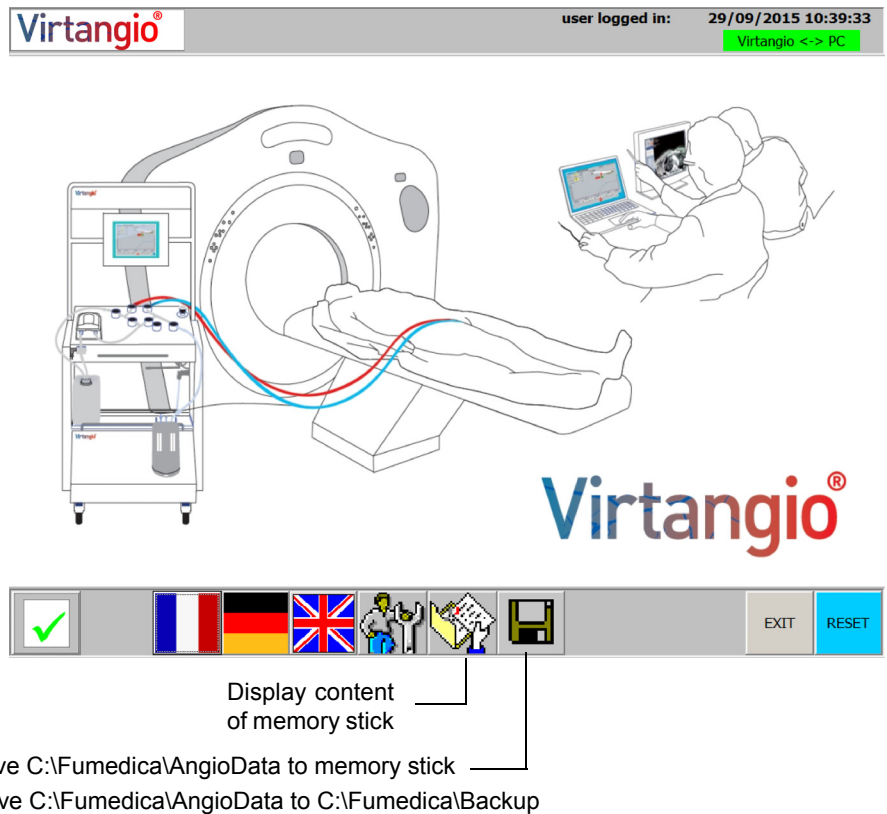


4.4 Data backup

The data will be saved on the local panel (only memory stick), the remote PC or on both depending on the settings.

4.4.1 Data backup on remote PC

This function can only be carried out on the remote PC.



4.4.2 Directory structure

The directory structure is as follows:

C:\Fumedica\ AngioData - angio data before export

C:\Fumedica\ Backup - angio data backup, after export

C:\Fumedica\ HMI_2_RT - angio program

4.5 Error display, troubleshooting

Errors are displayed at the top of the screen in the first or second line.

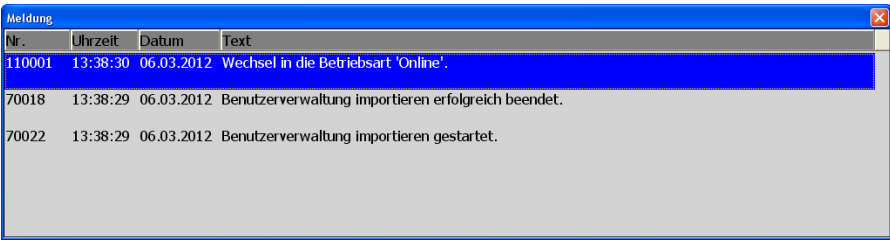
Alarm/messages in first line



Alarm/messages in second line



System status messages shown in a separate window relate to the connection to the CPU and panel, and are for information only.



4.5.1 General errors

Error	Cause	Remedy
Tubing set change is switched on.	• Tubing set change button active	→ Press Tubing set change button in Service menu.
Data from last angio not yet logged	• Special characters used when inputting "Case information -> Institute". "\ / £ \$" etc. are not permitted! • Data logging local, no USB memory stick inserted in machine panel. • Data logging remote, remote PC is switched off or Virtangio program has not been started.	→ Check and correct case information, finish angio and then confirm new case. → Check memory stick on local panel, finish angio and then confirm new case. → Check remote PC and WLAN transmission, finish angio and then confirm new case. → Press RESET button!! It is possible to continue operation and make an angio, but the data will not be recorded correctly.
No compressed air	• The compressor has not yet built up the necessary pressure. • Compressor M110.D6, relay K121.D6 or compressed air line defective • Pressure control S323.D4 defective	→ Press RESET and wait 1 minute. → Notify service technician → Notify service technician

4.5.2 Data input errors

Error	Cause	Remedy
Incorrect entry "Examining institute"	- Input field is blank or not correct. - Do not use special characters (\ / £ \$ etc.)	→ Correct input
Incorrect entry "Reference number"	Input field is blank	→ Enter information
Incorrect entry "tubing set barcode"	Input field is blank	→ Enter information
Angio number already used	This angio number has already been used before.	→ RESET and continue or → RESET and enter another angio number
Incorrect entry "Date of examination"	Input field is blank	→ Enter information
Reference already used	This reference has already been used before.	→ RESET and continue or → RESET and enter another reference number
Incorrect entry "Condition of test subject"	No button selected	→ Select button
Incorrect entry "Weight"	Input field is blank	→ Enter information
Age not specified	Input field is blank	→ Enter information
Height not specified	Input field is blank	→ Enter information
Incorrect entry "Sex"	No button selected	→ Select button
Incorrect entry "Livor mortis (dead spots)"	No button selected	→ Select button
Incorrect entry "Rigor mortis"	No button selected	→ Select button
Connection to body not specified	No button selected	→ Select button

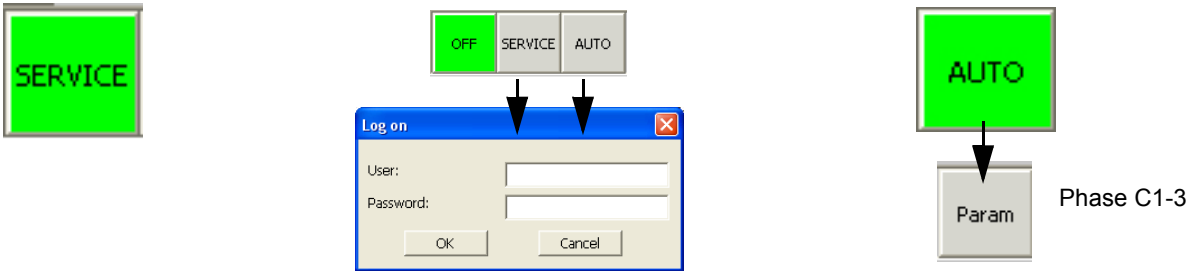
4.5.3 Errors in arterial/venous filling and arterial circulation

Error	Cause	Remedy
Pressure on arterial/venous line too great	- Tubing kinked - Complete arterial/venous block in body - Pressure sensor defective	→ Check tubing → See CT images → Check pressure sensor
Air bubbles / defective flow upstream of pump	- Tubing not positioned correctly in U-holder of bubble sensor - Tank has run out of Angiofil - Tubing set not correctly filled / mixed - Bubble sensor B323.B8 defective	→ Check tube positioning → Check tank contents → Check tubing set → Check sensor
Pump lid is open	-	→ Close pump lid correctly
Data cannot be logged, HMI switched off	No connection local (panel) or remote (PC)	→ Remote-PC: Check WLAN connection, PC switched on and Virtangio program started up? → Local panel: All cables inserted correctly?

5 Administrator Settings

5.1 Login for full access

In AUTO mode the login for full access gives access to the Parameters menu for pressure and volume control during the angio phases C1-3, or to the Service menus via the SERVICE button.



User	Password	Access authorisation
User 1	123	Limited access
User 2	123	Limited access
User 3	123	Limited access
Admin 1	*****	Full access
Admin 2	*****	Full access
Admin 3	*****	Full access
Fumedica	*****	Full access
Hedag	*****	Full access

5.2 Parameters menu in AUTO mode

The following display can only be called up from the angio phases C1-3:

- C1 = Arterial filling
- C2 = Venous filling
- C3 = Circulation

The relevant text is displayed according to the phase

Virtangio® user logged in: 09/02/2012 17:18:54
FUMEDICA

parameters arterial filling

pressure control:

pressure control:
The pressure never exceeds the
calculated pressure.
The flow rate results
automatically.

control
by
pressure

termination criteria (OR):

stop at
Volume

volume control:

volume control:
The flow rate is
observed. The pressure
will only limit by
maximum monitored.

control
by
volume

common parameters:

ramp time rising [sec]: 20

Max pump pressure [mBar]:
(stop in case of over pressure) 800

✓

RESET

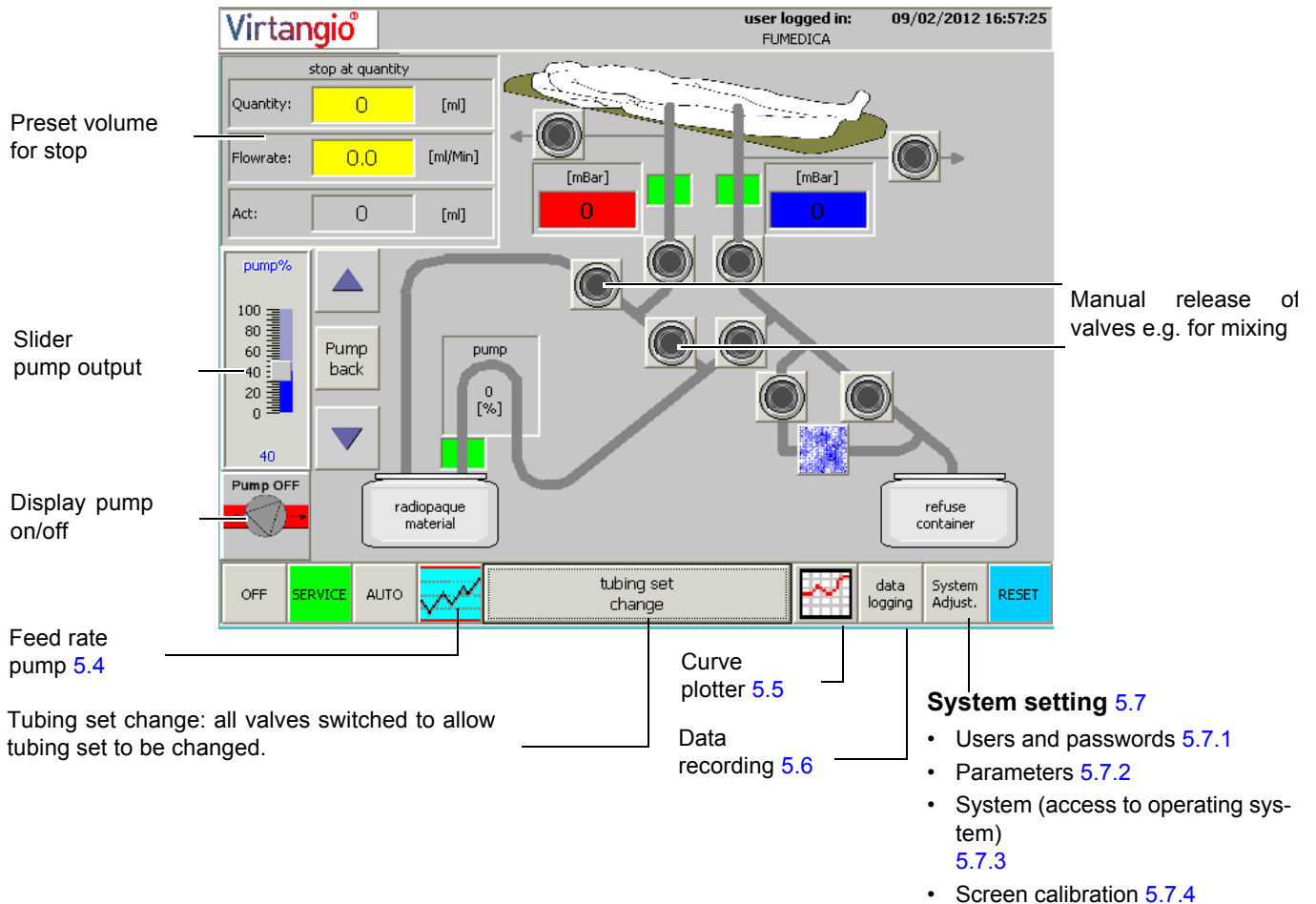
This page can be used to select the criteria for controlling and aborting.

5.3 Service overview

The following displays can only be called up from the Service overview page.

The most important functions can be carried out manually from the Service overview:

- Stop preset with pump volume [ml] or flow [ml/min] (yellow)
- Preset pump output [%] using slider
- Release valves



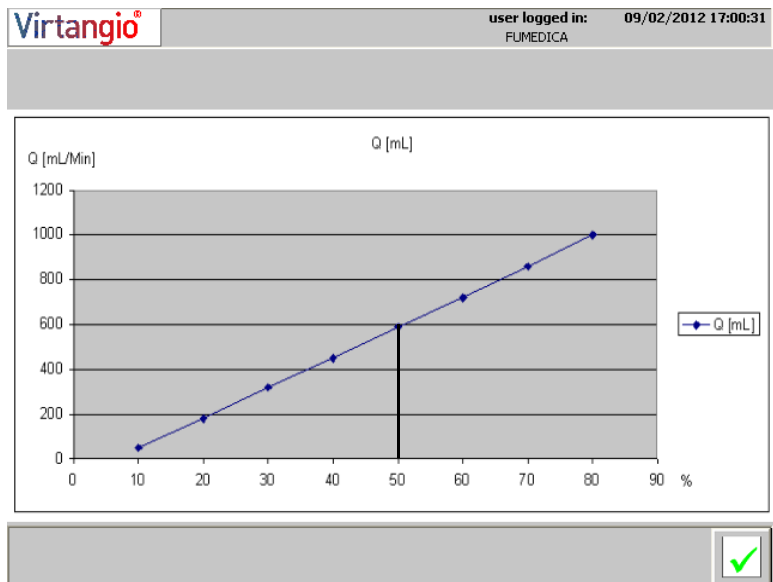
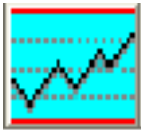
- If the preset volumes [ml] or flow [ml/min] (yellow) are zero, pump output is preset with the slider.



- ▲ Risk of excess pressure! Do not operate pump without having released relevant valves (e.g. mixing).

5.4 Pump feed rate

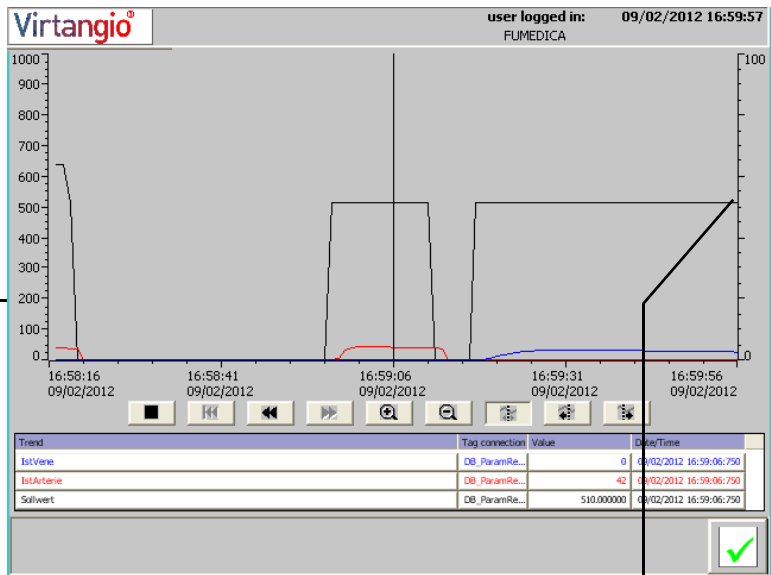
Display of pump output. The diagram shows the approximate output [ml/min] for the selection made with the slider [%].



5.5 Curve plotter



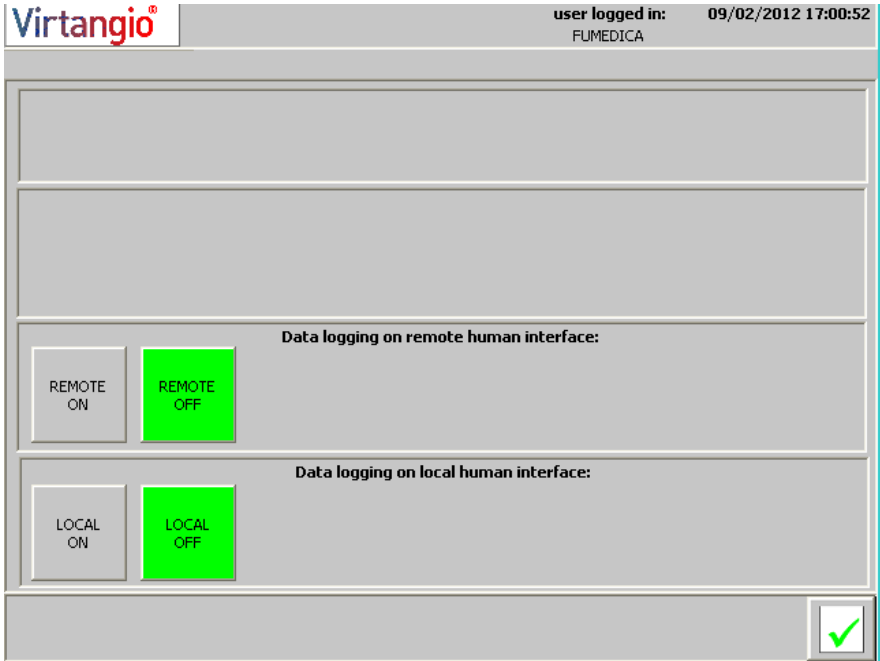
Red and blue curve –
pressure in mbar



Black curve – pump
output in %

5.6 Data recording

Setting for data logging.



Data logging can take place on the local panel, remote PC or on both.

Prerequisites for data logging:

Remote PC

The Virtangio program is running on the remote PC at the start of an angio with access to the local panel.

Local panel (machine)

Memory stick must be connected to local panel.

5.7 System setting

The System setting menu can be used to set the following information:

- Date and time
- Units for pressure, flow rate and volume
- Entry of user and password, selection of parameters, access to operating system and calibration of touch screen via submenu.



Virtangio®

user logged in:
FUMEDICA
09/02/2012 17:01:19

Set date and time:

09/02/2012 17:01:19
☒

Current pressure units:

unit
mBar

unit
Torr

unit
mmHg

Current flow rate units:

unit
ml/Min

unit
ccm/Min

unit
ml/Sec

unit
ccm/Sec

Current quantity units:

unit
ml

unit
ccm

user and passwords
data logging
PAR
SYS
CALIB

☒

Users and passwords
5.7.1

Parameters
5.7.2

System
5.7.3

Calibration
5.7.4



Data logging always made in SI units!

5.7.1 Passwords

Creation of users and passwords.

SERVICE

System Adjust.

user and passwords

Virtangio®

user logged in: 09/02/2012 17:02:00
FUMEDICA

User	Password	Group	Logoff time
Admin	*****	Group (9)	60
ADMIN1	*****	Group (9)	60
ADMIN2	*****	Group (9)	60
ADMIN3	*****	Group (9)	60
FUMEDICA	*****	Group (9)	60
HEDAG	*****	Group (9)	60
PLC User	*****	Unauthorized	5
USER1	*****	Group (1)	60
USER2	*****	Group (1)	60
USER3	*****	Group (1)	60

✓

→ Double-click on the fields in the column User or Password to edit these.

5.7.2 Parameters

A list of parameters can be found in section 5.8, page 38.

SERVICE

System Adjust.

PAR

Virtangio®

user logged in: 09/02/2012 17:02:28
FUMEDICA

▲
6
▼

monitoring venous bubble detection: 0 = OFF, 1 = ON

value:
1.00

WLAN-Region: EUROPE

WLAN-Channel: Cannel 01 / 2.412GHz

Machine-ID: FumedicaVIRT-V10-01

SW-Version: Fum_V10_01-20120209-01

✓

Select parameter

Description of parameter

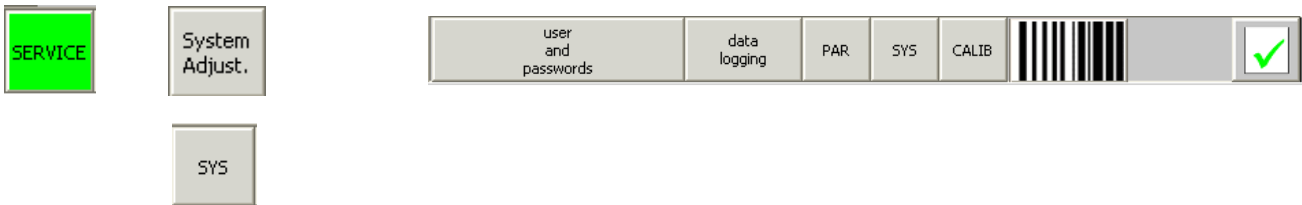
Current setting

Save setting

Art. No.: S600.1012 Rev.:c

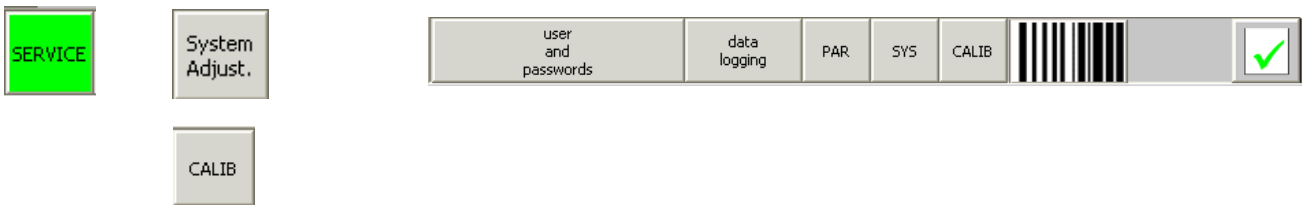
5.7.3 System

The SYS button ends the runtime and returns the user to the operating system of the panel (only local panel)



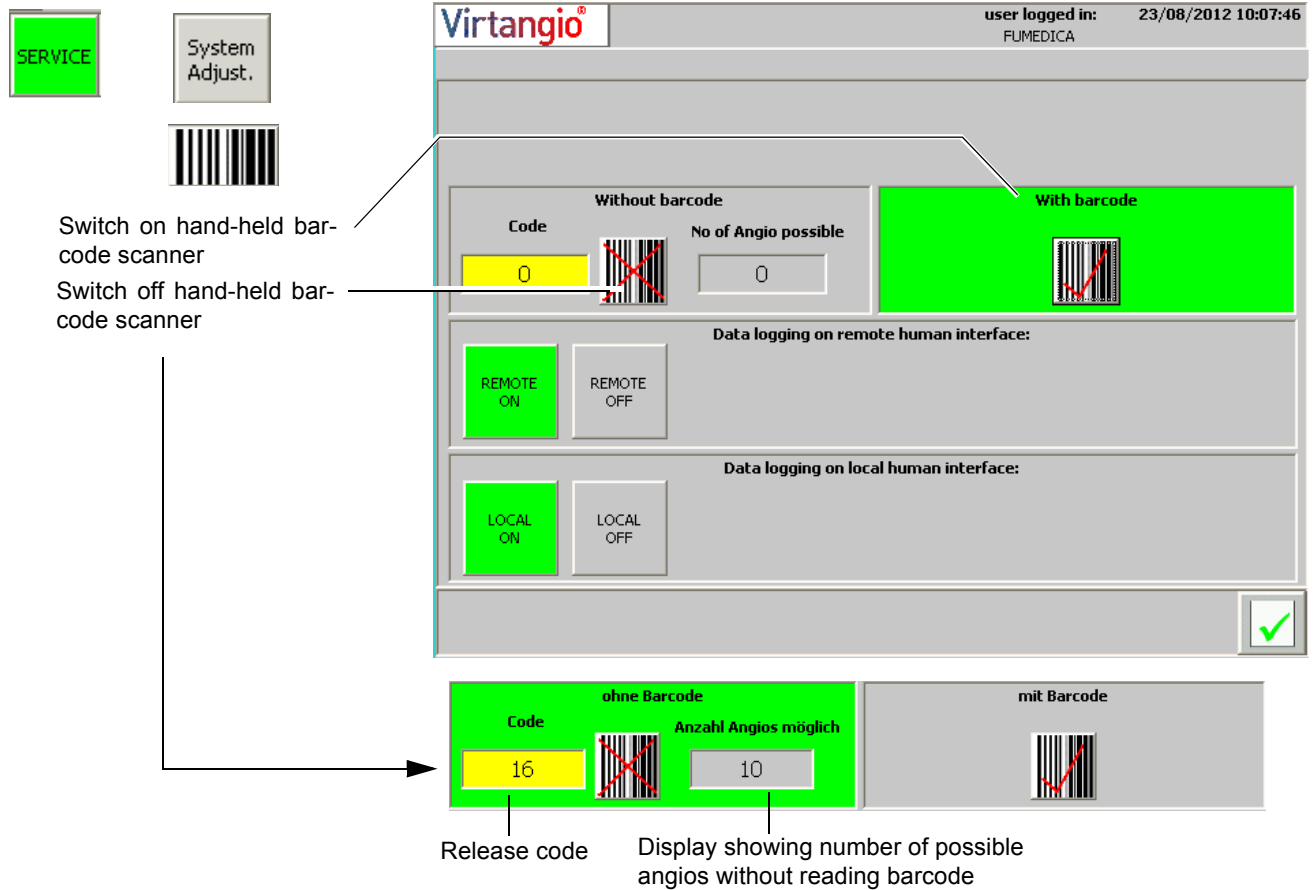
5.7.4 Calibration

CALIB is used to calibrate the touch screen.



5.7.5 Barcode setting

The settings can be used to select whether to activate the angios with the hand-held barcode scanner or using the release code.



With barcode:

- Each tubing set can be used max. twice on the same day.
- Before every angio the tubing barcode has to be read with the hand-held scanner in the "Case information" screen. To do so, the cursor must be positioned in the orange field "tubing set barcode" (field highlighted in blue)

Without barcode:

- The manufacturer (Fumedica) must be asked for the release code.
- After the number of angios activated has come to an end, a new release code needs to be entered.

5.8 Equipment parameters

No.	Meaning	Value range	Current value
01	Data logging HMI local: 0 = none, 1 = ON	0 / 1	1
	Switch local data logging on or off. If there is no memory stick in the machine, logging must be switched off. This parameter can also be edited using the relevant button on the local panel.		
02	Data logging HMI remote: 0 = none, 1 = ON	0 / 1	1
	Switch data logging on or off at remote PC. If no remote PC is available, logging must be switched off. This parameter can also be edited using the relevant button on the local panel.		
03	Monitoring pump lid: 0 = OFF, 1 = ON	0 / 1	1
	Monitoring can be switched off in the event of a pump defect. If monitoring is switched off, the message "Pump lid open" will continue to be displayed at the top of the screen but the pump can still be used.		
04	Monitoring air bubble detection at pump: 0 = OFF, 1 = ON	0 / 1	1
	Air bubble detection at the pump can be switched off in the event of a defect. If monitoring is switched off, air bubbles may be present in the system.		
05	Monitoring air bubble detection, arterial: 0 = OFF, 1 = ON	0 / 1	1
	Air bubble detection for arterial pre-filling can be switched off in the event of a defect. If monitoring is switched off, the arterial line must be filled using the footswitch.		
06	Monitoring air bubble detection, venous: 0 = OFF, 1 = ON	0 / 1	1
	Air bubble detection for venous pre-filling can be switched off in the event of a defect. If monitoring is switched off, the venous line must be filled using the footswitch.		
07	Standardisation of pump output	0.1 – 100	37.8
	This value is used for volume standardisation of the pump. The higher the value, the greater the feed rate. For control purposes, water can be pumped to a graduated beaker for 1 minute and compared with the setpoint value.		

No.	Meaning	Unit	Value range	Current
20	Mixing, mixing time	[100ms]	0 – 12000	100
	PAR[22].value = 1: Mixing time is input manually. PAR[22].value = 0: Mixing time is calculated: (SET.TotMixVolume * 3 * 0.6)			
21	Mixing, pump output with mixing	[%]	1 - 100	80
	80% = 1 litre / minute -> Value must not be changed!			
22	Mixing, entering mixing time	[]	0 / 1	1
	1: Mixing time is input manually. 0: Mixing time is calculated: (SET.TotMixVolume * 3 * 0.6)			
23	Mixing, cross-branch filling time	[100ms]	0 – 100	10
	Towards end of mixing, valve 6 / valve 7 is opened for half this time.			
26	Filling arterial line, monitoring of filling time	[100ms]	1 – 12000	200
	At the end of this time, filling is aborted with error.			
27	Filling arterial line, pump output	[%]	1 – 100	20
	Pre-filling carried out with this pump output			
28	Filling arterial line, pump output with footswitch	[%]	1 – 20	8
	Pre-filling carried out with this pump output if footswitch is activated			
29	Filling arterial line, max. pump pressure	[mbar]	0 – 1000	200
	If pressure selected here is exceeded, filling is aborted with error.			
30	Filling arterial line, max. filling volume	[ml]	0 – 1000	60
	When this delivery volume is reached, filling is completed correctly.			
31	Filling arterial line, waiting time for footswitch	[100ms]	0 – 1200	0
	During this time period, filling can be completed with the footswitch. If time is 0, the next process step will start automatically.			
32	Fill venous line, monitoring of filling time	[100ms]	1 – 12000	200
	At the end of this time, filling is aborted with error.			
33	Filling venous line, pump output	[%]	1 – 100	20
	Pre-filling carried out with this pump output			
34	Fill venous line, pump output with footswitch	[%]	1 – 20	8
	Pre-filling carried out with this pump output if footswitch is activated			
35	Filling venous line, max. pump pressure	[mbar]	0 – 1000	200
	If pressure selected here is exceeded, filling is aborted with error.			
36	Filling venous line, max. filling volume	[ml]	0 – 1000	60
	When this delivery volume is reached, filling is completed correctly.			
37	Filling venous line, waiting time for footswitch	[100ms]	0 – 1200	0
	During this time period, filling can be completed with the footswitch. If time is 0, the next process step will start automatically.			

No.	Meaning	Unit	Value range	Current value
40	Arterial vessel filling, bleed time	[100ms]	0 – 300	10
	The arterial line is bled for the period of time selected here before filling takes place. Bleeding reduces the pressure built up during pre-filling so filling of the body can start correctly with zero pressure.			
41	Arterial vessel filling, ramp time increasing	[sec]	0.1 – 60	20
	When vessel filling starts, pump output increases from zero to the maximum necessary output during the time selected here.			
42	Arterial vessel filling, ramp time decreasing	[sec]	0.1 – 60	2
	When vessel filling stops, pump output falls from maximum to zero during the time selected here.			
43	Arterial vessel filling, max. pump pressure	[mbar]	0 – 1000	800
	This pressure must never be exceeded during filling, or it will be aborted with error.			
44	Arterial vessel filling, minimum system deviation for end of filling	[mbar]	0 – 200	20
	Only with pressure control: If the control deviation during the time of PAR 45 is smaller than this value, filling will stop.			
45	Arterial vessel filling, time with minimum system deviation for end of filling	[100ms]	0 – 600	20
	Only with pressure control: If the control deviation during this time is smaller than PAR 45, filling will stop			
46	Arterial vessel filling, premature switchoff with volume control	[ml]	0 – 200	0
	Only with stopping by volume: Filling stops at setpoint minus PAR 46.			
50	Venous vessel filling, bleed time	[100ms]	0 – 300	10
	The venous line is bled for the period of time selected here before filling takes place. Bleeding reduces the pressure built up during pre-filling so filling of the body can start correctly with zero pressure.			
51	Venous vessel filling, ramp time increasing	[sec]	0.1 – 60	20
	When vessel filling starts, pump output increases from zero to the maximum necessary output during the time selected here.			
52	Venous vessel filling, ramp time decreasing	[sec]	0.1 – 60	2
	When vessel filling stops, pump output falls from maximum to zero during the time selected here.			
53	Venous vessel filling, max. pump pressure	[mbar]	0 – 1000	800
	This pressure must never be exceeded during filling, or it will be aborted with error.			
54	Venous vessel filling, minimum system deviation for end of filling	[mbar]	0 – 200	20
	Only with pressure control: If the control deviation during the time of PAR 45 is smaller than this value, filling will stop.			
55	Venous vessel filling, time with minimum system deviation for end of filling	[100ms]	0 – 600	20
	Only with pressure control: If the control deviation during this time is smaller than PAR 55, filling will stop			

No.	Meaning	Unit	Value range	Current value
56	Venous vessel filling, premature switchoff with volume control	[ml]	0 – 200	0
	Only with stopping by volume: Filling stops at setpoint minus PAR 56.			
60	Arterial circulation, maximum circulation time	[100ms]	1 – 12000	6000
	Reserve.			
61	Arterial circulation, ramp time increasing	[sec]	0.1 – 60	5
	When circulation starts, pump output increases from zero to the maximum necessary output during the time selected here.			
62	Arterial circulation, ramp time decreasing	[sec]	0.1 – 60	1
	When circulation stops, pump output falls from maximum to zero during the time selected here.			
63	Arterial circulation, max. pump pressure	[mbar]	0 – 1000	800
	This pressure must never be exceeded during circulation, or it will be aborted with error.			
64	Arterial circulation, minimum system deviation for end of circulation	[mbar]	0 – 200	20
	Only with pressure control: If the control deviation during the time of PAR 65 is smaller than this value, circulation will stop.			
65	Arterial circulation, time with minimum system deviation for end of circulation	[100ms]	0 – 600	20
	Only with pressure control: If the control deviation during this time is smaller than PAR 65, circulation will stop.			
66	Arterial circulation, premature switchoff with volume control	[ml]	0 – 200	0
	Only with stopping by volume: Circulation stops at setpoint minus PAR 66.			
70	Arterial filling: Flow rate ml/min [ml/min]	[100ms]	100 – 1400	800
	Factory preset. Loaded to angio parameter screen with every new angio.			
71	Arterial filling: Flow rate	[ml/sec]	1.5 – 24	13.3
	Factory preset. Loaded to angio parameter screen with every new angio.			
72	Arterial filling: Total volume	[ml]	05 – 10,000	1200
	Factory preset. Loaded to angio parameter screen with every new angio.			
75	Venous filling: Flow rate	[ml/min]	100 – 1400	800
	Factory preset. Loaded to angio parameter screen with every new angio.			
76	Venous filling: Flow rate	[ml/sec]	1.5 – 24	13.3
	Factory preset. Loaded to angio parameter screen with every new angio.			
77	Venous filling: Total volume	[ml]	05 – 10,000	1800
	Factory preset. Loaded to angio parameter screen with every new angio.			
80	Art. circulation: Flow rate	[ml/min]	100 – 1400	200
	Factory preset. Loaded to angio parameter screen with every new angio.			
81	Art. circulation: Flow rate	[ml/sec]	1.5 – 24	8.3
	Factory preset. Loaded to angio parameter screen with every new angio.			

No.	Meaning	Unit	Value range	Current value
82	Art. circulation: Total volume	[ml]	05 – 10,000	500
	Factory preset. Loaded to angio parameter screen with every new angio.			
90	Set filling volume	[ml]	50 – 1000	200
	Factory preset. Loaded to angio parameter screen with every new angio.			
91	Quantity of Angiofil in paraffin	[%]	0 – 100	6
	Factory preset. Loaded to angio parameter screen with every new angio.			

6 Maintenance

6.1 Maintenance interval



Note

The device must be serviced regularly. The following table lists the intervals and responsibilities for the maintenance work required.

If you have any problems or queries, please contact us directly using the following address:

FUMEDICA AG

Division Postmortem-Angio

Luzernerstrasse 91

5630 Muri, Switzerland

Tel.: +41 (0) 56 675 91 00

Fax: +41 (0) 56 675 91 09

E-mail: info@postmortem-angio.ch

Web: www.postmortem-angio.ch

Interval	Maintenance	Responsible
Before every use	• Visual inspection of device and accessories	→ User
Yearly	• Functional checks, poss. compressor oil change (see instructions for use of compressor)	→ Technician

6.1.1 Visual inspection of device

Check device for following damage/defects:

- Brakes on castors functioning
- Power connection and mains cable not damaged

6.1.2 Functional check

- Switch on device
- Start display appears

6.2 Cleaning



- ▲ Unplug the device from the mains before cleaning.
 - ▲ Do not use phenol-based cleaning products or peroxide compounds.
 - ▲ Do not use harsh cleaning products or scouring agents.
-

6.2.1 Clean housing

- Wipe down the surface of the device with a cloth moistened with disinfectant or cleaning solution (alcohol 70%). When doing so, no fluid should be allowed to enter the device.

6.2.2 Clean touch screen

- Wipe down the surface of the device with a cloth moistened with a mild cleaning solution. When doing so, no fluid should be allowed to enter the device.

6.2.3 Accessories and consumables



- ▲ Always use spare parts and consumables supplied by FUMEDICA AG or products approved by FUMEDICA AG Division Postmortem-Angio. Failure to comply with this instruction may be extremely dangerous and/or render the guarantee null and void.
-

All consumables and accessories for the Virtangio machine are available from your FUMEDICA AG agent.

A full list of all FUMEDICA AG agencies can be found on the FUMEDICA AG website (www.fumedica.com). If you have any problems, please get in touch with our HQ in Switzerland direct. Our staff would be delighted to help you at all times with any queries or concerns you might have.

6.3 Transport



- ▲ Do not leave device standing on or in front of ramps.
- ▲ Only ever negotiate steep ramps slowly and accompanied by a second person. The device weighs 88 kg.

When moving the device about indoors, release the parking brakes on the device. The device can now be moved about with little physical effort.

Engage the parking brakes at your destination to prevent the device from accidentally rolling away.

6.4 Disposal at end of working life



At the end of its working life you are obliged to collect the device separately and dispose of it via your local return and collection systems.

If you have no local return and collection system, you can send the device back to the distributor or manufacturer, who will then dispose of it properly. In this way you can contribute towards recycling, recovery and other methods of reusing electrical and electronic waste.

Failure to effect proper disposal presents a risk to the environment and human health due to the presence of hazardous substances in electrical and electronic equipment.

7 Technical data



Unless specified otherwise, the data relates to a temperature of 25°C.

7.1 System data

Manufacturer	FUMEDICA AG
Name of device	Virtangio® machine
Dimensions	1660 x 730 x 500 mm (h x w x d)
Weight	88 kg
Degree of housing protection	IP42
Power supply	200...240 VAC 50 Hz
Power consumption max.	350 VA at 230 VAC
Ambient conditions	
Operating temperature	• 0... 70°C at a relative humidity of 0...95% (non-condensing) • Air pressure 500...1060 hPa
Storage and transport temperature	• -20...70°C at a relative humidity of 0...95% (non-condensing) • Air pressure 700...1060 hPa
Safety standards	• EN/ISO 14421-1 • EN/ISO 12100-1/-2 • EN/ISO 13849-1 • EN/ISO 13850 • EN/ISO 60204-1 • EN/ISO 4414
EMC	• 2004/108/EC
Low Voltage Directive	• 2006/95/EC
Conformity	CE acc. to Machinery Directive 2006/42/EC Annex I

7.1.1 WLAN standards

Transmission standard	• IEEE 802.11b • IEEE 802.11g
Encryption	WPA, WPA2, WEP

7.1.2 Compressor data

Pressure vessel	1.5 litres
Max. pressure	6 bar/ 87 psi
Type of oil	Rolodex-Sitcom/32E

7.1.3 Contrast medium

Trade name	Angiofil®
Chemical composition	ester of iodized fatty acid
Colour	yellowish
Flash point	> 110°C
Relative density at 20°C	approx. 1.37

7.2 Minimum requirements for remote PC

Processor

2.8 GHz, 512 MB RAM

Hard disk

250 GB

USB port

2

WLAN Wi-Fi

Yes
