

AmoVes 200 Phantom System

English Translation of the Original Operating Manual

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1 General information

This original operating manual for the **AmoVes 200** phantom system contains all the necessary information for the safe and intended use of the phantom and its accessories.

During this activity, observe the following safety instructions:



WARNING

Failure to observe the original operating manual and the safety information of the phantom system and the accompanying pump!

Injury of personnel and damage to the product.

- Carefully read through the entire original operating manual before assembling and using the phantom system. The original operating manual contains important information concerning use.
- Only use the phantom system in the way described in this original operating manual.
- Keep the original operating manual together with the phantom system for reference.

1.1 Intended use

Many angiography devices provide useful additional functions. These additional functions often remain unused in clinical routine because the medical personnel do not have the expertise to use these functions correctly.

AmoVes 200 has been developed to demonstrate and provide training in the functions of angiography systems. It enables targeted training and further education of medical personnel in the use of angiography systems. Users can familiarize themselves with the technical possibilities of their system before examining and treating human patients.

AmoVes 200 can be used for the following applications:

- **Projectional radiography imaging techniques** of the vascular system using fluoroscopy (FL), digital radiography (DR), or digital subtraction angiography (DSA)
- **Three-dimensional imaging techniques** of the vascular system using rotational angiography (3D-DSA) and C-Arm CT (CACT)
- **Image-based navigation techniques** based on projectional imaging (road-map functions, DSA overlay techniques), and volume imaging (3D-DSA, CACT)
- **Image-based registration techniques**
- **Software-based assistance solutions** for procedural workflows (**workflow solutions**)
- **Software-based assistance solutions** for **needle placement**.

During this activity, observe the following safety instructions:



CAUTION

Improper use!

Injury of personnel or the patient and damage to the product.

- The phantom system is not a medical device. Only use the phantom system in the way described in this original operating manual.
- Only use the phantom system for demonstration and training purposes.

**CAUTION**

Improper use!

Injury due to metal projectiles and damage to the product.

- The phantom system has been developed for use in angiography devices and contains metal components. Do not use the phantom system in magnetic resonance imaging systems (MRI). Pre-existing image data were created using an MRI-compatible variant of the phantom system.
-

**CAUTION**

Unauthorized modification of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not modify the phantom system in any way. Any modification whatsoever is impermissible and could compromise the safety of the system.
-

1.2 Users

The phantom system must exclusively be sold, distributed or provided to and used only by persons of legal age with professional technical or medical education.

The user must have sufficient language skills to completely read and understand the original operating manual before first assembling and operation.

Observe the following safety instruction:

**CAUTION**

Improper use!

Injury of personnel or the patient and damage to the product.

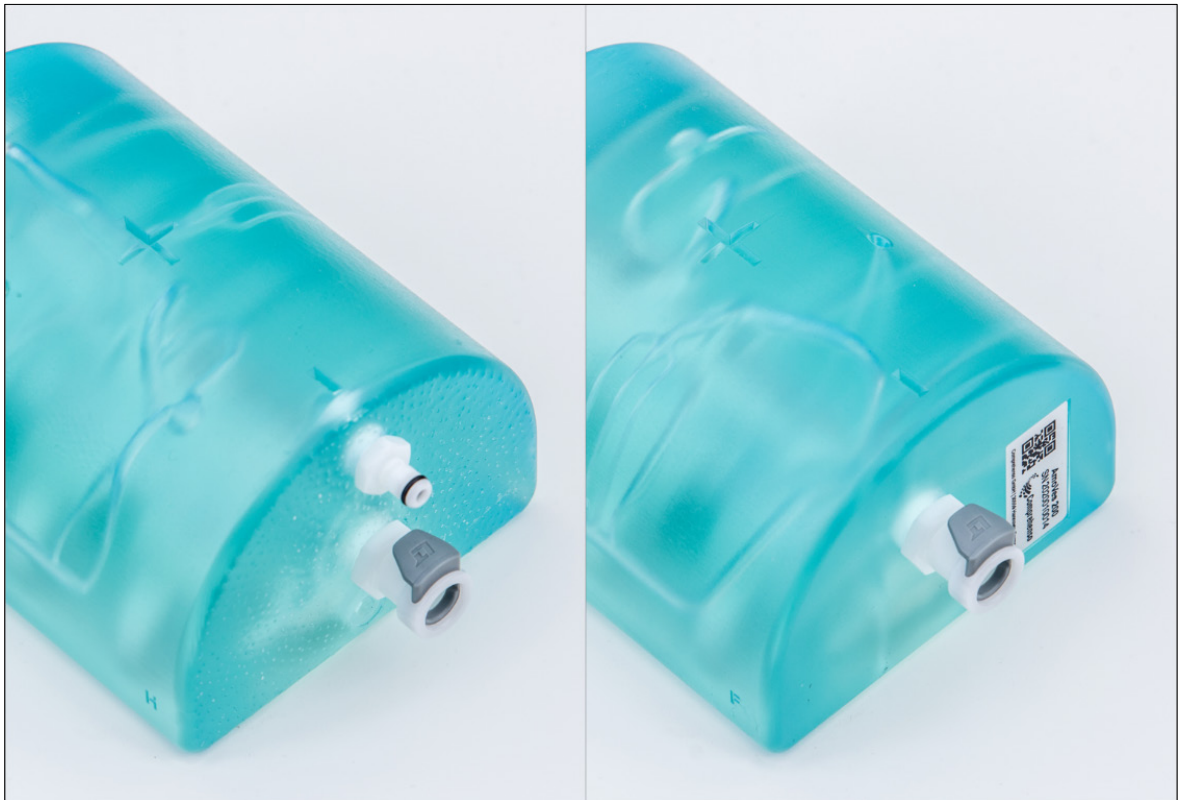
- The phantom system must only be used by persons of legal age with professional technical or medical education.
 - The phantom system may be used by persons of reduced physical, sensory, or mental ability, or persons with a lack of experience and/or knowledge as long as they are supervised or instructed in safe use of the phantom system and have understood the resulting risks.
 - Keep the phantom system and its accessories out of the reach of children.
-

1.3 Product description

The central element of the **AmoVes 200** phantom system is the **phantom body**. The phantom system has been developed for the use of **imaging, navigation, and registration techniques** in angiography.

The phantom body is manufactured by 3D printing of single units. Liquid can flow through the vascular tree located inside the phantom body via circulation sockets at the head end and foot end. An integrated contrast media injection system provides a simple way of adding contrast.

Phantom body: View of the head end and foot end



Contrast medium plug and circulation sockets at the head end and foot end.

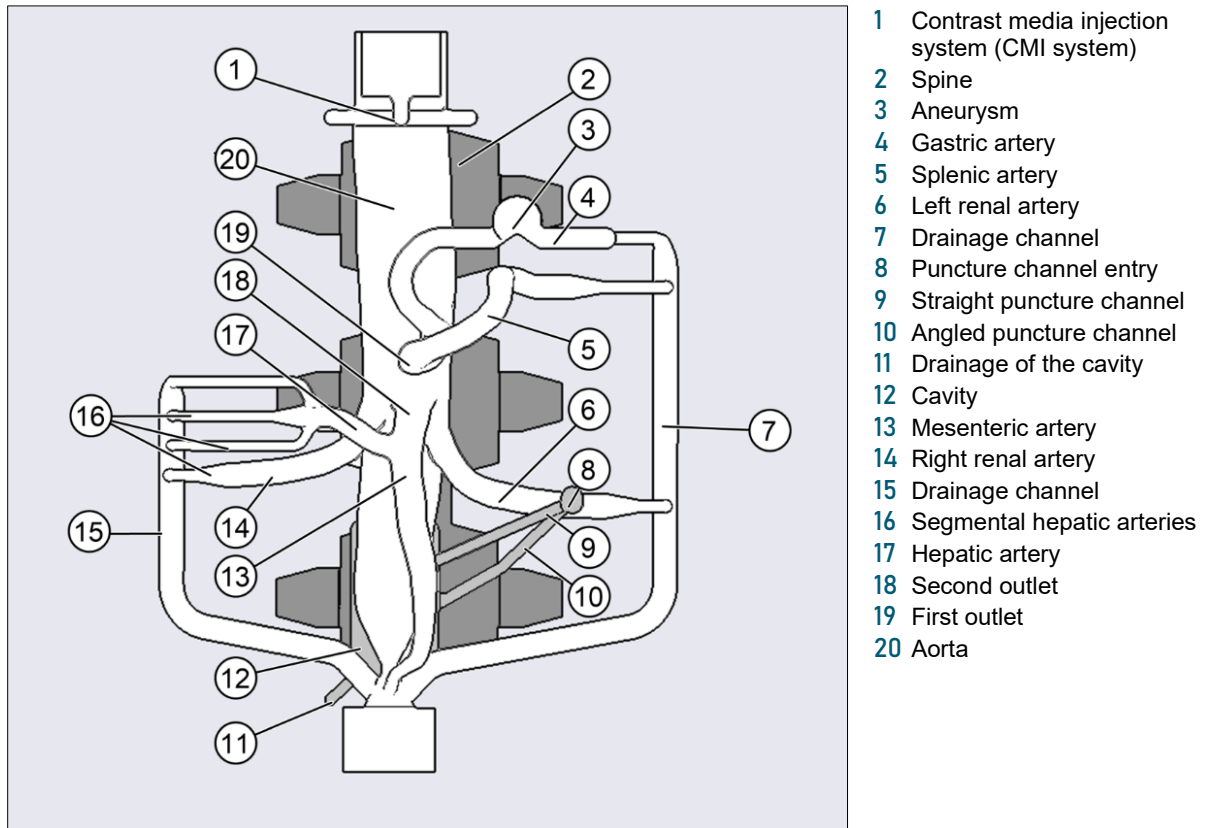
The pump supplied with the phantom system pumps water from the circulation reservoir of the phantom system through the short circulation tube and the inflow socket into the aorta of the phantom body. The vascular structure and the pump time volume have been dimensioned in such a way as to ensure that the liquid is distributed evenly to the aorta and its branches. The water flows out of the vascular branches through the drainage channels back into the aorta from where it passes through the outflow socket and the long circulation tube back into the circulation reservoir.

A contrast media injection system (CMI system) is integrated into the upper part of the aorta. The CMI system provides a simple way of perfusing the vascular tree with iodine-based contrast medium. If contrast medium is injected via the contrast medium injection tube (CMI tube), the contrast medium is distributed directly into and approximately homogeneously throughout the vascular system. It is therefore not necessary to insert a vessel catheter and this is not intended. In order to save using liquid iodine-based contrast medium, ambient air can also be used as a negative contrast medium.

A **stylized spine** is integrated into the phantom body, which provides contrast in fluoroscopy, computed tomography, and magnetic resonance imaging (T2 weighting). With this spine, it is possible to use registration techniques. For this purpose, DICOM datasets and DICOM series of different modalities are provided for the phantom system. Depending on the functional scope of your angiography device, the DICOM data can be registered and fused or overlaid with the images of the phantom body.

The phantom body provides two predefined puncture channels for **navigation-based needle placement techniques**. They cannot be used to learn how to puncture tissue but can be used to demonstrate correct needle alignment in imaging and for learning routine application of software-based assistance solutions.

Internal structure of the phantom body as seen from the front



Proper assembly and operation as well as **correct care** are essential to the unrestricted functioning of the phantom system. The vascular tree hidden inside the phantom body is protected from contrast medium deposits and microbial contamination by rinsing and disinfection techniques.

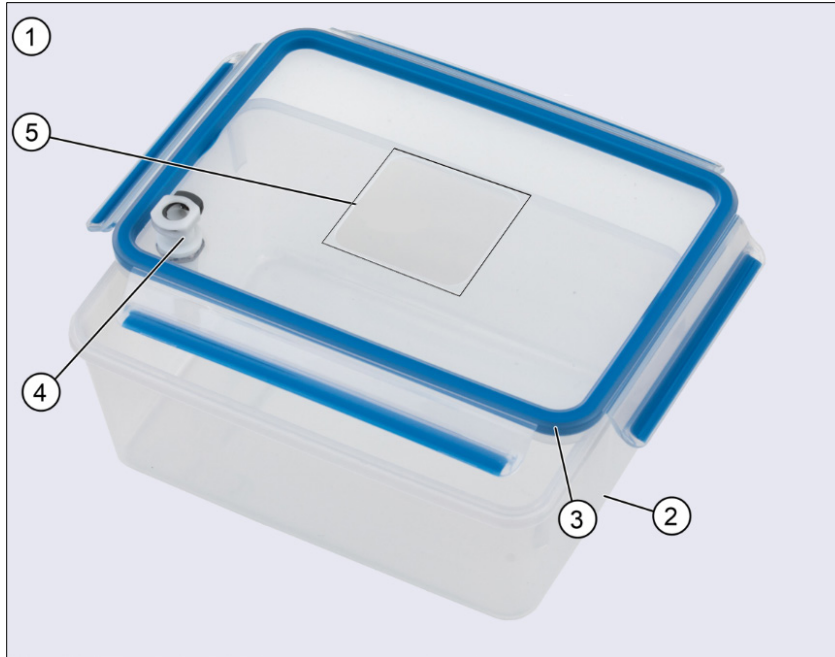
To use the phantom system, the **set of consumables** is required. This is either supplied with the phantom system or available separately.

1.4 Scope of delivery

The scope of delivery of the AmoVes 200 phantom system contains the following:

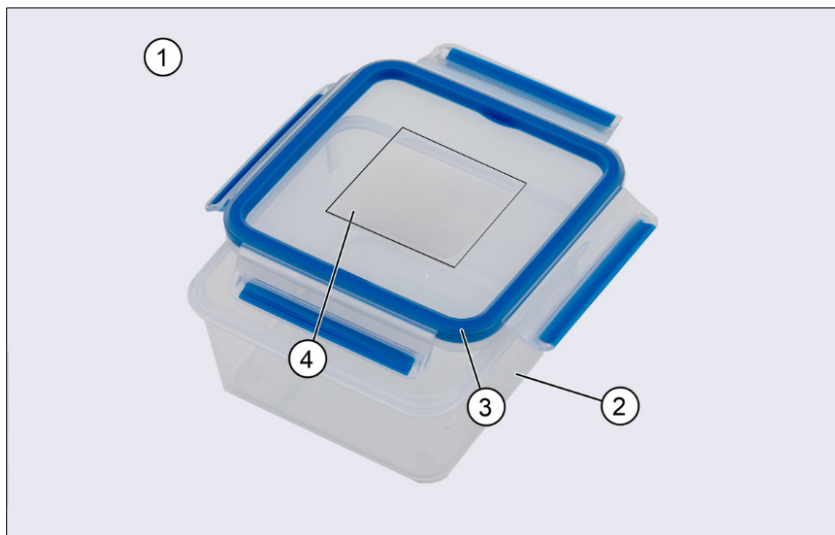
1.4.1 Reservoirs

Circulation reservoir



- 1 Circulation reservoir
- 2 Circulation tank
(Volume: 3.7 l / 125 fl oz)
- 3 Reservoir lid
- 4 Return flow socket
of reservoir
- 5 Center opening of the
reservoir lid (for the pump
tube and the power cable
of the pump)

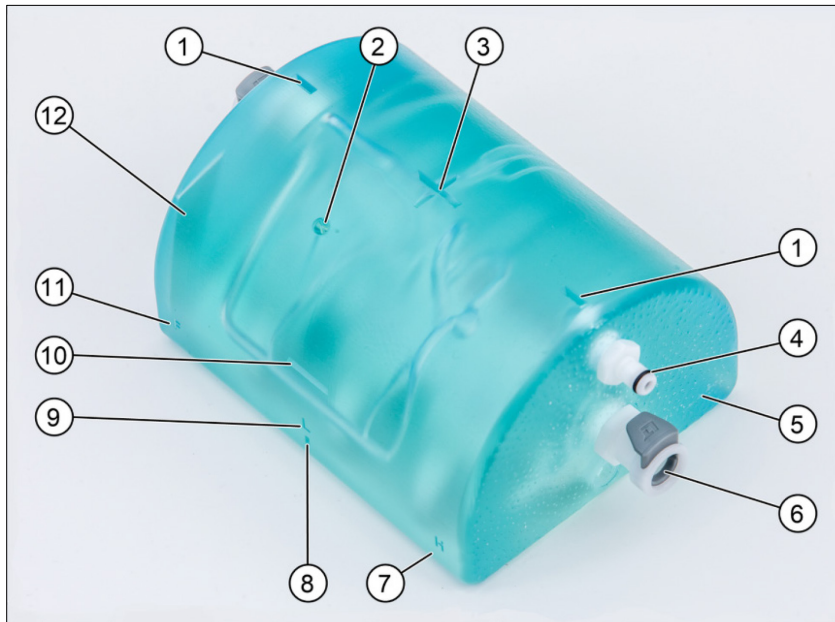
Cleaning reservoir



- 1 Cleaning reservoir
- 2 Cleaning tank
(Volume: 1.3 l / 44 fl oz)
- 3 Reservoir lid
- 4 Center opening of the lid
(for ventilation)

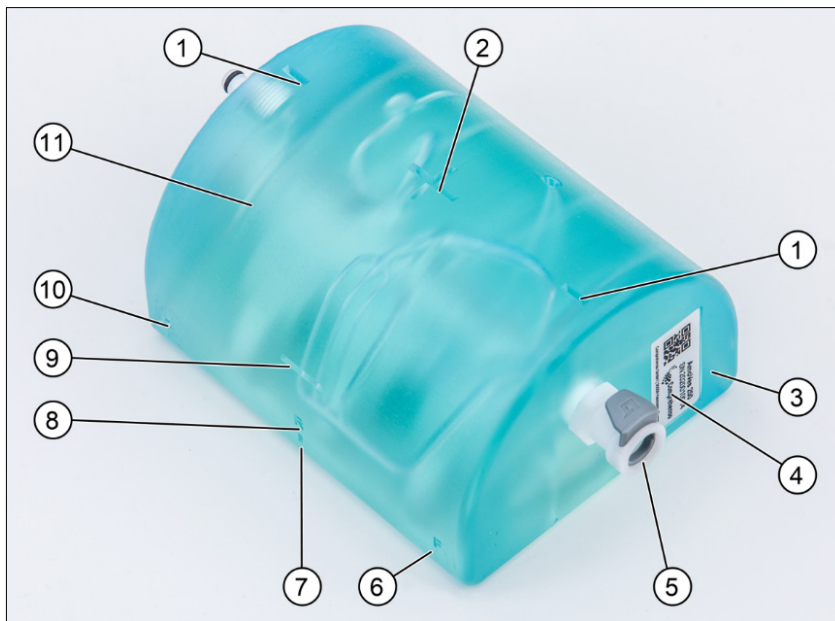
1.4.2 Phantom body

View of the phantom body head end



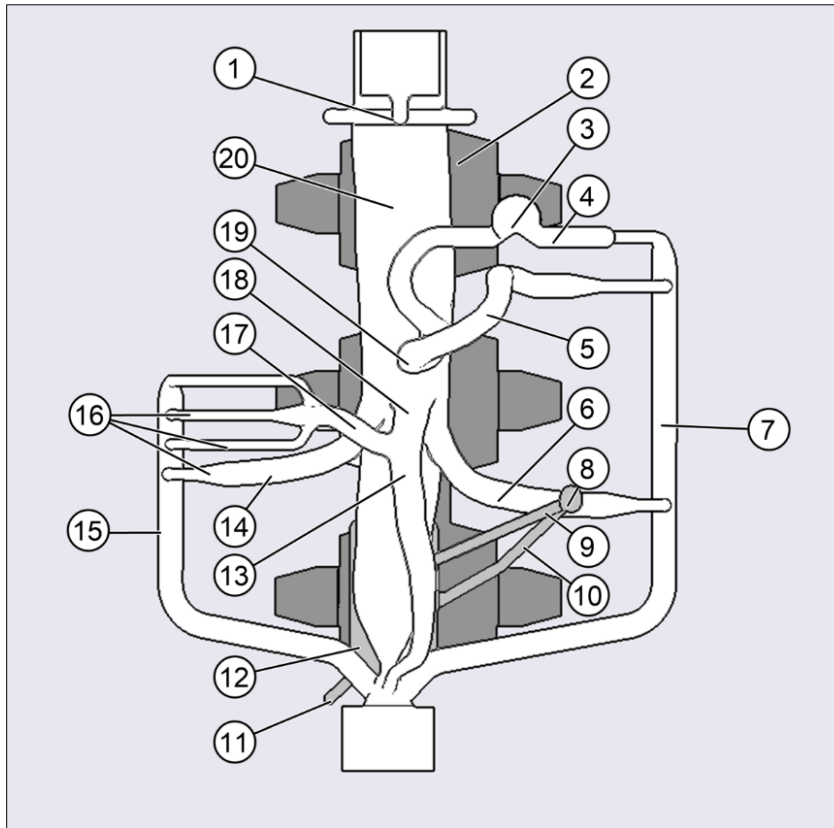
- 1 Center-line indicator
- 2 Puncture channel entry
- 3 Center position indicator
- 4 Contrast medium plug
- 5 Head end of phantom
- 6 Head-end circulation socket
- 7 Alignment indicator **H** (toward head)
- 8 Vertical position indicator
- 9 Alignment indicator **L** (left)
- 10 Horizontal position indicator
- 11 Alignment indicator **F** (toward feet)
- 12 Convex surface of phantom body

View of the phantom body foot end



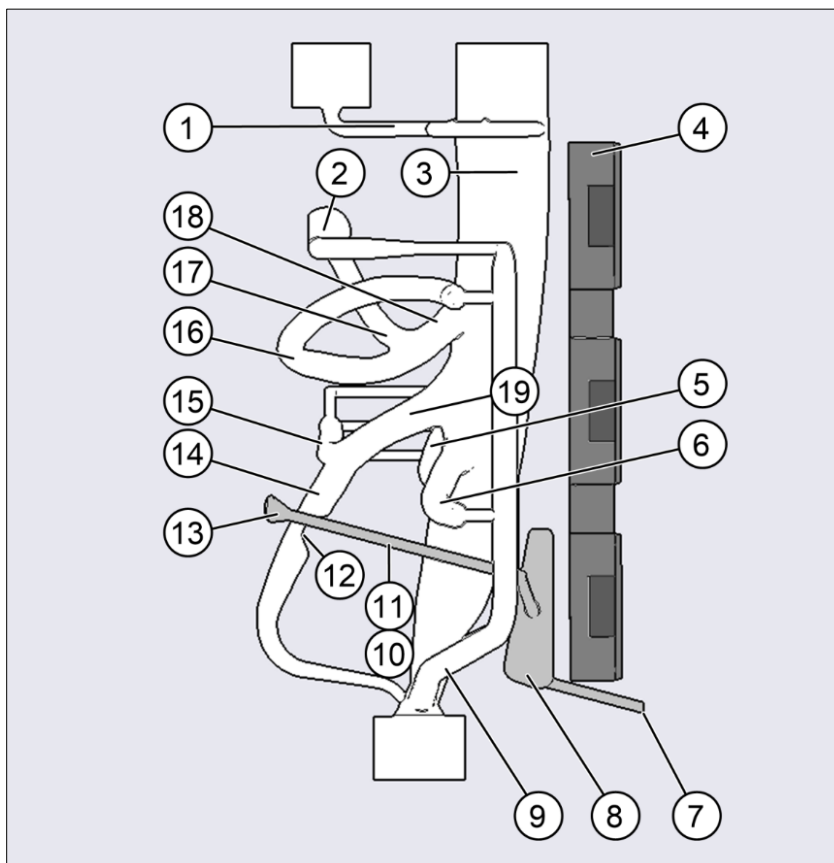
- 1 Center-line indicator
- 2 Center position indicator
- 3 Foot end of phantom
- 4 Type plate
- 5 Foot-end circulation socket
- 6 Alignment indicator **F** (toward feet)
- 7 Vertical position indicator
- 8 Alignment indicator **R** (right)
- 9 Horizontal position indicator
- 10 Alignment indicator **H** (toward head)
- 11 Convex surface of phantom body

Internal structure of the phantom body as seen from the front



- 12 Contrast media injection system (CMI system)
- 13 Spine
- 14 Aneurysm
- 15 Gastric artery
- 16 Splenic artery
- 17 Left renal artery
- 18 Drainage channel
- 19 Puncture channel entry
- 20 Straight puncture channel
- 21 Angled puncture channel
- 22 Drainage of the cavity
- 23 Cavity
- 24 Mesenteric artery
- 25 Right renal artery
- 26 Drainage channel
- 27 Segmental hepatic arteries
- 28 Hepatic artery
- 29 Second outlet
- 30 First outlet
- 31 Aorta

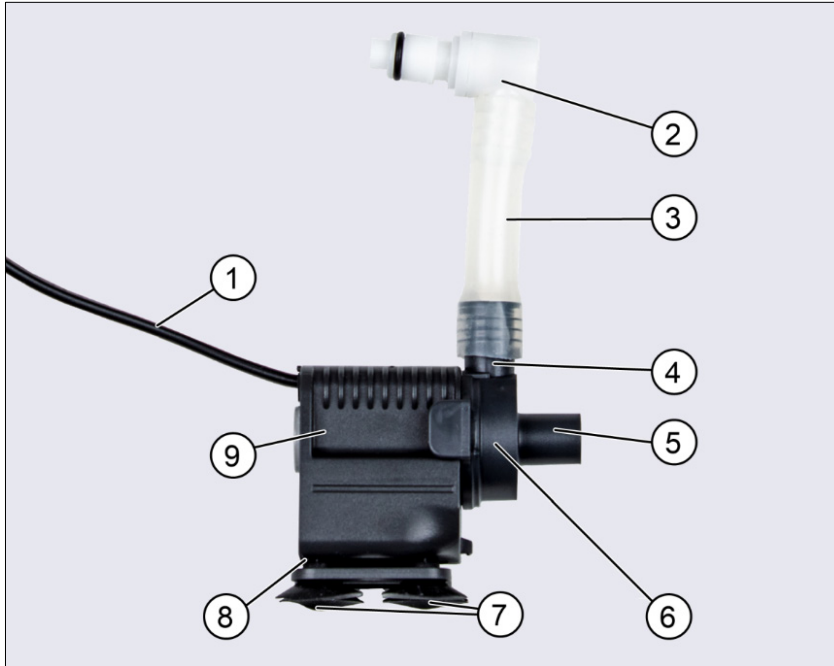
Internal structure of the phantom body as seen from the left side



- 1 Contrast media injection system (CMI system)
- 2 Aneurysm
- 3 Aorta
- 4 Spine
- 5 Right renal artery
- 6 Left renal artery
- 7 Drainage of the cavity
- 8 Cavity
- 9 Drainage channel
- 10 Straight puncture channel
- 11 Angled puncture channel
- 12 Stenosis
- 13 Puncture channel entry
- 14 Mesenteric artery
- 15 Hepatic artery
- 16 Splenic artery
- 17 Gastric artery
- 18 First outlet
- 19 Second outlet

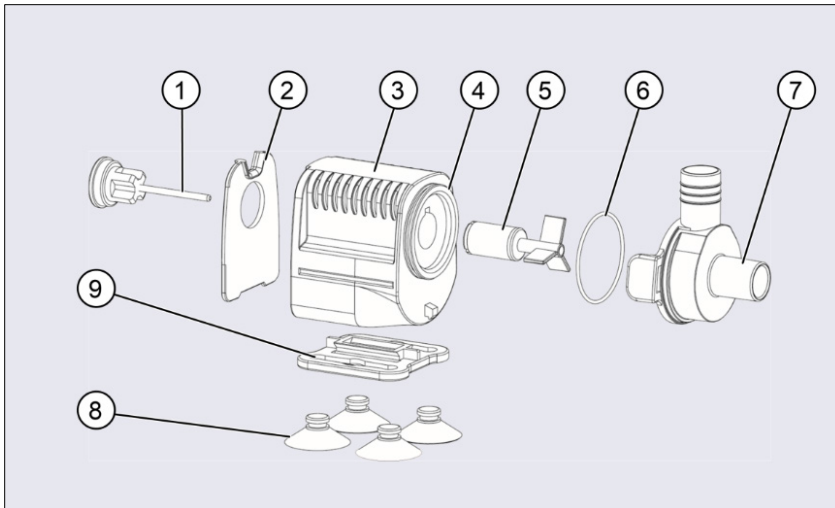
1.4.3 Pump

Pump (with pump tube connected)



- 1 Power cable
- 2 Pump tube plug
- 3 Connection tube
- 4 Pump outflow pipe
- 5 Pump inflow pipe
- 6 Antechamber
- 7 Suction cups
- 8 Baseplate
- 9 Pump housing

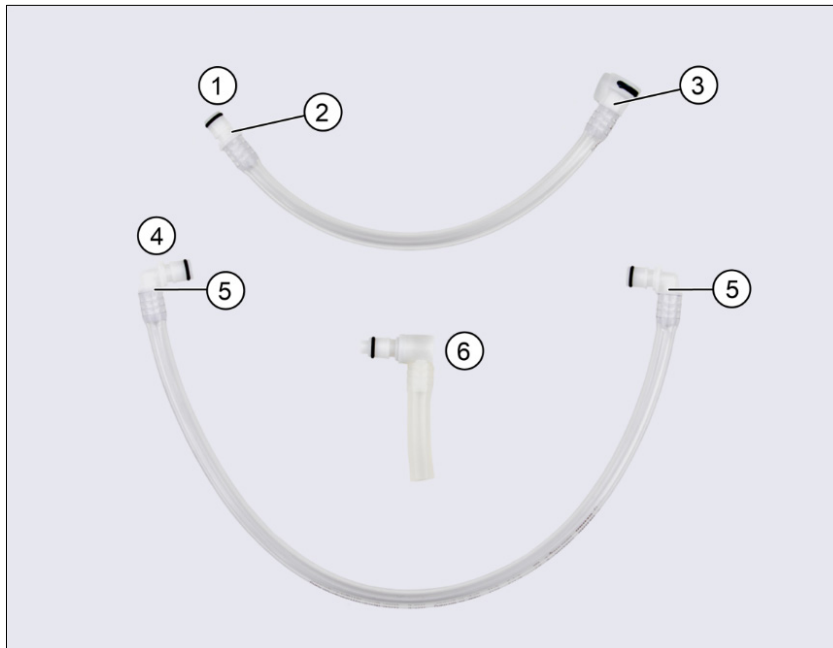
Individual parts of the pump



- 1 Axle
- 2 Cover
- 3 Pump housing
- 4 Slot for O-ring
- 5 Rotor
- 6 O-ring
- 7 Antechamber
- 8 Suction cups
- 9 Baseplate

1.4.4 Tubes

Tubes



- 1 Short circulation tube
- 2 Outflow plug
- 3 Inflow socket
- 4 Long circulation tube
- 5 Right-angled plug
- 6 Pump tube

1.4.5 Transportation case

Transportation case open, showing phantom and circulation reservoir

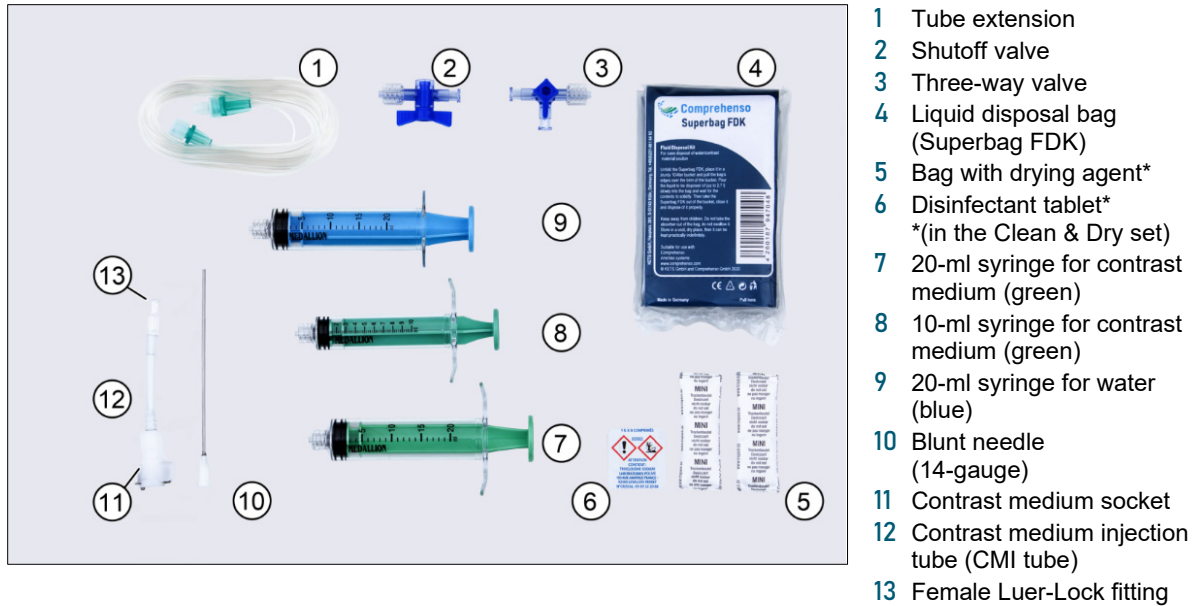


- 1 Transportation case
- 2 Recess for phantom (with phantom)
- 3 Recess for reservoir (with circulation reservoir)
- 4 Device card (not shown, see 12.3)

1.4.6 Set of consumables

A starter set of consumables is supplied with the phantom system in a separate pack. It can also be purchased separately through your dealer. The composition and number of components of the set of consumables may vary.

Components of the set of consumables



- 1 Tube extension
- 2 Shutoff valve
- 3 Three-way valve
- 4 Liquid disposal bag (Superbag FDK)
- 5 Bag with drying agent*
- 6 Disinfectant tablet*
*(in the Clean & Dry set)
- 7 20-ml syringe for contrast medium (green)
- 8 10-ml syringe for contrast medium (green)
- 9 20-ml syringe for water (blue)
- 10 Blunt needle (14-gauge)
- 11 Contrast medium socket
- 12 Contrast medium injection tube (CMI tube)
- 13 Female Luer-Lock fitting



In order to operate the phantom, you require the set of consumables, which is either provided or available as a spare part.

The consumables are suitable for multiple use. After they have been used for several days, they should be replaced.

Replace the CMI tube if the Luer-Lock fitting is leaking or broken, or the tube or its plug connection are leaking.

2 Safety instructions

To make safe use of the phantom system possible and ensure the safety of persons, the following warning and safety instructions must be observed.

Safety instructions are provided both in this chapter on safety and within the context of each potentially dangerous situation. Always read the safety instructions in the context of the current situation in order to ensure that you have understood them fully.

WARNINGS and **CAUTIONS** are indicated as follows in the text:



WARNING

A warning in this original operating manual means that death or serious injury can occur if the warnings are not observed.



CAUTION

A caution in this original operating manual means that moderate injury can occur if the cautions are not observed.

The warnings and cautions are structured as follows:



WARNING

Description of the hazardous situation: Formation of toxic gases due to improper mixing of liquids!

Description of the danger: Danger to life.

- **Description of the measures to avoid the danger:** Never mix disinfectants and descaling solution, as toxic gases can form.
-

2.1 General safety instructions

To ensure safe operation of the phantom system, its owner must make sure that everyone who uses the phantom system has read and understood that content of this original operating manual. The original operating manual contains safety instructions relevant to the user.

Observe the following general safety instructions.



WARNING

Failure to observe the original operating manual and the safety information of the phantom system and the accompanying pump!

Injury of personnel and damage to the product.

- Carefully read through the entire original operating manual before assembling and using the phantom system. The original operating manual contains important information concerning use.
- Only use the phantom system in the way described in this original operating manual.
- Keep the original operating manual together with the phantom system for reference.



CAUTION

Improper use!

Injury of personnel or the patient and damage to the product.

- The phantom system must only be used by persons of legal age with professional technical or medical education.
- The phantom system may be used by persons of reduced physical, sensory, or mental ability, or persons with a lack of experience and/or knowledge as long as they are supervised or instructed in safe use of the phantom system and have understood the resulting risks.
- Keep the phantom system and its accessories out of the reach of children.



CAUTION

Improper use!

Injury of personnel or the patient and damage to the product.

- The phantom system is not a medical device. Only use the phantom system in the way described in this original operating manual.
- Only use the phantom system for demonstration and training purposes.



CAUTION

Improper use!

Injury due to metal projectiles and damage to the product.

- The phantom system has been developed for use in angiography devices and contains metal components. Do not use the phantom system in magnetic resonance imaging systems (MRI). Pre-existing image data were created using an MRI-compatible variant of the phantom system.

2.2 Safety instructions for assembly and disassembly and for initial start-up

Observe the following safety instructions when assembling and disassembling and during initial start-up of the phantom system.



CAUTION

Escaping liquids!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Always protect the detector and the X-ray tube of the angiography device with a waterproof cover when you use the phantom system with liquids.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when you use the phantom system with liquids.
- Always assemble and disassemble the phantom system in the sequence described in the original operating manual to avoid water or contrast medium escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping liquids could damage electrical devices located in the vicinity, e. g. the angiography device.
- Do not tilt or cradle the tabletop of the angiography system when you use the phantom system with liquids. Water could spill out of the center opening of the reservoir lid.



CAUTION

Components of the phantom system within the travel range of the C-Arm.

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- When assembling and operating the phantom system, make sure that the electric cable of the pump, the circulation tubes, and the contrast media supply tube are outside the travel range of the C-Arm.
- Always position the phantom body on the side nearer the C-Arm and the circulation reservoir on the side nearer the angiography table stand. In that way, the electric cable of the pump, the circulation tubes, and the contrast media supply tube can be safely routed outside the travel range of the C-Arm.
- If necessary, secure the cables and tubes on the angiography table to prevent them colliding with the moving parts of the angiography table.
- Make sure that no strain is placed on cables and tubes when the C-Arm or patient table is moved, as movements by the angiography device could result in damage to the phantom system.

2.3 Safety instructions for operation

Observe the following safety instructions when operating the phantom system.



CAUTION

Unnoticed malfunctions!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Only operate the phantom system under constant supervision.



CAUTION

Unauthorized modification of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not modify the phantom system in any way. Any modification whatsoever is impermissible and could compromise the safety of the system.

2.3.1 Safety instructions for operation of the pump

Observe the following safety instructions when you operate the pump of the phantom system.



WARNING

Incorrect operating voltage or damage to the pump or cable!

Electric shock and damage to product.

- Make sure that the operating voltage specified on the type plate of the pump corresponds to the local supply voltage.
- Make sure that the pump is protected by means of a residual-current device (RCD) with a rated residual current of maximum 30 mA.
- Before use, check the pump and power cable for any visible signs of damage.
- If damage is found, do not use the pump but replace it.



WARNING

Improper cabling of the phantom system!

Electric shock!

- Always bring the power supply to the pump using a safety approved single plug extension cable not exceeding a total length of 25m (82 ft).
- Make sure that the amperage rating of the extension cable is not lower than the maximum amperage limited either by the circuit breaker or the fuse from the supplying socket outlet.
- Always connect the pump power plug to the extension cable on the tabletop.

**WARNING**

Moisture on the cable or power plug of the pump!

Electric shock or burns due to short-circuit current.

- Always keep the power cable of the pump dry.
 - When routing the cable always form a drip loop in front of the plug connection between the power plug and extension cable so that the power plug of the pump or the plug connection does not accidentally become wet.
 - If the power connector of the pump does accidentally become wet, disconnect the power supply before touching the power cable and power plug.
 - Do not start up the pump again until the power cable and power plug are completely dry.
-

**WARNING**

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Do not connect the pump to the power supply until the phantom system has been fully assembled.
-

**WARNING**

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Always disconnect the power supply of the pump before performing one of the following tasks:
 - placing your hand in the water of the circulation reservoir
 - disassembling the phantom system
 - taking apart or cleaning the pump
 - replacing parts of the pump
 - Always disconnect the power supply of the pump if liquid escapes from the phantom system.
-

**CAUTION**

Excessive strain on power cable!

Injury of personnel and damage to the product.

- During assembly and disassembly and maintenance, hold the pump by its housing and not by the power cable.
-

2.3.2 Safety instructions for operation with contrast media

Observe the following safety instructions when operating the phantom system with contrast medium.



CAUTION

Improper disposal of contrast medium solutions!

Contamination of the environment.

- Use the liquid disposal bags included in the set of consumables for environmental disposal.
 - Observe your local regulations regarding the disposal of contrast medium solutions.
-

2.3.3 Safety instructions regarding the use of the puncture channels

Observe the following safety instructions when using the puncture channels of the phantom body.



CAUTION

Improper use!

Injury of personnel and damage to the product.

- Insert only the blunt needles (with a maximum diameter of 14G), available as accessories, or soft, flexible wires into the puncture channel of the phantom body.
 - Do not insert any sharp needles or wires into the puncture channel. They could injure the user or damage the phantom.
-

2.4 Safety instructions for care and maintenance

Observe the following safety instructions when caring for and maintaining the phantom system.



WARNING

Formation of toxic gases due to improper mixing of liquids!

Danger to life.

- Never mix disinfectants and descaling solution, as toxic gases can form.



CAUTION

Unprofessional repair of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not perform repairs yourself if the connections on the phantom system leak. Repairs must only ever be performed by the manufacturer.
- Defective parts must always be replaced with original parts. Components must only ever be repaired by qualified personnel. Do not perform repairs yourself but contact the manufacturer.

2.5 Safety instructions regarding transportation

Observe the following safety instructions when transporting and storing the phantom system.



CAUTION

Falling phantom body during movement or transportation!

Injury of personnel, damage to product, and further material damage.

- The phantom body is slippery when it is damp. Dry the exterior of the phantom body before moving or transporting it.
- Hold the phantom body securely with both hands when moving and transporting it.
- If the phantom body falls, it may be damaged or destroyed. Always transport the phantom body with the utmost care.
- Always check that the phantom body is still intact after it has fallen.
- The phantom system must not be used if it is damaged.

3 Assembly and initial start-up of the phantom system

During this activity, observe the following safety instructions:



CAUTION

Escaping liquids!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Always protect the detector and the X-ray tube of the angiography device with a waterproof cover when you use the phantom system with liquids.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when you use the phantom system with liquids.
- Always assemble and disassemble the phantom system in the sequence described in the original operating manual to avoid water or contrast medium escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping liquids could damage electrical devices located in the vicinity, e. g. the angiography device.
- Do not tilt or cradle the tabletop of the angiography system when you use the phantom system with liquids. Water could spill out of the center opening of the reservoir lid.



CAUTION

Unnoticed malfunctions!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Only operate the phantom system under constant supervision.

Initial start-up of the phantom system consists of the following work steps:

- *Assembling the pump and circulation reservoir*
- *Filling the circulation reservoir*
- *Assembling the circulation circuit*
- *Initial start-up of the pump*
- *Positioning and registering the phantom*
- *Priming the contrast media injection system*
- *Functional test of the contrast media injection system*



For *Registration of image data* or *Use of the puncture channels* you only need the phantom body. In this case, only *Positioning and registering the phantom* is required.

3.1 Assembling the pump and circulation reservoir

During this activity, observe the following safety instructions:



WARNING

Incorrect operating voltage or damage to the pump or cable!

Electric shock and damage to product.

- Make sure that the operating voltage specified on the type plate of the pump corresponds to the local supply voltage.
- Make sure that the pump is protected by means of a residual-current device (RCD) with a rated residual current of maximum 30 mA.
- Before use, check the pump and power cable for any visible signs of damage.
- If damage is found, do not use the pump but replace it.



WARNING

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Do not connect the pump to the power supply until the phantom system has been fully assembled.



CAUTION

Excessive strain on power cable!

Injury of personnel and damage to the product.

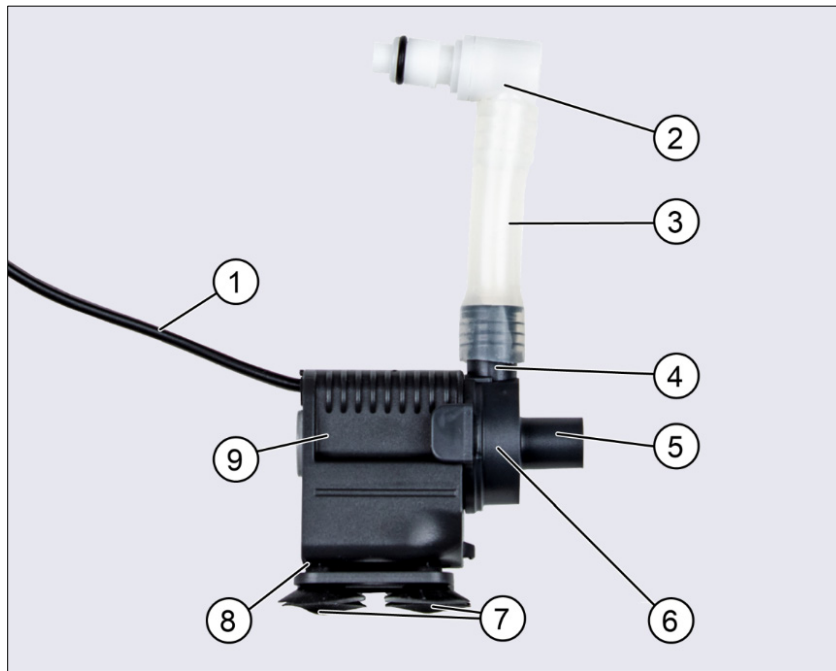
- During assembly and disassembly and maintenance, hold the pump by its housing and not by the power cable.



WORK STEPS

1. Secure the suction cups supplied with the phantom system to the baseplate.
2. Slide the baseplate onto the pump housing.
3. Plug the pump tube onto the upward facing pump outflow pipe so that it fits tightly.
4. Align the angled pump tube plug of the pump tube with the pump housing and the power cable.

Pump with pump tube connected



- 1 Power cable
- 2 Pump tube plug
- 3 Connection tube
- 4 Pump outflow pipe
- 5 Pump inflow pipe
- 6 Antechamber
- 7 Suction cups
- 8 Baseplate
- 9 Pump housing

5. Fasten the pump by means of the suction cups to the base of the circulation tank. Slightly moisten the suction cups for this. Position the pump so that the pump outflow pipe is located in the center of the circulation tank. Align the pump with pump tube plug with one of the long sides of the circulation tank. In the instructions that follow, this side will be called the *side nearest the phantom body*.
6. Route the power cable and the pump tube from inside the circulation reservoir through the center cutout in the lid and close the reservoir lid. Align the reservoir lid so that the return flow socket is located on the *side nearest the phantom body* of the circulation reservoir.

Circulation reservoir with pump



The arrow is pointing toward the phantom body/C-Arm.

3.2 Filling the circulation reservoir



PREPARATION

You have completed the following preparatory steps:



Assembling the pump and circulation reservoir



WORK STEPS

Fill 2.5 l (85 fl oz) of hand-warm tap water or distilled water through the center opening into the circulation reservoir.

Use the scale on the short side of the reservoir to measure the quantity of water.



The formation of gas bubbles in the vascular bed can be reduced by adding one drop of **dishwashing liquid** or **non-moisturizing liquid hand soap** to the water.

3.3 Assembling the circulation circuit

During this activity, observe the following safety instructions:



WARNING

Moisture on the cable or power plug of the pump!

Electric shock or burns due to short-circuit current.

- Always keep the power cable of the pump dry.
- When routing the cable always form a drip loop in front of the plug connection between the power plug and extension cable so that the power plug of the pump or the plug connection does not accidentally become wet.
- If the power connector of the pump does accidentally become wet, disconnect the power supply before touching the power cable and power plug.
- Do not start up the pump again until the power cable and power plug are completely dry.



CAUTION

Components of the phantom system within the travel range of the C-Arm.

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- When assembling and operating the phantom system, make sure that the electric cable of the pump, the circulation tubes, and the contrast media supply tube are outside the travel range of the C-Arm.
- Always position the phantom body on the side nearer the C-Arm and the circulation reservoir on the side nearer the angiography table stand. In that way, the electric cable of the pump, the circulation tubes, and the contrast media supply tube can be safely routed outside the travel range of the C-Arm.
- If necessary, secure the cables and tubes on the angiography table to prevent them colliding with the moving parts of the angiography table.
- Make sure that no strain is placed on cables and tubes when the C-Arm or patient table is moved, as movements by the angiography device could result in damage to the phantom system.



CAUTION

Falling phantom body during movement or transportation!

Injury of personnel, damage to product, and further material damage.

- The phantom body is slippery when it is damp. Dry the exterior of the phantom body before moving or transporting it.
- Hold the phantom body securely with both hands when moving and transporting it.
- If the phantom body falls, it may be damaged or destroyed. Always transport the phantom body with the utmost care.
- Always check that the phantom body is still intact after it has fallen.
- The phantom system must not be used if it is damaged.



PREPARATION

You have completed the following preparatory steps:

- ✓ The angiography table is covered with an absorbent underlay.
- ✓ *Assembling the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*



In order to operate the phantom, you require the set of consumables, which is either provided or available as a spare part.

The consumables are suitable for multiple use. After they have been used for several days, they should be replaced.

Replace the CMI tube if the Luer-Lock fitting is leaking or broken, or the tube or its plug connection are leaking.



WORK STEPS

1. Place the reservoir on the side of the absorbent underlay that is closest to the table stand.
2. Route the power cable of the pump on the angiography table toward the table stand **without connecting the power supply**.
3. Place a watertight object beneath it, for example, an armrest. In this way, you form a drip loop. If liquid runs along the cable, the drip loop will form an obstacle for water drops (blue water drop).

Assembled phantom system with pump and drip loop (arrow)



4. Place the phantom body on the side of the absorbent underlay nearest the C-Arm.
5. Align the head end of the phantom body with the reservoir. The head end of the phantom body is marked at the side with the alignment indicator **H**.

6. Connect the contrast medium socket of the contrast medium injection tube (CMI tube) to the contrast medium plug at the head end of the phantom body.
7. Close the CMI tube with the pressure-resistant shutoff valve.
8. Connect one right-angled plug of the long circulation tube to the circulation socket at the foot end of the phantom body.



When assembling and operating the phantom system, always make sure that the tubes are securely connected to the plug connections and that the plug connections of the tubes are correct.

If they are successfully connected, the plug connections engage with a click sound and are only released again when pressure is applied to the unlock button.

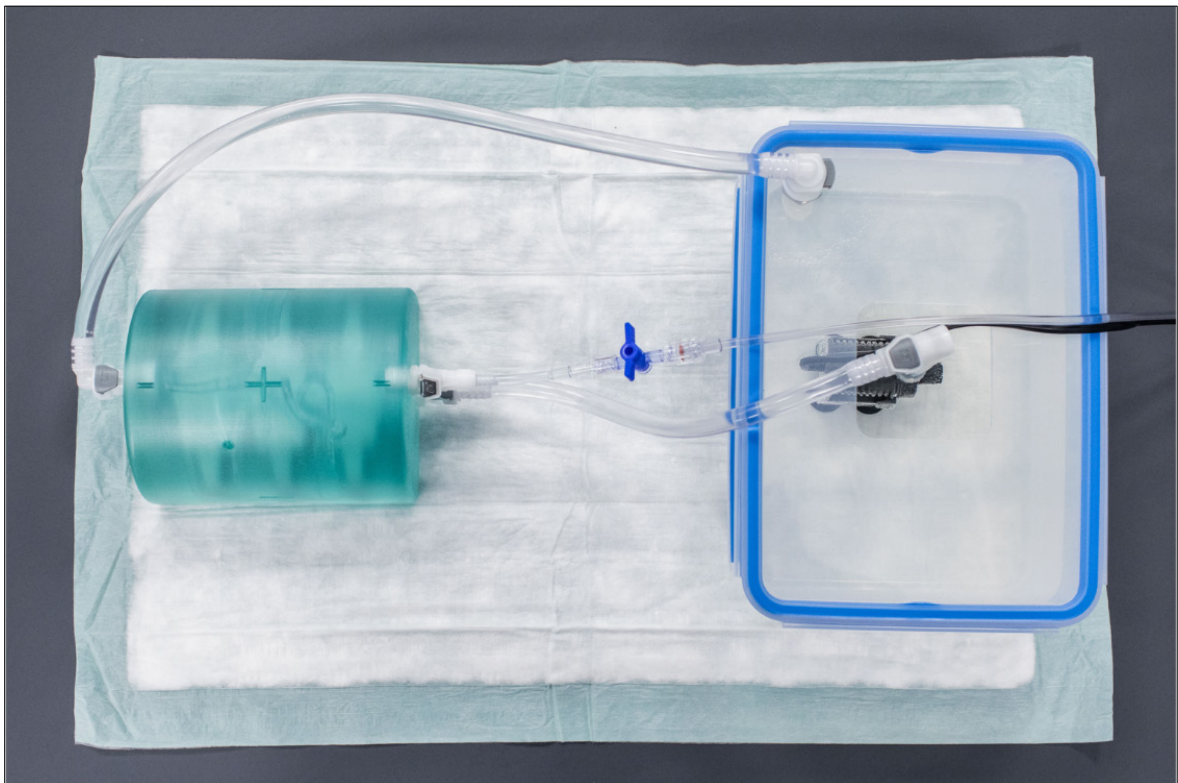
When assembling the phantom system, check that the connection position of the circulation tubes is correct. Only in this way is it possible to provide the vascular bed with contrast.

9. Plug the free right-angled plug of the long circulation tube into the return flow socket in the reservoir lid.
10. Connect the plug of the short circulation tube to the circulation socket at the head end of the phantom.
11. Plug the socket of the short circulation tube onto the plug of the pump tube.



You have now created the circulation circuit.

Fully assembled phantom system



3.4 Initial start-up of the pump

During this activity, observe the following safety instructions:



WARNING

Improper cabling of the phantom system!

Electric shock!

- Always bring the power supply to the pump using a safety approved single plug extension cable not exceeding a total length of 25m (82 ft).
- Make sure that the amperage rating of the extension cable is not lower than the maximum amperage limited either by the circuit breaker or the fuse from the supplying socket outlet.
- Always connect the pump power plug to the extension cable on the tabletop.



WARNING

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Always disconnect the power supply of the pump before performing one of the following tasks:
 - placing your hand in the water of the circulation reservoir
 - disassembling the phantom system
 - taking apart or cleaning the pump
 - replacing parts of the pump
- Always disconnect the power supply of the pump if liquid escapes from the phantom system.



CAUTION

Unnoticed malfunctions!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Only operate the phantom system under constant supervision.



PREPARATION

You have completed the following preparatory steps:

- ✓ The angiography table is covered with an absorbent underlay.
- ✓ *Assembling the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*
- ✓ *Assembling the circulation circuit*



WORK STEPS

1. Establish the power supply to the pump via a safety approved single plug extension cable.
2. Interrupt the power supply after 10 seconds for a few seconds in order to prime the pump.
3. Lift the phantom body and tilt it in all directions to allow any remaining air to escape from the vascular tree.



Do not operate the pump without water. During operation, the pump must be completely submerged below the water surface.

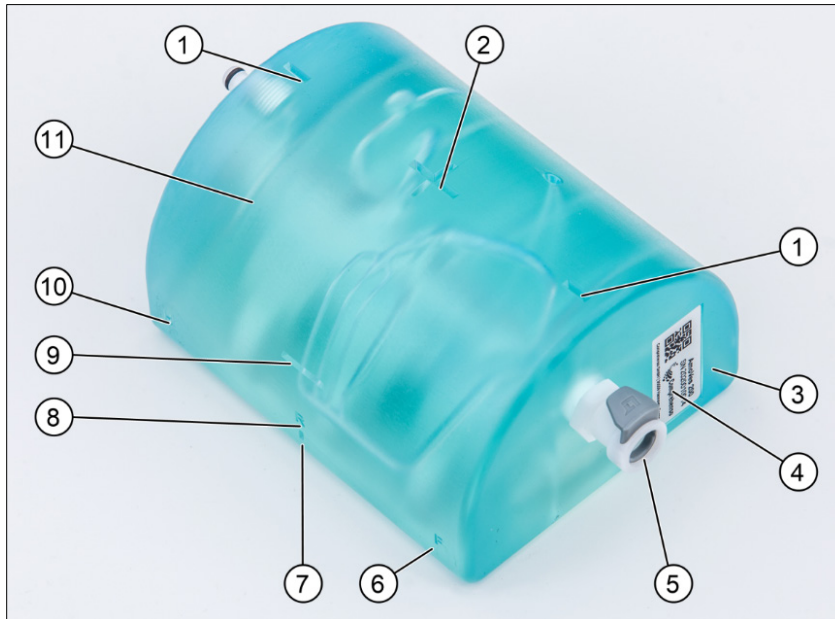
3.5 Positioning and registering the phantom



WORK STEPS

1. Position the phantom body at the center of the table of the angiography system. Use the position indicators and the center-line indicator of the phantom body to do this if the angiography device has a laser-light localizer.

View of the phantom body foot end



- 1 Center-line indicator
- 2 Center position indicator
- 3 Foot end of phantom
- 4 Type plate
- 5 Foot-end circulation socket
- 6 Alignment indicator **F** (toward feet)
- 7 Vertical position indicator
- 8 Alignment indicator **R** (right)
- 9 Horizontal position indicator
- 10 Alignment indicator **H** (toward head)
- 11 Convex surface of phantom body

2. In the angiography system, enter the orientation of the phantom as "Feet First - Supine".

3.6 Priming the contrast media injection system



PREPARATION

You have completed the following preparatory steps:

- ✓ The angiography table is covered with an absorbent underlay.
- ✓ *Assembling the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*
- ✓ *Assembling the circulation circuit*
- ✓ *Initial start-up of the pump*
- ✓ *Positioning and registering the phantom*



WORK STEPS

1. Place a 20-ml syringe on the shutoff valve of the contrast medium injection tube (CMI tube).
2. Open the shutoff valve and draw the air out of the CMI system with the syringe until the syringe fills with water.
3. Close the shutoff valve and release the syringe.
4. Empty the syringe into the reservoir through the center opening of the reservoir.
5. Repeat steps 1 to 4 until the CMI system is completely primed, that is contains no air, and the syringe fills with water only.

3.7 Functional test of the contrast media injection system

Before injecting the contrast medium into the phantom system, always check that the contrast media injection system is functioning correctly.



PREPARATION

You have completed the following preparatory steps:

- ✓ The angiography table is covered with an absorbent underlay.
- ✓ *Assembling the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*
- ✓ *Assembling the circulation circuit*
- ✓ *Initial start-up of the pump*
- ✓ *Positioning and registering the phantom*
- ✓ *Priming the contrast media injection system*



WORK STEPS

1. Place a 20-ml syringe on the shutoff valve of the contrast medium injection tube (CMI tube).
2. Close the shutoff valve and completely fill the syringe with water by aspiration.
3. Empty the water-filled syringe with high pressure into the CMI tube to check that the CMI system is functioning correctly.
It should be possible to do this within a few seconds with little resistance.
4. Close the shutoff valve at the CMI tube and remove the 20-ml syringe.



The phantom system is now ready for operation.

4 Operating the phantom system

During this activity, observe the following safety instructions:



CAUTION

Unnoticed malfunctions!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Only operate the phantom system under constant supervision.



CAUTION

Unauthorized modification of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not modify the phantom system in any way. Any modification whatsoever is impermissible and could compromise the safety of the system.

Possible contrast delivery methods are:

- *Manual gas injection*
- *Manual contrast medium injection*
- *Automatic contrast medium injection*

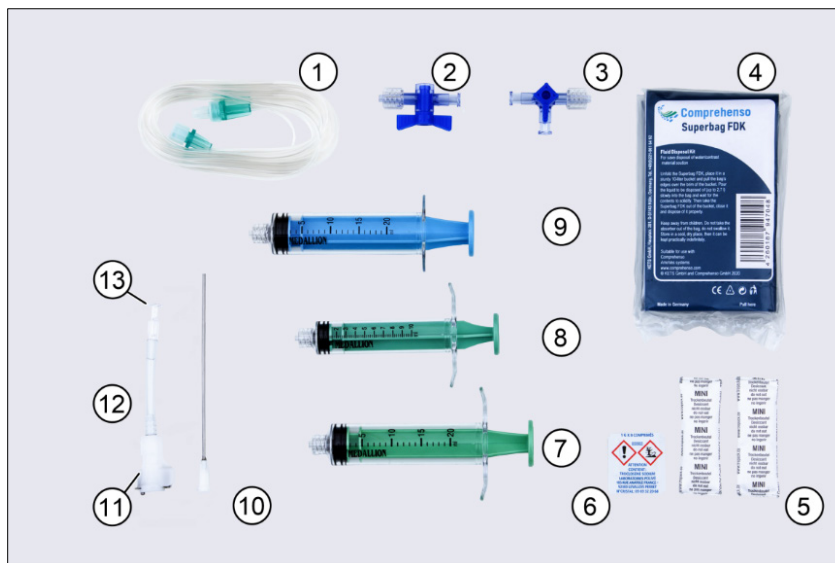
As soon as the phantom has been positioned and registered, the following are possible:

- *Registration of image data*
- *Use of the puncture channels*



The phantom system is supplied with accessories for initial use. You can use the materials, with the exception of the disinfectant tablet, the drying medium and the liquid disposal bag, multiple times if they have been sufficiently cleaned and dried.

Components of the set of consumables



- 1 Tube extension
- 2 Shutoff valve
- 3 Three-way valve
- 4 Liquid disposal bag (Superbag FDK)
- 5 Bag with drying agent*
- 6 Disinfectant tablet*
*(in the Clean & Dry set)
- 7 20-ml syringe for contrast medium (green)
- 8 10-ml syringe for contrast medium (green)
- 9 20-ml syringe for water (blue)
- 10 Blunt needle (14-gauge)
- 11 Contrast medium socket
- 12 Contrast medium injection tube (CMI tube)
- 13 Female Luer-Lock fitting

4.1 Manual gas injection

For providing contrast of the vascular tree, ambient air can be used as a negative contrast medium.

Instead of ambient air, you can also use CO₂ to provide contrast. However, using CO₂ offers no advantage over the use of ambient air.



PREPARATION

You have completed the following preparatory steps:



Assembly and initial start-up of the phantom system



WORK STEPS

1. Select a suitable acquisition protocol for CO₂ on the angiography device.
2. Connect the shutoff valve of the CMI tube with a tube extension.
3. Place a three-way valve on the end of the tube extension.
4. Place a 20-ml syringe filled with gas on the three-way valve.
5. Open the shutoff valve and the three-way valve.
6. Start image acquisition and, after you have acquired the mask image, inject gas through the tube extension into the CMI system of the phantom.
7. Close the shutoff valve and the three-way valve.



Complete and simultaneous filling of all vascular branches cannot be achieved perfectly for technical reasons and depends on the volume of gas injected.

After the injection of gas, the vascular tree fills with water again.

Gas can only escape from the vessels of the phantom body by fluid motion and displacement. It may therefore be necessary to lift and tilt the phantom body to completely fill all vascular branches and the aneurysm with water.

4.2 Manual contrast medium injection

To provide contrast in the vascular tree, clear, water-soluble iodine-based contrast medium can be injected manually into the vascular bed.



PREPARATION

You have completed the following preparatory steps:



Assembly and initial start-up of the phantom system



WORK STEPS

1. Select a suitable acquisition protocol for iodine-based contrast medium on the angiography device.
2. Connect the shutoff valve of the CMI tube with a tube extension.
3. Place a three-way valve on the end of the tube extension.
4. Place a 20-ml syringe on the three-way valve.
5. Open the shutoff valve and the three-way valve, draw out the air in the tube extension and fill the syringe with water.
6. Close the three-way valve and remove the syringe.
7. Empty the syringe into the circulation reservoir through the center opening of the reservoir lid.
8. Repeat steps 4 to 7 until the tube extension and the three-way valve are completely primed.
9. To administer the contrast medium injection, place a 10-ml syringe or a 20-ml syringe filled with contrast medium on the three-way valve.
10. Open the three-way valve. Start image acquisition and after the mask image, inject the contrast medium via the tube extension into the CMI system of the phantom.



Chapter *Contrast medium protocols* contains suggested protocols for manual injection of iodine-based contrast medium.

11. Close the shutoff valve and the three-way valve.



If large quantities of iodine-based contrast medium are used, the circulating water may become perfused with contrast medium so that the vascular tree becomes visible.

Water that is too old leads to microbial contamination of the phantom system.

To prevent unwanted contrast or microbial contamination, you must regularly replace the water in the phantom system (*Replacing the circulating water*).

In order to avoid contrast medium deposits, rinse the phantom system regularly after operating it with contrast medium (*Rinsing the phantom system*).

4.3 Automatic contrast medium injection

To provide contrast in the vascular tree, clear, water-soluble iodine-based contrast medium suitable for intravenous injection can be automatically injected into the vascular bed.

Automatic injectors can be used for administering contrast medium. In this case, please observe the injector original operating manual.



PREPARATION

You have completed the following preparatory steps:



Assembly and initial start-up of the phantom system



WORK STEPS

1. Select a suitable acquisition protocol for iodine-based contrast medium on the angiography device.
2. Prime the pressure tube of the syringe pump.
3. Connect the shutoff valve of the CMI tube to the pressure tube of the syringe pump.
4. Open the shutoff valve.
5. Start image acquisition and, after you have acquired the mask image, inject the contrast medium into the CMI system of the phantom using the syringe pump.



Chapter *Contrast medium protocols* contains suggested protocols for automated injection of iodine-based contrast medium.

Observe a maximum injection rate of 10 ml/s.

Observe a maximum contrast medium volume of 35 ml per injection.

6. Close the shutoff valve.



If large quantities of iodine-based contrast medium are used, the circulating water may become perfused with contrast medium so that the vascular tree becomes visible.

Water that is too old leads to microbial contamination of the phantom system.

To prevent unwanted contrast or microbial contamination, you must regularly replace the water in the phantom system (→ *Replacing the circulating water*).

In order to avoid contrast medium deposits, rinse the phantom system regularly after operating it with contrast medium (→ *Rinsing the phantom system*).

4.4 Registration of image data

The use of pre-existing image data plays an important role in image-guided procedures. The registration of image data permits these image data to be displayed true to position and scale during the intervention, for example, by image fusion.

During this activity, observe the following safety instructions:



CAUTION

Improper use!

Injury due to metal projectiles and damage to the product.

- The phantom system has been developed for use in angiography devices and contains metal components. Do not use the phantom system in magnetic resonance imaging systems (MRI). Pre-existing image data were created using an MRI-compatible variant of the phantom system.

Registration techniques can be used with the phantom system. For that reason, we provide various CT, MRI, and C-Arm CT examinations of the phantom body with the phantom system.

Visible structures in the phantom system that also exhibit contrast in the pre-existing image data are used as registration landmarks in fluoroscopy (FL), digital radiography (DR), and digital subtraction angiography (DSA).

The **spine** of the phantom system provides contrast in:

- fluoroscopy (FL)
- digital radiography (DR)
- CT and C-Arm CT
- T2 weighting in MRI

The **vascular tree** of the phantom system exhibits contrast when contrast medium is introduced in:

- fluoroscopy (FL)
- digital radiography (DR)
- digital subtraction angiography (DSA)
- CT and C-Arm CT



When registering the phantom system, make sure that you enter the orientation correctly (*Feet First – Supine*).

The practical application of registration techniques varies from device to device. Please refer to the original operating manual of your angiography system for details of use.

4.5 Use of the puncture channels

During this activity, observe the following safety instructions:



CAUTION

Improper use!

Injury of personnel and damage to the product.

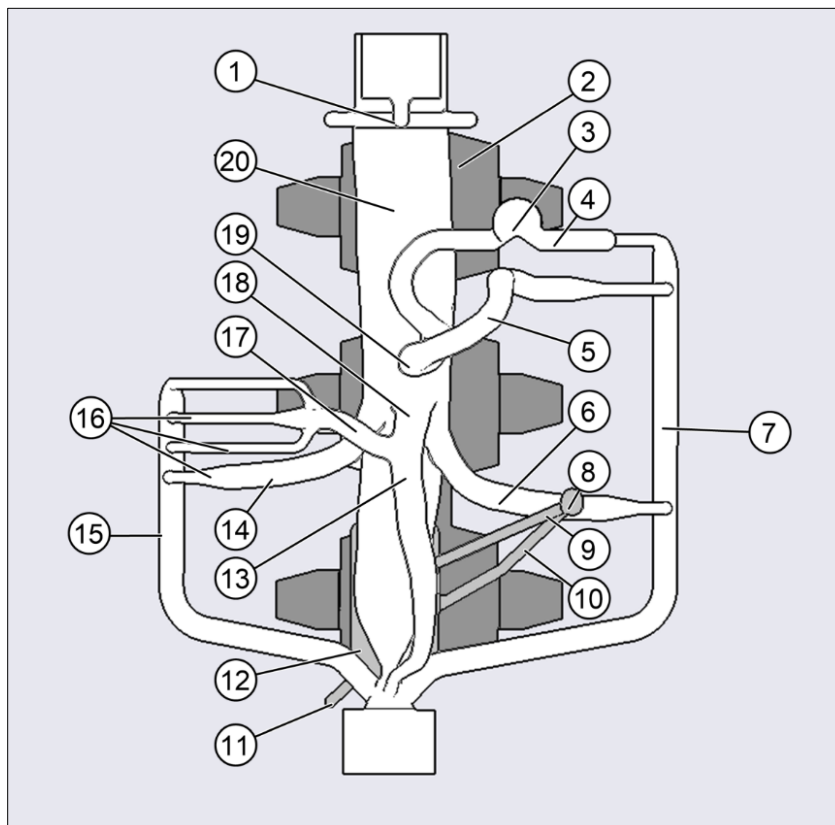
- Insert only the blunt needles (with a maximum diameter of 14G), available as accessories, or soft, flexible wires into the puncture channel of the phantom body.
- Do not insert any sharp needles or wires into the puncture channel. They could injure the user or damage the phantom.

4.5.1 Needle placement

Some angiography systems have navigation applications that make it possible to place needles using fluoroscopy or a laser-light localizer.

In order to be able to use these navigation applications on the phantom system, too, the system provides two puncture channels. When lateral fluoroscopy is centered on the puncture channels, both puncture channels are overlaid and therefore cannot be distinguished from each other.

Internal structure of the phantom body as seen from the front



- 1 Contrast media injection system (CMI system)
- 2 Spine
- 3 Aneurysm
- 4 Gastric artery
- 5 Splenic artery
- 6 Left renal artery
- 7 Drainage channel
- 8 Puncture channel entry
- 9 Straight puncture channel
- 10 Angled puncture channel
- 11 Drainage of the cavity
- 12 Cavity
- 13 Mesenteric artery
- 14 Right renal artery
- 15 Drainage channel
- 16 Segmental hepatic arteries
- 17 Hepatic artery
- 18 Second outlet
- 19 First outlet
- 20 Aorta

4.5.1.1 Straight puncture channel

The straight puncture channel runs from the joint puncture channel entry on the convex surface of the phantom body in a **straight** line to the cavity between the aorta and the spine.

A blunt needle can be pushed right through to the cavity. Therefore, the straight puncture channel can be used as a *successful needle path*.



Do not fill the phantom with liquid through the puncture channel as it will remain in the phantom body, become agglutinated and may cause microbial contamination.

4.5.1.2 *Angled puncture channel*

The angled puncture channel runs from the joint puncture channel entry in the convex surface of the phantom body to the cavity between the aorta and the spine along an **angled** path.

A blunt needle can therefore only be pushed only as far as the blunt angle of the channel. Therefore, the **angled** puncture channel can be used as an *unsuccessful needle path*.

4.5.2 **Wire overlay**

A soft wire can be inserted via the puncture channel into the cavity between the aorta and the spine. When fluoroscopy is applied from the front, this technique makes the wire appear to move in the aorta. This can be used for *road-map techniques*, for example.

5 Caring for and maintaining the phantom system

During and after use, you must care for the phantom system in the way described in this original operating manual.

During this activity, observe the following safety instructions:



CAUTION

Unprofessional repair of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not perform repairs yourself if the connections on the phantom system leak. Repairs must only ever be performed by the manufacturer.
- Defective parts must always be replaced with original parts. Components must only ever be repaired by qualified personnel. Do not perform repairs yourself but contact the manufacturer.

Caring for and maintenance of the phantom system comprises the following work steps:

- *Emptying the phantom system*
Before disassembling the phantom system.
- *Replacing the circulating water*
To prevent unwanted contrast when using iodine-based contrast medium and to prevent microbial contamination
- *Rinsing the phantom system*
To prevent dried contrast medium residue
- *Back-rinsing the phantom system*
To remove foreign bodies from the vascular bed
- *Disinfecting the phantom system*
To prevent microbial contamination
- *Descaling the phantom system*
To remove limescale deposits.
- *Cleaning the pump*
To maintain functionality

5.1 Emptying the phantom system

When the phantom system is emptied, the circulating liquid is removed from it.

Empty the phantom system before disassembling it. If the phantom system is used for several days, we recommend emptying and rinsing the phantom system daily. (→ *Rinsing the phantom system*)

During this activity, observe the following safety instructions:



WARNING

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Always disconnect the power supply of the pump before performing one of the following tasks:
 - placing your hand in the water of the circulation reservoir
 - disassembling the phantom system
 - taking apart or cleaning the pump
 - replacing parts of the pump
- Always disconnect the power supply of the pump if liquid escapes from the phantom system.



CAUTION

Escaping liquids!

Injury of personnel and damage to the product and electrical devices (e. g. angiography device).

- Always protect the detector and the X-ray tube of the angiography device with a waterproof cover when you use the phantom system with liquids.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when you use the phantom system with liquids.
- Always assemble and disassemble the phantom system in the sequence described in the original operating manual to avoid water or contrast medium escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping liquids could damage electrical devices located in the vicinity, e. g. the angiography device.
- Do not tilt or cradle the tabletop of the angiography system when you use the phantom system with liquids. Water could spill out of the center opening of the reservoir lid.

**CAUTION**

Falling phantom body during movement or transportation!

Injury of personnel, damage to product, and further material damage.

- The phantom body is slippery when it is damp. Dry the exterior of the phantom body before moving or transporting it.
 - Hold the phantom body securely with both hands when moving and transporting it.
 - If the phantom body falls, it may be damaged or destroyed. Always transport the phantom body with the utmost care.
 - Always check that the phantom body is still intact after it has fallen.
 - The phantom system must not be used if it is damaged.
-

**CAUTION**

Excessive strain on power cable!

Injury of personnel and damage to the product.

- During assembly and disassembly and maintenance, hold the pump by its housing and not by the power cable.
-

**CAUTION**

Improper disposal of contrast medium solutions!

Contamination of the environment.

- Use the liquid disposal bags included in the set of consumables for environmental disposal.
 - Observe your local regulations regarding the disposal of contrast medium solutions.
-



WORK STEPS

1. Disconnect the power supply of the pump.
The phantom system is emptied passively.
2. Close the shutoff valve of the CMI tube.
3. Remove any tube extensions from the shutoff valve of the CMI tube.
4. Release the inflow socket of the short circulation tube from the pump tube plug.
5. Lift the phantom body together with all its circulation tubes above the level of the circulation reservoir (as shown in the figure).

The liquid now runs out of the short circulation tube and the phantom body through the long tube into the reservoir.
6. Set the phantom body down again.
7. Open the shutoff valve of the CMI tube.
8. Again lift the components above the level of the circulation reservoir. The remaining liquid now flows out.
9. Close the shutoff valve of the CMI tube.
10. Release the right-angled plug of the long circulation tube from the return flow socket in the reservoir lid and connect it to the inflow socket of the short circulation pipe.
The remaining liquid can now not escape.
11. Unfasten the reservoir lid and remove the pump.
12. Dispose of the liquid from the circulation reservoir.

Emptying the phantom system



If you have used iodine-based contrast medium, you must now *Rinsing the phantom system* to prevent any contrast medium residue from drying in the phantom body.

5.2 Replacing the circulating water

If large quantities of iodine-based contrast medium are used, the circulating water may become perfused with contrast medium so that the vascular tree becomes visible. To prevent unwanted contrast, you must regularly replace the water in the phantom system.



Replace the water in the circulation reservoir no later than after 10 hours.

Replace the water in the circulation reservoir as soon as a total of 100 ml contrast medium per 1 l of water has been injected.



WORK STEPS

1. Perform *Emptying the phantom system*.
 2. Perform the work step *Assembling the pump and circulation reservoir*.
 3. Perform the work step *Filling the circulation reservoir*.
 4. Perform *Assembling the circulation circuit*
 5. Perform *Initial start-up of the pump*.
 6. If necessary, repeat the work step *Positioning and registering the phantom* .
 7. Perform the work step *Priming the contrast media injection system* .
-



The phantom system is again ready for operation.

5.3 Rinsing the phantom system

If iodine-based contrast medium has been injected into the phantom system, you must rinse the system after *Emptying the phantom system* and before disassembly to ensure that no dried contrast medium deposits are left in it. If the phantom system is used for several days, we recommend emptying and rinsing the phantom system daily.



Rinse the phantom system on a sufficiently large table with an absorbent underlay. It is not necessary to set up the system on an angiography table.



PREPARATION

You have completed the following preparatory steps:



Emptying the phantom system



WORK STEPS

1. Perform the work step *Assembling the pump and circulation reservoir*.
2. Perform the work step *Filling the circulation reservoir*.
3. Perform *Assembling the circulation circuit*
4. Perform *Initial start-up of the pump*.
5. Let the pump run for 2 minutes.
Make sure that contrast medium residue has been rinsed out of the phantom system.
6. In the meantime, rinse the CMI tube several times. To do this, place an empty 20-ml syringe on the shutoff valve of the CMI tube.
7. Open the shutoff valve of the CMI tube and fill the syringe with water by aspiration.
8. Empty the syringe by injecting the contents into the CMI tube.
9. Repeat steps 6 to 8 several times.
10. Perform *Emptying the phantom system* again.

5.4 Back-rinsing the phantom system

Foreign bodies and impurities in the circulation liquid can become deposited on the vascular bed and block the vascular branches. In this case, the phantom system must be back-rinsed to unblock the passages through the vascular tree.



Perform back-rinsing of the phantom system on a sufficiently large table with an absorbent underlay. It is not necessary to set up the system on an angiography table.



PREPARATION

Where relevant, you have completed the following preparatory steps:



Emptying the phantom system



WORK STEPS

1. Perform the work step *Assembling the pump and circulation reservoir*.
2. Perform the work step *Filling the circulation reservoir*.
3. Perform *Assembling the circulation circuit*.
To ensure that the circulation liquid flows in the opposite direction to that of the normal setup, that is, from the foot end to the head end, the circulation tubes must be exchanged.



If you perform back-rinsing after *Initial start-up of the pump*, first *Emptying the phantom system* and then *Assembling the circulation circuit* must be performed again to prevent the circulation liquid from escaping from the phantom system.

4. Press the unlock button of the circulation socket at the head end of the phantom body to release the short circulation tube from the phantom body.
5. Press the unlock button of the circulation socket at the foot end of the phantom body to release the long circulation tube from the phantom body.
6. Turn the phantom body around 180°. The position of the head end and the foot end of the phantom body are now reversed.
7. Connect the right-angled plug of the long circulation tube to the circulation socket at the head end of the phantom body.
8. Connect the circulation socket at the foot end of the phantom body to the outflow plug of the short circulation tube.



You have now set up the reversed circulation circuit.

9. Perform *Initial start-up of the pump*.
10. Let the pump run for 5 minutes.
This should rinse foreign bodies out of the vascular bed into the circulation reservoir.
11. Perform *Emptying the phantom system*.

5.5 Disinfecting the phantom system

Disinfect the phantom system regularly.

During this activity, observe the following safety instructions:



WARNING

Formation of toxic gases due to improper mixing of liquids!

Danger to life.

- Never mix disinfectants and descaling solution, as toxic gases can form.

Microbial contamination of the phantom system must be avoided at all costs in the medical environment.

Therefore, disinfect the phantom system

- when you have finished using it or
- no later than 5 days after it has been filled with water.

Use only the disinfectants recommended here and listed in chapter *Disinfectants* to disinfect the phantom system.

Also perform *Cleaning the pump* at regular intervals.



Disinfect the phantom system on a sufficiently large table with an absorbent underlay. It is not necessary to set up the system on an angiography system.



PREPARATION

You have completed the following preparatory steps:



Emptying the phantom system



WORK STEPS

1. Perform *Assembly and initial start-up of the phantom system*. To do this, fill the reservoir with 2.5 liters (85 fl oz) of ready-to-use disinfectant solution.
2. Start up the pump.
The interior of the phantom body is disinfected while the pump is in operation.
3. Let the pump run for 15 minutes. Make sure that you do not exceed the contact time of the disinfectant solution.
4. In the meantime, rinse the CMI tube several times. To do this, place an empty 20-ml syringe on the shutoff valve of the CMI tube.
5. Open the shutoff valve and fill the syringe with disinfectant solution.
6. Empty the syringe by injecting the contents into the CMI tube.
7. Repeat steps 4 to 6 several times.
8. Perform *Emptying the phantom system*.

9. Dispose of the disinfectant solution.
10. Rinse off any residue disinfectant solution that has escaped and dry the phantom system with soft cosmetics tissues or single-use hand towels.



If the phantom system was only operated with gaseous contrast medium and **no iodinated contrast medium** was used, the *Circulation medium* can be used directly to prepare the disinfection solution.

In this case, the disinfectant tablet (see *Disinfectants*) can be dissolved in the circulation reservoir when the pump is at a standstill.

5.6 Descaling the phantom system

If water contains lime, limescale deposits in the vascular bed can impair the flow. In this case, descale the phantom system.

During this activity, observe the following safety instructions:



WARNING

Formation of toxic gases due to improper mixing of liquids!

Danger to life.

- Never mix disinfectants and descaling solution, as toxic gases can form.

Use only the descaling solutions recommended here and listed in chapter Descaling agents to descale the phantom system.



Descal the phantom system on a sufficiently large table with an absorbent underlay. It is not necessary to set up the system on an angiography system.



PREPARATION

You have completed the following preparatory steps:



Rinsing the phantom system



Emptying the phantom system

To descale the phantom system, the cleaning reservoir is used to reduce the effective circulation volume to 1 liter (34 fl oz).



WORK STEPS

1. Attach the pump tube to the pump.
(→ *Assembling the pump and circulation reservoir*)
2. In addition, place the cleaning reservoir without its lid in the empty circulation reservoir.
3. Position the cleaning reservoir so that you can close the lid of the circulation reservoir and both the return flow socket and its tube as well as the center opening in the lid of the circulation reservoir are located above the cleaning reservoir (as shown in the figure).
4. Fasten the pump by means of the suction cups to the base of the cleaning tank. Slightly moisten the suction cups for this. Position the pump so that the pump outflow pipe is located in the center of the circulation tank. Align the pump with pump tube plug with one of the long sides of the circulation tank. This side will be referred to as the *side nearest the phantom body* in the following instructions (as shown in the figure).
5. Fill the cleaning tank with 1 liter (34 fl oz) ready-to-use, approx. 35°C warm (hand-warm) descaling solution.
6. Route the power cable and the pump tube from inside the circulation reservoir through the center cutout in the lid of the circulation reservoir and close the reservoir lid. Align the reservoir lid in such a way that the return flow socket is located on the *side nearest the phantom body* of the reservoir and is thus located above the cleaning tank (as shown in the figure).

Cleaning reservoir in circulation reservoir with pump



The arrow is pointing toward the phantom body/C-Arm.

7. Perform *Assembling the circulation circuit*.
8. Perform *Initial start-up of the pump*.
9. Rinse the phantom body for 2 minutes with the descaling solution.
10. In the meantime, rinse the CMI tube several times. To do this, place an empty 20-ml syringe on the shutoff valve of the CMI tube.
11. Open the shutoff valve and fill the syringe with descaling solution.
12. Empty the syringe by injecting the contents into the CMI tube.
13. Repeat steps 10 to 12 several times.
14. Close the shutoff valve of the CMI tube and remove the syringe.
15. Disconnect the power supply of the pump. Allow the descaling solution to take effect for 12 hours.
16. Perform *Emptying the phantom system* and dispose of the descaling solution.
17. Perform *Rinsing the phantom system* to remove descaling solution residue.
18. Rinse the components of the phantom system with clear water and dry them with soft cosmetics tissues or single-use hand towels.

5.7 Cleaning the pump

Clean the pump of the phantom system regularly. The pump can be cleaned, for example, after *Disinfecting the phantom system*.

During this activity, observe the following safety instructions:



WARNING

The phantom system draws electrical power!

Electric shock or burns due to short-circuit current.

- Always disconnect the power supply of the pump before performing one of the following tasks:
 - placing your hand in the water of the circulation reservoir
 - disassembling the phantom system
 - taking apart or cleaning the pump
 - replacing parts of the pump
- Always disconnect the power supply of the pump if liquid escapes from the phantom system.



WARNING

Moisture on the cable or power plug of the pump!

Electric shock or burns due to short-circuit current.

- Always keep the power cable of the pump dry.
- When routing the cable always form a drip loop in front of the plug connection between the power plug and extension cable so that the power plug of the pump or the plug connection does not accidentally become wet.
- If the power connector of the pump does accidentally become wet, disconnect the power supply before touching the power cable and power plug.
- Do not start up the pump again until the power cable and power plug are completely dry.



CAUTION

Excessive strain on power cable!

Injury of personnel and damage to the product.

- During assembly and disassembly and maintenance, hold the pump by its housing and not by the power cable.



CAUTION

Unauthorized modification of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

- Do not modify the phantom system in any way. Any modification whatsoever is impermissible and could compromise the safety of the system.



CAUTION

Unprofessional repair of the system!

Injury of personnel and incorrect functioning and/or damage to the product.

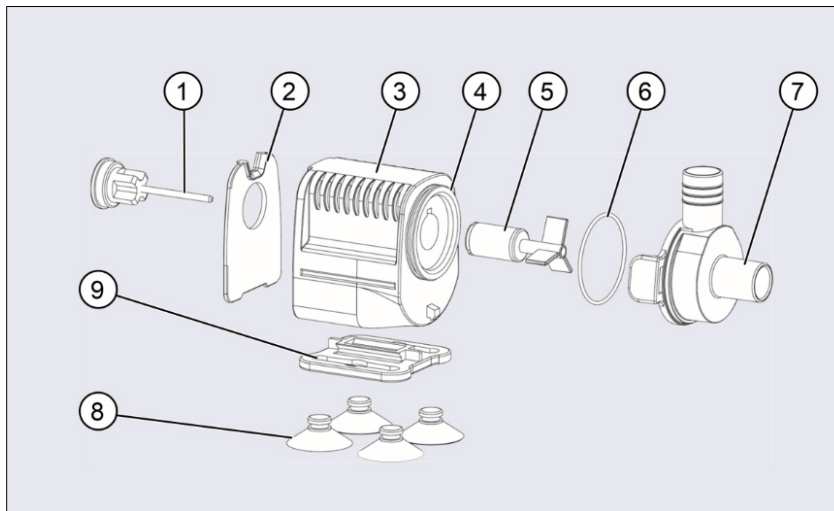
- Do not perform repairs yourself if the connections on the phantom system leak. Repairs must only ever be performed by the manufacturer.
- Defective parts must always be replaced with original parts. Components must only ever be repaired by qualified personnel. Do not perform repairs yourself but contact the manufacturer.



WORK STEPS

1. Remove the antechamber of the pump.
2. Remove the O-ring from the slot on the pump housing.
3. Pull the rotor from the axle out of the pump housing. Clean the pump housing, the antechamber, the O-ring, and the rotor with a soft brush and clean water.

Individual parts of the pump



- 1 Axle
- 2 Cover
- 3 Pump housing
- 4 Slot for O-ring
- 5 Rotor
- 6 O-ring
- 7 Antechamber
- 8 Suction cups
- 9 Baseplate

4. Check the components for damage.
If you notice a defect, replace the defective component or the entire pump.
5. Reassemble the pump.

6 Disassembly, transportation, and storage of the phantom system

When disassembling the phantom system, you must remove the remaining liquid from the system and dry the phantom system.

After it has been disassembled, the phantom system is transported and stored in the transportation case provided. To take up any remaining liquid residue in the phantom, two unused drying agent bags (included in the **Clean & Dry Set**) are placed in the case during transportation and storage.



The phantom system is delivered in a robust and padded transportation case. Use this transportation case to transport the phantom system in order to avoid damage.

Do not expose the phantom system and its components to temperatures below 0°C or above 35°C.



PREPARATION

You have completed the following preparatory steps:

- ✓ *Caring for and maintaining the phantom system*
- ✓ *Emptying the phantom system*



WORK STEPS

1. Press the unlock button of the connection socket of the CMI tube to release the tube from the contrast medium plug at the head end of the phantom body.
2. Press the unlock button of the circulation socket at the head end of the phantom body to release the short circulation tube from the phantom body.
3. Press the unlock button of the circulation socket at the foot end of the phantom body to release the long circulation tube from the phantom body.
4. Press the unlock button of the inflow socket of the short circulation tube to disconnect the circulation tubes.
5. Place the empty circulation reservoir with the lid closed on a stable surface.
6. Place the phantom body with the foot end on the lid of the reservoir in such a way that the circulation socket points into the center opening of the lid and the phantom body stands securely (drainage position).
7. Leave the phantom body in the drainage position for several minutes so that the remaining liquid can escape.
8. Tilt the phantom body multiple times and return it to the drainage position so that remaining liquid flows out.
Small amounts of liquid deposits, in particular, in the vessel structures with a narrow lumen, cannot be completely removed.
9. Dry the phantom body, the pump, and the circulation reservoir with soft cosmetics tissues or single-use hand towels.
10. Dry the pump tube, the CMI tube, and the circulation tubes with soft cosmetics tissues or single-use hand towels.

11. Place the phantom body in the phantom recess in the transportation case. The head end of the phantom body should point toward the handle of the case. Place the circulation tubes on the bottom of the circulation tank.

Transportation case open, showing phantom and circulation reservoir



- 1 Transportation case
- 2 Recess for phantom (with phantom)
- 3 Recess for reservoir (with circulation reservoir)
- 4 Device card (not shown, see 12.3)

12. Place the socket and the plugs on one side of the circulation tank bottom and lay the tubes coiled inside each other and not on top of each other.
13. Place the closed cleaning reservoir on top of the circulation tubes (not on the plugs).
14. Use the closed cleaning reservoir to store dry accessories.
15. Place the pump on the plugs and socket of the circulation tubes.
16. Close the circulation reservoir.
17. Pay attention to the position of the return flow socket in the reservoir lid: Lack of space does not allow it to lie on top of the cleaning reservoir.
18. Place the circulation reservoir in the reservoir recess in the transportation case.
19. When transporting or storing the phantom system in the closed case, place two new drying agent bags (included in the **Clean & Dry Set**) at the side of the phantom body.



Store the phantom system in the transport case. Leave the lid of the case open until the liquid residues in the phantom system have dried completely.

7 Remediating faults

Unexpected events can occur when using the phantom system. The table below is provided to help you to remedy faults yourself.



If you cannot solve the problem yourself, visit our website <https://comprehenso.de> or contact our customer support. The contact data are listed in chapter *Manufacturer and service*.

Problem	Possible solution
After priming, air often collects again in the vascular bed of the phantom.	<ul style="list-style-type: none"> • Check the water level. If necessary, top up the circulation reservoir with water. No air bubbles should form under the return flow socket of the reservoir. • Check that the pump is correctly assembled: The right-angled plug must face toward the pump housing and the power cable and thus point away from the pump inflow pipe. If correctly assembled, the pump inflow pipe points away from the return flow socket and the phantom body. • Prime the short circulation tube by lifting the entire system. By rotating the phantom body, trapped air can be removed from the vascular bed. Gently tap the phantom body.
Liquid cannot be withdrawn from or injected into the CMI tube.	<ul style="list-style-type: none"> • Check whether the CMI tube is obstructed. If the tube is obstructed, e.g. by contrast medium deposits, replace the CMI tube. • Fill the blue 20-ml syringe with circulation liquid and try to inject the liquid through the CMI tube. If the obstruction becomes loose, rinse the CMI system several times until you can withdraw and inject circulation liquid without any resistance. (→<i>Rinsing the phantom system</i>) • Do not use the phantom system if the resistance persists. Contact support.
The vascular tree either exhibits no contrast or insufficient contrast when gas is injected.	<ul style="list-style-type: none"> • Check whether the circulation tubes have been connected in the correct sequence. • Vary the injection speed and injection volume: If gas is injected too quickly, water is pushed out of the short circulation tube and escapes into the circulation reservoir.
The vascular tree does not exhibit or barely exhibits contrast when contrast medium is injected.	<ul style="list-style-type: none"> • Check whether the circulation tubes have been connected in the correct sequence. • Check whether the CMI tube is obstructed. • Change the water. If a large quantity of contrast medium has already been administered, the difference in density between the injected contrast medium and the circulation water decreases.
The vascular tree exhibits insufficient contrast when liquid iodine-based contrast medium is injected.	<ul style="list-style-type: none"> • Individual vascular branches could be obstructed by foreign bodies. Perform back-rinsing. (→<i>Back-rinsing the phantom system</i>) • Individual vascular branches could be obstructed by limescale. Descale the phantom system. (→<i>Descaling the phantom system</i>)

Problem

The phantom system leaks and water is escaping.

Possible solution

- Disconnect the power supply of the pump, mop up the liquid with absorbent material and look for the leak.
- Close the shutoff valve at the CMI tube. Inspect the Luer-Lock fitting on the CMI tube. Inspect the shutoff valve. Replace the CMI tube and the shutoff valve, if necessary.
- Check that the plug connections fit tightly.
- Check the screw connections on the phantom body for leaks. The inflow sockets are specially sealed around the thread and should only be replaced by an expert if they leak. In this case, contact support.

8 Disposal

The phantom system is designed for a useful life of about 2 years. For hygienic reasons, this useful life should not be exceeded if the equipment is used on a regular basis.

The **pump** is subject to the 2012/19/EU WEEE (Waste Electrical and Electronic Equipment) directive. It must not be disposed of with other waste. Instead, it should be taken to the collection points to enter the process for treatment, collection, recycling and disposal. For more information on where you can drop off your waste equipment for recycling, please contact your local city office, your waste disposal service or the dealer where you purchased the product.

Comprehenso GmbH complies with the national implementation of the 2012/19/EU WEEE (waste electrical and electronic equipment) directive. The WEEE directive regulates the treatment, collection, recycling and disposal of electrical and electronic devices and their components. Under the directive, old equipment must be labelled, collected separately and disposed of properly.

9 Contrast medium protocols

9.1 Suggested protocols for manual contrast medium injection

	Fluoroscopy (FL), Digital Subtraction Angiography (DSA), Digital Radiography (DR)	Rotational Angiography (acquisition time 5 s)	C-Arm CT (acquisition time 6 s)
X-ray delay	0 s	2 s ¹	1.5 s ²
Rise time	Manual injection	Manual injection	Manual injection
Contrast medium	300 mg Iodine/ml	300 mg Iodine/ml	300 mg Iodine/ml
Syringe type	10 ml	20 ml	20 ml
Contrast medium volume	6-8 ml	20 ml	20 ml
Injection delay	if necessary, until mask image	0 s	0 s
Volume	6-8 ml	20 ml	20 ml
Contrast medium concentration	100 %	100 %	100 %
Flow rate	maximum, corresponds to ~ 6 ml/s	~ 2.5 ml/s	~ 2.5 ml/s
Injection duration	~ 1-2 s	8 s	8 s

¹ Contrast medium injection starts after completion of the mask run, approx. 2 s before filling starts

² Contrast medium injection starts approx. 1.5 s before image acquisition starts.

9.2 Suggested protocols for contrast medium injection with a two-piston syringe pump

	Fluoroscopy (FL), Digital Subtraction Angiography (DSA), Digital Radiography (DR)		Rotational Angiography (acquisition time 5 s)		C-Arm CT (acquisition time 6 s)	
X-ray delay	0 s		2.5 s ³		2.5 s	
Rise time	0.8 s		0.8 s		0.8 s	
Contrast Medium (CM)	300 mg Iodine/ml		300 mg Iodine/ml		300 mg Iodine/ml	
Contrast medium volume	5 ml		21 ml		14 ml	
Injection delay	1st phase	2nd phase	1st phase	2nd phase	1st phase	2nd phase
	1.5 s	0 s	0 s	0 s	0 s	0 s
Volume	CM	Water	CM	Water	CM	Water
	5 ml	10 ml	30 ml	20 ml	28 ml	16 ml
Contrast medium concentration	100 %	0 %	70 %	0 %	50 %	0 %
Flow rate	5 ml/s	5 ml/s	5 ml/s	5 ml/s	4 ml/s	4 ml/s
Injection duration	1 s	2 s	6 s	4 s	7 s	4 s

³ Contrast medium injection starts after completion of the mask run and approx. 2.5 s before filling starts

9.3 Suggested protocols for contrast medium injection with a single-piston syringe pump

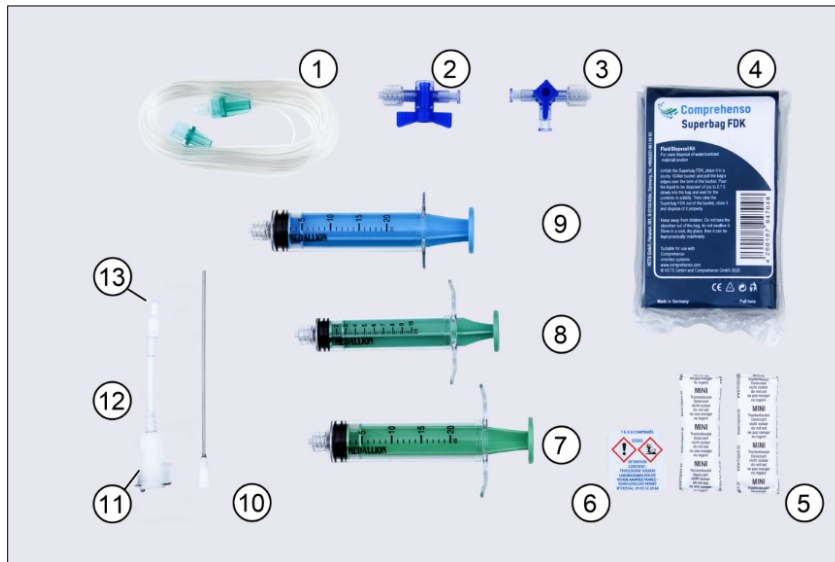
	Fluoroscopy (FL), Digital Subtraction Angiography (DSA), Digital Radiography (DR)	Rotational Angiography (acquisition time 5 s)	C-Arm CT (acquisition time 6 s)
X-ray delay	0 s	1 s ⁴	1.5 s
Rise time	0.8 s	0.8 s	0.8 s
Contrast medium	300 mg Iodine/ml	300 mg Iodine/ml	300 mg Iodine/ml
Contrast medium volume	6 ml	20 ml	18 ml
Injection delay	1.5 s	0 s	0 s
Volume	6 ml	20 ml	18 ml
Contrast medium concentration	100 %	100 %	100 %
Flow rate	6 ml/s	3.4 ml/s	2.5 ml/s
Injection duration	1 s	5.9 s	7.2 s

⁴ Contrast medium injection starts after completion of the mask run, approx. 1 s before filling starts

10 Consumables, operating equipment and care materials

In the following sections, details are given of all the consumables that are required for the operation of the phantom system.

Components of the set of consumables



- 1 Tube extension
- 2 Shutoff valve
- 3 Three-way valve
- 4 Liquid disposal bag (Superbag FDK)
- 5 Bag with drying agent*
- 6 Disinfectant tablet*
*(In the Clean & Dry set)
- 7 20-ml syringe for contrast medium (green)
- 8 10-ml syringe for contrast medium (green)
- 9 20-ml syringe for water (blue)
- 10 Blunt needle (14-gauge)
- 11 Contrast medium socket
- 12 Contrast medium injection tube (CMI tube)
- 13 Female Luer-Lock fitting

For assembly, initial start-up, and operation, you require:

Contrast medium injection tube (CMI tube)	for initial start-up of the circulation circuit
Shutoff valve	
Tube extension	
Three-way valve	for manual gas injection and contrast medium injection
10-ml syringe for contrast medium (green)	
20-ml syringe for contrast medium (green)	
20-ml syringe for water (blue)	for rinsing the system
Blunt needle (14-gauge)	for insertion in the puncture channel

For care and disassembly, you require:

Superbag FDK

Liquid disposal bag

for environmentally friendly disposal of
contrast medium solutions

Clean & Dry Set

Disinfectant tablet

for producing the disinfectant solution

Drying agent bag

for drying the phantom system during
transportation and storage

Please inform yourself under <https://comprehenso.de/> about the available consumable packages.

10.1 Circulation medium

The following circulation media can be used for operating the phantom system:

- **Tap water**
- **Distilled water**

The phantom system is filled with 2.5 l (85 fl oz) of water. Usually, tap water is suitable. Only if the water quality is insufficient should you resort to distilled or clear, boiled water. Using distilled water prevents limescaling.



The formation of gas bubbles in the vascular bed can be reduced by adding one drop of **dishwashing liquid** or **non-moisturizing liquid hand soap** to the water.

10.2 Contrast medium

For contrast, only use ambient air, carbon dioxide, or contrast media that fulfill the following criteria:

- Clear
- water-soluble
- suitable for intravenous injection
- iodine-based, with an iodine content of up to 300 mg/ml.

The contrast medium does not have to be sterile, but must have no visible impurities.

During this activity, observe the following safety instructions:



CAUTION

Improper disposal of contrast medium solutions!

Contamination of the environment.

- Use the liquid disposal bags included in the set of consumables for environmental disposal.
 - Observe your local regulations regarding the disposal of contrast medium solutions.
-

10.3 Disinfectants

To disinfect the phantom system, only use the disinfectant tablets provided in the **Clean & Dry Set** to make up the disinfectant solution.

During this activity, observe the following safety instructions:



WARNING

Formation of toxic gases due to improper mixing of liquids!

Danger to life.

- Never mix disinfectants and descaling solution, as toxic gases can form.



WORK STEPS

1. Product 2.5 liters of ready-to-use disinfectant solution.



A separate set of instructions is provided with the disinfectant tablet. Observe these instructions when making up and applying the disinfectant solution.

Do not use any other (e. g. aldehyde- or alcohol-based) disinfectants, as these can damage the components of the phantom system.

2. With the solution, perform *Disinfecting the phantom system*.

10.4 Descaling agents

Use only citric acid solution to descale the phantom system. Observe the instructions of the manufacturer when making up and applying the descaling solution.

To descale the phantom system, use 1 l of citric acid solution in the concentration 50 g citric acid in 1 l of water. Citric acid is available in powder form from food stores.

During this activity, observe the following safety instructions:



WARNING

Formation of toxic gases due to improper mixing of liquids!

Danger to life.

- Never mix disinfectants and descaling solution, as toxic gases can form.



WORK STEPS

1. Completely dissolve 50 g of citric acid in 1 l of water.
2. With the solution, perform *Descaling the phantom system*.

11 Manufacturer and service

Manufacturer: Comprehenso GmbH
Sophie-Küppers-Str. 50
30559 Hanover
Germany
www.comprehenso.de

Service contact: phantom-support@comprehenso.de

We provide digital media for our phantom systems in our media portal.

The device card of your phantom system contains a hyperlink to the media portal.

12 Symbols, type plate and device card

12.1 Symbols

The following symbols on the type plate and outer packaging have the following meaning:



The CE mark symbolizes the conformity of the product with the applicable requirements that the European Community places on the manufacturer. By affixing the CE mark, the manufacturer declares that the product complies with all applicable EU regulations and that a corresponding conformity assessment procedure has been carried out.



The symbol shown can be found on the product or on its packaging. It indicates that parts of this product (extension cord, pump) must not be disposed of with other waste. Instead, the devices should be taken to the collection points to enter the process for treatment, collection, recycling and disposal. For more information on where you can drop off your waste equipment for recycling, please contact your local city office, your waste disposal service or the dealer where you purchased the product.



Please observe the instructions given in the original operating manual!

12.2 Type plate

The following type plate is attached to the side of the phantom body:

Type plate



- 1 Product name
- 2 Serial number
- 3 Key
- 4 Manufacturer specification
- 5 QR-Code (2;3)
- 6 CE mark
- 7 Production year and month (YYMM)

12.3 Device Card

Each phantom system comes with a device card. The device card contains important information about the phantom system and refers to the digital user manual (this original operating manual) and digital media for the phantom system.

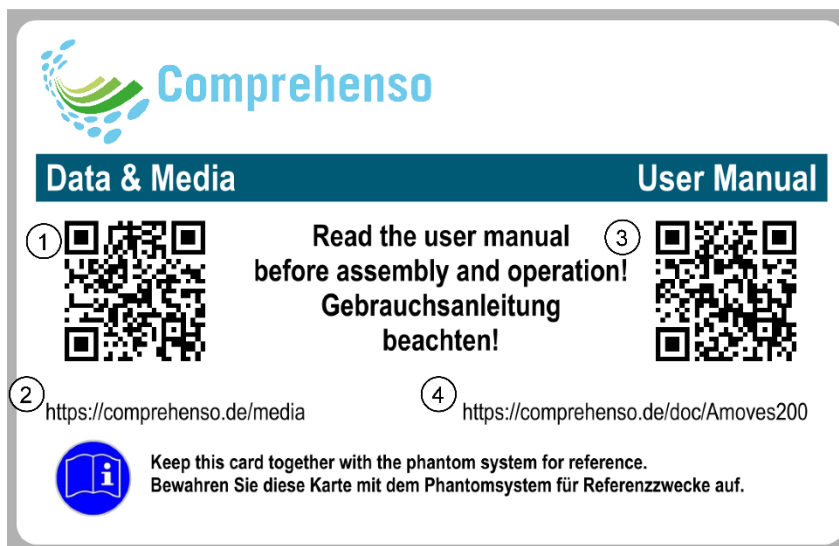
Keep the device card with the URL of the digital original operating manual with the phantom system for reference.

Device card – front view



- 1 Product name
- 2 Serial number
- 3 Key
- 4 Production year and month (YYMM)
- 5 QR-Code (2;3)
- 6 Manufacturer specification

Device card – back view



- 1 QR-Code (2)
- 2 Digital media URL
- 3 QR-Code (4)
- 4 User manual URL (Original operating manual)

13 Technical data

13.1 Technical data, Product variants

AmoVes 200 Phantom System (EU)	... (US)	... (AUS)	... (UK)
Material No.	CMP22001 CMP22011 [#]	CMP22002 CMP22012 [#]	CMP22003 CMP22013 [#]	CMP22004 CMP22014 [#]
Storage temperature	0 – 40°C (32 – 104°F)			
Dimensions of the package	467 x 400 x 205 mm (w x h x d)			
Dimensions of the product	455 x 365 x 190 mm (w x h x d)			
Gross weight	6.64kg	6.72kg	6.72kg	6.72kg
Net weight	6.00kg	6.08kg	6.09kg	6.09kg
Pump version for	European union	USA, Canada	Australia	United Kingdom
Power supply	230-240V, 50Hz	120V, 60Hz	220-240V, 50Hz	220-240V, 50Hz
Plug type	Type C (2 pins)	Type A (2 pins)	Type I (2 pins)	Type G (2 pins)
Power cord length	1.5 m	7.55ft	2.3 m	2.2 m
Power consumption	2.6W			

[#] AmoVes 200PRO Variant for frequent/heavy use

13.2 Part numbers

AmoVes 200 Phantom System (EU)	... (US)	... (AUS)	... (UK)
Material No.	CMP22001 CMP22011 [#]	CMP22002 CMP22012 [#]	CMP22003 CMP22013 [#]	CMP22004 CMP22014 [#]
Transportation case	CMP2200-M40 CMP2201-M39 [#]			
Phantom body	CMP2200-K05 CMP2201-K05 [#]			
Circulation reservoir	CMP2200-K10			
Cleaning reservoir	CMP2200-K11			
Short circulation tube	CMP2200-K08			
Long circulation tube	CMP2200-K09			
Pump tube	CMP2200-K13			
CMI tube	CMP2200-K07			
Pump	CMP22001-K15	CMP22002-K15	CMP22003-K15	CMP22004-K15

[#] AmoVes 200PRO Variant for frequent/heavy use

14 Declaration of conformity

In terms of the EC Machinery Directive 2006/42/EC, Appendix II 1.A

The manufacturer

Comprehenso GmbH
Sophie-Küppers-Str. 50
30559 Hanover
Germany

hereby declares that the following machine, in the version placed on the market by the manufacturer, complies with all relevant provisions of the 2006/42/EC "Machine Directive" directive - including the amendments valid at the time of this declaration.

Product	Phantom system
Model	AmoVes 200 ...
Serial number:	SN XX 200 ...
Trade name:	AmoVes 200 Phantom System
Year of construction:	2022

Function description:

AmoVes 200 has been developed to demonstrate and provide training in the functions of angiography systems.

The machine also complies with the relevant provisions of the following additional directives - including the changes valid at the time of this declaration:

Reference	Name
2011/65/EU	Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment
2014/30/EU	Directive 2014/30/EU relating to electromagnetic compatibility

The following harmonized standards according to EC Machinery Directive 2006/42/EC Article 7 (2) were applied:

Reference	Name
EN 60335-1:2012/A11: 2014	Safety of electrical appliances for household use and similar purposes - Part 1: General requirements IEC 60335-1:2010 (Modified)
EN ISO 12100:2010	Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)

The following standards harmonized according to other directives, other technical standards or parts thereof, and other specifications were applied:

Reference	Name
EN 60335-2-41:2003/A2:2010	Safety of electrical appliances for household use and similar purposes - Part 2-41: Particular requirements for pump
EN 61000-3-2:2014	Electromagnetic Compatibility (EMC) - Part 3-2: Limits - Limits for harmonic currents (device input current 16 A per phase)
EN 61000-3-3:2013	Electromagnetic Compatibility (EMC) - Part 3-3: Limit values - limitation of voltage changes, Voltage fluctuations and flicker in public Low-voltage supply networks for devices with a Rated current = 16 A per phase that does not[...]
EN 62233:2008	Procedure for measuring the electromagnetic fields of Household appliances and similar electrical appliances in terms on the safety of people in electromagnetic fields

The authorized community resident responsible for compiling the technical documents:

Hannover, 11.02.2022

Bernhard Meyer

(Managing Director)