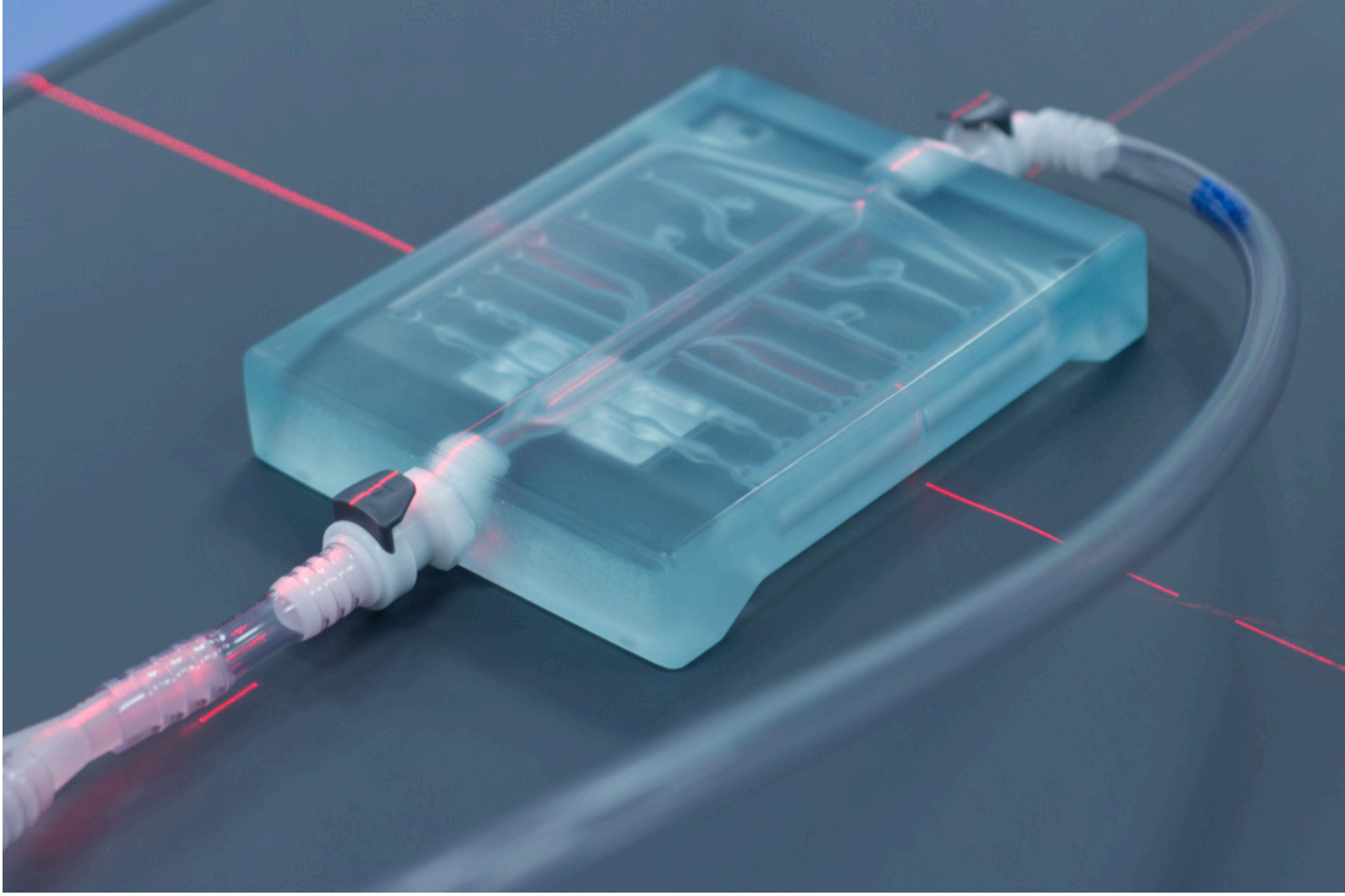

AmoVip 200 Phantom System

Translation of the Original Instructions

Comprehenso

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https://comprehenso.de/IP.

Contents

1 General information

This translation of the original instructions for the AmoVip 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 instructions and the safety information of the phantom system!

Injury of personnel and damage to the product.

- Carefully read through the entire original instructions before assembling and using the phantom system. They contain important information concerning use.
- Only use the phantom system in the way described in these original instructions.
- Keep the original instructions together with the phantom system for reference.

1.1 Intended use

The AmoVip 200 phantom system with phantom body was developed to simulate and train endovascular procedures under fluoroscopic or visual control.

AmoVip 200 can be used for simulation and for training of the following endovascular procedures:

- ***Endovascular catheterization*** of the vascular system
- ***Projectional radiography imaging techniques*** of the vascular system
- ***Introduction of solid materials*** (coils, plugs, and stents)
- ***Introduction of liquid materials*** (liquid embolic agents, adhesives)

To prevent the entrainment of materials with the circulation medium into the circulation reservoir and the pump, the return tube supplied for the phantom body must be used. Depending on the phantom body, a filter is integrated into the return tube.

If vessel branches of the phantom body are blocked by the introduction of materials, the phantom body with its return tube can be ordered separately as a replacement item and replaced.

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 these original instructions.
- Only ever use the phantom system for simulation and training purposes.

CAUTION

Improper use!

Injury due to metal projectiles and damage to the product.

- The phantom system can be used in angiography devices. It contains metal components. For this reason, do not use the phantom system in magnetic resonance imaging (MRI) systems.

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.
- Only ever use permitted replacement materials and circulation media, and approved accessories.

1.2 Users

The phantom system must only ever be sold or passed on to and used by persons of legal age with technical or medical training.

The user must have sufficient language skills to be able to read and understand completely the original instructions or the translations of the original instructions before assembly and operation.

Observe the following safety instruction:

CAUTION

Improper use!

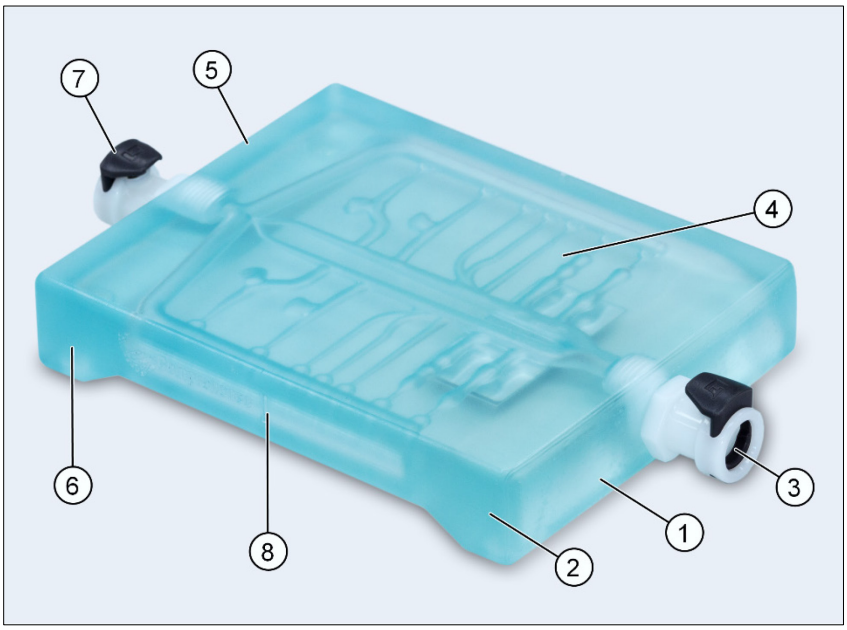
Injury of personnel or the patient and damage to the product.

- The phantom system must only be used by persons of legal age with technical or medical training.
- 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 AmoVip 200 phantom system was developed to train in endovascular procedures **under fluoroscopic** or **visual control**. The central element of the AmoVip 200 phantom system is the phantom body with vascular bed. The vascular bed situated in the interior can be filled with liquid through the inflow and outflow socket.

View of the phantom body



1 Inflow side of the phantom body
2 Marking **IN**
3 Inflow socket
4 Vascular bed
5 Outflow side of the phantom body
6 Marking **OUT**
7 Outflow socket
8 Vertical position indicator

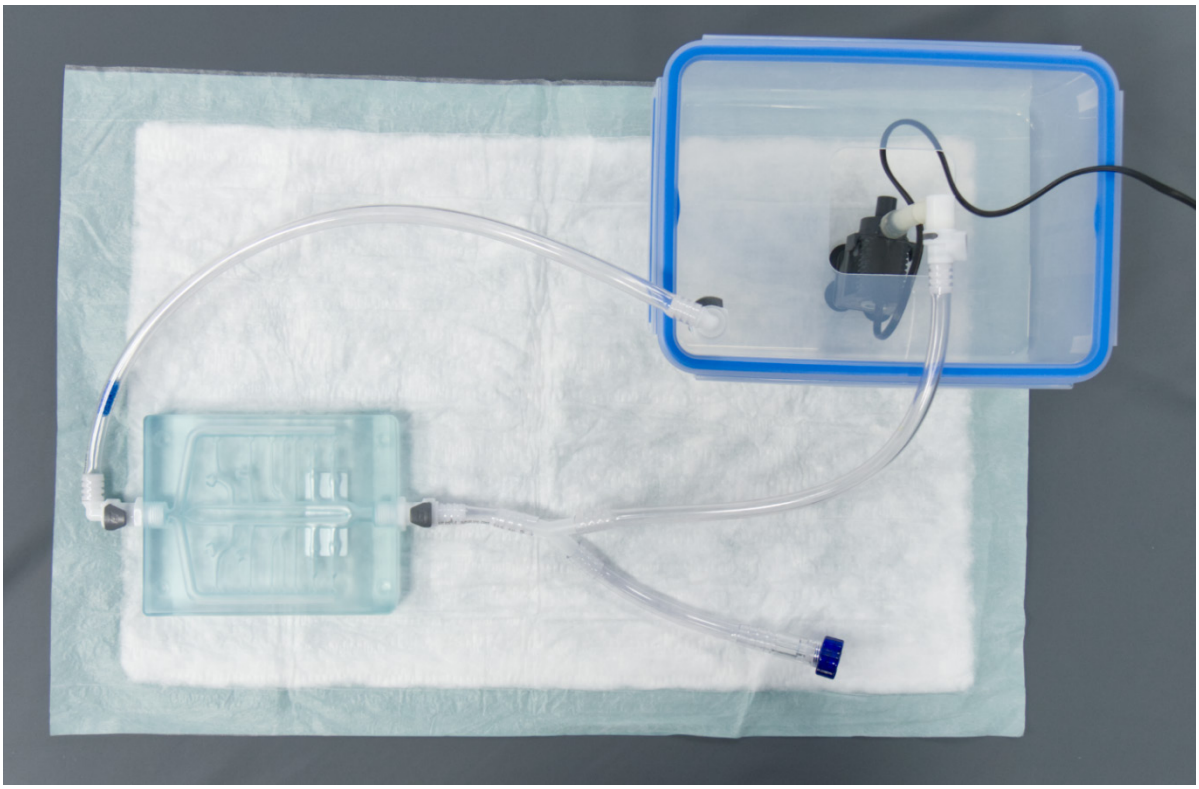
The pump pumps the circulation medium from the circulation reservoir of the phantom system via the pump tube through the Y-shaped supply tube with Tuohy-Borst adapter and the inflow socket into the central vessel of the phantom body. The vascular bed, the pump time volume, and the return tube for the phantom body have been dimensioned in such a way as to ensure that the liquid is distributed evenly to the vascular bed. The circulation medium flows out of the vascular branches through the drainage channels from where it passes through the outflow socket and the return tube back into the circulation reservoir.

Valves, catheters, and wires suitable for endovascular use can be introduced into the phantom body through the Tuohy-Borst adapter. It is also possible to implant coils and plugs.

To enable the injection of liquid embolic agents, the phantom body in conjunction with the return tube must be set up in such a way that liquid embolic agents cannot enter the circulation reservoir.

The phantom body is manufactured by 3D printing of single units. If vessel branches of the phantom body are permanently blocked by the introduction of materials, the phantom body with the associated return tube can be ordered separately as replacement material (see *Replacement materials and accessories*) and replaced.

Fully assembled phantom system



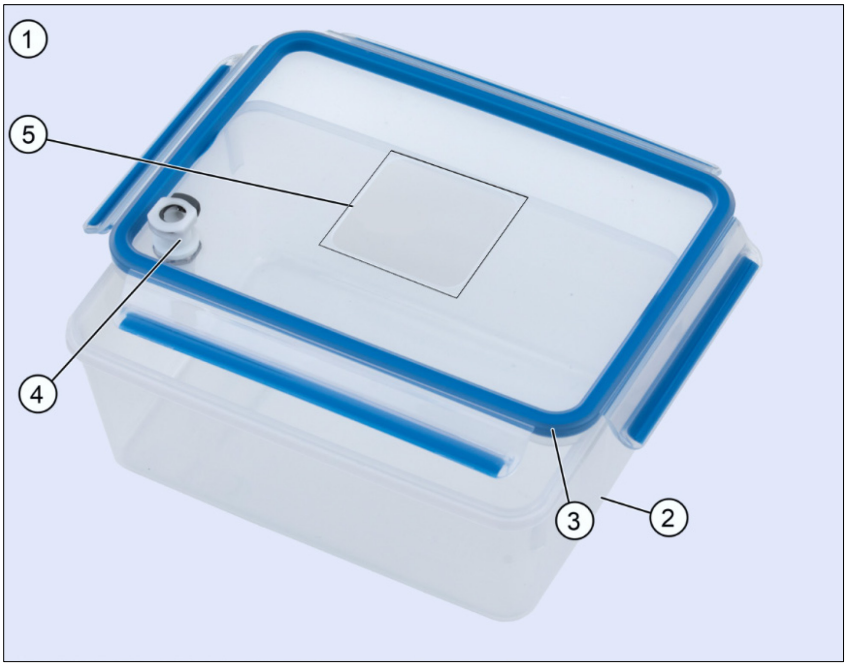
Proper assembly and operation as well as correct care after use are essential to the unrestricted functioning of the phantom system.

1.4 Scope of delivery

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

Reservoir

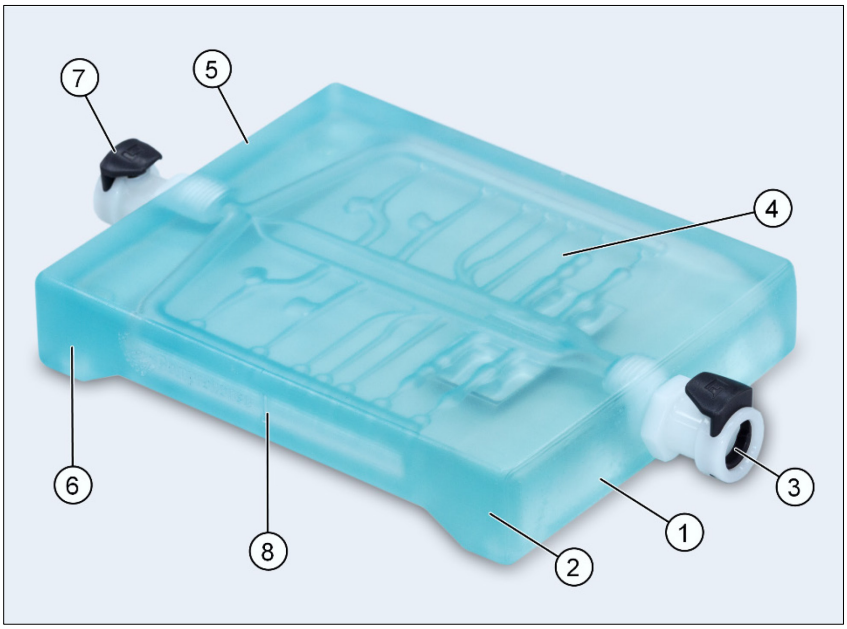
Circulation reservoir



1 Circulation reservoir
2 Circulation tank (3.7 l)
3 Reservoir lid
4 Return socket of reservoir
5 Center opening of the reservoir lid (for the pump tube and the power cable of the pump)

Phantom body

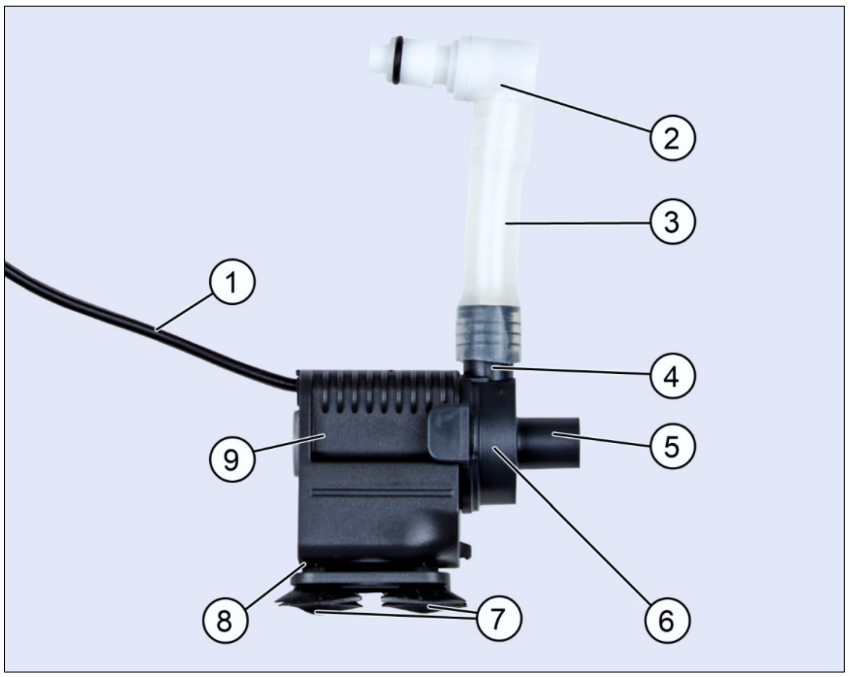
View of the phantom body



1 Inflow side of the phantom body
2 Marking **IN**
3 Inflow socket
4 Vascular bed
5 Outflow side of the phantom body
6 Marking **OUT**
7 Outflow socket
8 Vertical position indicator

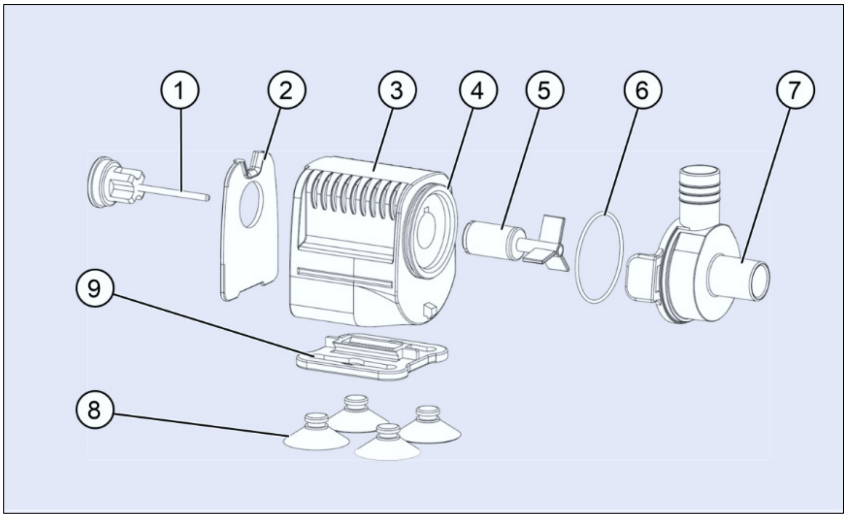
Pump

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

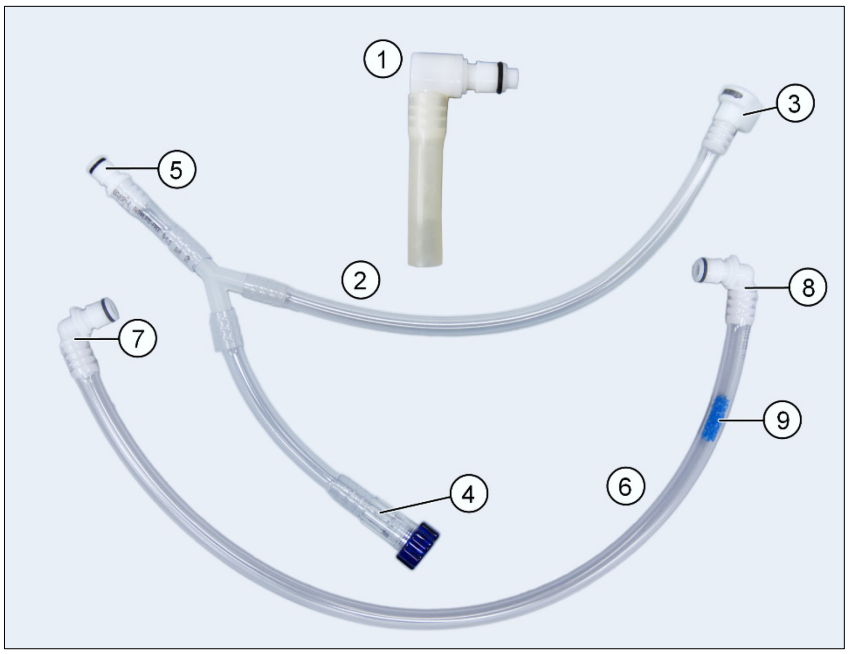
Individual parts of the pump



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

Tubes

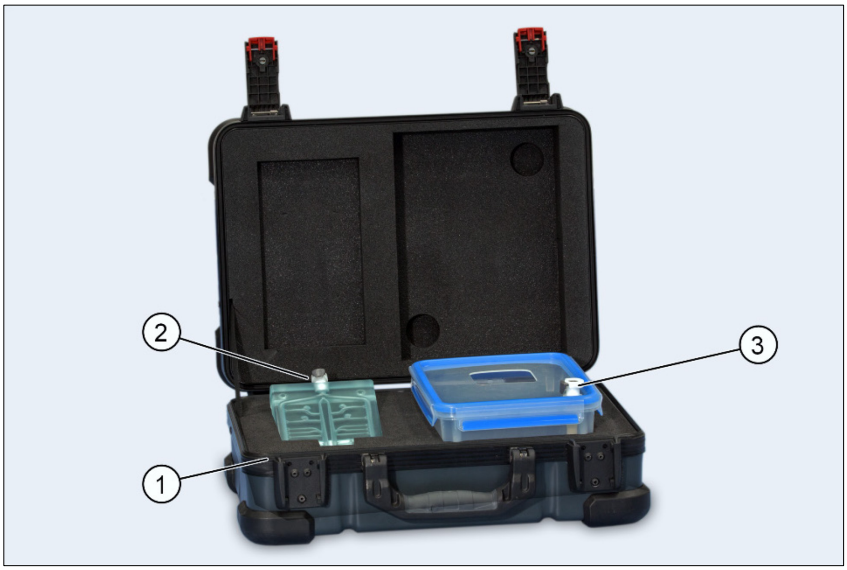
Tubes



1 Pump tube
2 Y-shaped supply tube with Tuohy-Borst adapter
3 Supply socket
4 Tuohy-Borst adapter
5 Supply plug
6 Return tube
7 Angled return plug
8 Angled outflow plug
9 Filter in the return tube (depending on the phantom body)

Transportation case

Transportation case open, showing phantom body and circulation reservoir



1 Transportation case
2 Recess for phantom (with phantom)
3 Recess for reservoir (with circulation reservoir)
4 Device card (not depicted, see **11.3**)
5 Transportation case key (no depicted)

Replacement materials and accessories

AmoVip 200 phantom body replacement package

The replacement packages contain replacement phantom bodies and the associated supply and return tubes.

Circulation medium kits

If special requirements are made of the circulation medium, circulation medium additives can be ordered as accessories.

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.
- Only ever use permitted replacement materials and circulation media, and approved accessories.

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 these original instructions means that death or serious injury can occur if the warnings are not observed.

CAUTION A caution in these original instructions 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: The phantom system draws electrical power!

Description of the danger: **Electric shock or burns due to short-circuit current.**

- **Description of the measures to avoid the danger:** Do not connect the pump to the power supply until the phantom system has been fully assembled.

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 the content of these original instructions. The original instructions contain safety instructions relevant to the user.

Observe the following general safety instructions.

WARNING

Failure to observe the original instructions and the safety information of the phantom system!

Injury of personnel and damage to the product.

- Carefully read through the entire original instructions before assembling and using the phantom system. They contain important information concerning use.
- Only use the phantom system in the way described in these original instructions.
- Keep the original instructions 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 technical or medical training.
- 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 these original instructions.
- Only ever use the phantom system for simulation and training purposes.

CAUTION

Improper use!

Injury due to metal projectiles and damage to the product.

- The phantom system can be used in angiography devices. It contains metal components. For this reason, do not use the phantom system in magnetic resonance imaging (MRI) systems.

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 to personnel, 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 using the phantom system with the circulation solution.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when using the phantom system with circulation solution.
- Always assemble and disassemble the phantom system in the sequence described in the original instructions to avoid circulation solution escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping circulation solution could damage electrical devices located in the vicinity, e.g. the angiography device.
- Do not incline or tip the tabletop of the angiography system when you are using the phantom system with circulation solution. It could escape through the central opening of the reservoir lid.

CAUTION

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

Injury to personnel, 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

Uncontrolled malfunctions!

Injury to personnel, 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.
- Only ever use permitted replacement materials and circulation media, and approved accessories.

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 rating 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 provide the power supply to the pump using a safety-tested single plug extension cable that has a total length of no more than 25 m.
- Make sure that the maximum permissible current of the extension cable is not lower than the maximum current that is limited either by the miniature circuit breaker or the fuse of the power outlet from which the power is supplied.
- 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 pump 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 plug 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 filled 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 circulation medium 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.

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 bag available as an accessory for environmentally friendly disposal.
- Observe your local regulations regarding the disposal of contrast medium solutions.

Safety instructions for operation with circulation media

Observe the following safety instructions when operating the phantom system with circulation media containing additives.

CAUTION

Improper disposal of the circulation medium!

Contamination of the environment.

- Use the liquid disposal bag supplied with the circulation medium additive to solidify and dispose of the circulation medium.
- Observe your local regulations regarding the disposal of the circulation medium

Safety instructions for operation with endovascular products

Observe the following safety instructions when operating the phantom system with endovascular products.

CAUTION

Introduction of rigid, pointed, or sharp products into the phantom system!

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

- Only ever introduce products developed for endovascular use into the phantom system.
- Do not use rigid, pointed, or sharp products that could damage the phantom system. Damage could impair the safety of the system.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

2.4 Safety instructions for care and maintenance

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

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 to personnel, 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 using the phantom system with the circulation solution.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when using the phantom system with circulation solution.
- Always assemble and disassemble the phantom system in the sequence described in the original instructions to avoid circulation solution escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping circulation solution could damage electrical devices located in the vicinity, e.g. the angiography device.
- Do not incline or tip the tabletop of the angiography system when you are using the phantom system with circulation solution. It could escape through the central opening of the reservoir lid.

CAUTION

Uncontrolled malfunctions!

Injury to personnel, 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:

- *Assembly of the pump and circulation reservoir*
- *Filling the circulation reservoir*
- *Assembly of the circulation circuit*
- *Initial start-up of the pump*
- *Priming the phantom body and the supply tube*
- *Positioning and registering the phantom*

3.1 Assembly of 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 rating 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!

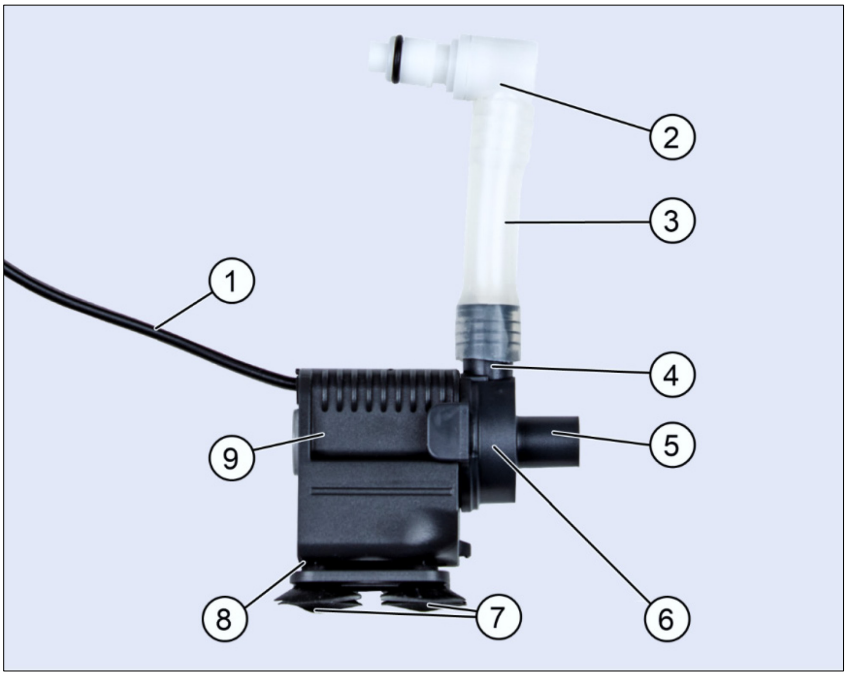
Injury of personnel and damage to the product.

- 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. This side will be referred to as the *side nearest the phantom body* in the following instructions.

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 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.

3.2 Filling the circulation reservoir

PREPARATION

You have completed the following preparatory steps:

✓ The angiography table is covered with an absorbent underlay.

✓ *Assembly of the pump and circulation reservoir*

WORK STEPS

1. Fill 2.5 l of circulation medium into the circulation reservoir through the center opening in the reservoir lid.

2. Use the scale on the short side of the reservoir to measure the quantity of circulation medium.

- The AmoVip 200 phantom system can be operated with various circulation media. You will find suitable circulation media under *Circulation media*.
- The circulation medium additives can be dissolved directly in the circulation reservoir. After the addition of circulation medium additives, wait until they have dissolved completely.
- The accumulation of gas bubbles in the vascular bed can be reduced by adding a drop of **dishwashing liquid** or **non-moisturizing hand-washing soap** to the circulation medium.
- To avoid leaving residues, perform *Rinsing the phantom system* after using the circulation media with additives.

3.3 Assembly of 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 pump 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 plug 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 to personnel, 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.
- ✓ *Assembly of the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*

The **Y-shaped supply tube with Tuohy-Borst adapter** is suitable for multiple use. The Y-shaped supply tube with Tuohy-Borst adapter should be replaced no later than after use with three phantom bodies.

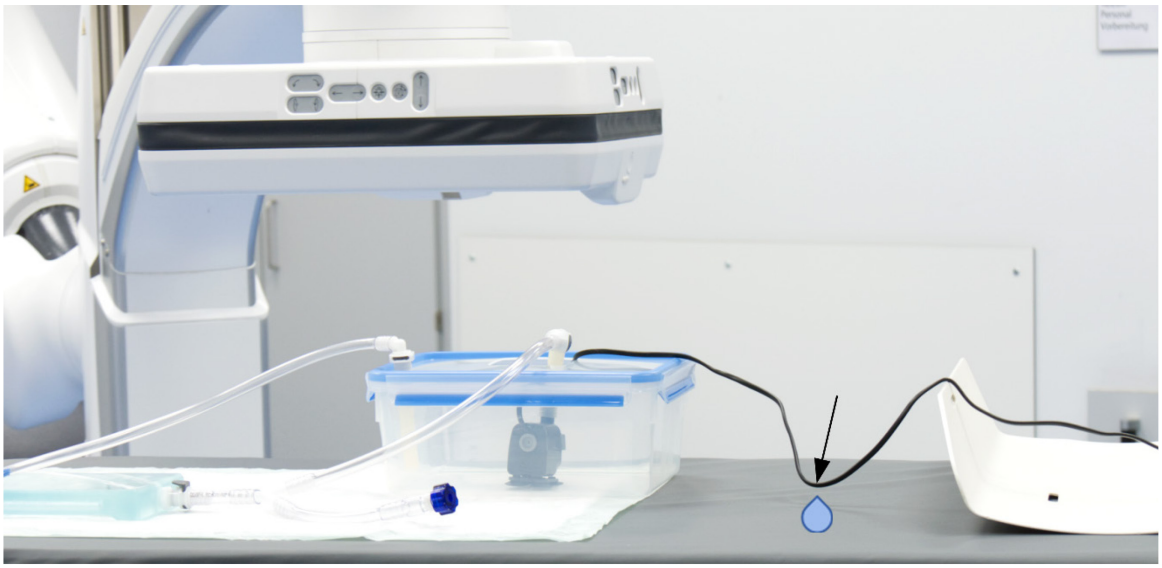
Also replace the Y-shaped supply tube with Tuohy-Borst adapter if the Tuohy-Borst adapter, the supply plug, or the supply socket leaks, or the tube connector or the tube breaks.

The **return tube** is suited for single use in conjunction with the associated phantom body. If a filter is integrated (depending on the vascular bed of the phantom body), it can only provide its protective function if it is replaced regularly, especially when used with liquid embolic agents.

WORK STEPS

1. Place the reservoir longways on the absorbent underlay that is closest to the table stand. The orientation and position of the components relative to each other are shown in the illustration of the fully assembled phantom system.
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 next to the reservoir on the side of the absorbent underlay nearest the C-Arm. The orientation and position of the components relative to each other are shown in the illustration of the fully assembled phantom system.

5. Align the inflow side of the phantom body with the reservoir. The inflow side of the phantom body is marked at the side with the alignment indicator ***IN***.

6. Connect the Y-shaped supply tube with Tuohy-Borst adapter to the inflow socket of the phantom body. Lock the Tuohy-Borst adapter by rotating it.

7. Connect the angled outflow plug of the return tube (right-angled plug near to the filter) to the outflow socket 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.

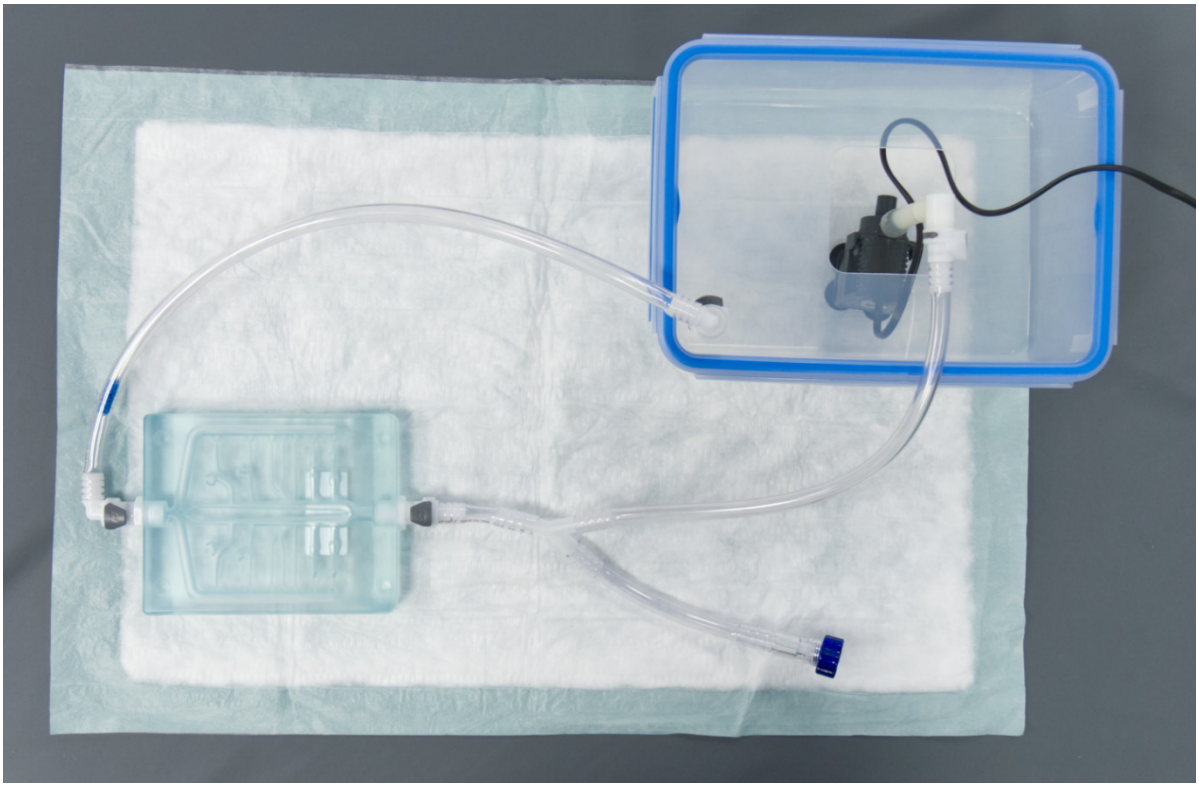
When assembling the phantom system, check that the connection position of the circulation tubes is correct. Only in this way, is correct flow through the vascular bed possible.

8. Plug the angled return plug of the return tube (right-angled plug furthest from the filter) into the return socket in the reservoir lid.

9. Connect the inflow socket of the Y-shaped supply tube with Tuohy-Borst adapter to the pump tube plug.

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 provide the power supply to the pump using a safety-tested single plug extension cable that has a total length of no more than 25 m.
- Make sure that the maximum permissible current of the extension cable is not lower than the maximum current that is limited either by the miniature circuit breaker or the fuse of the power outlet from which the power is supplied.
- 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 filled 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 circulation medium escapes from the phantom system.

CAUTION

Uncontrolled malfunctions!

Injury to personnel, 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.
- ✓ *Assembly of the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*
- ✓ *Assembly of the circulation circuit*

WORK STEPS

1. Bring the power supply to the pump using a safety-tested single plug extension cable.
2. Interrupt the power supply after 10 seconds for a few seconds in order to prime the pump.

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

3.5 Priming the phantom body and the supply tube

PREPARATION

You have completed the following preparatory steps:

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

WORK STEPS

1. Lift the phantom body above the level of the supply tube.
2. Tilt it in all directions. This causes the air to escape from the supply tube and the vascular tree of the phantom body into the circulation reservoir with the flow of the circulation medium.
3. If necessary, tap the side of the phantom body on the table or the underlay to cause the air to escape faster.

3.6 Positioning and registering the phantom

PREPARATION

You have completed the following preparatory steps:

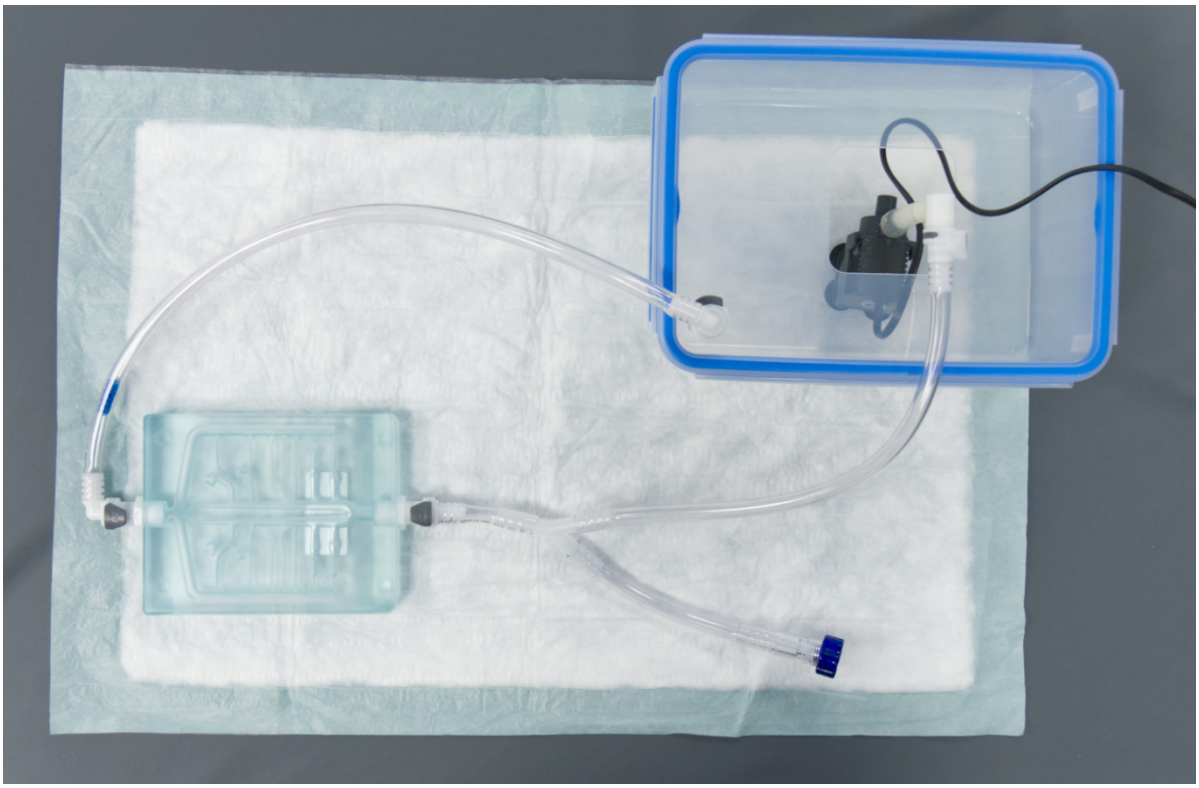
- ✓ The angiography table is covered with an absorbent underlay.
- ✓ *Assembly of the pump and circulation reservoir*
- ✓ *Filling the circulation reservoir*
- ✓ *Assembly of the circulation circuit*
- ✓ *Initial start-up of the pump*
- ✓ *Priming the phantom body and the supply tube*

WORK STEPS

1. Position the phantom body on the table of the angiography system.
2. In the angiography system, enter the orientation of the phantom as "Feet First - Supine".

The phantom system is now ready for operation.

Fully assembled phantom system



4 Operating the phantom system

During this activity, observe the following safety instructions:

CAUTION

Uncontrolled malfunctions!

Injury to personnel, 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.
- Only ever use permitted replacement materials and circulation media, and approved accessories.

CAUTION

Introduction of rigid, pointed, or sharp products into the phantom system!

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

- Only ever introduce products developed for endovascular use into the phantom system.
- Do not use rigid, pointed, or sharp products that could damage the phantom system. Damage could impair the safety of the system.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

4.1 Catheterization of the vascular tree

Valves, catheters, and wires suitable for endovascular use can be introduced into the phantom body through the Tuohy-Borst adapter.

PREPARATION

You have completed the following preparatory steps:

✓ *Assembly and initial start-up of the phantom system*

WORK STEPS

1. Place absorbent material under the Tuohy-Borst adapter of the Y-shaped supply tube.
2. Prepare the material to be introduced, for example, a hemostatic valve or a catheter for introduction into the vascular bed.
3. Open the Tuohy-Borst adapter of the Y-shaped supply tube by turning it until the material to be introduced through the Tuohy-Borst adapter can be introduced into the Y-shaped supply tube.
4. Turn the Tuohy-Borst adapter of the Y-shaped supply tube to close it again.

If possible, use a hemostatic valve to avoid repeated opening and closing of the Tuohy-Borst adapter and the resulting exit of circulation medium.

---

5. Introduce a catheter through the applied hemostatic valve. Position the introduced catheter at the relevant site in the vascular tree. Note that the catheter in the supply tube may get caught at the Y-piece and at the plug connections. For this reason, use a guidewire to advance the catheters as in endovascular interventions.
6. After completion of the catheterization, remove the valve or the catheter while opening the Tuohy-Borst adapter of the Y-shaped supply tube slightly.
7. Close the Tuohy-Borst adapter of the Y-shaped supply tube.

4.2 Contrast medium injection

To provide contrast in the vascular tree of the AmoVip 200, clear, water-soluble iodine-based contrast medium suitable for intravenous injection can be injected into the vascular bed.

PREPARATION

You have completed the following preparatory steps:

✓ *Assembly and initial start-up of the phantom system*

✓ *Catheterization of the vascular tree*

WORK STEPS

1. Position a catheter at the desired site in the vascular bed.
2. On the angiography device, select a suitable acquisition protocol for iodine-based contrast medium.
3. Inject contrast medium through the catheter into the vascular bed of the phantom body.

- If large quantities of iodine-based contrast medium are used, the circulation medium is contrasted and the vascular bed becomes visible. In this case, replace the circulation medium.
- To avoid leaving contrast medium residues, perform *Rinsing the phantom system* after using an iodine-based contrast medium.
- Contrast medium injection can be performed manually or automatically.

4.3 Introduction of endovascular products

With the AmoVip 200 phantom system, it is possible to implant coils and plugs in the vascular tree.

Injection of liquid embolic agents is enabled by a filter integrated into the return tube that prevents liquid embolic agents from entering the circulation reservoir.

PREPARATION

You have completed the following preparatory steps:

✓ *Assembly and initial start-up of the phantom system*

✓ *Catheterization of the vascular tree*

WORK STEPS

1. Position a suitable angiography catheter at the relevant site in the vascular tree of the phantom body.
2. Choose a suitable product. You will find suitable catheters and endovascular products under *Catheters and endovascular products*. In particular, pay attention to the specifications for the embolic agent type and the embolic agent quantity when liquid embolic agents are used.

   Implant or inject the desired product under visual or fluoroscopic control.

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 user 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 circulation medium*
  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.
- *Cleaning the pump*
  To maintain functionality

5.1 Emptying the phantom system

When the phantom system is emptied, the circulation medium 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 filled 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 circulation medium escapes from the phantom system.

CAUTION

Escaping liquids!

Injury to personnel, 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 using the phantom system with the circulation solution.
- Always place an absorbent underlay beneath the circulation reservoir, tubes, and phantom body when using the phantom system with circulation solution.
- Always assemble and disassemble the phantom system in the sequence described in the original instructions to avoid circulation solution escaping from the phantom system.
- Check the phantom system for leaks during initial start-up and operation. Escaping circulation solution could damage electrical devices located in the vicinity,
  e.g. the angiography device.
- Do not incline or tip the tabletop of the angiography system when you are using the phantom system with circulation solution. It could escape through the central 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 bag available as an accessory for environmentally friendly disposal.
- Observe your local regulations regarding the disposal of contrast medium solutions.

CAUTION

Improper disposal of the circulation medium!

Contamination of the environment.

- Use the liquid disposal bag supplied with the circulation medium additive to solidify and dispose of the circulation medium.
- Observe your local regulations regarding the disposal of the circulation medium

WORK STEPS

1. Disconnect the power supply of the pump.
   The phantom system is emptied passively.
2. Remove any catheters that have been placed.
3. Close the Tuohy-Borst adapter.
4. Disconnect the inflow socket of the Y-shaped supply tube with Tuohy-Borst adapter 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 supply tube and the phantom body through the long circulation tube into the reservoir.
6. Set the phantom body down again.
7. Open the Tuohy-Borst adapter.
8. Again lift the components above the level of the circulation reservoir. The remaining liquid now flows out.
9. Release the right-angled plug of the return tube from the return socket in the reservoir lid and connect it to the inflow socket of the Y-shaped supply tube with Tuohy-Borst adapter.
   The remaining liquid can now not escape.
10. Unfasten the reservoir lid and remove the pump.
11. Dispose of the liquid from the circulation reservoir.

Emptying the phantom system

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

To avoid leaving residues, *Rinsing the phantom system* must be performed after using circulation medium additives.

5.2 Replacing the circulation medium

If large quantities of iodine-based contrast medium are used, the circulation medium is contrasted and the vascular bed becomes visible. To prevent unwanted contrast and microbial contamination, you must regularly replace the circulation medium in the phantom system.

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

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

WORK STEPS

1. Perform *Emptying the phantom system*.
2. Perform *Assembly of the pump and circulation reservoir*.
3. Perform *Filling the circulation reservoir*.
4. Perform *Assembly of 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 *Priming the phantom body and the supply tube*

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 or **circulation medium additives** have been used, you must rinse the system with water 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 *Assembly of the pump and circulation reservoir*.
2. Perform *Filling the circulation reservoir*.
3. Perform *Assembly of the circulation circuit*
4. Perform *Initial start-up of the pump*.
5. Let the pump run for 2 minutes.
   This ensures that residue is rinsed out of the phantom system.
6. Perform *Emptying the phantom system* again.

5.4 Back-rinsing the phantom system

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

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 *Assembly of the pump and circulation reservoir*.
2. Perform *Filling the circulation reservoir*. Use water or distilled water as the circulation medium.
3. Perform *Assembly of the circulation circuit* To ensure that the circulation liquid flows in the opposite direction to that of the normal setup, that is, from the outflow side to the inflow side of the phantom body, in the following the connections for the supply tube and the return tube must be swapped round.

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

4. To do this, press the unlock button of the inflow socket to release the supply plug of the Y-shaped supply tube from the phantom body.
5. Press the unlock button of the outflow socket to release the angled outflow plug of the return tube from the phantom body.
6. Turn the phantom body through 180°. The position of the inflow side and the outflow side of the phantom body are now reversed.
7. Connect the angled outflow plug of the return tube to the inflow socket of the phantom body.
8. Connect the outflow socket of the phantom body to the supply plug of the Y-shaped supply 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.
11. Perform *Emptying the phantom system*.

5.5 Cleaning the pump

Clean the pump of the phantom system regularly. The pump can be cleaned, for example, after *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 filled 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 circulation medium 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 pump 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 plug 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.
- Only ever use permitted replacement materials and circulation media, and approved accessories.

CAUTION

Unprofessional repair of the system!

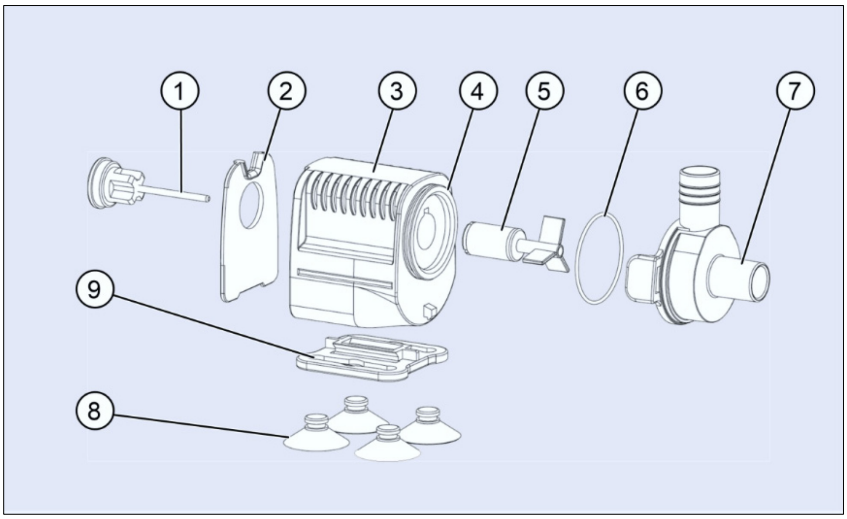
Injury of personnel and incorrect functioning and/or damage to the product.

- 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.

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 Y-shaped supply tube to disconnect it from the pump tube.
2. Press the unlock button of the inflow socket of the phantom body to release the Y-shaped supply tube with Tuohy-Borst adapter from the phantom body.
3. Press the unlock button of the outflow socket of the phantom body to release the return tube from the phantom body.
4. Press the unlock button of the return socket of the reservoir to release the return tube from the circulation reservoir.
5. Sway the phantom body so that the remaining liquid can flow out of the phantom body. Phantom bodies used up by the introduction of material can be disposed of directly with the return tube.
6. Remove the pump tube from the pump outflow pipe.
7. Dry the phantom body, the pump, and the circulation reservoir with soft cosmetics tissues or single-use hand towels.
8. Dry the pump tube, the Y-shaped supply tube with Tuohy-Borst adapter, and the return tube with soft cosmetics tissues or single-use hand towels.
9. Place the phantom body in the phantom recess in the transportation case. Place the pump, the pump tube, the Y-shaped supply tube with Tuohy-Borst adapter, and the return tube on the floor of the circulation tank.
10. Close the circulation reservoir. Place the circulation reservoir in the reservoir recess in the transportation case.

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

Leave the lid of the case open until all residual liquid inside the phantom system has completely dried.

7 Remedying 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.	• Check the water level. If necessary, top up the circulation reservoir with water. No air bubbles should form under the return 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 socket and the phantom body. • Prime the Y-shaped supply tube with Tuohy-Borst adapter by lifting the entire system. Trapped air can be removed from the vascular bed by rotating the phantom body. Gently tap the phantom body.
The vascular tree does not exhibit or barely exhibits contrast when contrast medium is injected.	• Check whether the circulation tubes have been connected in the correct sequence. • Check whether the catheter used is obstructed. • Change the circulation medium. If a large quantity of contrast medium has already been administered, the difference in density between the injected contrast medium and the circulation medium decreases.
The vascular tree exhibits insufficient contrast when liquid iodine-based contrast medium is injected.	• Individual vascular branches could be obstructed by foreign bodies. Perform back-rinsing. *(→Back-rinsing the phantom system*)
The phantom system leaks and water is escaping.	• Disconnect the power supply of the pump, mop up the liquid with absorbent material and look for the leak. • Close the valve on the Tuohy-Borst adapter. Replace the Y-shaped supply tube if it leaks. • 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 substantially if the equipment is used on a regular basis.

The phantom body is designed for a maximum duration of use of up to 2 weeks after permanent introduction of products. When the phantom body is replaced, a new return tube is supplied. This is also replaced.

The Y-shaped supply tube can be used for up to three phantom bodies. It must be replaced immediately if it leaks.

The pump is subject to the WEEE Directive 2012/19/EU (waste electrical and electronic equipment). It must not be disposed of with other waste. Instead, it should be brought to the return points to enter the process for treatment, collection, recycling, and disposal. For further information about where your waste equipment can be handed over for recycling, contact your local authority, your waste disposal service, or the dealer from whom you purchased the product.

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

9 Consumables

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

9.1 Circulation media

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 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.

- ***Water with additives***

For certain applications, such as the use of liquid embolic agents, specific requirements are made of the circulation medium for the hardening process. For these applications, specific circulation medium additives are available as accessories.

Use only the circulation medium additives available as accessories to avoid damage to the phantom system.

The formation of gas bubbles in the vascular bed can be reduced by adding a drop of dishwashing liquid or non-moisturizing hand-washing soap to the circulation medium.

CAUTION

Improper disposal of the circulation medium!

Contamination of the environment.

- Use the liquid disposal bag supplied with the circulation medium additive to solidify and dispose of the circulation medium.
- Observe your local regulations regarding the disposal of the circulation medium

9.2 Contrast medium

Use only contrast media for contrasting that meet 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 bag available as an accessory for environmentally friendly disposal.
- Observe your local regulations regarding the disposal of contrast medium solutions.

9.3 Catheters and endovascular products

The AmoVip 200 phantom system was developed to simulate and train endovascular procedures. For this purpose, endovascular products can be introduced into the phantom body through the Tuohy-Borst adapter.

During this activity, observe the following safety instructions:

CAUTION

Introduction of rigid, pointed, or sharp products into the phantom system!

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

- Only ever introduce products developed for endovascular use into the phantom system.
- Do not use rigid, pointed, or sharp products that could damage the phantom system. Damage could impair the safety of the system.

CAUTION

Improper introduction of liquid embolic agents into the phantom system!

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

- Only ever introduce small quantities of liquid embolic agents into the vascular tree of the phantom body to avoid entrainment into the return tube.
- Only ever introduce liquid embolic agents under visual or radiographic control. End introduction when the liquid embolic agent from the vascular bed flows into the drainage channels.
- Ensure sufficient solidification in the vascular bed by choosing a suitable embolic agent and circulation medium.

The following products intended for endovascular use can be used with the AmoVip 200 phantom system:

- Valves (up to 9 French)
- Catheters (up to 9 French)
- Guidewires
- Microcatheters
- Microwires
- Coils and plugs
- Other products that were developed for endovascular use provided they are not pointed, sharp, and/or rigid and can be introduced without damaging the phantom system.

Injection of liquid embolic agents is enabled by a filter integrated into the return tube. The introduction of liquid embolic agents **irreversibly occludes** the branches of the vascular bed. The phantom body must therefore be ***replaced*** for future use (see ***Replacement materials and accessories***).

Only liquid embolic agents that have the following properties must ever be introduced:

- ***Compatibility*** with the materials of the AmoVip 200 phantom system
- ***Solidification*** of the liquid embolic agent in the vascular bed with adhesive properties
- No entry of the embolic agent into the return tube due to ***limitation of the quantity***

10 Manufacturer and service

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

Industrial property rights and patents relating to our brand and products are listed at:

https://comprehenso.de/IP

Service contact: phantom-support@comprehenso.de

We provide digital media, where applicable, for our phantom systems in our media portal. The device card of your phantom system contains a link to the media portal.

11 Symbols, rating plate, and device card

11.1 Symbols

The following symbols on the rating plate and the outer packaging have the following meanings:

The CE marking indicates the conformity of the product with the valid requirements that the European Union makes of manufacturers. By applying the CE marking, the manufacturer declares that the product conforms to all valid EU regulations and that a conformity assessment procedure has been performed for this purpose.

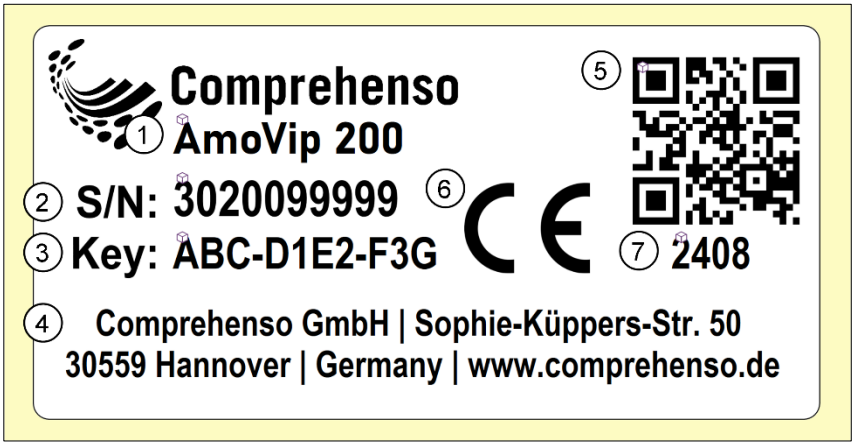
The symbol depicted appears on the product or on its packaging. It indicates the parts of the product (extension cable, pump) must not be disposed of with other waste. Instead, the equipment should be brought to the return organizations to enter the process for treatment, collection, recycling, and disposal. For further information about where your waste equipment can be handed over for recycling, contact your local authority, your waste disposal service, or the dealer from whom you purchased the product.

Observe the original instructions!

11.2 Rating plates

The following rating plate is attached to the phantom system:

Rating plate



1 Product name
2 Serial number
3 Key
4 Manufacturer's data
5 QR code (2;3)
6 CE marking
7 Year and month of production (YYMM)

11.3 Device card

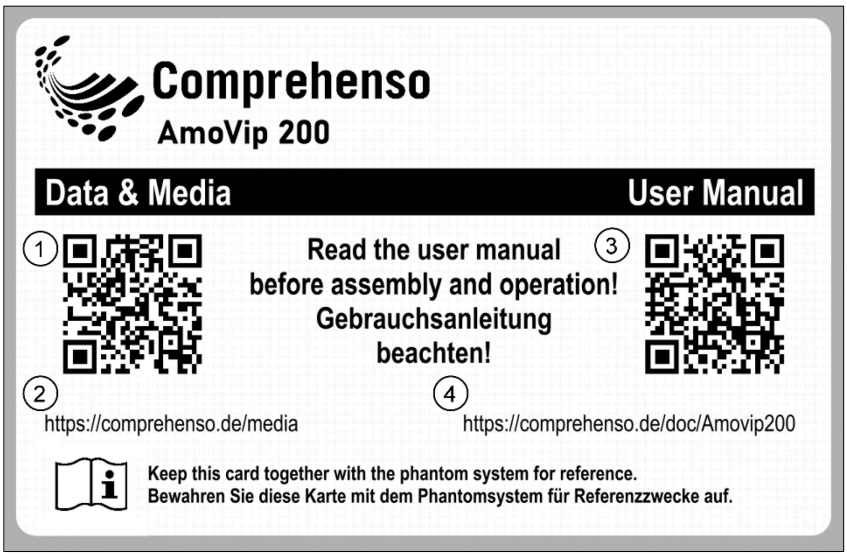
Every phantom system is supplied with a device card. This contains important information about the phantom system and a link to the digital manual (these original instructions) and digital media for the phantom system.

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

Device card - front

1 Product name
2 Serial number
3 Key
4 Year and month of production
5 QR code (2;3)
6 Manufacturer's data

Device card - back



1 QR code (2)
2 URL of the digital media
3 QR code (4)
4 URL of the digital manual (original instructions)

12 Technical data

12.1 Technical data, product variants

AmoVip 200 Phantom System …	**… (EU)**	**… (US)**	**… (AUS)**	**… (UK)**
Item No.	CMP24001	CMP24002	CMP24003	CMP24004
Storage temperature	0 – 40°C (32 – 104°F)			
Packaging dimensions	467 x 400 x 205 mm (w x h x d)			
Product dimensions	455 x 365 x 190 mm (w x h x d)			
Gross weight	6.36kg	6.44kg	6.44kg	6.44kg
Net weight	5.73kg	5.81kg	5.81kg	5.81kg
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-pole)	Type A (2-pole)	Type I (2-pole)	Type G (2-pole)
Length of the power cable	1.5 m	7.55ft	2.3 m	2.2 m
Power consumption	2.6W			

12.2 Part numbers

AmoVip 200 Phantom System …	**… (EU)**	**… (US)**	**… (AUS)**	**… (UK)**
Item No.	CMP24001	CMP24002	CMP24003	CMP24004
Transportation case	CMP2201-M39			
Phantom body	CMP24011			
Circulation reservoir	CMP2200-K10			
Y-shaped supply tube	CMP2400-K08			
Return tube	CMP2400-K09			
Pump tube	CMP2400-K13			
Pump	CMP22001-K15	CMP22002-K15	CMP22003-K15	CMP22004-K15

13 EC declaration of conformity

In accordance with the EC Machinery Directive 2006/42/EC, Annex II, 1.A

The manufacturer

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

hereby declares that the following machinery in the version placed on the market by the manufacturer meets all relevant provisions of Directive 2006/42/EC "Machinery Directive", including any amendments valid at the time of this declaration.

Product:	Phantom system
Model:	AmoVip 200 …
Serial number:	**SN 30200 …**
Trade name:	AmoVip 200 Phantom System
Year of construction:	2024

Description of function:
The AmoVip 200 phantom system was developed to simulate and train in endovascular procedures under fluoroscopic or visual control.

The machinery also meets the relevant provisions of the following directives, including any amendments valid at the time of this declaration:

Reference	Name
2011/65/EU	Restriction of the use of certain hazardous substances in electrical and electronic equipment 2011/65/EU
2014/30/EU	Electromagnetic compatibility 2014/30/EU

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

Reference	Name
EN 60335-1:2012/A11: 2014	Household and similar electrical appliances - Safety - 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 have been applied:

Reference	Name
EN 60335-2-41:2003/A2: 2010	Household and similar electrical appliances - Safety - Part 2-41: Particular requirements for pumps
EN 61000-3-2:2014	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)
EN 61000-3-3:2013	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection
EN 62233:2008	Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure

Person resident in the Community authorized to compile the relevant technical documents:

Hanover, Nov. 1, 2024

Bernhard Meyer

(CEO)