Instructions for Use

Max™ 3
ulricheasyINJECT

Max™ 2M
ulricheasyINJECT

MRI Contrast media injector

ulrich medical

In these instructions for use, information that only applies to your device is labeled with the model identifier.

- ▷ Place a check mark in the left column for your device.
- ▷ Optionally, you can also enter the device's serial number in the 2nd column.

Your device details	Serial number	Device ID	Model	Symbol
		XD 10150	Max 3	
		XD 10140	Max 2M	

Table 1. Device identification

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1 About this document

These instructions for use and the associated supplements are part of the ulrich**easy**INJECT Max 2M / Max 3 product (called "injector system" below) from software version 2.1.x and higher and are valid until replaced by a later revision of the instructions for use. These instructions for use and the associated supplementary sheets describe safe and proper use of the product.

- Read the instructions for use and all supplements before using the product.
- Keep the instructions for use and all supplements readily available with the product at all times.
- Read all applicable documents before using the product.

1.1 Applicable documents

Document	Catalog number
Instructions for use "Instructions for use Patient tubing for ulrich**easy**INJECT CT / MRI"	XD 10830-US
Instructions for use “Instructions for use Patient tubing for ulrich**easy**INJECT CT / MRI without RFID”	XD 10831-US
Instructions for use "Instructions for use for Easy-Click-Cassette – flex"	XD 10822-US
Instructions for use "Instructions for use for spike for Easy-Click-Cassette – flex"	XD 10823-US

Table 2. Applicable documents

1.2 Labeling and symbols

Labeling	Meaning
DANGER!	**Hazards to persons.** Failure to observe these warnings can lead to death or serious injury with permanent disabilities.
WARNING!	**Hazards to persons.** Failure to observe these warnings can lead to severe injury.
CAUTION!	**Hazards to persons.** Failure to observe these warnings can lead to minor injury.
NOTE!	**Indicates a property damage message.** If not avoided, the device, its components, and accessories may be damaged.
	Information for understanding, facilitating operation or improving workflows.
✓	Requirement. Indicates a condition to be met before an action is performed.

Labeling	Meaning
▶	Handling instructions. Indicates a situation where the operator has to take specific action.
1. 2.	Multi-step handling instructions. Observe the sequence.
➥	Results, or outcome of a specific user or system action

Table 3. Labeling and symbols

1.3 Abbreviations

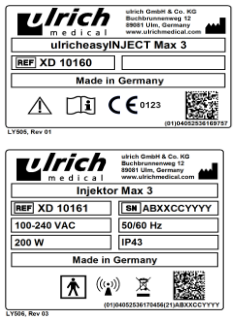
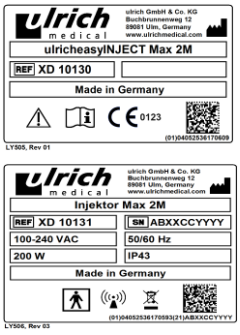
Abbreviation	Meaning
CM	Contrast media
COM	Serial port
CT	Computed tomography
EMC	Electromagnetic compatibility
ESD	Electrostatic discharge
IBP	Imaging Bulk Packages
IFU	Instructions for Use
RF	Radio frequency
MR	Magnetic resonance
MRI	Magnetic resonance imaging
NaCl or Saline	NaCl and Saline are used interchangeably within this context of this document. Both terms signify 0.9% saline solution.
PET	Positron Emission Tomography
TSC	Technical safety check
USB	Universal serial bus
WLAN	Wireless local area network

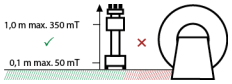
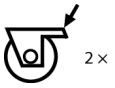
Table 4. Abbreviations

2 Symbols and terms on the product and packaging

2.1 Product

2.1.1 Injector

Symbol / Term	Meaning
A	Ampere
COM	Serial port
Hz	Hertz
IP43	Protection class
REF	Catalogue number
SN	Serial number
V AC	Volt (alternating current)
V DC	Volt (direct current)
⚠	Caution
	Consult instructions for use
CE 0123	CE mark with identification number of the notified body
EAC	Eurasian Conformity Mark (only applicable to Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan)
	Manufacturer
	Max 3 type labels
	Max 2M type labels

Symbol / Term	Meaning
	Type BF applied part
	Permissible load on tray
	WLAN
	Warning, Hot surface
	Non-ionizing electromagnetic radiation
	Equipotentiality
	Protective earth (ground)
	Segregated collection of electrical and electronic devices; lead battery, not to be disposed of with domestic waste
	Injector weight
	No sitting
	No stepping on surface
	Refer to instruction manual/booklet
	Do not charge in MRI room
	Move and place injector system for injection inside the MRI room only up to a magnetic field strength of max. 350 mT (measured at 1.0 m above floor) **and** max**.** 50 mT (measured at 0.1 m above floor).
	Lock at least two parking brakes after positioning
	Do not hold / move the injector by the injector head. Risk of tipping over and consequential damage due to increased magnetic attraction.

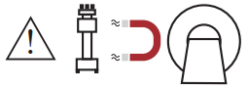
Symbol / Term	Meaning
	Danger of magnetic attraction of the injector by the MRI scanner / personal injury and damage to property if the safety conditions are not observed.
	**MR Conditional** – A product which does not demonstrate any deliberate hazards in the specific MRI environment

Table 5. Symbols on the injector

2.1.2 Touch terminal

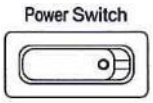
Symbol / Term	Meaning
	On/off switch
DC IN 12–24 V	Direct current voltage 12–24 V
OTG	USB on-the-go port
USB	USB connection
LAN	LAN port
HDMI	HDMI port
COM1	COM1 port
COM2	COM2 port

Table 6. Symbols on the touch terminal

2.2 Packaging

2.2.1 Injector system

Symbol / Term	Meaning
	This way up
	Fragile, handle with care
	Keep dry
	Temperature limit
	Atmospheric pressure limitation

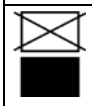
Symbol / Term	Meaning
	Humidity limitation
	Do not stack
	Eurasian Conformity Mark (only applicable to Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan)
	Hazardous materials class 9 – lithium batteries

Table 7. Symbols on the packaging of injector and touch terminal

3 Indications for use

ulrich**easy**INJECT Max System (Max 2M and Max 3) is a contrast media management system that is indicated for the controlled, automatic administration, on the venous side, of contrast media and saline (NaCl), to human subjects undergoing diagnostic examinations in magnetic resonance (MR) applications.

ulrich**easy**INJECT Max is specifically indicated for use in MRI procedures for the delivery of Clariscan (Gadoterate Meglumine) Injection, - GE Healthcare Inc .contrast media as supplied in approved single dose bottles.

Easy-Click-Cassette – flex Max 2M and Easy-Click-Cassette – flex Max 3 are used for a maximum time of twenty four (24) hours or a maximum of 96 bottles of contrast media, or whichever comes first. Time per IBP contrast media or saline container depends on each contrast media’s or saline’s use time expiration with a maximum of twenty four (24) hours per IBP contrast media or saline container. Use time expiration per single dose contrast media container is a maximum of four (4) hours per contrast media container, unless otherwise stated by the contrast media labeling.

Spike for MRI disposable is for single-bottle use only and must be discarded with the media container. The Patient tubing must be discarded after each patient procedure.

ulrich**easy**INJECT Max is to be used only by and under quasi-continuous supervision of trained healthcare professionals in an appropriate licensed healthcare facility, in a room designated for radiological procedures that involve intravascular administration of contrast agent.

The ulrich**easy**INJECT Max is not intended for injection of contrast media (CM) for high-pressure angiography.

3.1 Contraindications

The ulrich**easy**INJECT Max 2M / Max 3 injectors are not intended for the administration of contrast medium during high-pressure angiography or other applications that do not comply with the intended use.

The injector is not protected against the effects of defibrillation. Before a defibrillator is used, the patient must be disconnected from ulrich**easy**INJECT Max 2M / Max 3 injector.

Do not add any disposables (i.e. connector tubing or valves) to the ulrich**easy**INJECT Max 2M / Max 3 disposables or in conjunction with the patient tubing that are not provided by ulrich medical. No valves or other connectors may be placed in-line between the patient tubing and the patient cannula. The disposables identified in this IFU are designed, manufactured, and tested for connection with cannulas for pressure injections.

Do not use ulrich**easy**INJECT Max 2M / Max 3 injectors with any other contrast media (other than those described in this IFU). Any other contrast media are inappropriate and should not be used.

Do not operate the injector and terminal, including any accessories, in potentially explosive atmospheres or in the vicinity of combustible materials (especially anesthetic drugs, detergents, and oxygen-enriched environments).

3.2 Patient group

Patients receiving a contrast medium enhanced MRI examination. Patient demographics may be determined by the contrast media used with ulrich**easy**INJECT Max.

4 Safety notes

The instructions for use are part of the injector system.

- Keep the instructions for use for the operating personnel readily available near the injector system at all times.
- Carefully read the instructions for use.
- Observe the safety notes provided in the instructions for use.
- For your own safety, the safety of the patient and third parties, and as required by the applicable regulations, guidelines, and laws, read and observe the following safety notes.

4.1 Safe operation of the injector system

- Check that the injector system is in proper condition before each use, and only operate it in proper condition.
- Only set up the injector system in accordance with ulrich medical’s installation instructions.
- Install and use the touch terminal only outside the MRI / PET examination room.
- Only charge the battery in the injector outside the MRI room.
- Move the injector in the MR room only up to a maximum magnetic field strength of 50 mT (at a height of 0.1 m above the floor) and position it for the injection.

- If a 30 mT safety line already exists or a safety line has been designated by ulrich medical or by a person authorized by ulrich medical, only position the injector outside this safety line for the injection.
- To move the injector, always hold it by the handlebar and secure it with at least 2 parking brakes after positioning.
- Do not hold / move the injector by the injector head. Risk of tipping over and consequential damage due to increased magnetic attraction.
- Ensure that the patient tubing is not tangled or trapped between the injector and the patient table of the MRI scanner.
- Check the injector system for damage before operating it.
- Do not operate the injector system when there is visible damage.
- In case of visible damage to cables, plugs, housing, or other components, take the injector system out of operation.
- In case of visible damage to the roll pump cover, take the injector system out of operation.
- Only allow installation, repairs, and technical safety checks to be performed by ulrich medical or by persons authorized by ulrich medical.
- Only allow the injector's rechargeable batteries to be replaced by ulrich medical or by specialist staff authorized by ulrich medical; the batteries may also only be replaced outside the patient's environment.
- Do **not** modify the injector system or components without permission from ulrich medical.
- **Radiofrequency radiation exposure information:**
  The radiated output power of the device is far below the FCC radio frequency exposure limits. Nevertheless, the device should be used in such a manner that the potential for human contact during normal operation is minimized

Special instructions regarding safe use of the injector system in CM Select mode

- Perform rinsing programs if the injector system is set up and in CM Select mode.
- Do not plug a Saline (NaCl) rinse bottle with a volume > 250 mL into the spike with holder (I) of the Easy-Click-Cassette – flex for performing the CM Spike Flush procedure.
- If the CM sensor detects air at a CM connection point during rinsing with NaCl or the CM Spike Flush process was manually canceled, the currently plugged-in Saline (NaCl) rinse bottle and the spike must be discarded, a new Saline (NaCl) rinse bottle and spike must be connected, and the entire rinse process must be repeated.

Risk of injury for patients due to magnetically induced movements of improperly installed device components in the MRI room. An MRI scanner may magnetically attract the touch terminal and thereby cause injury to individuals.

- In accordance with IEC 60601-1, only set up and operate the touch terminal outside the MRI examination room.

The use of tubing combinations, tubing systems, disposables, components or accessories not approved by ulrich medical or handled in an improper way jeopardizes the life and safety of the patient and the operator and compromises the proper functioning of the injector system.

- Only use components (accessories, interfaces, disposables, power cords, and mains adapters) that have been approved by ulrich medical.
  – Other components can cause damage to the injector system and affect the injector system's immunity to interference.
- Only use approved original products from ulrich medical.

- Counterfeits and other brands are not designed for use with the injector and have not been tested for use with the injector.
- ulrich medical will only assume responsibility if disposables approved by ulrich medical are used during operation.

The use of thin-walled media containers unsuitable for the configured flow compromises the proper functioning of the injector system: If the flow is too high, the media containers can "collapse", so that the injection is interrupted.

- When using media containers made of thin-walled plastic: Ensure that the flow set in the injection program is suitable.

4.2 Person-related safety notes

4.2.1 Operating entity’s responsibilities

- Ensure that the relevant legal and regulatory requirements and the relevant guidelines and definitions of the local establishment are observed when handling the injector system.

Technical safety checks and repairs

- Perform regularly scheduled technical safety checks.
- Only allow repairs and technical safety checks to be performed by ulrich medical or by persons authorized by ulrich medical.

Environmental, transport and storage conditions

- Observe and comply with the current guidelines, laws, and standards for transporting the injector system and its components.
- Observe the defined environmental parameters for operating the injector.

Personnel training and qualification

- Ensure that qualified medical personnel are trained to operate the injector system according to the instructions for use only by ulrich medical, or by staff authorized by ulrich medical.
- Ensure that the injector system is only operated by qualified medical personnel who have completed training, and only in accordance with the Instructions for Use.
- Ensure that the injection parameters required for the examination are only specified by qualified medical personnel who have completed training.

4.2.2 User’s duties

Use

Malfunctions and errors during use due to simultaneously operating injector and touch terminal.

- The injector and touch terminal must be operated by the same person.

Cleaning

Risks of injuries and infections if the cleaning of the injector system is not done properly or omitted.

- Observe the notes on cleaning in these instructions for use.

Disposal

Contact with leaking contrast media due to improper disposal leads to skin irritations and irritations of mucous membranes.

- Carefully dispose of disposables and packaging according to the national provisions.

4.2.3 Hazards to users

Electrical hazards

WARNING! Risk of electric shock when the injector is connected to the power supply without protective earth conductor.

- Only connect the power cord of the injector to a power outlet with a protective earth conductor.

WARNING! Risk of electric shock and burns when a defibrillator is used on a patient connected to the injector.

- Separate the patient from the injector before using a defibrillator.

Sterility – risk of infection

CAUTION! Infection of the user due to inadequate hygiene when handling sterile disposables.

- Handle all sterile disposables carefully.
- Do not touch the tips of the spikes, spikes with holders, or injection needles after removing the protective caps.

CAUTION! Infection of the operator due to improper handling of contaminated disposables.

- Properly dispose of contaminated disposables.

Risks of injury

CAUTION! Risk of injury for operators due to magnetically induced movements of improperly installed device components in the MRI room. An MRI scanner may magnetically attract the touch terminal and its accessories and thereby cause injury to individuals.

- In accordance with IEC 60601-1, only set up and operate the touch terminal outside the MRI examination room.

CAUTION! Injuries (bruises, etc.) due to injector falling over as a result of being improperly moved or improperly set up.

- During setup: Set the injector up in such a way that it is outside the range of motion of the scanner’s parts at all times.
- When operating or moving the injector:
  - Do not move or set the injector up on surfaces with an inclination > 10°.
  - Do not sit on the injector. Do not step or sit on the injector base.
  - Do not hold / move the injector by the injector head.
- Before moving the injector: Release the parking brakes on the injector base.
- While moving the injector:
  - Only hold the injector by the handle.
  - Do not roll the injector over power cords.
- While moving the injector over slopes: Observe the limitations of use (inclination ≤ 10°).

- While moving the injector over low obstacles and on uneven surfaces:
  - Reduce speed appropriately.
  - Provide suitable transport routes.
- After moving the injector: Secure the injector against unwanted movement by applying the parking brakes on the injector base.

CAUTION! Risk of crush injuries due to careless opening of the roll pump cover or careless handling of movable parts of the injector system and accessories.

- While closing the roll pump cover, ensure that no body parts or pieces of clothing are under the cover.

CAUTION! Risk of injuries due to stumbling over improperly laid out patient tubing.

- During setup, fix the patient tubing over the drip cup. Install the sling in a way to avoid accidentally being caught.
- When connecting the patient tubing to the patient, place it in such a way that it is visible to the user and third parties, and does not pose a tripping hazard.

CAUTION! Cuts from spikes, spikes with holders, or broken media containers.

- Handle spikes, spikes with holders, and media containers carefully.

CAUTION! Allergic reaction to disposables.

- Use protective gloves as needed.

CAUTION! Contact with leaking contrast media leads to skin irritations and irritations of mucous membranes. Improper handling of media containers and disposables during setup and strip down can lead to contrast media leakage.

- Precisely follow the instructions for setup and strip down.
- Avoid direct skin contact with leaked contrast media while setting up and stripping down the media containers.
  - Immediately remove leaked contrast media.
- Use protective gloves as needed.

4.2.4 Hazards to the patient

Proper use, ambient conditions and installation

CAUTION! Risk of injuries for the patient when the injector is used outside the intended use and ambient conditions.

- Comply with the approved ambient conditions for the injector system, → section 18.
- Comply with the approved environmental conditions and use conditions for contrast media and Saline (NaCl) specified in the Summary of Product Characteristics.

Sterility – risk of infection

CAUTION! Infection of the patient due to inadequate hygiene when handling sterile disposables.

- Handle all sterile disposables carefully.
- Use aseptic technique when handling all disposables.

- Do not use disposables if the packaging is damaged, or the protective caps are missing or not seated properly.
- Ensure that the Easy-Click-Cassette – flex and the patient tubing remain free of contamination.
- Replace the Easy-Click-Cassette – flex after use with 96 bottles or 24 hours, whichever occurs first.
- Do not touch the tips of the spikes or spikes with holders after removing the protective caps.
- While changing the media container, also change the spikes and spikes with holders.
  - After removing an empty media container, disconnect the Luer lock connector and discard the spike. If replacing the container with the same contrast media (i.e. the new contrast media is identical to the removed contrast media), equip the connection point with a new media container and new spike using aseptic technique. If replacing the container with a different contrast media (i.e. the new contrast media is different from the removed contrast media), perform the rinsing process and then equip the connection point with a new media container and new spike using aseptic technique.
- Before initiating an injection, check to make sure:
  - the saline (NaCl) solution and contrast media containers are installed in their correct location on the injector,
  - the expiration date and time is written on the contrast media,
  - for Imaging Bulk Package (IBP) contrast media, the saline tag is completed and hung on the saline (NaCl) bottle.
- Use new patient tubing for each new patient.
- Position the end of the patient tubing over the drip cup in such a way that it does not touch the drip cup.

CAUTION! Risk of infections for patients due to contamination of the tubing system when tubing extensions are used.

- Do not use tubing extensions (e.g., "Heidelberg extension").

CAUTION! Risk of infections for patients due to contamination of the tubing system when the patient tubing is improperly removed.

- Immediately dispose of the patient tubing after separating it from the patient.
- Do **not** fix the end of the patient tubing to the injector.

CAUTION! Risk of infections for patients due to contamination of the tubing system. When no media container is present, ambient air is sucked into the tubing system.

- Only vent media supply tubing when a media container is plugged in.

CAUTION! Infection of the patient due to contamination of the Easy-Click-Cassette – flex while patient tubing is not connected.

- After removing the patient tubing, immediately equip the Easy-Click-Cassette – flex with new patient tubing.
  - Do not remove the protective cap from the patient-side Luer lock connector until the patient is connected.

CAUTION! Risk of infections for patients due to contamination of the tubing system.

When the tubing segment for the roll pump is threaded out, ambient air is sucked into the tubing system.

- If the tubing segment for the roll pump on the Easy-Click-Cassette – flex was threaded out: Do not use the Easy-Click-Cassette – flex anymore. Strip down and discard the Easy-Click-Cassette – flex.

CAUTION! Infection of the patient due to improper handling of contaminated disposables.

- Properly dispose of contaminated disposables.

Risk of injury and infection

CAUTION! Risk of injuries to the patient due to improper positioning of the media containers.

- Before starting an injection, check for correct positioning of the media containers with Saline (NaCl) and contrast media.

WARNING! Risk of injury to the patient due to air injection, overdosage, and flow reduction. The use of tubing extensions leads to differences with the pressure regulation in the tubing system.

- Do not use tubing extensions (e.g., "Heidelberg extension").

CAUTION! Risk of injuries and infections of the patient due to improper use of disposables.

- Do not continue to use disposables after their expiry date has passed.
- Do not continue to use disposables after their service life has expired.
- Do not use disposables that were not stored under the recommended storage conditions.
- Only use cannulas suitable for the injector system’s pressure and flow.
- Only use cannulas approved for pressure injections.
- Do not use any cannulas without provided information.
- Only use disposables approved for single use once and do not reprocess them.
- Dispose of disposables immediately after use. Make sure that used and contaminated disposables do not come in contact with the injector anymore.
- When one or more media containers must be discarded because their maximum service life has expired (see manufacturer’s instructions for the media container): Also discard the tubing system.

CAUTION! Risk of injury to the patient due to the use of damaged tube combinations, tubing systems or disposables.

- Only use undamaged disposables.

CAUTION! Risk of injuries or infection of the patient when troubleshooting the injector system while the patient is connected to the injector.

- Separate the patient from the injector before troubleshooting the injector system.

Blood loss

CAUTION! Patient loses blood due to leakage of the disposables. Improper use of disposables can lead to leakage of the tubing system.

- Handle disposables carefully.

Air injection

WARNING! Risk of air injection into patients when using disposables (patient tubing, cannulas) not designed for maximum pressure.

- Only use cannulas suitable for the injector system's pressure and flow.

WARNING! Risk of air injection into patients due to manipulation of sensors and components of the tubing system.

- Do not manipulate sensors or the tubing system.

WARNING! Risk of air injection to patients due to air in the tubing system.

- Ensure that the disposable is undamaged.
- Each time, ensure that there is no air in the tubing system.
- Vent media supply tubing after each time the media containers and spikes are replaced.
- Visually inspect the patient tubing to make sure it is free of air before connecting it to the patient.
- Do not connect the patient to the injector until the tubing system has been filled and vented.
- Before connecting the patient to the injector, check that the SafeConnect of the patient tubing is correctly connected to the connection point of the Easy-Click-Cassette – flex.
  - Ensure that the SafeConnect's locking catches audibly click into the Easy-Click-Cassette – flex.

WARNING! Risk of air injection into patients due to air in the tubing system after automatic filling.

- After automatic filling, ensure that there is no air in the tubing system.

WARNING! Risk of air injection in patients when opening the roll pump cover.

- Only open the roll pump cover when no patient is connected to the tubing system.

WARNING! Risk of air injection into patients due to ambient air being drawn into injector components.

- For cannulation of the patient, use a standard pressure-resistant indwelling venous cannula with no additional injection port.
- Do not perform any injections through additional injection ports on the indwelling venous cannula.

Irritation due to contrast media

CAUTION! Contact with leaking contrast media leads to skin irritations and irritations of mucous membranes. Improper handling of media containers and disposables during setup and strip down can lead to contrast media leakage.

- Avoid direct skin contact by the patient with contrast media.

– Immediately remove leaked contrast media.

Risk of injury and allergic reactions

WARNING! Risk of allergic reactions and anaphylactic shock for the patient due to an incorrect contrast medium.

- Before injection, ask the patient about possible contrast media allergies.
- Do not use radioactive contrast media.

DANGER! Risk of cardiac or renal insufficiency to the patient due to use of an incorrect injection program. Operation of the injector by different people or multiple people can lead to mix-ups when selecting the injection program.

- The injector and touch terminal must be operated by the same person.

WARNING! Risk of allergic reactions and anaphylactic shock for the patient due to an incorrect contrast medium. When a contrast medium not compatible to the selected injection program is installed during injector setup by mistake, it may get into the tubing system.

- While setting up and plugging in the media containers: Make sure the contrast media in the installed media container corresponds to the configured contrast medium in the injection program.
- If a contrast media unsuitable for the injection program was plugged in: Strip down the injector and replace the tubing system.

WARNING! Risk of allergic reactions and anaphylactic shock to the patient due to an incorrect contrast medium.

- **Max 3** only: With automatic switchover of connection points: Make sure that the same medium is installed in both connection points.

WARNING! Risk of allergic reactions and anaphylactic shock to the patient due to mixture of contrast media in the tubing system.

- Ensure that rinsing of the system is completed according to this IFU when changing contrast media.

WARNING! Risk of allergic reaction and anaphylactic shock in the patient due to incorrect position of the Easy-Click-Cassette – flex. If the Easy-Click-Cassette – flex comes loose from one or both of the latching points, this can lead to mixing of media and to injection of mixed media (CM, NaCl).

- When inserting the Easy-Click-Cassette – flex: Ensure that the Easy-Click-Cassette – flex's locking catches audibly click into both latching points.
- If the Easy-Click-Cassette – flex came loose from one latching point: Change the Easy-Click-Cassette – flex, media container, spike, and patient tubing.

WARNING! Risk of allergic reactions and anaphylactic shock to the patient due to rinsing the tubing system while the patient is still connected.

- Before rinsing, venting, and filling: Ensure that the patient is **not** connected to the injector.

WARNING! Risk of allergic reactions and anaphylactic shock for the patient due to use of an incorrect injection program.

- Before the injection: Make sure the selected injection program, the programmed boli and the injection parameters are suitable for the patient.

CAUTION! Risk of nausea for the patient due to overly rapid contrast media injection.
- Before the injection: Check the configured flow in the injection program screen.

DANGER! Risk of cardiac or renal Insufficiency for the patient due to an overdosage of contrast media.
- Before the injection: In the injection program, check the volume of contrast media to be administered.

Injury to veins

WARNING! Risk of injury to blood vessels (injuries to veins) due to an excessively high flow of the contrast media.
- Before the injection: Make sure the selected injection program, the programmed boli and the injection parameters are suitable for the patient.

WARNING! Risk of injury to veins due to imprecise puncture of the patient.
- Before the injection: Check the position of the puncture cannula.

Hypothermia

WARNING! Risk of hypothermia of the patient due to a too low medium temperature.
- Do not use injection media significantly cooler than room temperature.
- Comply with manufacturer’s instructions for the contrast medium.

Blood coagulation, embolism

DANGER! Risk of blood coagulation and pulmonary embolism due to a too high medium temperature.
- Do not use injection media significantly warmer than room temperature.
- Comply with manufacturer’s instructions for the contrast medium.

Electrical risks, risk of burns

WARNING! Risk of electric shock and burns when a defibrillator is used on a patient connected with the injector.
- Separate the patient from the injector before using a defibrillator.

DANGER! Risk of electric shock, burns and cardiac arrest in case of direct contact of the patient with the injector. Potential differences in the injector due to damaged or improperly routed cables or the combination of the injector and other non-approved devices may lead to injuries when the metallic surfaces of the injector are touched.
- Ensure that the injector and other devices and components present in the vicinity of the injector are in proper condition.
- During the entire procedure, ensure that the patient does not come into contact with the injector and is only connected to the injector through the patient tubing.

- Ensure that the patient does not come into contact with the touch terminal.

4.2.5 Hazards for the patient in CM Select mode (Max 3 only)

Risk of injury and allergic reactions

WARNING! Risk of injection of incorrect contrast media if instructions are not followed.
- Perform all instructions for the rinsing programs exactly as in the specified sequence.
- Make sure that the patient is disconnected from the injector before a rinsing program is started.

WARNING! Risk of allergic reactions and anaphylactic shock for the patient due to an incorrect contrast medium. Plugging in incompatible contrast media or an incorrect configuration in media selection can lead to the injection of incompatible or incorrect contrast media and can cause patient injuries.
- Only use an approved combination of compatible contrast media at the two connection points.
  - Comply with the information about approved combinations according to the table, → section 5.1.3.
  - Request information from ulrich medical or from a distributor authorized by ulrich medical.
- Correctly perform configuration in the media selection.
- Ensure that the selected injection program is suitable for the patient.
- Ensure that the configuration in the media selection is consistent with the plugged in contrast media.
- Executing the rinsing program is insufficient for patients who have experienced severe anaphylactic reactions in the past to the previously used contrast medium.
  - Before performing an injection for patients who have experienced severe anaphylactic reactions in the past to the previously used contrast medium, replace the entire tubing system (Easy-Click-Cassette – flex, spikes, and patient tubing).

WARNING! Allergic reaction and anaphylactic shock in the patient due to incorrect position of the Easy-Click-Cassette – flex. When **CM Select mode** is active, mixing of media and injection of mixed media (CM, NaCl) can occur in the following cases:
  - If the Easy-Click-Cassette – flex is incorrectly inserted.
  - If the Easy-Click-Cassette – flex comes loose from one or both latching points while the tubing system is filled.

- When inserting the Easy-Click-Cassette – flex: Ensure that the Easy-Click-Cassette – flex's locking catches audibly click into both latching points.

When switching from CM Select mode

WARNING! Risk of allergic reactions and anaphylactic shock to the patient due to mixing of contrast media. In the case of an injection where one of the two contrast media that were used in the previous injection in **CM Select mode** is used at both connection points, residues of the other contrast medium may be left in the tubing system.
- When replacing media containers, also replace the spikes.
- Fill, rinse, and vent the Easy-Click-Cassette – flex.

4.3 Product-related safety notes

4.3.1 Injector system

Transmission problems

Data transfer errors and malfunctions of the injector system due to too great a distance between the injector and the WLAN antenna in the MRI room.

- Do not exceed a distance of 14 m between the injector and the WLAN antenna in the MRI room.

Delivery of media

- Ensure that the SafeConnect is correctly connected.
- Only deliver media if the Easy-Click-Cassette – flex is connected to the patient tubing by means of the SafeConnect.

4.3.2 Injector

Ambient conditions

Risk of damage to the injector when the injector is used outside the intended use and ambient conditions.

- Comply with the approved ambient conditions for the injector system, → section 18.
- Comply with the approved environmental conditions and use conditions for contrast media and Saline (NaCl) specified in the Summary of Product Characteristics.
- Prevent excessive warming from exposure to sunlight.

Malfunctioning of sensors due to high infrared radiation.

- Avoid increased infrared radiation due to infrared light.

Material damage

Damage to the injector system and its accessories due to use of unapproved or unsuitable cleaning agents.

- Do not use any alcoholic or alcohol-containing cleaning agents. **Exception:** Roll pump delivery and guide rollers, → section 13.
- Do not use solvents or strong cleaning agents.
- When using cleaning agents, comply with the manufacturer’s instructions for use and safety.

Risk of damage to the injector due to the injector tipping or falling over.

- When operating or moving the injector:
  - Do not move or set the injector up on surfaces with an inclination > 10°.
  - Do not sit on the injector. Do not step or sit on the injector base.
- Before moving the injector:
  - Release the parking brakes on the injector base.
- While moving the injector:
  - Only hold the injector by the handle.
  - Do not hold / move the injector by the injector head
- While moving the injector over slopes:
  - Observe the usage limits.
- While moving the injector over low obstacles and on uneven surfaces:
  - Reduce speed appropriately.
  - Provide suitable transport routes.
- After moving the injector:

– Secure the injector against unwanted movement by applying the parking brakes on the injector base.

Risk of damage to the power cord due to driving over the cable.

- When operating or moving the injector:
  – Do not roll the injector over the power cord.
  – Before moving the injector, pull the mains plug out of the power socket, and hang the power cord on the holder on the injector.
- Do not use a damaged power cord.

Condensation of water

Risk of damage to the injector due to condensation.

- Do not immediately use the injector when it has been brought from a cold room into a warm room.
- Before use, wait until the injector has warmed up to room temperature.

4.3.3 Touch terminal

Risk of damage to components of the injector system and other devices in the MRI room due to magnetically induced movement. An MRI scanner may magnetically attract the touch terminal.

- In accordance with IEC 60601-1, only operate the touch terminal outside the MRI examination room.

4.3.4 Power supply

- Ensure that the mains plug and the power cord are easily accessible at all times.

Risk of damage to the injector due to connecting the power cord to an unsuitable power supply.

- Do not use portable multiple socket outlets.
- Only connect the injector’s power cord (for charging the battery) and the touch terminal’s power cord directly to separate power outlets.

Risk of damage to the injector due to charging the rechargeable battery in the MRI room.

- Only charge the battery in the injector outside the MRI room.

Power cord

Risk of damage and malfunctions of the injector due to crushing and/or bending of the power cord.

- Place the power cord in such a way as to avoid it being squashed or kinked, or rolled over by heavy objects, such as beds.

4.3.5 Disposables

Contrast media

Leaking or dripping contrast media or Saline (NaCl) can cause damage to the injector and other devices.

- Immediately wipe up any leaked contrast media and Saline (NaCl).

4.4 Combination with other devices and ambient conditions

Combination with other devices is only allowed after consultation with ulrich medical.

Connecting additional devices to the injector system requires compliance with the relevant standards, → section 19.

4.4.1 Person-related safety notes

Risk of injury to Operators and Patient

DANGER! Risk of burns, electric shock and cardiac arrest in case of direct contact of patient and injector. Potential differences in the injector due to damaged or improperly routed cables or the combination of the injector and other non-approved devices may lead to injuries when the metallic surfaces of the injector are touched.

- Ensure that the injector and other devices and components present in the vicinity of the injector are in proper condition.

Potentially explosive atmospheres

DANGER! Operating the injector in environments containing flammable or explosive gases poses a threat to the lives of the patient and operator.

- Do not operate the injector and touch terminal (including all accessories) in areas with explosion hazards or in the vicinity of flammable substances (particularly anesthetics, cleaning agents, or in an oxygen-enriched environment).

4.4.2 Product-related safety notes

With auxiliary equipment connected to the interfaces of the injector system:
Risk of damage and malfunctions of the injector.

- Ensure that all additional equipment verifiably fulfills the relevant specifications and the system standards.

Risk of damage to the injector due to damaged or improperly routed cables or the combination of the injector and other non-approved devices.

- Ensure that the injector and potential additional equipment and connected devices are an approved combination, and that they are in proper condition.

Defibrillator

Risk of damage and malfunctions of the injector.
The injector is not protected against the effects of defibrillation.

- Separate the patient from the injector before using a defibrillator.

RF radiation

Risk of malfunctions to the injector system due to RF radiation.
Devices radiating RF electromagnetic waves (e.g., mobile phones and electrosurgical devices) can cause malfunctions if they are in the vicinity of the injector system.

- Set up the injector system and other devices adequately to prevent interference from RF radiation.

5 Model overview and functions

The ulrich**easy**INJECT injector system is available in several models, each with different standard functions and additional options.

Function	Max 2M ulricheasyINJECT	Max 3 ulricheasyINJECT
MRI	**x**	**x**
Multi-use	**x**	**x**
Connection points (heads)	**2**	**3**
Rechargeable battery	**x**	**x**
WLAN	**x**	**x**
Standard functions		
CM Loop	–	**x**
Elapsed time	**x**	**x**
Time-controlled pause	**x**	**x**
NaCl backup (automatic)	**x**	**x**
NaCl buffer (automatic)	**x**	**x**
Timer	**x**	**x**
Pressure limit	**x**	**x**
Pause	**x**	**x**
Remainder display	**x**	**x**
Start delay	**x**	**x**
Software options		
Same patient	**x**	**x**
Vein check	**x**	**x**
CM Select	–	**x**
Device versions		
Mobile pedestal version	**x**	**x**

Table 8. Functional overview of the models

5.1 Functions

5.1.1 Operating the injector

The device has been designed to allow the operator access to all control elements from an ergonomic position during all necessary operating steps.

RFID identification

The Easy-Click-Cassette – flex and patient tubing (XD 10701 / XD 10702) contain a microchip (RFID chip) with a signature and usage data, which are checked by the device during setup

and operation. Upon being filled for the first time, the Easy-Click-Cassette – flex and patient tubing are marked as "used."
After the maximum approved service life, the Easy-Click-Cassette – flex and patient tubing are invalidated and can no longer be used.
The RFID chip also allows for automatic detection of the patient tubing length and adjustment of the volume of the initial Saline (NaCl) bolus.

Workflow guidance

The injector control unit shows information and messages that guide the operator through the complete workflow. Messages appear for each of the required work steps, e.g. for insertion of the Easy-Click-Cassette – flex or replacement of the patient tubing. The workflow continues to the next step only after the current step is confirmed.

Usage of the touch terminal and the injector control unit

Typically, the injection programs are created and started on the touch terminal. The control unit on the injector is primarily intended for system setup and configuration and interactions for replacing the patient tubing, configuration of the media, and to perform the vein check.

Tubing system

The tubing system for the injector is connected via a convenient Easy-Click-Cassette – flex and a patient tubing

Media list

A list of the contrast media types, and the corresponding media volumes is stored in the injector system. The list can be customized by means of the **Media** menu, → section 10.4.

Filling the tubing system with NaCl

During filling and venting, the Easy-Click-Cassette – flex and the patient tubing are rinsed and filled with Saline (NaCl). The filling volume depends on the patient tubing length, and is automatically adjusted to the various patient tubing lengths by means of RFID identification (only for XD 10701 / XD 10702) or needs to be set up correctly in the injector settings if patient tubings without RFID (XD 10751 / XD 10752) are used.

NaCl backup

The automatic NaCl backup prevents premature injection termination due to empty contrast media containers.
When the amount of contrast media in the media containers is less than scheduled in the injection program, the operator can confirm via a message that the missing contrast media volume should be replaced by NaCl during the injection. On the terminal, the automatic NaCl backup is indicated in the graphical bolus display. When the NaCl backup is executed during an injection, a warning beep will sound and a message appears on the injector control unit. The **Injector Settings** menu can be used to set an individual limit for the maximum NaCl backup volume, → section 10.2.

NaCl Buffer

The **NaCl Buffer** function optimizes the separation of the NaCl bolus from the CM bolus and vice versa.

If a pause or a time-controlled pause is set in the injection program after a NaCl bolus, the injector system automatically stops **before** this pause, at the volume specified as the NaCl buffer. This ensures that no contrast medium will be injected before the pause.
If a pause or time-controlled pause is set in the injection program after a CM bolus, the injector system automatically stops **after** this pause, at the volume specified as the NaCl buffer. This ensures that the programmed CM volume will be completely injected before the pause.
When the NaCl bolus is smaller than the NaCl buffer, its volume will be increased to the volume of the NaCl buffer.

Remainder

The **Remainder** function compares the calculated remainder in the media containers with the programmed injection volume. The remainder in media containers is automatically calculated by the injector system.
After each media change, before venting is performed, the operator needs to enter the correct volumes of each new installed media container on the control unit, in order for the injector system to correctly calculate the remainder.. The last entered volume from the previous media attachments is suggested as the default value.
After optional entry of the media volumes into the injector's control unit, and after plugging in the media containers, the current remainders of CM and NaCl in the media containers can be viewed on the touch terminal in the **Connection Points and Media** section, and on the injector's control unit by pressing the **Media** status / action button.
If the remainder of CM or NaCl in the media containers is insufficient for a subsequent injection, a message appears on the touch terminal and on the control unit (together with a blue background of the **Media** status / action button) and when opening the bolus editor on the touch terminal.

Injections will not be able to use the total specified volume of the media containers:

- In order to ensure that there are no air bubbles, small quantities are discarded during the initial filling of the tubing system.
- Small quantities remain in the tubing system.

NaCl volumes delivered by the **Vein check** function are deducted from the remainder.

Elapsed time

After an injection ends, the **Elapsed time** is displayed on the touch terminal and on the control unit.

Timer

It is possible to program a timer for a bolus (NaCl or CM) in an injection program. The timer appears as a clock symbol at the start of a bolus. A start delay for the injection can be set as a time-controlled pause before the first NaCl bolus, → section 8.2.7.

Pressure limit

This function displays the default or temporary pressure limit on the touch terminal. It is possible to configure a temporary pressure limit for the current injection on the touch terminal.

Vein check (optional)

This function can be used to check for correct positioning of the cannula with a specific flow rate to prevent possible extravasation.

Same patient (optional)

This software option can be used to perform further injections on the same patient without having to replace the patient tubing. After each injection, a prompt appears asking if the next injection will be performed to the same or a new patient.
Injections with the **Same patient** software option can be performed up to the maximum allowed injection volume of 400 mL (NaCl and CM) or 200 mL (CM) per patient.

5.1.2 CM Loop mode (Max 3 only)

The injector system enables CM Loop mode if the same type of contrast media was configured on both connection points.
In CM Loop mode, if a media container runs dry, the injector system automatically switches to the other media container. This ensures continuous workflow as well as optimized contrast media management:

While in CM Loop mode, if the **CM Select** option is disabled (**only Max 3, optional**), only one contrast media type can be selected per Easy-Click-Cassette – flex for both connection points.

If is intended to continue with a different **compatible** contrast media type afterwards, the spike must be discarded and the tubing system must be rinsed with NaCl.

5.1.3 CM Select mode (only Max 3, optional)

DANGER! Risk of injection of incorrect contrast media if instructions are not followed

- Perform all instructions for the rinsing programs exactly as in the specified sequence.
- Make sure that the patient is disconnected from the injector before a rinsing program is started.

DANGER! Risk to patients who have experienced severe anaphylactic reactions in the past

- Executing the rinsing program is insufficient for patients who have experienced severe anaphylactic reactions in the past to the previously used contrast medium.
- Before a contrast media injection to these patients, replace the entire tubing system (Easy-Click-Cassette – flex, spikes, and patient tubing).

DANGER! Risk of inadequate rinsing

- If the CM sensor detects air at a CM connection point during rinsing with NaCl or the CM Spike Flush process was manually canceled, the currently plugged-in NaCl rinse bottle must be discarded, a new NaCl rinse bottle must be plugged in and the entire rinse process must be repeated.

In **CM Select mode**, the injector can be equipped with two different contrast media when using the rinsing programs listed below.
This option allows access to one of the two contrast media via the injection program.
In addition, the type of contrast medium on one or both connection points can be switched to another compatible type of contrast medium.

The rinsing programs are used to reduce possible CM remainders in the tubing system (Easy-Click-Cassette – flex and patient tubing) below the harmlessness threshold.

The injector system enables the **CM Select mode** if two different contrast media have been configured. The operator must make sure that the configured contrast media are approved according to the compatibility list. Accordingly, only those injection programs using the currently plugged in contrast media can then be selected.

When **CM Select mode** is enabled, the injector does not switch to the other connection point when a media container has run dry.

For information on the software symbols on the injector control unit for using CM Select mode, see, → section 7.2.2.

Contrast media compatibility list

The table indicates the approved contrast media for use with ulrich**easy**INJECT Max. Only these contrast media can safely be used by the user and ensure safe use in conjunction with the rinsing programs listed below.

MRI contrast media compatibility list
Gadavist IBP, Gadvist single-dose, Clariscan single-dose, MultiHance single-dose,

Table 9. Compatibility list

Procedure for the rinsing programs

Symbol	Meaning
	A, B and C are possible CM Select combinations
	Symbol for changeover of the CM
	Information that helps to understand or optimize workflows

Table 10. Icons for using CM Select

Case A: Easy-Click-Cassette – flex
Injector set up in CM Select mode

Different CM type from injection (n) to injection (n+1)
Injection (n)  **/ Injection (n+1)** 
Injection (n)  **/ Injection (n+1)** 

- ✓ Injection (n) has been performed.
- ✓ New patient tubing connected to the system.
- ✓ Patient tubing not yet connected to the patient.
- ✓ Empty drip cup before starting the rinsing program.

1. Fill/rinse new patient tubing.
   - ► In the main menu, press the **Filling/rinsing / Vent** status / action button. Confirm by pressing **OK**.

- ▸ A safety message appears stating that the patient tubing is not yet connected to the patient and the drip cup must be emptied. Ensure that the patient is not yet connected to the patient tubing.
- ▸ Press the "**Filling/rinsing**" button.

2. Check the system to make sure it is free of air and confirm with **OK**.
3. Perform advanced rinsing.
   - ▸ In the main menu, press the **Filling / rinsing / Vent** status / action button.
     A safety message appears, stating that the patient tubing is not yet connected to the patient and the drip cup must be emptied. Ensure that the patient is not yet connected to the patient tubing and the drip cup is empty.
   - ▸ Press the **Advanced rinse** button. Advanced rinsing is started. Pause and continue rinsing as needed.
4. Check the system to make sure it is free of air and confirm with **OK**.

Case B: Easy-Click-Cassette – flex
Changing the CM type at a connection point

a) 

2 identical CM → 2 different CM on each CM connection point

- The CM Select function should be activated.
- Injection was performed and patient tubing changed and filled with NaCl.

b) 

2 different CM → the same CM is to be connected to both CM connection points

- The CM Select function should be disabled.
- Injection was performed and patient tubing changed and filled with NaCl.

c) 

2 different CM → on one CM connection point, an alternative CM is to be connected.

- CM Select function is enabled.
- Injection was performed and patient tubing changed and filled with NaCl.

In all three cases (a, b, c), the following operating steps must be performed.

1. In the main menu, press the **Media** status / action button. The **Media** menu appears.
2. At the connection point where the contrast media type is to be changed, press the **symbol for the connection point (CM 1 new / CM 2 new)**.
3. Press the **symbol for the media container**. The **Media Selection** view appears.
4. Press the **Medium** field. The media list appears.
5. Select **CM Spike Flush** from the media list.
   - The minimum volume for the NaCl rinse bottle is automatically displayed in the **Volume** field.
6. Confirm the input for the media container by pressing **OK**. The **Media** menu appears.
7. **Changing from a CM bottle to an NaCl rinse bottle**
   - ▸ Remove the CM bottle and spike from the swabable valve and dispose of it.
   - ▸ Connect a new spike for NaCl or spike for CM with holder (l) under aseptic conditions to the swabable valve.
   - ▸ Attach a **new NaCl rinse bottle** to the spike.

8. Confirm the **Media** menu by pressing **OK**. A safety message appears, stating that the patient tubing should not yet be connected to the patient and the drip cup must be emptied.
9. If the patient has already been connected to the patient tubing:
   - ▶ Disconnect the patient tubing from the patient.
   - ▶ Discard patient tubing.
   - ▶ Connect a new patient tubing.
10. Empty the drip cup.
11. Press the **Filling/rinsing** button. Rinsing is started.
    - ▶ Pause and continue rinsing as needed.
12. Check that the tubing system is free of air and confirm this by pressing **OK**.
13. In the main menu, press the **Media** status / action button. The **Media** menu appears.
14. At the connection point that is equipped with the NaCl rinse bottle, press the **symbol for the connection point (CM 1 new / CM 2 new)**.
15. Press the **symbol for the media container**. The **Media Selection** view appears.
16. Press the **Medium** field. The media list appears.
17. Use the arrow symbols to scroll through the list, and press the desired medium.

    The selected medium appears in the **Medium** field.
18. Press the **Volume** field. The **Volume** list appears.
19. Use the arrow symbols to scroll through the list and select the volume of the media container. The selected volume appears in the **Volume** field.
    - ▶ As needed, use the **Partial volume** field to enter the partial volume of the media container with the numeric keypad.
20. Confirm the input for the media container by pressing **OK**. The **Media** menu appears.
21. **Changing from a NaCl rinse bottle to another CM bottle**
    - ▶ Remove the NaCl rinse bottle and spike from the swabable valve of the CM connection point and dispose of it.
    - ▶ Connect a new spike and CM bottle with the previously selected CM type under aseptic conditions to the swabable valve of the Easy-Click-Cassette – flex. Confirm the **Media** menu by pressing **OK**. A safety message appears, stating that the patient tubing is not yet connected to the patient and the drip cup must be emptied.
23. If the patient has already been connected to the patient tubing:
    - ▶ Disconnect the patient tubing from the patient.
    - ▶ Discard patient tubing.
    - ▶ Connect a new patient tubing.
24. Empty the drip cup.
25. Press **Filling/rinsing** button.
    - Filling is started.
26. Check that the tubing system is free of air and confirm this by pressing **OK**.

If it is intended to change the contrast media type at both CM connection points, then the previously described steps 1–26 are to be repeated for the second connection point.

6 Injector system

6.1 Structure and model

The ulrich**easy**INJECT injector system for multi-use MRI applications is available as a mobile pedestal version in two model variants.

Model	Media connection points	NaCl	CM
ulrich**easy**INJECT Max 3	3	1	2
ulrich**easy**INJECT Max 2M	2	1	1

Table 11. Model variants

The injector system consists of the injector and the touch terminal. Disposables and media containers are needed for operation.

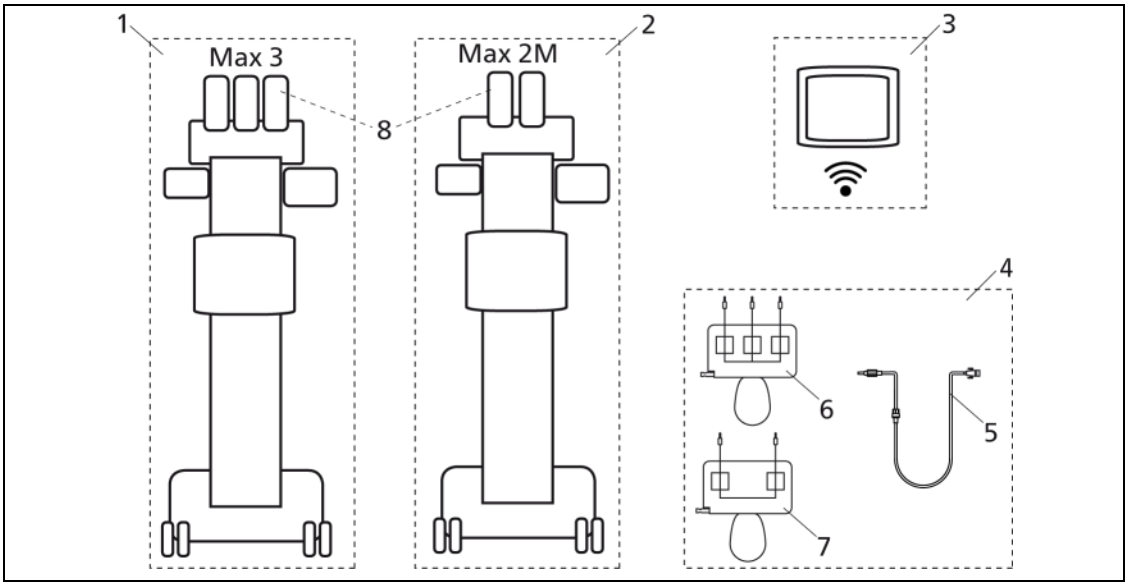


Figure 1. Injector system and disposables

1 Max 3 injector
2 Max 2M injector
3 Touch terminal
4 Disposables (tubing system)
5 Patient tubing
6 Easy-Click-Cassette – flex 3 (Max 3)
7 Easy-Click-Cassette – flex 2M (Max 2M)
8 Media container (not included in scope of delivery)

Connection between Injector and touch terminal

The injector and touch terminal are connected via WLAN (802.11b/g/n).

6.1.1 Mobile pedestal version

The injector system consists of the following components.

- Injector with:
  - Feeding unit with 2 or 3 connection points, depending on model
  - Injector head (with control unit, roll pump, and patient tubing unit) and injector column
  - Injector base

- Touch terminal

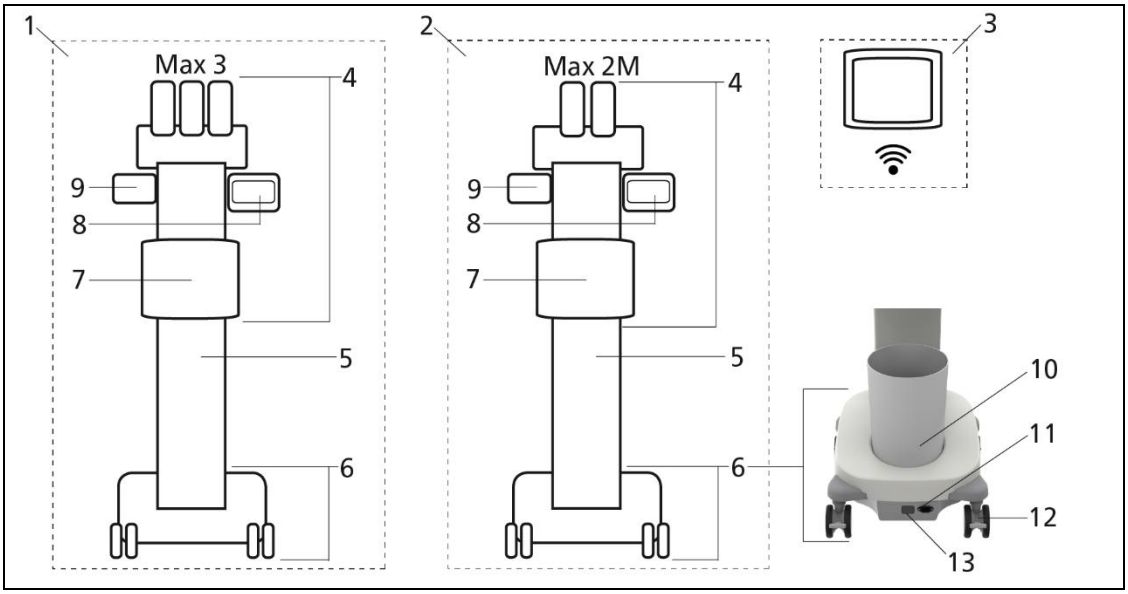


Figure 2. Design of the injector system

1 Max 3 injector
2 Max 2M injector
3 Touch terminal
4 Injector head with feeding unit
5 Injector column
6 Injector base
7 Roll pump with roll pump cover
8 Control unit
9 Patient tubing unit
10 Waste bin (convenience pack, optional)
11 Connection for power supply
12 Casters with parking brakes
13 Type label

The mobile pedestal version has a stable injector base including the injector column for mounting the injector head. A rechargeable battery with a battery charger used to power the injector is integrated into the injector base.

6.2 Injector head

The injector head consists of the following components:

- Feeding unit (2 or 3 connection points, depending on model)
- Roll pump (with insertable Easy-Click-Cassette – flex)
- Patient tubing unit (for patient tubing and drip cup)
- Control unit with touch display

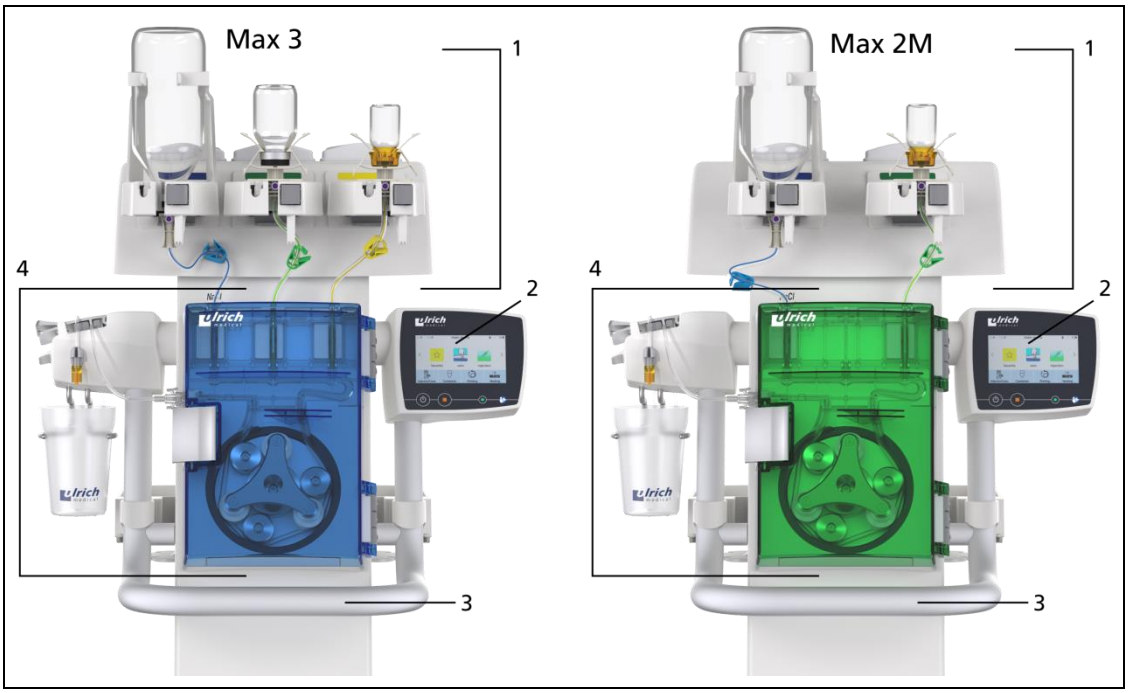
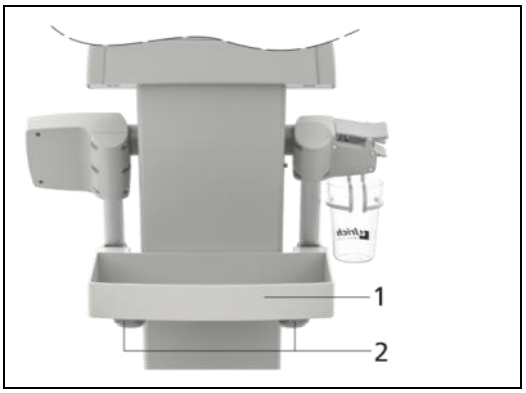


Figure 3. Design of the injector head

1 Feeding unit
2 Control unit with touch display
3 Handle
4 Roll pump and patient tubing unit



1 Tray (convenience pack, optional)
2 Power cord holder

Figure 4. Design of the injector head (rear view)

6.2.1 Feeding unit

The feeding unit consists of the following components:

- Connection point for media holder
- Media holder
- Status indicator

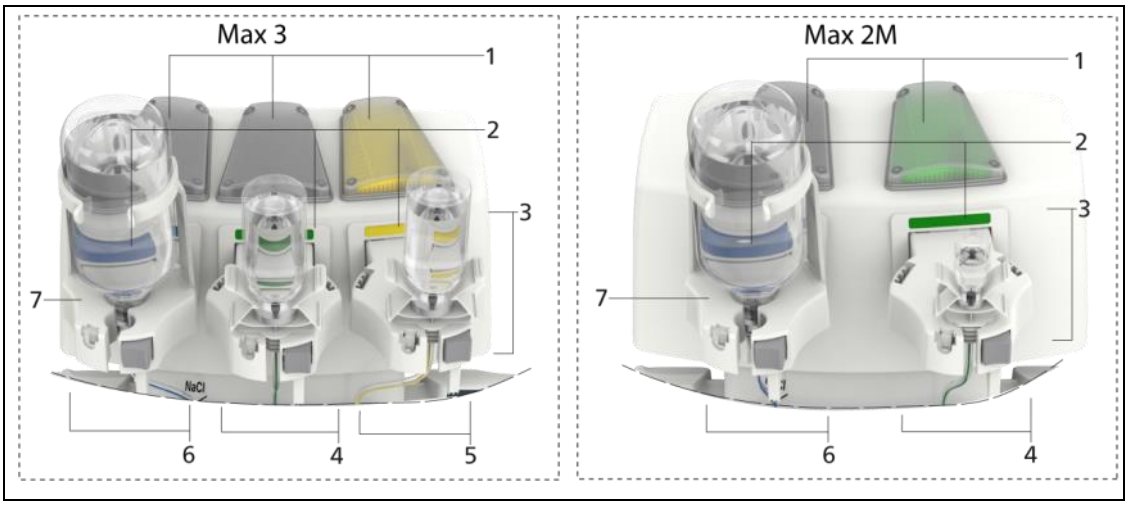


Figure 5. Feeding unit

1 Status indicator (LEDs)
2 Color indication
3 Connection points
4 Connection point (CM 1)
5 Connection point (CM 2, **Max 3** only)
6 Connection point (NaCl)
7 Media holder

The feeding unit has connection points (3) for the installation of media holders (7) where the DIN and ISO standard media containers with different filling volumes are inserted. A status indicator (1) on the feeding unit shows which connection points are active as well as their status. The connection points are color-coded (2) for the appropriate media. The NaCl connection point (6) is on the left side when viewed from the operator's position.

Connection point	**Color indication**		**Medium**
	Max 3	**Max 2M**	
left			NaCl
center		–	Contrast media
right			Contrast media

Table 12. Connection point color indication

Status indicator

The status indicator shows the status of the media container installed in the connection point. The corresponding LED is activated when the respective medium is dispensed up to the end of the patient tubing and injected into the patient. The LED status indicator can be enabled and disabled via the **Injector Settings** menu, → section 10.2.

LED	**Status**	**Meaning**
Blue	Active	NaCl is injected into the patient.
Green	Active	Contrast medium 1 is injected into the patient.
Yellow (**Max 3** only)	Active	Contrast medium 2 is injected into the patient.

Table 13. Status indicator of the feeding unit

Media holder

Insert the media holders into the connection points of the feeding unit. The media containers are installed in the media holders. Press the unlock button (4) to unlock the openings (1, 2) so that a media container can be inserted or removed.

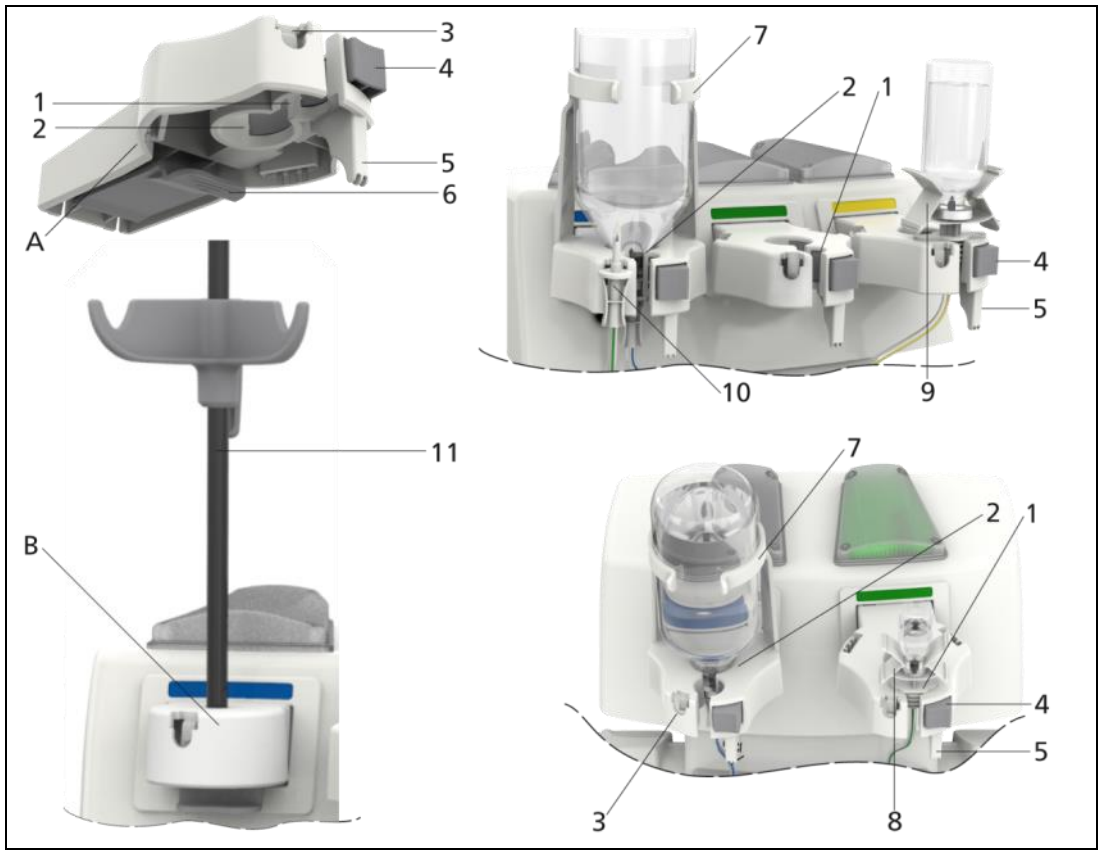


Figure 6. Media holder

A Media holder for media bottle
B Media holder for media rod (convenience pack)
1 Small opening
– (media container with CM)
2 Large opening
– (media container with NaCl)
3 Park position for spike
4 Lock (media container, spikes)
5 Handle
6 Unlock button (media holder)
7 Bottle holder
8 Spike with Holder s for CM
9 Spike with Holder l For CM
10 Spike for NaCl
11 Media rod

- The media containers for CM are inserted into the small opening (1) (with holder s or holder l depending on the bottle size. See Table 14 below).
- The large opening (2) is intended to insert NaCl media containers only at the connection point for NaCl. Bottle holders (7) for the stabilization of large NaCl media containers can be installed in the media holder. It is possible to install the spike (10) for the NaCl media container in park position (3) during setup.

- A special media holder (B) is available for the media rod.

Press the unlock button (6) at the bottom of the media holder to press the media holder out of the connection point. Then grab the handle (5) to pull it out.

Media holders are available for the following media container sizes:

Connection point	Opening	Bottle neck diameter	Spike / spike with holder
NaCl	Large	33 mm	Spike
CM	Small	21 mm	Holder s
CM	Small	33 mm	Holder l

Table 14. Overview of connection points and media container sizes

It is possible to equip the media holders with an optional media rod for the installation of media in bags and plastic bottles. Bags with a maximum capacity of 2000 mL can be hung on the media rod.

6.2.2 **Roll pump with** Easy-Click-Cassette – flex **and patient tubing unit**

The roll pump (6) consists of three delivery rollers (8) and three guide rollers (7). The unlock button (2) allows the cover to be opened and closed (1). The Easy-Click-Cassette – flex (11) is inserted into the receptacle (4) and held securely in place by means of the latching position (3). The patient tubing's SafeConnect is inserted at the connection point (10). The tubing segment (9) for the roll pump is automatically threaded into the roll pump after the cover (1) is closed and the patient tubing is connected. Automatically threading out the tubing segment for the roll pump is activated on the injector control unit.

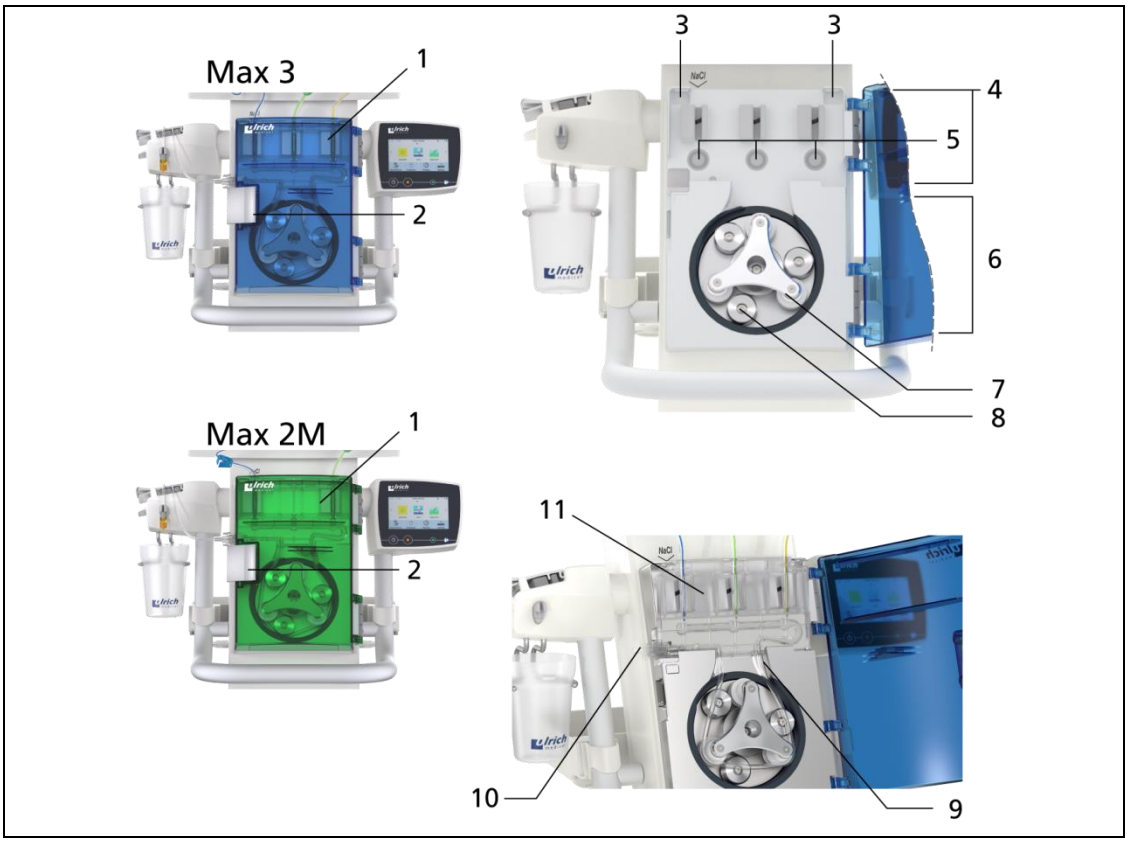


Figure 7. Roll pump

1 Roll pump cover
2 Unlock button (roll pump cover)
3 Latching points for the Easy-Click-Cassette – flex
4 Receptacle for the Easy-Click-Cassette – flex
5 Valves
6 Roll pump
7 Guide roller
8 Delivery roller
9 Tubing segment for roll pump
10 Connection point for SafeConnect
11 Easy-Click-Cassette – flex

Patient tubing and drip cup

At the side next to the roll pump, fix the patient tubing (7) with the lock (1) in the air detector (2) of the patient tubing unit. The end of the patient tubing with the Luer-Lock connector (8) can be parked in the holder (5).
The patient tubing's SafeConnect (9) is inserted into the connection point of the Easy-Click-Cassette – flex.
Insert the drip cup (3) into the holder (4) for collecting excess medium delivered during filling and venting of the tubing system.

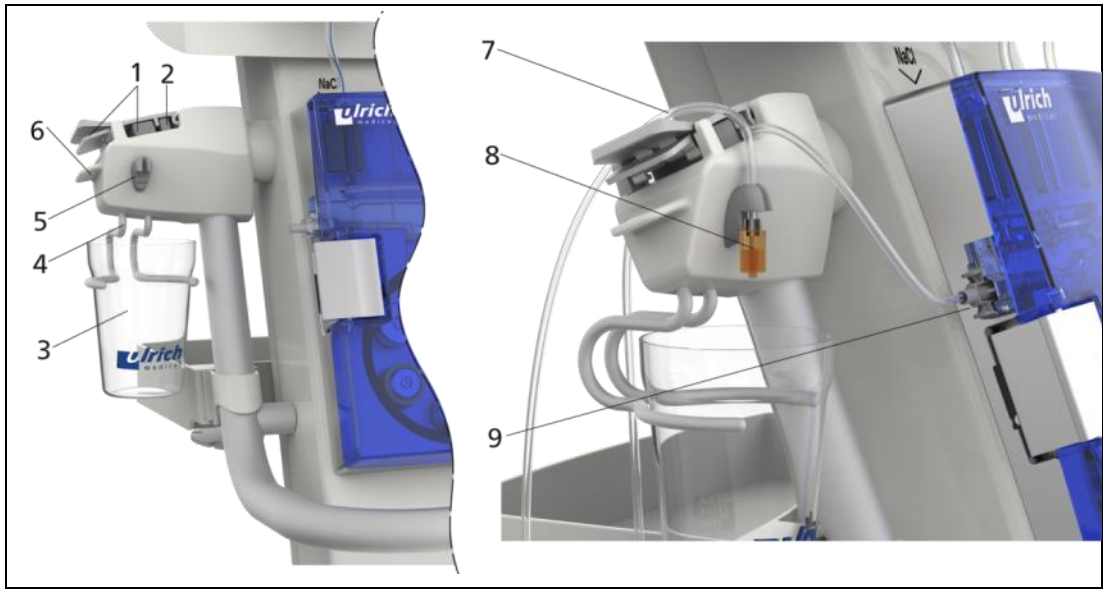
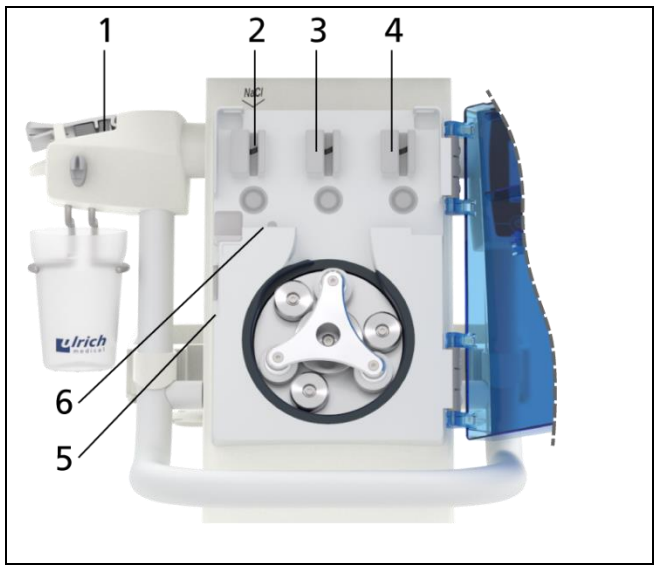


Figure 8. Patient tubing unit

1 Lock for patient tubing
2 Air detector
3 Drip cup
4 Holder (drip cup)
5 Holder (patient tubing)
6 Counterholder (for closing the lock for patient tubing)
7 Patient tubing
8 Luer lock connector on patient tubing
9 SafeConnect on patient tubing

6.2.3 Sensors and detectors on the injector head

Sensors and detectors monitor the media delivery in the Easy-Click-Cassette – flex and in the patient tubing, as well as the status of the roll pump cover. Messages and warnings appear on the control unit and the touch terminal.



1 Air detector
2 Media detector (NaCl)
3 Media detector (CM)
– (**Max 3** only)
4 Media detector (CM)
– (Max 3 and Max 2M)
5 Sensor (roll pump cover)
6 Pressure sensor

Figure 9. Sensors on the injector

One media detector (2, 3, and 4) for each connection point sits behind the media supply tubing and detects whether the media supply tubing contains liquid or air bubbles. A pressure

sensor (6) is attached below the media detector to monitor the pressure conditions in the Easy-Click-Cassette – flex. An air detector (1) in the patient tubing unit detects small air bubbles within the patient tubing. A sensor (5) on the injector monitors if the roll pump cover is closed or not.

6.3 Tubing system

The tubing system consists of the Easy-Click-Cassette – flex with connectible spikes for NaCl / CM and the patient tubing that is connected by means of a SafeConnect. All tubing ends are closed by protective caps.

6.3.1 Tubing system with Easy-Click-Cassette – flex

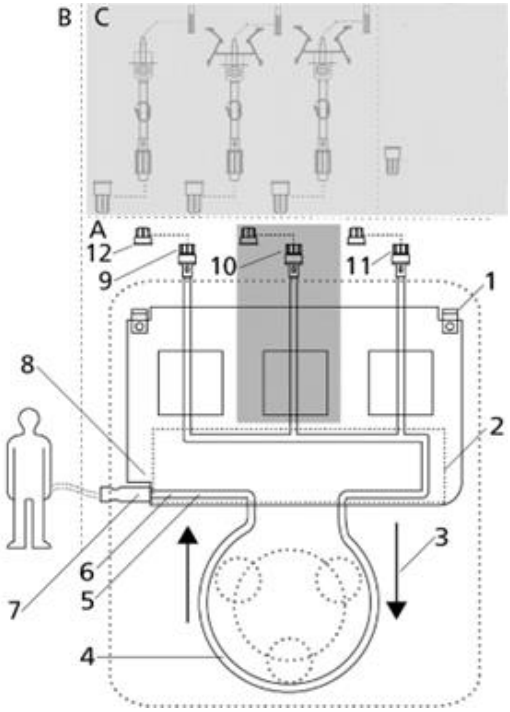


Figure 10. Tubing system with Easy-Click-Cassette – flex

A Device side with Easy-Click-Cassette – flex

B Patient side with patient tubing

C Removable spikes with Luer lock connectors and protective caps (not included in scope of delivery)

1 Latches

2 Valve membrane

3 Media flow direction

4 Tubing segment for roller pump

5 Pressure measurement cell

6 Particle filter

7 SafeConnect with protective cap

10–11 Swabbable valve for CM by means of a spike with holder l or s (XD 10705 / XD 10706). The swabable valve (10) is only part of the Easy-Click-Cassette 3 – flex design.

12 Protective caps with air filter for swabable valve with Luer lock connector

8 RFID chip
9 Swabable valve for NaCl by means of spikes

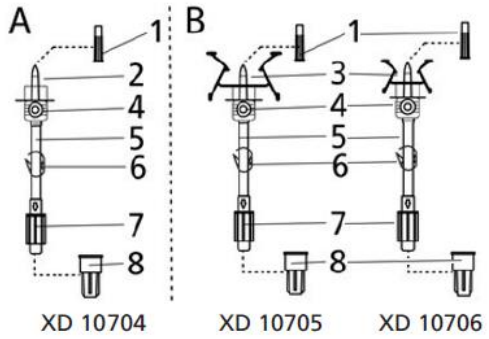


Figure 11. Media spikes for tubing system with Easy-Click-Cassette – flex

A Spike for NaCl
B Spike for CM
1 Protective cap for spike
2 Spike
3 Spike with holder l or holder s
4 Air filter
5 Media supply tubing
6 Clip for sealing off the media supply tubing
7 Luer lock connector for connecting to the swabable valve of the Easy-Click-Cassette – flex 3 / 2M
8 Protective cap for Luer lock connector

Easy-Click-Cassettes – flex

Depending on the injector model, the Easy-Click-Cassette – flex comes in 2 different models with the associated spikes for NaCl and CM:

- Easy-Click-Cassette 3 – flex (XD 10716)
- Easy-Click-Cassette 2M – flex (XD 10717)
- Spike for CT (CM / NaCl), MRI (NaCl) (XD 10754)
- Spike for MRI (CM) – holder l (XD 10755)
- Spike for MRI (CM) – holder s (XD 10756)

The Easy-Click-Cassette – flex is inserted into the receptacle in the injector head. The media spikes for NaCl and CM are connected to the swabable valves of the Easy-Click-Cassette – flex by means of an aseptic procedure, and the respective media containers are connected to the spikes. The tubing segment for the roll pump is automatically threaded into the roll pump after the patient tubing is connected and the roll pump cover is closed.
The Easy-Click-Cassette – flex must be replaced and disposed of after a maximum usage period of 24 h or after 96 bottles of contrast media, whichever is first. The spikes must be replaced with each media container.

Maximum flow for Easy-Click-Cassette – flex

Combination	Max. flow	Note:
XD 10754	10 mL/s	–
XD 10755	6 mL/s	–
XD 10756	6 mL/s	–

Table 15. Max. flow – Easy-Click-Cassette – flex

With the Easy-Click-Cassette – flex, an automatic reduction of flow can occur when drawing contrast medium from CM bottles into the tubing system when the flow rate is set to 6 mL/s or higher.

During the automatic flow reduction, injected boli will be administered as needed with a reduced flow as compared to the programmed value:

Container type	Programmed flow	Reduced flow
CM bottles	> 6 mL/s	6 mL/s

Table 16. Reduced flow

The flow reduction is limited exclusively to injection of the NaCl pre-bolus (22.5 mL for XD 10701 / XD 10751 and 25.5 mL for XD 10702 / XD 10752), proved the volume of all subsequent CM boli does not exceed 20 mL (when using XD 10701 / XD 10751) or 23 mL (when using XD 10702 / XD 10752). During the flow reduction, a system pressure drop occurs. It is indicated in the pressure curve and is normal system behavior. If a bolus with reduced flow is injected, this is indicated with the flow reduction symbol (→ section 8.2.3) below the appropriate bolus.

Spikes / spikes with holders

Spikes without holders are used to connect NaCl media containers. The spikes with holders facilitate correct and secure fixation of CM containers. All spikes have an air filter in the air supply duct that prevents contamination of the tubing system due to intake of ambient air.

Clips

The clips on the spikes are closed when stripping down the system or media containers needs to be changed, in order to prevent media from dripping out.

SafeConnect

The patient tubing with SafeConnect (protection against contact) is connected to the Easy-Click-Cassette – flex.

Particle filter

A particle filter is integrated into the Easy-Click-Cassette – flex to retain foreign bodies.

6.3.2 Patient tubing

The patient tubing connects the Easy-Click-Cassette – flex to the patient. On the patient-side end, a Luer lock connector and two integrated check valves are attached. The SafeConnect on the device-side end can be connected to the Easy-Click-Cassette – flex.

The following lengths are supported:

- 250 cm
- 320 cm

Check valves

The check valve is self-closing. It only opens when a medium flows in the defined direction. In case of counter-pressure or no media flow, the valve remains closed.

6.4 Optional accessories

Information on the accessories, → section 16.2.

6.4.1 Convenience pack

The convenience pack consists of the following optional units:

- **Waste bin**
  The waste bin has a capacity of 10 L and is used for discarding used disposables.
- **Tray**
  Items with a total weight of up to 2 kg can be deposited on the tray.
- **Media rod**
  Alternatively, media bags with a capacity of maximum 2000 mL can be used as media containers. The media bag is suspended from the media rod's swivel hook.

6.4.2 Drip cup

Special drip cup to be placed in the drip cup holder to catch excess media delivered during the filling process.

6.4.3 Adapter ring

The adapter ring serves to adapt CM bottles with a bottle neck diameter of 21 mm to a CM spike with a large holder.

6.5 Power supply

6.5.1 Injector

During operation, the injector is powered by a rechargeable battery. The rechargeable battery is in the injector base. The battery charger in the injector controls the charging of the battery and protects the battery from harmful operating conditions.
When the injector is connected to a power supply system, the charger within the injector checks if the rechargeable battery needs to be charged, no matter if the injector is on or off. When the power supply by the battery is interrupted, the injector turns off. A running injection is canceled and a message appears on the touch terminal that the connection to the injector was lost. During the charging process, the injector cannot be operated.

6.5.2 Battery charge indicator

The battery charging status is displayed on the control unit and on the touch terminal by a specific symbol. Starting from the 1st warning level the battery must be charged.

Symbol	Meaning	Warning Level
	Charging status > 90%	–
	Charging status 71–90%	–
	Charging status 51–70%	–
	Charging status 31–50%	–

Symbol	Meaning	Warning Level
	Charging status 11–30%	< 23% 1st warning level: **Battery low** The battery should be charged
	Charging status 0–10%	< 8% 2nd warning level: **Battery almost empty** Only one more injection can be performed, for the same patient 0% 3rd warning level: **Battery empty**

Table 17. Battery charging status: display on the control unit and touch terminal

6.5.3 Touch terminal

Information on the touch terminal, → section 8.

The touch terminal is located within the MRI control room and is permanently powered via the power cord.

- Loss of power to the touch terminal interrupts the connection to the injector. An ongoing injection will be canceled.
- Loss of power to the injector interrupts the connection to the touch terminal. An ongoing injection will be canceled.

6.5.4 Charge the rechargeable battery in the injector

We recommend charging the rechargeable battery when the charging status drops to 1 bar.

CAUTION! Risk of tripping for personnel due to an improperly routed power cord!

- ► When the power cord is placed on the floor, ensure that it does not pose a tripping hazard.

NOTE! Risk of material damage when the battery is charged within magnetic fields!

Risk of overheating of the rechargeable battery and destruction of the device electronics.

- ► Only charge the battery in the injector outside the MRI scanner room.

✓ Injector outside the examination room
✓ Injector in park position
✓ Brakes engaged on the injector base

1. Connect the power cord to the injector.
2. Connect the mains plug of the power cord to a wall power outlet.
   A message appears on the injector's control unit.
3. Acknowledge the message.

➥ The battery is charged.

When the touch terminal and / or control unit is switched on, an optical charging indicator appears on the respective display.

The battery is charged after a maximum of 4 h.

After charging the battery

1. Switch on the injector (control unit), → section 6.8.
   – Check the charging status on the control unit or the touch terminal.

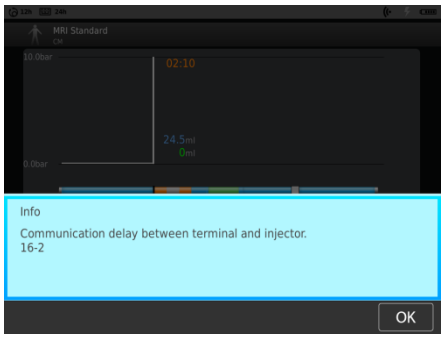
– Switch off the injector (control unit).
2. Remove the mains plug from the wall power outlet.
3. Remove the power cord from the injector and store it on a safe place.
4. Release the brakes at the injector base.
5. Roll the injector to its park position or to the examination room.
6. Apply the brakes at the injector base.

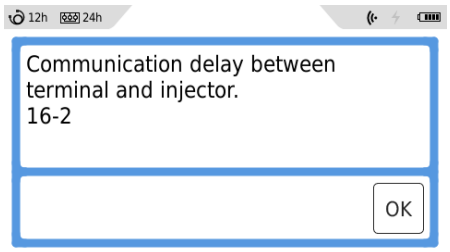
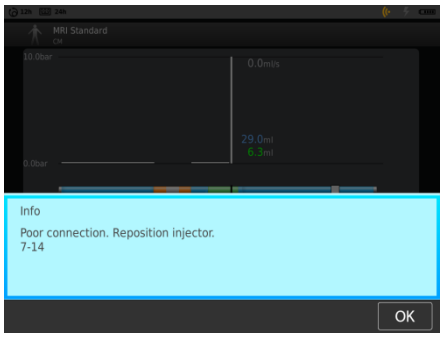
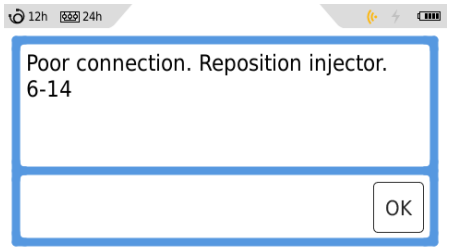
6.6 Connection between injector and touch terminal

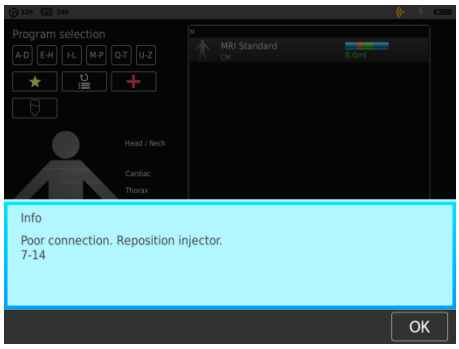
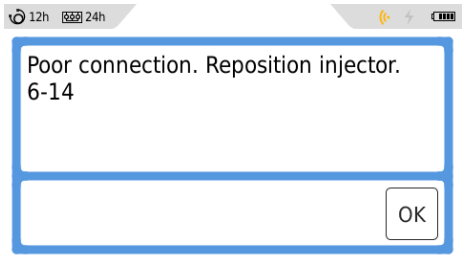
The connection between the injector and the touch terminal is established via WLAN (802.11b/g/n).
A stable WLAN communication between the injector and the touch terminal can only be guaranteed, if the injector is in the MRI examination room.

The status of the WLAN connection is displayed on the touch terminal and the injector's control unit.

WLAN status / Injector status	**Display touch terminal / control unit on the injector Action**
Connection exists	In the status line of the touch terminal and the control unit on the injector, the symbol **WLAN connection status** is displayed in black 

WLAN status / Injector status	Display touch terminal / control unit on the injector Action
The WLAN connection cannot be established after switching on the touch terminal and the injector	The welcome screen is displayed on touch terminal and / or control unit:  Control unit welcome screen  Touch terminal welcome screen **Action** ▶ Check whether the injector and touch terminal are switched on. ▶ Check whether the injector is in the MR examination room. ▶ Choose the location where injector and touch terminal are set up appropriately to allow the connection to be established.
• WLAN connection between touch terminal and injector interrupted for ≥ 500 ms • Injection started or paused	If the WLAN connection is interrupted for ≥ 500 ms after the start of an injection, the current injection is automatically stopped for safety reasons and the following message is displayed on the touch terminal and the control unit of the injector.  Message on the touch terminal

WLAN status / Injector status	Display touch terminal / control unit on the injector Action
	 Message on the control unit of the injector If the WLAN connection remains interrupted, the symbol **WLAN connection status** is displayed in orange after 3000 ms in the status line of the touch terminal and the injector's control unit . In addition, the following message appears on the touch terminal and the injector's control unit.  Message on the touch terminal  Message on the control unit of the injector **Action** ▶ Confirm the message on the touch terminal or on the injector's control unit with OK ▶ Check whether a WLAN connection has been established (symbol **WLAN connection status** is displayed in black) ▶ Change the position of the injector in the MRI room if necessary

WLAN status / Injector status	Display touch terminal / control unit on the injector Action
	▶ Continue the injection
• WLAN connection between the touch terminal and the injector interrupted for ≥ 3000 ms • Injector in "Standby mode" or injection started or paused	In the status line of the touch terminal and the control unit on the injector, the symbol **WLAN connection status** is displayed in orange . The following message appears on the touch terminal and the injector's control unit.  Message on the touch terminal  Message on the control unit of the injector **Action**

WLAN status / Injector status	Display touch terminal / control unit on the injector Action
	▶ Confirm the message on the touch terminal or on the injector's control unit with OK ▶ Change the position of the injector in the MRI room if necessary ▶ Check whether a WLAN connection has been established (symbol **WLAN connection status** is displayed in black)

Table 18. Status of the WLAN connection

6.7 Move the injector and position it in the MRI scanner room

DANGER! Risk of personal injury and material damage due to magnetic attraction of the injector by the MRI scanner if the safety conditions are not observed.

- ▶
- ▶ Move the injector in the MR room only up to a maximum magnetic field strength of 50 mT (at a height of 0.1 m above the floor) and position it for the injection.
- ▶ If a 30 mT safety line already exists or a safety line has been designated by ulrich medical or by a person authorized by ulrich medical, only position the injector outside this safety line for the injection.
- ▶ To move the injector, always hold it by the handlebar and secure it with at least 2 parking brakes after positioning.
- ▶ Do not hold / move the injector by the injector head. Risk of tipping over and consequential damage due to increased magnetic attraction.
- ▶ Ensure that the patient tubing is not tangled or trapped between the injector and the patient table of the MRI scanner.

Additional safety note in connection with Philips MRI scanner::

- ▶ When the injector is not in use, always move it to the parking position designated by ulrich medical or by a person authorized by ulrich medical and secure it with at least 2 parking brakes (see Fig. 13).

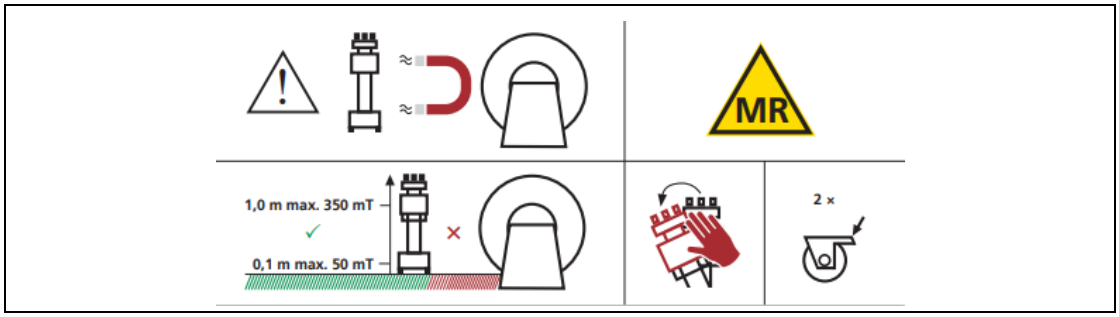


Figure 12. Safety label

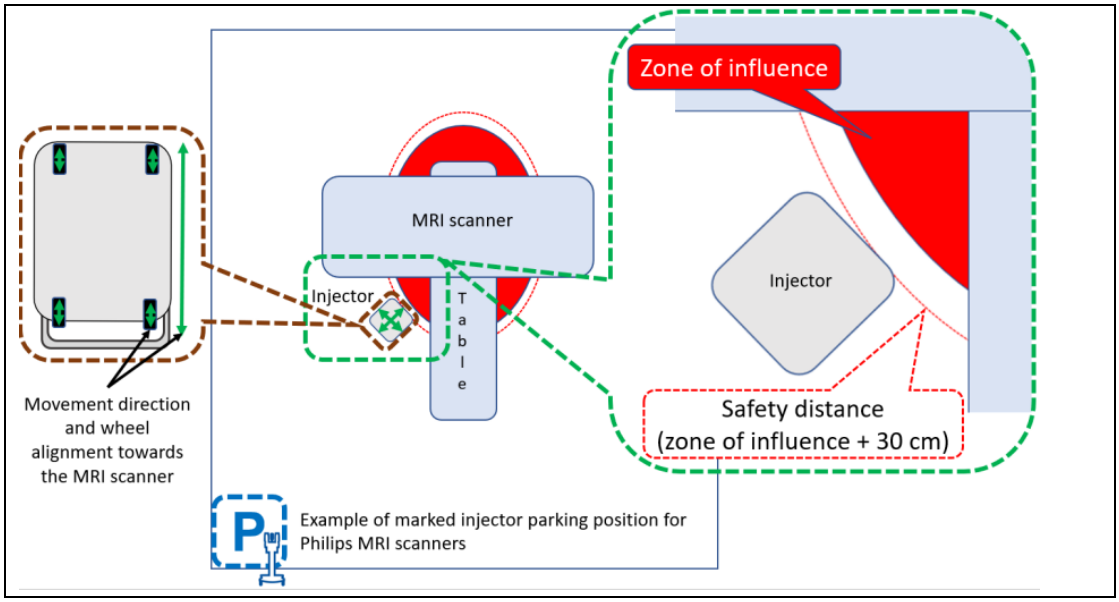


Figure 13. Safety line & park position

6.8 Switching the injector system on and off

In most use cases, the injector and the touch terminal are switched on in the morning or at the start of operations and are switched off at the end of operations.

6.8.1 Switching injector on

✓ Battery charged

At the control unit

▶ Briefly press the **On / Off** button.
The injector is started. The welcome screen appears on the control unit. The injector establishes a connection to the touch terminal.

➥ If the injector is already set up, messages appear to confirm the current system configuration. Depending on the use case, the messages can be acknowledged or rejected.

➥ If the injector is not yet set up, the **Setup** workflow message appears.

6.8.2 Switch touch terminal on

✓ Power supply established

On the touch terminal

▶ Press the **On / Off** button.
The touch terminal is switched on. The status LED is illuminated. The welcome screen appears on the touch screen. The injector establishes a connection to the touch terminal.

➥ When the injector is ready, the main menu with the choice of programs appears on the touch terminal.

6.8.3 Switch off the injector system

✓ Injector stripped down

At the control unit / at the touch terminal

If the connection between the injector and touch terminal is interrupted (→ section 6.6), the following steps must be performed separately on the control unit and touch terminal.

1. On the control unit **or** on the touch terminal: Briefly press the **On / Off** button.

If the message, **"Shut down injector system. Are you sure?"**, appears:

2. Confirm the message by pressing **OK**.

➥ The injector and the touch terminal will be shut down and switched off.

6.9 Forced stop of the injector

In special situations, it may be necessary to stop the injector and to cancel ongoing actions (injection programs, filling the tubing system, and other functions). This will stop all mechanical processes on the injector, e.g., an ongoing injection will be canceled.

It is not possible to continue an action that was canceled when the injector was stopped. A message appears on the control unit's touch display and on the touch terminal.

The **Stop** button on the control unit cann**ot** be used to perform an EMERGENCY STOP of the injector. The **Stop** button does **not** interrupt the voltage supply to the injector.

▶ At the control unit: Press the **Stop** button.

➥ The current injector action is canceled. The injector will be stopped.

7 Control unit with touch display

7.1 Control unit

The injector control unit allows the user to perform the essential operating functions.
The control unit consists of the following components:

- Touch display with user interface
- Buttons and display / indicators

1 Touch display
2 **On / Off** button
3 **Stop** button
4 **Power** indicator

Figure 14. Control unit with touch display

Press the buttons on the housing of the control unit to switch the injector on / off or stop it. When the injector is stopped, an ongoing injection will be canceled.

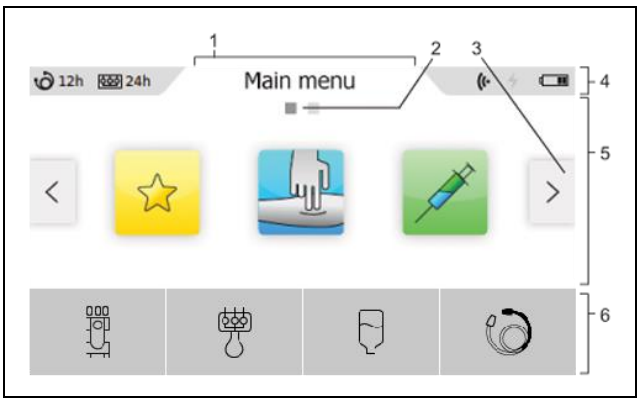
Symbol	Name	Meaning
	**On / Off** button	Switch the injector on / off.
	**Stop** button	Cancel the current action (e.g., an injection). Stop the injector. An action that canceled by the **Stop** button cannot be continued.
	**Power** indicator	Status indicator: The injector is connected to the power supply system via the power cord.

Table 19. Buttons and indicators on the control unit

7.2 Touch display on the control unit

7.2.1 Main menu

The main menu of the touch display provides access to all executable functions as well as the basic status indicators of the injector system.



1 Menu header
2 Main menu page
3 Navigation arrows
4 Status line
5 Main menu (with application buttons)
6 Status / action buttons

Figure 15. Main menu

Status line

The status line of the touch display shows basic status indicators of the injector system.

Symbol	Name	Meaning
	**Tube**	Remaining service life of the patient tubing • Expressed in hours: **h** • Expressed in minutes when < 1 h: **'**
	**Easy-Click-Cassette – flex**	Remaining service life for the Easy-Click-Cassette – flex • Expressed in hours: **h** • Expressed in minutes when < 1 h: **'**
	**WLAN connection status**	WLAN connection established
	**WLAN connection status**	WLAN connection interrupted
	**Charging process**	Battery is charging
	**Rechargeable battery**	Battery charging status

*Table 20. Status line of the **Main menu***

Main menu with application buttons

Use the **application buttons** to perform specific steps of an injection.

Symbol	Name	Meaning
	**Injection**	Prepare the injection.
	**Favorites**	Displays the injection programs that were selected as favorites on the touch terminal. Select a preconfigured injection program from the favorites list.
	**Vein check**	Perform vein check.

*Table 21. Application buttons in the **Main menu***

Status / action buttons

Use the **Status / action buttons** to perform the basic daily functions: Set up / strip down injector system, media selection, fill / vent tubing system, and replace patient tubing. In the majority of use cases, additional steps (creating, editing, and starting injection programs) will be performed via the touch terminal.

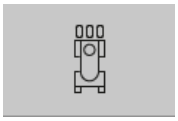
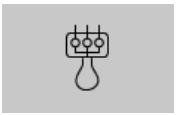
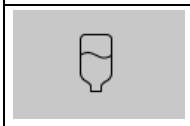
Symbol	Name	Meaning
	Injector (only status indicators)	Indicate the status of the injector (e.g., low battery, system settings, overpressure).
	Cassette	Start the workflow for injector setup and strip down. Perform volume adjustment.
	Media	Indicate the status and filling level of the media containers. Configure media.
	Tubing System Filling/rinsing / Vent	Fill and rinse the tubing system (Easy-Click-Cassette – flex and patient tubing). Vent the tubing system (Easy-Click-Cassette – flex and patient tubing).

*Table 22. Status / action buttons in the **Main menu***

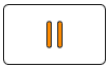
The **Status / action buttons** can be color-coded in order to indicate the status of one of the injector components. Messages will then appear. You can then tap to make the message visible. The color indications have the following meanings.

Symbol	Name	Meaning
	**Gray**	Status **OK**.
	**Blue**	Note Status information for a device component, e.g. for a media container. An action has not been finished, has been canceled, or has been performed incorrectly. To continue the workflow, it may be necessary for the operator to perform an additional or new action.
	**Yellow**	Safety message It is necessary to perform this step to safely continue the workflow.

Table 23. Color indication of the status / action buttons on the touch display of the control unit

7.2.2 Standard symbols

The following symbols are used consistently on all touch display screens.

Symbol	Name	Meaning
	**Main menu**	Switch to main menu.
	**Back**	Return to the previous screen. Any entered / edited data will be discarded.
	Arrow symbol: **up / increase**	Scrolls the list up. Increases the entered value.
	Arrow symbol: **down / decrease**	Scrolls the list down. Decreases the entered value.
	**Same patient**	Workflow for the same patient: Repeat the injection with the same patient.
	**New patient**	Workflow for the next patient: Perform an injection with a new patient.
	**Start**	Start the selected action. (Fill, vent, volume adjustment)
	**Pause**	Pause the current action. (Fill, vent, volume adjustment)
	**Start injection**	Start injection or Vein check.
	**Pause injection**	Pause injection.
	**Stop**	Cancel the current action.

Symbol	Name	Meaning
	**Confirm**	Entries are confirmed and saved.
	**Settings**	Switches to the **Settings** menu.
	**Setup**	Switches to the **Setup** workflow.
	**Strip down**	Switches to the **Strip down** workflow.
	**Filling/rinsing**	Start **Filling/rinsing**. Fill and rinse the tubing system. The **Filling/rinsing** menu appears.
	**Vent**	Display the **Vent** menu.
	**Vent (NaCl flush)**	Perform **NaCl flush**. Vent the Easy-Click-Cassette – flex and patient tubing (NaCl flush).
	**Vent media supply tubing**	Manually vent the media supply tubing up to the media channel in the Easy-Click-Cassette – flex.
	**Remove tubing system**	Start **Strip down** workflow.
	**Volume adjustment**	Perform volume adjustment workflow for an Easy-Click-Cassette – flex.
	**Perform volume adjustment**	Start volume adjustment.
	**Advanced rinse**	Perform an advanced rinse of the Easy-Click-Cassette – flex (see case A, CM Select mode → section 5.1.3).

Table 24. Standard symbols on the touch display of the control unit

7.2.3 Messages

While an application is running, e.g., an injection program or a vein check, messages with colored backgrounds can appear. These messages provide information, notes and additional instructions to be observed and executed depending on the status. Depending on the color indication, the messages have the following status.

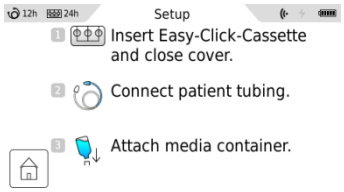
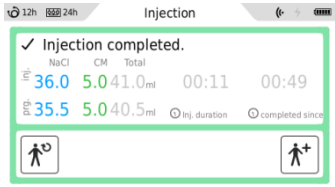
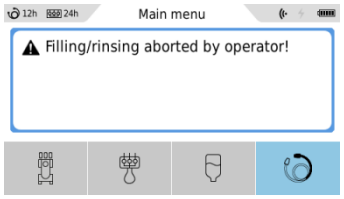
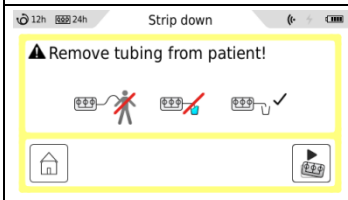
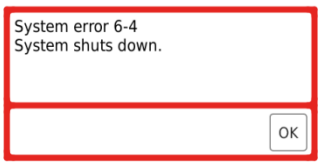
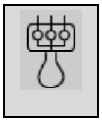
Symbol	Frame	Meaning
	No color	Workflow message • Message for the user regarding the next steps in the workflow.
	Green	Information message • Workflow status is **OK**. • This message appears for example after successful completion of an injection program.
	Blue	Note • Status information for a device component, e.g. for a media container. • An action has not been finished, has been canceled, or has been performed incorrectly. • To perform the workflow, it may be necessary for the operator to perform an additional or new action.
	Yellow	Safety message • Safely continuing to perform the workflow requires an action by the user.
	Red	Error message • Device error. The injection is canceled. • Follow instruction given in the message.

Table 25. Color indication of messages on the touch display of the control unit

7.2.4 Easy-Click-Cassette – flex **/ Injector menu**



The **Easy-Click-Cassette – flex** menu allows the user to start the processes for setting up and stripping down the injector system as well as volume adjustment of the inserted cassette.

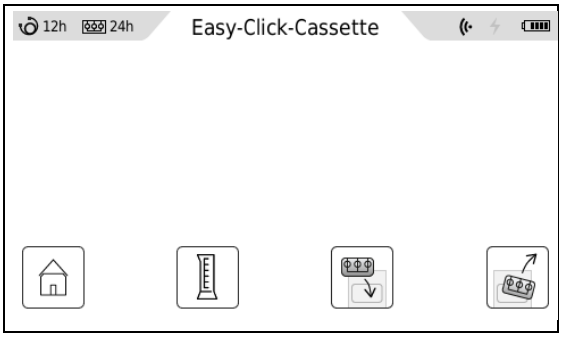


*Figure 16. **Easy-Click-Cassette-flex** menu*

Volume adjustment

The **Settings > Injector setting** menu (Section 10.2) allows ulrich**easy**INJECT Max 2M / Max 3 injectors to define that a volume adjustment must be performed for each new Easy-Click-Cassette – flex after setting up the system.

This indicates the recommended setting ensuring optimum volume delivery accuracy of the system.

As an alternative, the volume adjustment can be called up and performed at any time after the setup from the **Easy-Click-Cassette – flex** menu at the control unit of the injector.

Perform volume adjustment (activated in the Settings > Injector setting) menu

- ✓ Injector set up with Easy-Click-Cassette – flex, patient tubing and media (NaCl, CM).
- ✓ Patient not connected to the patient tubing.

1. Make sure that the tubing system is free of air and confirm the safety message by pressing **OK.**
   - ➥ At the injector's control unit and the touch terminal, the following message appears: **"Volume adjustment required"**
2. Press **OK** to confirm the message.
   - ➥ The safety message appears stating that the patient tubing is not yet connected to the patient and that the drip cup must be emptied
3. Ensure that the patient tubing is not yet connected to the patient.
4. Empty the drip cup and place back into drip cup holder.
5. Ensure that the patient tubing is inserted into the patient tubing holder so that the Luer lock connector is in place over the drip cup without contacting the drip cup.
6. Press the **Perform volume adjustment** button.
   - ➥ The measured volume of NaCl is delivered to the drip cup
   - ➥ The measured volume input screen appears
7. Transfer NaCl from the drip cup to the graduated cylinder (XD2000E-353-257), read the volume in mL, use the arrow keys to set the value and confirm with **OK**.

Perform volume adjustment individually (deactivated in the Settings > Injector settings) menu

- ✓ Injector set up with Easy-Click-Cassette – flex, patient tubing and media (NaCl, CM).
- ✓ Patient not connected to the patient tubing.

1. Press the **Cassette status / action** button in the main menu of the touch display.

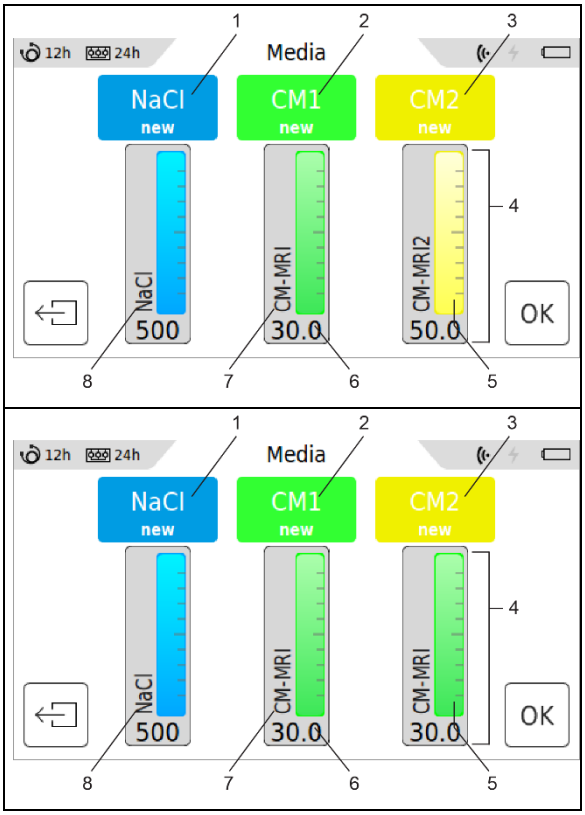
2. Press the **Volume adjustment** button.
   ➥ The safety message appears indicating that the patient tubing is not yet connected to the patient and the drip cup must be emptied
3. Ensure that the patient tubing is not yet connected to the patient.
4. Empty the drip cup and place back into drip cup holder.
5. Ensure that the patient tubing is inserted into the patient tubing holder so that the Luer lock connector is in place over the drip cup without contacting the drip cup.
6. Press the **Perform volume adjustment** button.
   ➥ The measured volume of NaCl is delivered to the drip cup
   ➥ The measured volume input screen appears
7. Transfer NaCl from the drip cup to the graduated cylinder (XD2000E-353-257), read the volume in mL, use the arrow keys to set the value and confirm with **OK**.

7.2.5 Media menu

In the **Media** menu, you can see which connection points are equipped by which media. You can select the desired medium for each connection point.

This section describes the basic sequence when performing this action.
▷ Only perform the following instructions in connection with the workflow, → section 9.

The symbols for the connection points are color-coded when a **new** media container has been plugged in and has not yet been configured. As soon as the media container is configured, the connection point symbol color changes to white and the symbol for the media container will be color-coded. The symbol for an empty media container appears white. Connection points without media containers are displayed in gray.



1 Symbol for the connection point for NaCl (here: newly equipped)
2 Symbol for the connection point for CM 1 (here: newly equipped)
3 **Max 3** only: Symbol for the connection point for CM 2 (here: newly equipped)
4 Symbol for the media container
5 Fill level bar indicator of **Max 3**:
  – yellow CM Select mode (above)
  – green CM Loop mode (below)
6 Remainder in media container
7 Name of the contrast medium
8 Name of the NaCl container

*Figure 17. **Media** menu*

For the ulrich**easy**INJECT **Max 2M** model, only one connection point for CM is displayed.

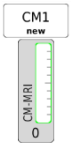
Symbol	Marking	Meaning
	*Blue*	Connection point with NaCl, newly equipped
	*Green*	Connection point with CM 1, newly equipped
	Yellow	**Max 3** only: Connection point with CM 2, newly equipped
	*White / green (CM1)* *White / green (CM2 – CM Loop)* *White / yellow (CM2 – CM Select)*	Connection point (here: CM 1 as an example) • equipped if the symbol for media container (4) displays information for medium (5 to 7)
	*White / white*	Connection point (here: CM 1 as an example) • equipped, media container (4) empty
	*White / gray*	Connection point (here: CM 2 as an example) • not equipped if symbol for media container (4) is gray
	*White / green / green CM1* *White / green / yellow CM2*	Connection point (here: CM 2 as an example) • "use first" is activated, when the symbol for media container (4) has a green (CM1) or yellow (CM2) background

*Table 26. Symbols in the **Media** menu*

Media Selection and Media List

For each connection point, a menu exists with the **Media Selection** and the **Media List**, in which you can select the medium that is present in the media container on a connection point, and the volume.

For Max 3:

CM Loop mode:
If both CM connection points are equipped and configured with the same type of contrast media, the injector switches automatically to the other media container if one media container runs dry.
In addition, you can use the **use first** function to specify that the contrast medium will be delivered from the selected media container first.

CM Select mode:
If the two CM connection points are equipped and configured with different types of contrast media, the CM Select mode is automatically enabled.
The system then automatically injects each contrast medium programmed in the injection protocol, provided it has been configured on one of the two connection points.

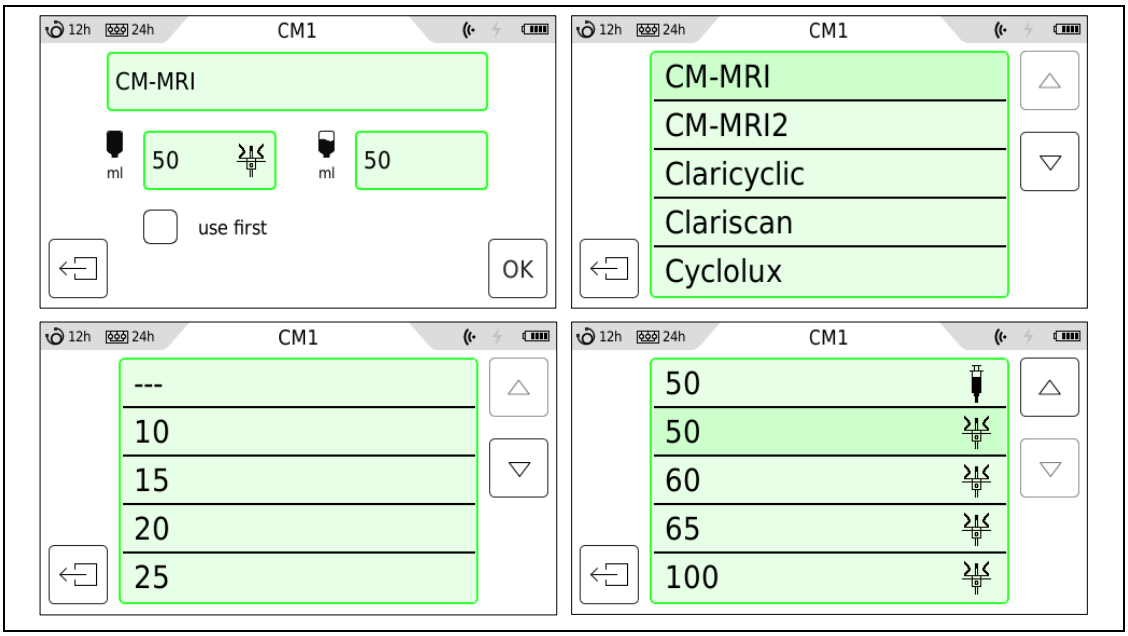


Figure 18. ***Media Selection***, ***Media List***, ***Volume***, *and* ***Type of Media Container*** *menus*

Symbol / Field	Name	Meaning
CM-MRI	**Medium** for CM 1 field	Switch to media list for CM 1.
ml 10	**Volume** field **for the media container**	Select volume of media container.
ml 125	**Partial volume** field	Enter the desired partial volume.
use first	**use first** function	CM is delivered first from this media container (only Max 3 in CM Loop mode).
CM-MRI CM-MRI2	**Media** list for CM 1	Select the medium for CM 1. The selected medium is highlighted.
100 125 150	**Volume** lists (Easy-Click-Cassette – flex)	Select volume of media container. The selected volume of media container is highlighted.

*Table 27. Symbols in the **Media Selection** menu*

Configure Media Containers

1 In the main menu, press the **Media** status / action button.
The **Media** menu appears.
2 Press the symbol for a (not equipped) connection point.
The symbol for the connection point is displayed as **equipped**:
– The connection point for NaCl appears blue.
– The 1st CM connection point appears in green.
– **For Max 3:** The 2nd CM connection point appears in yellow.
3 Press the media container symbol for an equipped connection point.
The **Media Selection** view appears.

Selecting the Medium

1 Press the **Medium** field.
The media list appears.
2 Use the arrow symbols to scroll through the list, and press the desired medium.
The selected medium appears in the **Medium** field.

No other media can be selected for NaCl.

Selecting the Volume and Partial volume

1 Press the **Volume and Type of Media Container** field.
The **Volume and Type of Media Container** list appears.
2 Use the arrow symbols to scroll through the list and select the desired volume of media container.
The selected volume and type of media container appears in the **Volume and Type of Media Container** field.

Optional:

3 Press the **Partial volume** field.
A numeric keypad for entering a partial volume appears.
4 Use the numeric keypad to enter the partial volume.
The partial volume appears in the **Partial volume** field.

Max 3: In CM Loop mode, the **use first** function can also be selected. If it is enabled, contrast media will be used from this media container first.

Completing the configuration of the media containers

▶ Confirm the entries by pressing **OK**.
The selection is saved. The next menu of the workflow appears.

– or –

▶ In case of an incorrect entry: Press the **Back** button.
The selection is **not** saved.
The main menu appears.

7.2.6 Filling/rinsing / Vent

In the **Filling/rinsing / Vent** menu, you can fill and rinse the tubing system. In the standard workflow, the patient is not yet connected to the injector during filling, rinsing, and venting.

Filling/rinsing

If necessary, filling/rinsing can be paused and continued, or canceled in emergency situations.

This section describes the basic sequence when performing this action.

▷ Only perform the following instructions in connection with the workflow, → section 9.

Screen for progress and status

On the screen, the blue bar represents the progress of filling the tubing system.

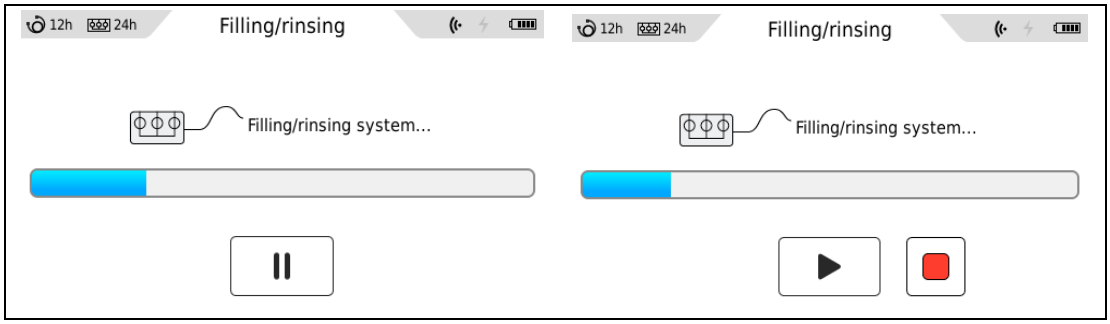


*Figure 19. **Filling/rinsing** view (left: running; right: paused)*

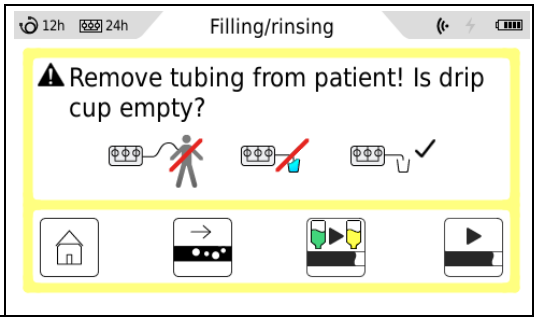
Symbol	Name	Meaning
		Progress bar for the filling process.
	Pause	Pause filling of the tubing system.
	Start	Continue filling of the tubing system.
	Stop	Cancel filling of the tubing system.

*Table 28. Elements in the **Filling/rinsing** screen*

Filling/rinsing the tubing system

1 In the main menu, press the **Filling/rinsing / Vent** status / action button. The safety message **"Remove tubing from patient!"** appears.

2 Ensure that the patient is **not** connected to the patient tubing.



3 If the patient has been connected to the patient tubing:
   – Disconnect the patient tubing from the patient. Discard patient tubing.
   – Connect a new patient tubing.
4 Confirm the safety message: Press the **Filling/rinsing** button.
5 The **Filling/rinsing** screen appears. Filling starts.

*Figure 20. **Filling/rinsing** menu*

Pausing / continuing the filling/rinsing process

1 Press the **Pause** button. The filling/rinsing process stops.
2 Press the **Start** button. The filling/rinsing process continues.

Cancelling the Filling/rinsing process

The **Stop** button is not enabled until the **Pause** button has been pressed.

▶ Press the **Stop** button.
The filling/rinsing process will be canceled.

The main menu appears with the message **"Filling/rinsing aborted by operator!"**. The status / action buttons **Filling/rinsing** and **Vent** have blue backgrounds.

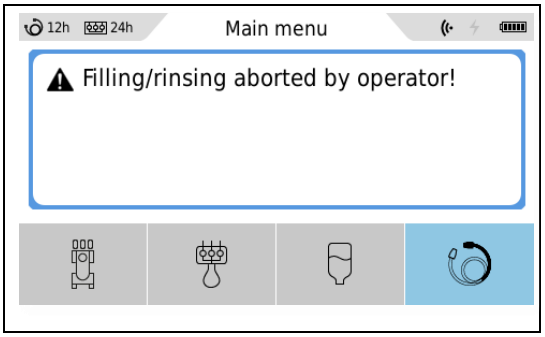


*Figure 21. **Filling/rinsing** view*

Completing the Filling/rinsing process

When the filling/rinsing process is finished:
The safety message **"Check if system is free of air, vent if necessary!"** appears.

▶ Check the tubing system to make sure it is free of air and if so, acknowledge the confirmation request with **OK**.

➥ The **Main menu** appears.

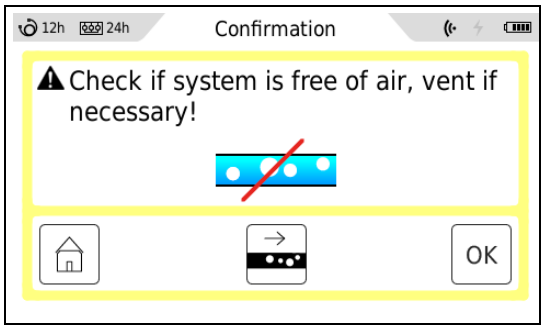
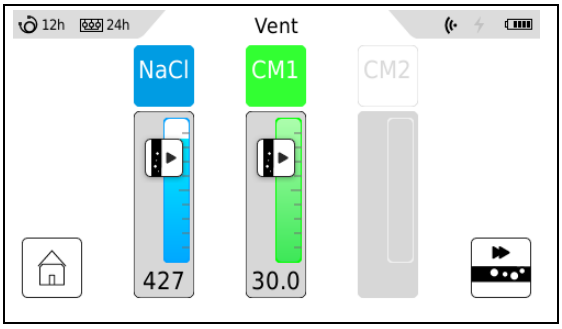


Figure 22. Check free of air message

Vent

This section describes the basic sequence when performing this action.

▷ Only perform the following instructions in connection with the workflow, → section 9, when air is found within the system.



During venting, ensure that the patient is not yet connected to the injector.
During venting, air bubbles that are potentially in the tubing system are removed.

The venting process involves **2 steps**.

*Figure 23. **Vent** menu*

The 2nd can also be performed independently of the 1st step, if there are air bubbles in the Easy-Click-Cassette – flex and the patient tubing after filling.

Symbol	Name	Meaning
	**Vent media supply tubing**	1st step: Manually vent the media supply tubing up to the media channel in the Easy-Click-Cassette – flex.
	**Vent (NaCl flush)**	2nd step: Vent and rinse the Easy-Click-Cassette – flex (starting from the media channel) and the patient tubing (NaCl flush).

*Table 29. Options in the **Vent** menu*

1st step: Venting media supply tubing
When manually venting the media supply tubing, air bubbles that are possibly present are conveyed to the media channel in the Easy-Click-Cassette – flex, → section 6.3.

Therefore, in the next step, the Easy-Click-Cassette – flex and the patient tubing must additionally be rinsed with NaCl (NaCl flush) starting from the media channel to ensure proper transport of the air bubbles to the exit point at the drip cup.

2nd step: Vent (NaCl flush)
When venting the tubing system, air bubbles potentially caught in the media channel of the Easy-Click-Cassette – flex and in the patient tubing, and contrast media potentially conveyed into the Easy-Click-Cassette – flex will be transported by a so-called NaCl flush from the media channel, through the tubing segment for the roll pump, through the patient tubing, and out to the exit point at the drip cup.

As needed, you can pause and continue the venting process (NaCl flush) and you can also cancel it in case of emergency.

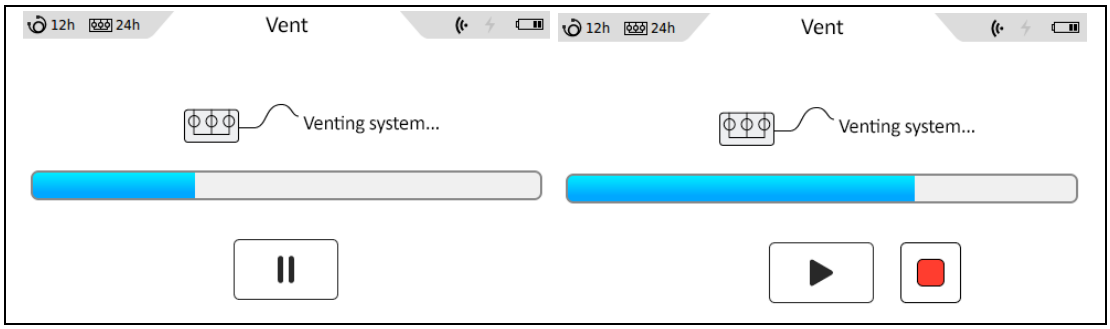


*Figure 24. **Vent** view (left: running; right: paused)*

Symbol	Name	Meaning
		Progress bar for the venting process.
	Pause	Pause venting.
	Start	Continue venting.
	Stop	Cancel venting.

*Table 30. Elements on the **Vent** screen*

1st step: Venting media supply tubing

1. In the main menu, press the **Filling/rinsing / Vent** status / action button.
   The safety message **"Remove tubing from patient!"** appears.
2. Ensure that the patient is **not** connected to the patient tubing.
3. If the patient has been connected to the patient tubing:
   - ▸ Disconnect the patient tubing from the patient. Discard patient tubing.
   - ▸ Connect a new patient tubing.

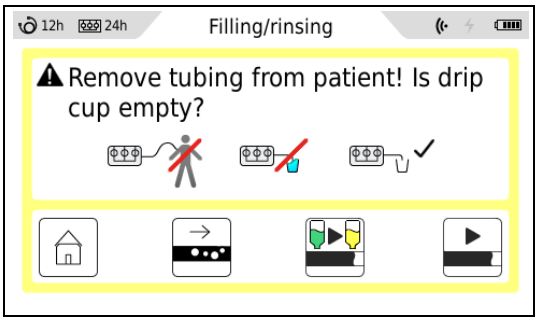


Figure 25. "Remove tubing from patient!" safety message

4. Confirm the safety message: Press the **Vent** button.
   The **Vent** menu appears.
5. One by one, vent the media supply tubing with detectable air bubbles for each connection point.
   – Press the **Vent media supply tubing** button on the relevant connection point (1, 2) and hold it down.

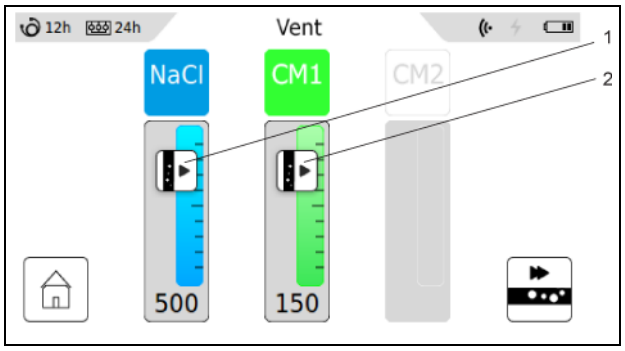


*Figure 26. **Vent** menu*

Release the **Vent media supply tubing** button when all air bubbles have been conveyed out of the media supply tubing into the media channel of the Easy-Click-Cassette – flex.

6. Repeat the venting process for every connection point until there are no longer any detectable air bubbles in the media supply tubing.
   ➥ The **Vent (NaCl flush)** button blinks with a **yellow** background.
7. Continue with the next step: Vent (NaCl flush).

2nd step: Vent (NaCl flush)

✓ The **Vent (NaCl flush)** button blinks with a **yellow** background.

▶ Press the **Vent (NaCl flush)** button (1).
The **Vent** view appears.
The Easy-Click-Cassette – flex is rinsed with a NaCl flush from the media channel to the exit point at the patient tubing.

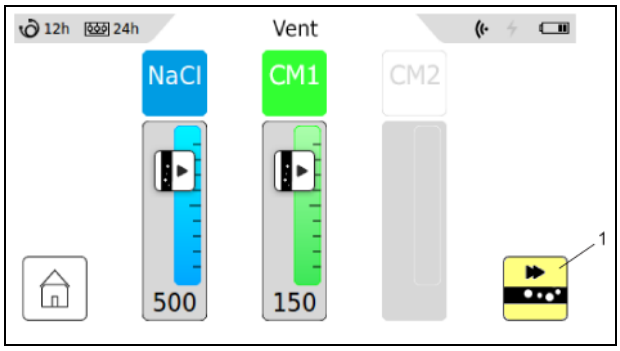


*Figure 27. **Vent** view*

Pausing / continuing the venting process

▶ Press the **Pause** button.
The venting process stops.

▶ Press the **Start** button.
The venting process continues.

Canceling the venting process

The **Stop** button is not enabled until the **Pause** button has been pressed.

▶ Press the **Stop** button.
The venting process will be canceled.
The message **"Venting aborted by operator!"** appears. The **Vent** status / action button has a blue background.

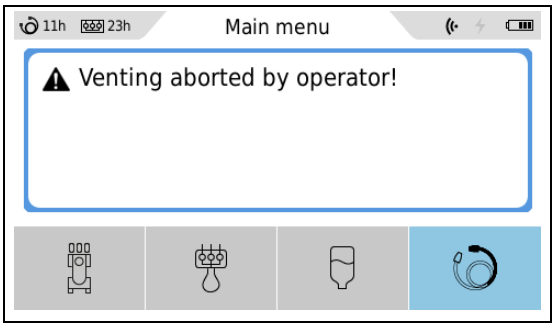


Figure 28. "Venting aborted by operator!" safety message

Completing the venting process

If the vent (NaCl flush) process is finished:

The safety message **"Check if system is free of air, vent if necessary!"** appears.

▶ Check the tubing system to make sure it is free of air and if so, acknowledge the confirmation request with **OK**.

➥ The **Main menu** appears.

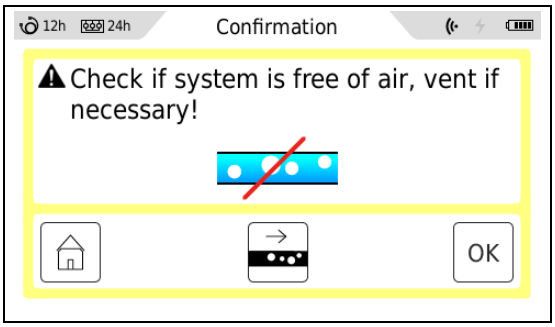


Figure 29. The safety message "Check if system is free of air, vent if necessary!"

7.2.7 Favorites menu

In most use cases, you will select and start an injection program on the touch terminal. Optionally, you can select an injection program on the control unit in the **Favorites** menu.

This section describes the basic sequence when performing this action.

▷ Only perform the following instructions in connection with the workflow, → section 9.

It is recommended to select and start an injection program on the control unit, for example if you want to stand next to the patient for better observation when starting the injection.
The injection programs to be displayed in the **Favorites** menu can be configured on the touch terminal.

A favorite that has been selected is highlighted in yellow.

*Figure 30. **Favorites** menu*

Selecting an injection program from Favorites

1. In the main menu, press the **Favorites** application button.
   The **Favorites** menu appears.
2. Press the desired injection program in the list.
   The selected injection program is highlighted in yellow.
3. Confirm by pressing **OK**.
   The main menu appears.

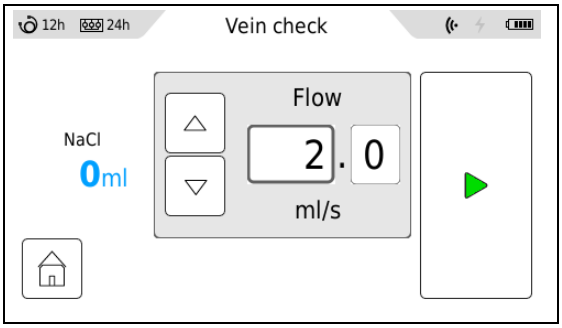
➥ Now you can start the injection with the selected injection program, → section 9.3.

7.2.8 Vein check menu

In the **Vein check** menu, you can perform the vein check and set the flow for the vein check.

This section describes the basic sequence when performing this action.

▷ Only perform the following instructions in connection with the workflow, → section 9.



The vein check can be used to check for correct positioning of the cannula with a specific flow rate.

The vein check can only be performed from the injector control unit.

*Figure 31. **Vein check** menu*

Symbol / Field	Name	Meaning
NaCl 16 ml	**NaCl volume**	Total injected volume (NaCl)
2.0	**Flow**	Fields for setting values for volume per unit time [mL/s]

*Table 31. Options in the **Vein check** menu*

Perform Vein check

1. In the main menu, press the **Vein check** application button.
   The **Vein check** menu appears.
2. In the **Flow** field, set the planned flow with the arrow keys.

Starting and stopping the Vein check

1. Press the **Start** button and hold it down.
   NaCl is fed according the set flow. The vein check is performed as long as the button is pressed.
2. Release the **Start** button.
   The vein check is stopped.

Stopping the Vein check

▶ Press the **Main menu** button.

➥ The vein check is finished and the main menu appears.

After 30 s of inactivity, this function will be automatically exited.

7.2.9 Injection menu

In the **Injection** menu, you can perform an injection that has been prepared and can view the essential information for the running injection.

This section describes the basic sequence when performing an injection program.
▷ Only perform the following instructions in connection with the workflow, → section 9.

The screens for the process and status of an injection present symbolic representations of the details regarding the pressure sequence and program sequence of the injection. In addition, messages regarding the injection may be displayed.
If necessary, injections can be paused and continued or canceled in emergency cases.

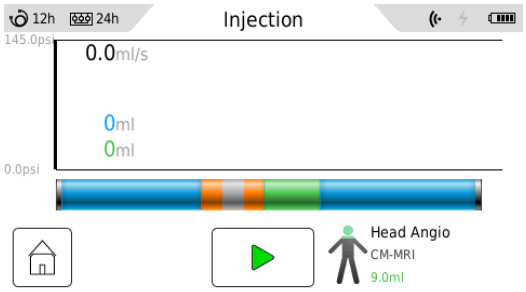


Figure 32. Main view

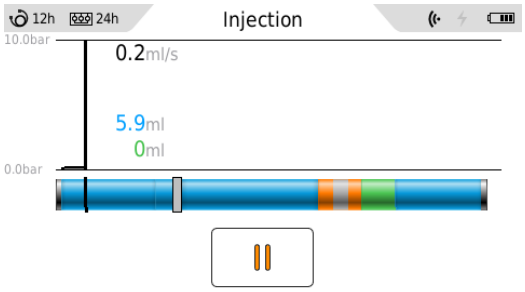


Figure 33. View while an injection is running

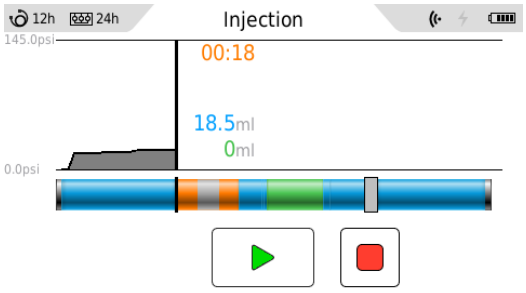
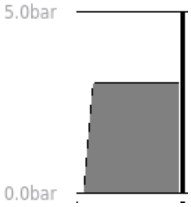
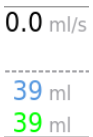


Figure 34. View while an injection is paused

Symbol / Field	Name	Meaning
	Pressure sequence for the injection (with pressure lines for orientation) Black line: marks the Luer lock connection to the end of the patient tubing	
	View of flow and injected volume: • black: Flow (unit depends on the setting) • blue: currently injected NaCl volume (mL) (actual volume) • green: currently injected contrast medium volume (mL) (actual volume)	

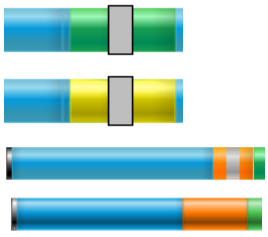
Symbol / Field	Name	Meaning
	Program sequence (symbolic): • blue: NaCl bolus • green: CM bolus (CM connection point 1) • yellow: CM bolus (CM connection point 2) in CM Select mode (only **Max 3**) • orange / gray / orange: pause • orange: time-controlled pause • gray rectangle: medium currently contained in the Easy-Click-Cassette – flex (here: CM)	
	Injection program name Symbol and name of body region	
	**Pause**	Pause injection
	**Start**	Continue injection
	**Stop**	Cancel injection The message **"Injection aborted by operator!"** appears

*Table 32. Elements of the **Injection** menu screens*

Messages regarding the injection status

When an injection is finished or canceled, messages appear in the **Injection** menu.

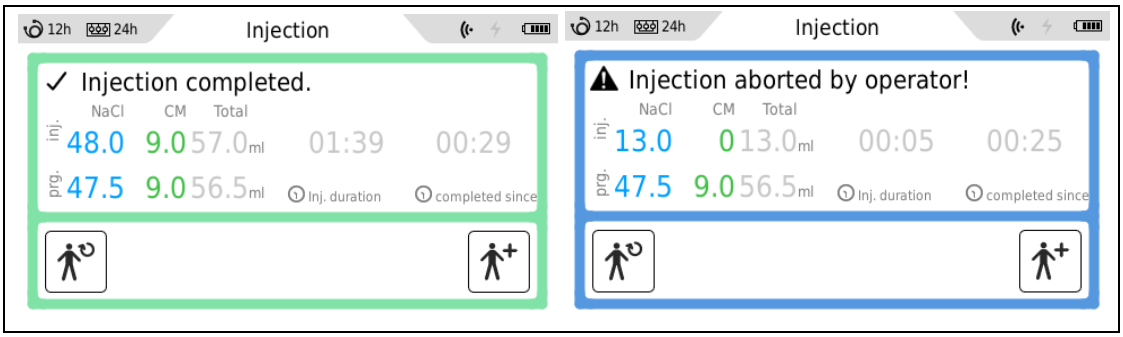
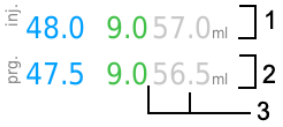


Figure 35. Messages regarding the injection status

Symbol	Name	Meaning
	1 Volume already injected (since program start) 2 Programmed volume 3 Total volume (NaCl and CM) • blue: NaCl • green: CM	
	Inj. duration	Duration of the injection

Symbol	Name	Meaning
...	*Ended since*	Elapsed time since the end of the last injection

Table 33. Message elements

Performing an injection

In most use cases, the operator selects and starts the injection program at the **touch terminal**. It is recommended to start an injection on the **control unit** if you want to stand next to the patient to start the NaCl pre-bolus and in doing so to check whether the indwelling venous cannula is correctly seated.

Confirm messages that appear on the control unit and the touch terminal during the injection by touching the screen.

✓ Workflow instructions followed, → section 9.

▶ On the touch terminal: In the **Program selection** menu, select an injection program via the **Programs**, **Program selection** or **Body region** sections.
– or –

▶ At the control unit:
  – In the main menu, use the **Favorites** application button to select an injection program.
  – In the main menu, press the **Injection** application button.
  The **Injection** menu appears.

Starting an injection

▶ Press the **Start** button.
The injection starts.

Pausing / continuing the injection

It is possible to stop (pause) and continue an injection program.

1. To pause the injection: Press the **Pause** button.
   The injection is paused.
2. To continue the injection: Press the **Start** button.
   The injection is continued.

Cancelling an injection

It is possible to cancel (stop) an injection program to finish it prematurely. After that, the injection cannot be continued anymore.
The **Stop** button is not enabled until the **Pause** button has been pressed.

▶ Press the **Stop** button.
The injection is canceled.

↪ On the control unit and on the touch terminal, the message **"Injection aborted by operator!"** appears.

Ending the injection

Normally, an injection program is automatically executed up to its end, i.e. until the process is completed.

- ↪ On the control unit, the information message **"Injection completed."** appears with an overview of the completed injection.
- ↪ On the touch terminal, an overview of the completed injection appears.

8 Touch terminal

8.1 Structure

The touch terminal is in the monitoring room and is operated from a touch-sensitive display (touch screen). The touch terminal is powered via a power supply unit.
On the touch terminal, you can configure the basic settings of the injector system and perform all activities to create, edit, and perform injection programs and to monitor processes.

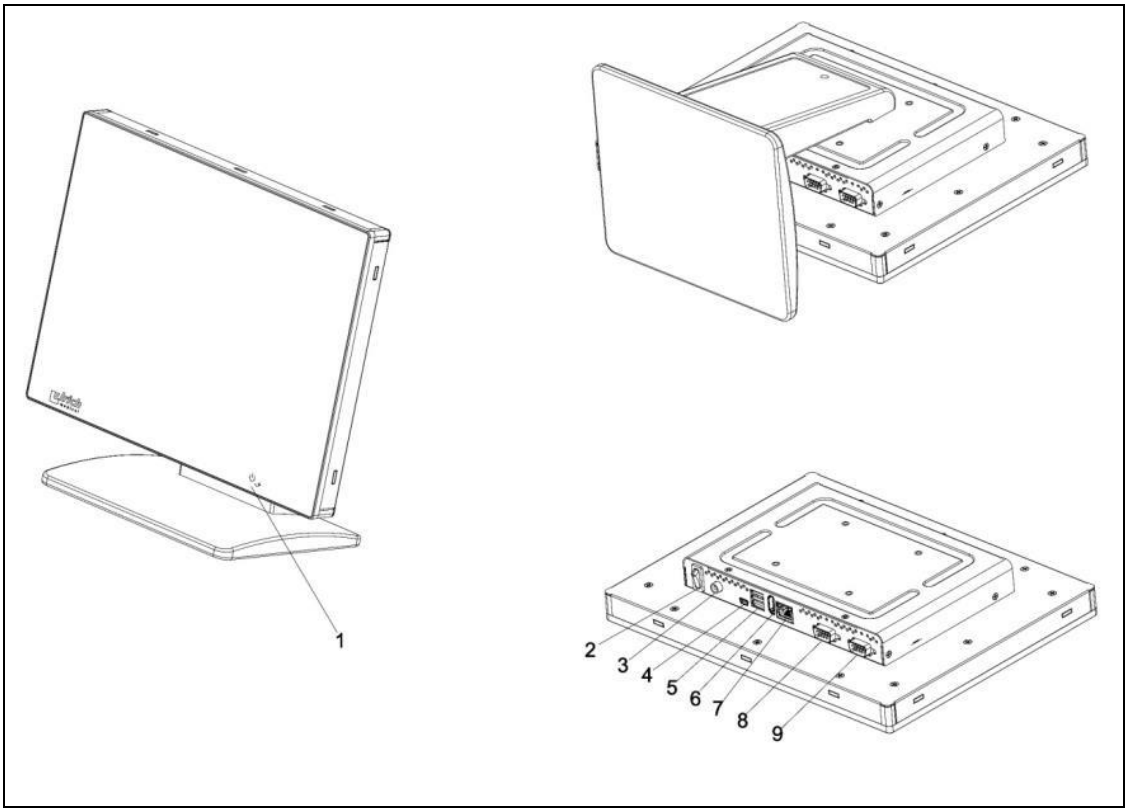


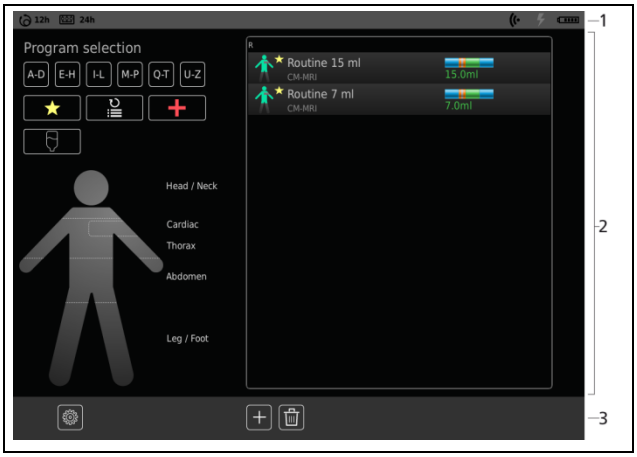
Figure 36. Touch terminal

1 On / off switch symbol
2 On / Off switch
3 DC IN 12–24 V
4 USB-OTG port
5 USB ports
6 HDMI port
7 LAN port
8 COM1 port
9 COM2 port

8.2 User interface of the touch terminal

8.2.1 Layout of the user interface

Every screen of the user interface has a similar layout and contains common symbols and elements to inform the user about the status of the injector system or to execute specific functions. Depending on the corresponding menu-specific screen, different elements appear in the status and function line. Enabled control elements appear in white, disabled controls are grayed out.



1 Status line
2 Area with menu-specific screens
3 Function bar

Figure 37. Layout of the user interface

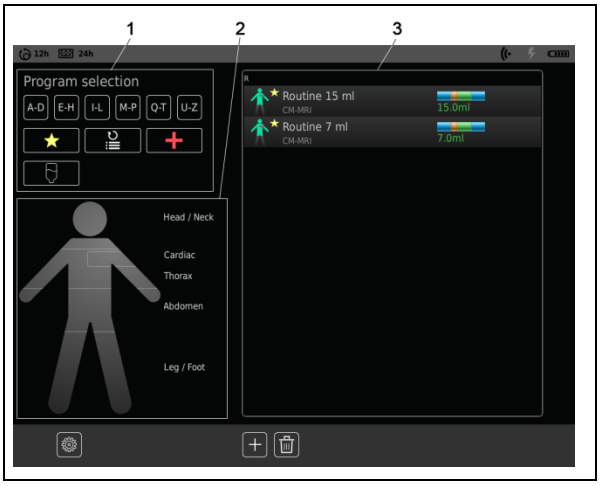
Symbol	Name	Meaning
Status line		
	–	Remaining service life of the patient tubing • Expressed in hours: **h** • Expressed in minutes when < 1 h: **'**
	–	Remaining service life for Easy-Click-Cassette – flex • Expressed in hours: **h** • Expressed in minutes when < 1 h: **'**
	–	Prepare the injection.
	–	Saved program was edited.
	**WLAN**	Status of the WLAN connection.
	**Charging process**	Injector battery is charging.
	**Rechargeable battery**	Battery operation of the injector. Charging status of the injector battery.
Function bar		
	**Start**	Start injection.
	**Pause**	Pause injection.
	**Stop**	Cancel injection.
	**OK**	Confirm and save input.

Symbol	Name	Meaning
	**Same patient**	Workflow for the same patient: Repeat the injection with the same patient.
	**New patient**	Workflow for the next patient: Perform an injection with a new patient.
	**Main menu**	Switch to the main screen.
	**Program selection**	Switch to program selection.
	**Settings**	Switch to settings.
	**Back**	Switch to the previous view (input is not saved).
	**New program**	Create a new program. Open the bolus editor.
	**Delete**	Delete program.
	**Save**	Save a program or input.
Area with menu-specific screens		
	**Arrow symbol** **Up / Increase**	Scrolls the list up. Increases the entered value.
	**Arrow symbol** **Down / Decrease**	Scrolls the list down. Decreases the entered value.
	**Numeric keypad**	Allows the entry or deletion of numeric values.
	**Keyboard**	Allows the entry or deletion of characters. The characters on the keyboard depend on the configured keyboard layout.

Table 34. Symbols and elements of the touch terminal user interface

8.2.2 Program selection menu

In this screen, it is possible to filter, sort and view the saved injection programs and to run and delete an existing program or to add new program.



1 **Program selection (filter)** section
2 **Body region** section
3 **Programs** section

Figure 38. Main menu with program selection

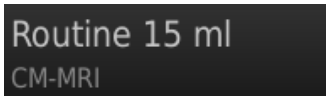
Symbol	Name	Meaning
Program selection / body region section		
	**Program filter**	Button for the alphabetical program selection list.
	**Favorites**	The programs only displays programs that are saved as favorites.
	**History**	The programs only shows recently used programs.
	**Trauma**	Quick selection of the program for use in trauma applications.
	**Available Media**	The programs only shows programs with the CM that are available on the injector.
	**Body regions**	Selection of a body region program by body symbols or names.
Programs Section		
		Body region of the selected program (highlighted in light green).
		1st line: program name. 2nd line: name of the programmed CM.
		Program saved as favorite.
		Program for trauma application.
		1st line: smaller view of program boli. 2nd line: total volume of the contrast media.

Table 35. Symbols and elements of the main menu

8.2.3 Injection main menu

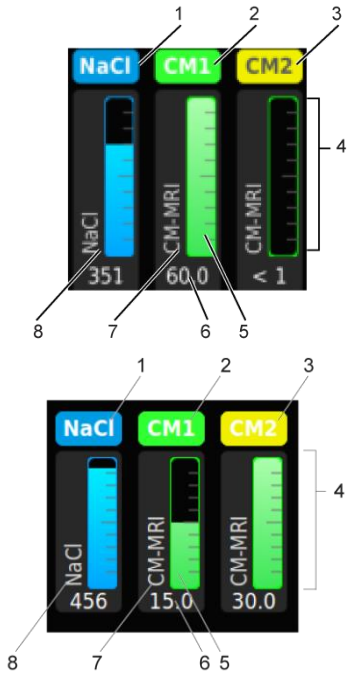
The **Main menu (Injection)** view allows the user to perform an injection program and to view the status of all injector system components.

1 **Injection Program** section
2 Details on the injection program boli
3 Entire injection program
4 Detail window for program detail (movable)
5 **Injector status** section
6 **Pressure limit** section
7 **Information for Injection** section
8 **Volume** section
9 **Connection points and media** section

*Figure 39. **Injection** screen*

For the ulrich**easy**INJECT **Max 2M** model, only one connection point for CM is displayed.

Symbol	Name	Color / Parameter
Injection Program section		
	**NaCl bolus**	Blue
	**CM bolus**	Green **Max 3** only: CM Loop mode: Green CM Select mode: • CM 1: Green • CM 2: Yellow
	**Time-Controlled Pause**	Orange The running injection is paused with the specified pause duration After the configured time the injection will be automatically continued
	**Manual Pause**	Orange / silver / orange The running injection is paused until the user continues it by pressing the **Start** button

Symbol	Name	Color / Parameter
	**Bolus Display**	Bolus volume (unit depends on the setting) Bolus flow (unit depends on the setting) Calculated time / bolus (unit depends on the setting)
	**Calculated NaCl backup volume**	Note Calculated volume of the NaCl backup (CM substitution)
	**NaCl Backup**	Shaded blue CM bolus that is expected to be substituted with NaCl backup
	**NaCl Backup**	Note Entire injection program section CM bolus that is expected to be substituted with NaCl backup
	**Timer**	Symbol for configured timer
	**Flow reduction**	If this symbol is displayed below a bolus (NaCl or CM), a flow reduction may occur during injection of this bolus
Connection points and media section		
	1 Symbol for connection point, equipped by NaCl 2 Symbol for connection point, equipped by CM 1 3 **Max 3** only: 2nd connection point, equipped by CM 2 – Yellow: CM Select mode (figure above) – Green: CM Loop mode (figure below) 4 Symbol for the media container 5 Fill level bar, current fill level of the media container 6 Remainder in media container 7 Name of the contrast medium 8 Name of the NaCl container
Volume section		

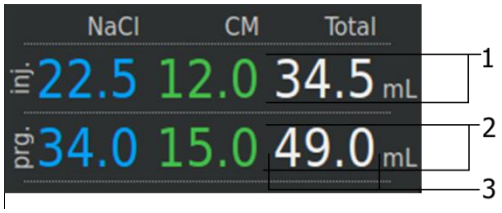
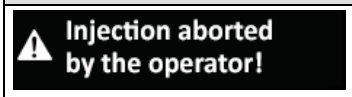
Symbol	Name	Color / Parameter
		1 Volume already injected (since program start) 2 Total volume to be injected 3 Total volume (NaCl and CM) • blue: NaCl • green: CM
Injector Status Section – Status / action buttons		
	**Injector** (only status indication)	Indicate the status of the injector (e.g., low battery, system settings, overpressure)
	**Cassette**	Indicate the status of the cassette
	**Media**	View status of the media containers
	**Filling/rinsing**	View messages regarding filling and rinsing
	**Vent**	View messages regarding venting
	**Pressure limit section**	Set patient-related maximum system pressure limit
Inj. duration		Duration of the injection
ended since		Elapsed time since the end of the last injection

*Table 36. Symbols and elements from the **Injection** screen*

8.2.4 Messages

While an application is running, e.g., an injection program or a vein check, messages with colored backgrounds may appear on the user interface, and colored borders may be displayed for buttons. These messages provide information, notes and additional instructions to be observed and executed depending on the status. Depending on the color indication, the messages have the following status.

Symbol	Frame	Meaning
	–	Messages regarding workflow • Action not completed or canceled. • In addition, a button can be color-coded to indicate an applicable message.

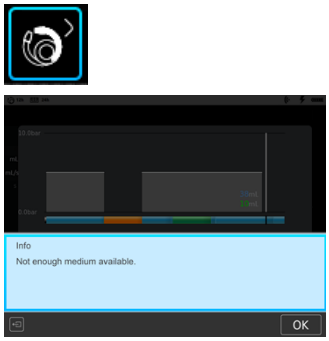
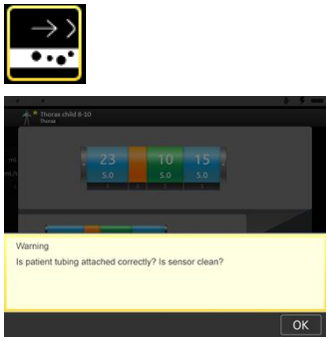
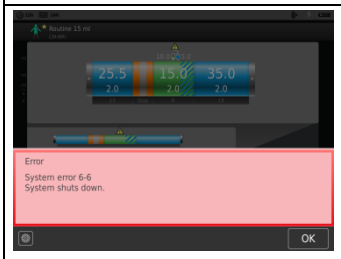
Symbol	Frame	Meaning
	Blue	Note • Status information for a device component, e.g. for a media container. • An action has not been finished, has been canceled, or has been performed incorrectly. • To perform the workflow, it may be necessary for the operator to perform an additional or new action. • A button for which there is a message is color-coded. • Upon pressing the button, a message appears with further information.
	Yellow	Safety message: • Safely continuing to perform the workflow requires an action by the user. • A button for which there is a safety message is color-coded. • Upon pressing the button, a safety notes appears with further information.
	Red	Error message: • Device error. The injection was canceled. • The injector system (injector and touch terminal) must be restarted.

Table 37. Color indication of the messages at the touch terminal

8.2.5 Injection screen

This screen appears during an ongoing injection. It provides an overview of all essential data about the injection sequence.

Figure 40. View while an injection is running

Figure 41. View while an injection is paused

This view appears when an injection has been canceled by the user. It provides an overview of all essential data about the injection sequence and the message concerning the injection termination.

Figure 42. View when an injection is canceled

This view appears when an injection has been completed. It provides an overview of all essential data about the injection sequence.

Figure 43. View when an injection has finished

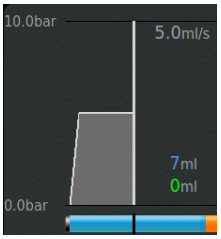
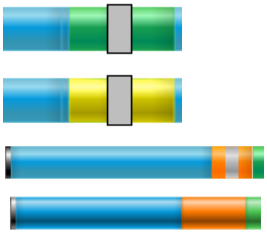
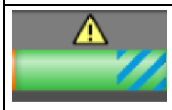
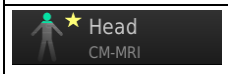
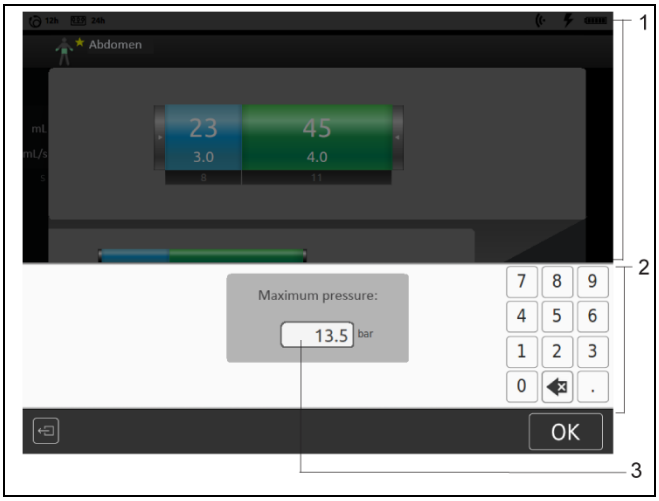
Symbol / Field	Name	Meaning
	Pressure sequence of the injection (with pressure line for orientation): • white line: marks the Luer lock connection at the end of the patient tubing View of flow and injected volume: • blue: currently injected NaCl volume (actual volume) (unit depends on the setting) • green: currently injected contrast medium (actual volume) (unit depends on the setting) • gray: flow (unit depends on the setting)	
	Program sequence (symbolic): • blue: NaCl bolus • green: CM bolus • yellow: CM 2 in CM Select mode (only **Max 3**) • orange / gray / orange: manual pause • orange: time-controlled pause • gray rectangle: medium currently contained in the Easy-Click-Cassette – flex (here: CM)	
	**CM Substitution**	Note Shaded blue: CM bolus that is substituted with NaCl backup
	Name of the selected injection program; body region icon; indication of the programmed CM type	
	**Start**	Start or continue an injection
	**Pause**	Pause injection
	**Stop**	Cancel injection The message **"Injection aborted by operator!"** appears

*Table 38. Symbols and elements from the **Injection** screen*

8.2.6 Pressure limit screen

In this screen, you specify the maximum pressure limit for a specific patient. The pressure limit that is set on this screen applies to all of the next patient's injections.

As soon as **New patient** is selected after an injection, the pressure limit is reset to the default pressure limit.



1 **Injection Program** screen (with currently selected program)
2 Numeric keypad
3 Field for pressure specification

*Figure 44. **Pressure limit** screen*

The pressure limit can be set between 2 and 14 bars in increments of 0.1 bars. When the pressure limit is exceeded during an injection, a warning beep sounds, the button for setting a patient-specific pressure limit is highlighted yellow, and the flow is automatically reduced until the maximum pressure limit is reached.
If the pressure still increases due to obstruction, the injection will be canceled and a warning message appears.

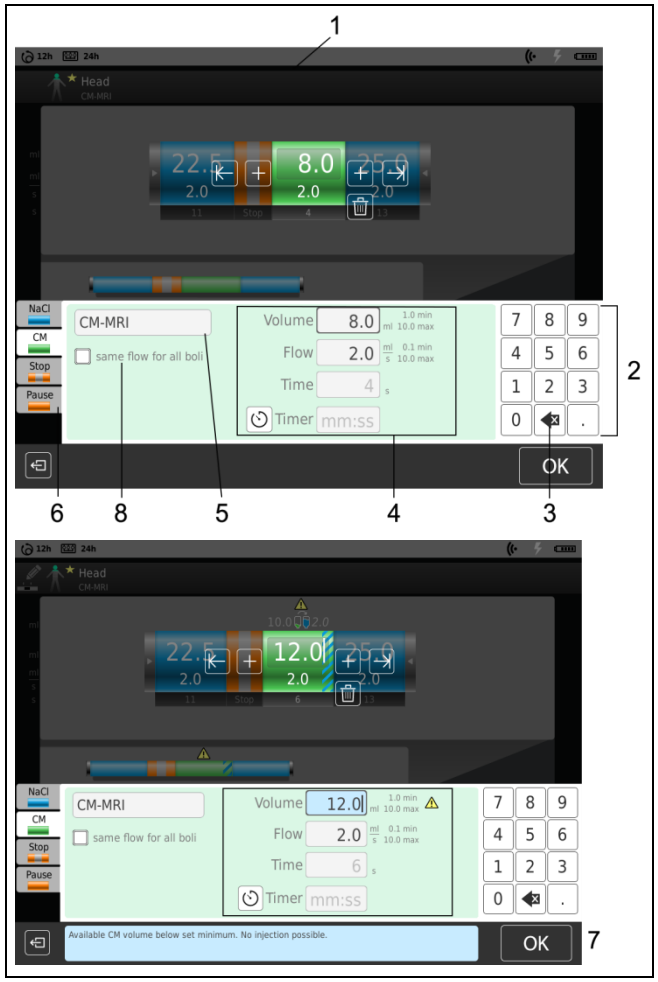
Setting the Pressure limit

1. In the **Injection Program** screen, press the **Pressure limit** button.
   A dialog with a text box and the numeric keypad appears.
2. Enter the desired value for the maximum pressure limit.
3. Confirm by pressing **OK**.
   The previous menu appears. The current injection program appears.

➥ The **Pressure limit** is enabled.

8.2.7 Bolus Editor screen

In the **Bolus Editor**, you can edit existing injection programs and create new injection programs. You can edit each bolus and add or delete boli or elements (e.g. stop or pause sequences). Enter the desired values in the input fields with the numeric keypad. The min and max values indicate the valid value range for the setup.
After the entry, the injector system validates the entered values and highlights the corresponding input fields in case of errors.



1 **Bolus Display** section
2 **Bolus Register** section
3 Numeric keypad
4 Programming panel
5 Media selection
6 List of boli and elements
7 View for **CM substitution** function
8 Set all boli to the same flow value

*Figure 45. **Bolus Editor** screen*

Symbol	Name	Meaning
Bolus Display section		
	**Insert**	Insert bolus / element.
	**Select**	Select the left or right bolus.
	**Delete**	Delete bolus / element.
Bolus Register		
	**NaCl Bolus**	Set the selected element as an NaCl bolus. The programming panel for the bolus appears.
	**CM Bolus**	Set the selected element as a CM bolus. The programming panel for the bolus appears.

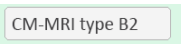
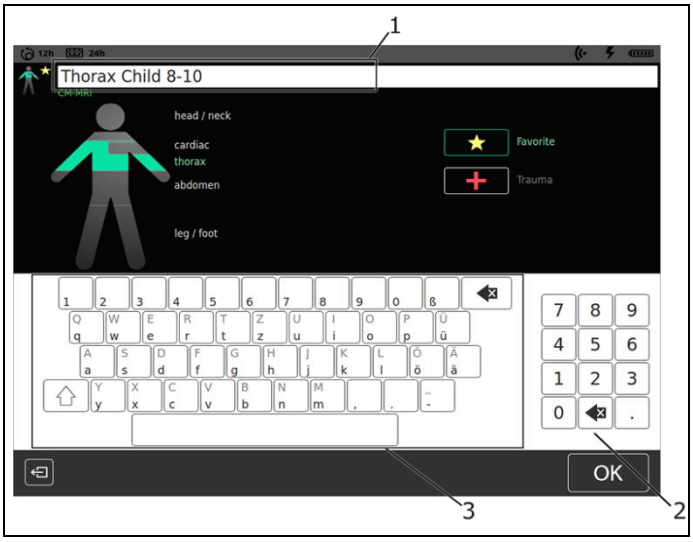
Symbol	Name	Meaning
	**Pause**	Set the selected element as a manual pause. The programming panel for stop appears. This element inserts a manual pause into the sequence of the injection program which lasts until the user continues the injection by pressing the **Start** button.
	**Time-Controlled Pause**	Set the selected element as a time-controlled pause. The programming panel for the pause appears. This element inserts a pause with a specified duration into the sequence of the injection program. A time-controlled pause can also be set before the first NaCl bolus as a start delay for the injection program.
Programmable fields for a bolus		
Same flow for all boli		Sets the same flow for all boli.
Volume		Input field for the bolus volume (unit depends on the setting), indicating the possible minimum and maximum values.
Flow		Input field for the bolus flow (unit depends on the setting), indicating the possible minimum and maximum values.
Time		The time specification for the bolus [s]. Time cannot be set but is automatically calculated by the injector system.
Timer / count down		Input field for the timer [mm:ss]. Time is incremented by the timer. To decrement timer time: Check the countdown check box.
Programming panel for the CM bolus		
	**CM selection**	Select the contrast media.

*Table 39. Symbols and elements from the **Bolus Editor** screen*

8.2.8 Save injection program screen

In the **Save injection program** screen, you can save newly created or edited injection programs.



1 Input field for the program name
2 Numeric keypad
3 Keyboard

*Figure 46. **Save injection program** screen*

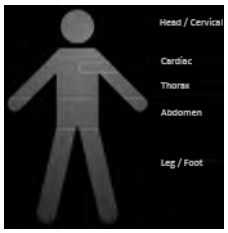
Symbol	Name	Meaning
	**Body region**	Select the body region for which the program is created (using the body symbol or the names).
	**Favorite**	Mark a program as a favorite.
	**Trauma**	Mark a program for trauma application.

*Table 40. Save symbols and elements from the **Save injection program** screen*

8.3 Creating and saving injection programs

Injection programs are created and edited on the touch terminal with the bolus editor.

8.3.1 Creating an injection program

1. In the **Program selection** menu, press the **New Program** button.
   The **Bolus Editor** (→ section 8.2.7) appears with the initial NaCl bolus and the input fields for the boli. The volume of the first NaCl bolus is set according to the length of the patient tubing.
2. In the **Bolus Display** section: Select and define all desired boli with the **Select** and **Insert** buttons.
3. In the **Bolus Register** section: Enter values into the programming panel of the relevant bolus register via the numeric keypad.
4. Confirm by pressing **OK**.

➥ The **Injection** main menu appears.

Optionally, you can now save the newly created injection program, → section 8.3.3.

A newly created injection program does not appear **until** it has been saved in the programs of the **Program selection** menu.

8.3.2 Editing an injection program

Starting the Bolus Editor

If the injection program is already saved and appears in the programs:

- In the **Program selection** menu in the **Programs** section, select the desired injection program.
  The **Injection** main menu appears with program details.
- In the **Injection Program** section, press any bolus.
  The **Bolus Editor** appears with the bolus display and the bolus register.

If the injection program was not saved and is visible in the **Injection** main menu with the program details:

- In the **Injection Program** section, press any bolus.
  The **Bolus Editor** appears with the bolus display and the bolus register.

Editing an injection program

1. In the **Bolus Display** section: Press the bolus you want to edit.
   The bolus register including detailed information on the selected bolus appears.
2. In the **Bolus Register** section: Enter the values via the numeric keypad.
3. Edit all program details and boli one by one.
4. Confirm by pressing **OK**.

➥ The **Injection** main menu appears.

Optionally, you can now save the edited injection program, → section 8.3.3.

8.3.3 Saving an injection program

1. In the **Injection** main menu, press the **Save** button.
   The **Save** view appears.
2. Enter the name of the injection program via the keyboard and the numeric keypad.
   It is also possible to change the name of an edited injection program via keyboard and numeric keypad.
3. (Optional) To mark the program as a favorite: Press the **Favorite** button.
4. (Optional) To assign a program to a body region: Press the area for the body region.
5. (Optional) To mark a program as a trauma application: Press the **Trauma** button.
6. Confirm by pressing **OK**.
   The injection program is saved.

➥ The **Injection** main menu appears. The saved program appears in the programs.

8.3.4 Deleting an injection program

1. In the **Injection** main menu, press the **Delete** button.
2. Select the program to be deleted from the programs.
   A message appears.

3. In order to acknowledge the message and confirm the deletion of the injection program, press the **OK** button.

➥ The program is deleted from the programs.

▶ In order to cancel the deletion process, press the **Back** button.

9 Using the Injector System

9.1 Preparing the injector system at the beginning of each day

9.1.1 Install media holder

✓ Injector system installed, → section 11.1

At the injector

1. Insert the media holders one by one into the connection points.
2. Make sure that the media holders click audibly into the connection points.

9.1.2 Prepare the injector

⚠ **DANGER! Risk of personal injury and material damage due to magnetic attraction of the injector by the MRI scanner if the safety conditions are not observed!**

- ▸ Only move the injector in the MRI scanner room outside an existing 30 mT safety line or the safety line designated by ulrich medical or by a person authorized by ulrich medical and position it for the injection.
- ▸ Do not place the injector to a magnetic field strenght >50 mT (at a height of 0.1 m).
- ▸ To move the injector, always hold it by the handlebar and secure it with at least 2 parking brakes after positioning.
- ▸ Do not hold / move the injector by the injector head.
  Risk of tipping over and consequential damage due to increased magnetic attraction.
- ▸ Ensure that the patient hose can move freely (e.g., not trapped in the patient couch, etc.).

✓ Media holders inserted
✓ Injector system in proper condition
✓ Battery adequately charged

1. When the battery is charged:
   – Remove the mains plug from the power outlet, remove the power cord from the injector and store it on a safe place.
2. Roll the injector to the examination room.
3. Lock the parking brakes at the injector base.
   – Check that the injector is in a secured condition.

⚠ **CAUTION!** Risk of injury for operators due to magnetically induced movements of improperly installed device components in the MRI room. An MRI scanner may magnetically attract the touch terminal and its accessories and thereby cause injury to individuals.

▶ In accordance with IEC 60601-1, only set up and operate the touch terminal outside the MRI examination room.

9.1.3 Switch the injector system on

✓ Injector prepared

On the touch terminal

▶ Press the **On / Off** button.
The touch terminal is switched on. The welcome screen appears.

At the injector

▶ At the control unit: Press the **On / Off** button.
The injector is started. The welcome screen appears.

The injector establishes a connection to the touch terminal.

➥ As soon as the injector is ready, the workflow message **Setup** appears on the control unit, and the main menu with the program selection appears on the touch terminal.

➥ If the injector is already set up, messages appear to confirm the current system configuration. Depending on the use case, the messages can be acknowledged or rejected.

The status of the connection is indicated by means of the **WLAN** symbol on the touch screen of the touch terminal, and on the touch display of the control unit, → section 6.6.

9.2 Setting up the injector each day

✓ Injector system prepared

After the injector system has been switched on, if the injector detects that no tubing system is inserted yet, the **Setup** workflow message appears on the injector's control unit.

Proceed as follows to manually load the setup process.

At the control unit

1. In the main menu, press the **Cassette** status / action button.
2. Press the **Setup** button.
   The **Setup** workflow message appears with a list of the 3 steps to be performed during setup.

9.2.1 Insert the Easy-Click-Cassette – flex

✓ **Setup** menu visible on the control unit

At the injector

1. Open the roll pump cover.
2. Unpack the Easy-Click-Cassette – flex.
   - Ensure that the package does not appear damaged, the packaging seal is not broken, and the expiration date is not expired.
   - Use aseptic technique when opening the Easy-Click-Cassette – flex package.
3. Using aseptic technique, insert the Easy-Click-Cassette – flex into the insertion field for the Easy-Click-Cassette – flex.
4. Ensure that both locking catches of the Easy-Click-Cassette – flex are engaged in the latching points in the insertion field.
5. Ensure that the tubing segment for the roller pump of the Easy-Click-Cassette – flex is positioned outside of the 3 guide rollers. If necessary, position the tubing segment for the roller pump outside of the guide rollers (see Fig. 47).


Figure 47. **Correct position** of the tubing segment

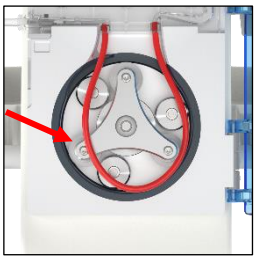



Figure 48. **Incorrect position** of the tubing segment

6. Turn any white guide roller to 12 o'clock position (Fig. 49).

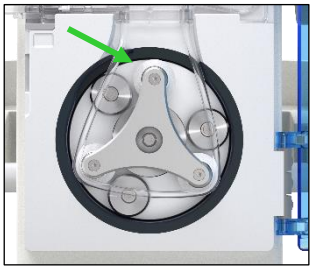


Figure 49. Position of the white guide roller to 12 o'clock

7. Using a finger, gently press in the tubing segment and turn the roller pump in clockwise direction with the other hand until the white guide roller has caught the tubing segment (Fig. 50).

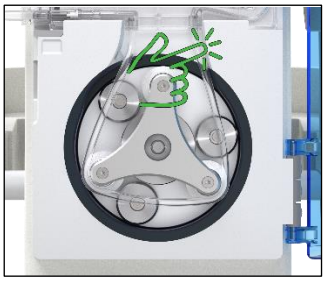


Figure 50. Pressing in the tubing segment

8. Continue to turn the roller pump in clockwise direction until the white guide roller with the tubing segment is in 2–3 o'clock position (Fig. 51) or until the guide roller (metal) comes into contact with the tubing segment.

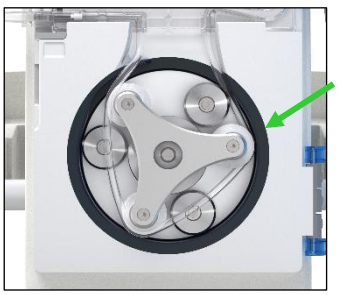


Figure 51. Position of the white guide roller to 2–3 o'clock

9. Close the roller pump cover.

9.2.2 Connect the patient tubing to the Easy-Click-Cassette – flex

✓ Easy-Click-Cassette – flex inserted

At the injector

1. Insert the drip cup into the drip cup holder.
2. Unpack the patient tubing.
   – Confirm that the package does not appear damaged, the packaging seal is not broken, and the expiration date has not passed.
   – Open the package using aseptic technique.
3. Remove the protective cap from the SafeConnect on the patient tubing using aseptic technique.
   – Remove the protective cap at the connection point for SafeConnect on the Easy-Click-Cassette – flex.
4. Connect the patient tubing with SafeConnect to the connection point of the Easy-Click-Cassette – flex.
5. Insert the patient tubing into the air detector and close the lock.
   The tubing segment for the roll pump is automatically threaded into the roll pump.
   – Confirm that the tubing segment for the roller-pump was correctly fit into the roller-pump.
6. Insert the end of the patient tubing (patient side) into the patient tubing holder so that the Luer lock connector is in place over the drip cup without contacting the drip cup.
   – Do **not** remove the protective cap from the Luer lock connector.

9.2.3 Connect the Spikes to Easy-Click-Cassette – flex

✓ Easy-Click-Cassette – flex inserted

At the injector

1. Confirm that the packaging for Spikes do not appear damaged, the packaging seal is not broken, and the disposables are not expired.
2. Remove the protective cap of the swabable valve for NaCl and the desired swabable valves for CM on the Easy-Click-Cassette – flex.
3. Under aseptic conditions, disinfect the swabable valves on the Easy-Click-Cassette – flex.

a) At the left connection point (NaCl):
   – Under aseptic conditions, open the Spike for CT (CM / NaCl), MRI (NaCl) and remove the protective cap from the Luer lock connector of the Spike.
   – Remove the media holder for NaCl.
   – Under aseptic conditions, connect the Spike for CT (CM / NaCl), MRI (NaCl) to the Luer lock connector on the swabable valve of the Easy-Click-Cassette – flex.
   – Replace the media holder and mount the spike for CT (CM / NaCl), MRI (NaCl) into the park position of the left media holder (NaCl).

b) At the right connection point (CM):
   – Under aseptic conditions, open the Spike for MRI (CM) with holder l or holder s.
   – Remove the protective cap of the Luer lock connector of the spike for MRI (CM) with holder l or holder s.
   – Remove the media holder for CM.
   – Under aseptic conditions, connect the Spike for MRI (CM) to the Luer lock connector on the swabable valve of the Easy-Click-Cassette – flex.

- Replace the media holder.
- On the media holder, press and hold the lock (media container), and insert the Spike for CM into the small opening in the (CM) media holder.
- In doing so, ensure that the media supply tubing hangs straight down.
- Release the lock again.

c) **Max 3** only: As needed, repeat the process for the spike for MRI (CM) with holder l or holder s at the central connection point (CM).

9.2.4 Attach media containers

✓ Patient tubing connected to the Easy-Click-Cassette – flex

At the injector: attaching the media container for NaCl

✓ Spike inserted in park position of the media holder (NaCl)
✓ Spike connected to swabable valve of Easy-Click-Cassette – flex

1. Remove the sterile cap from the media container.
2. Place the media container on a suitable support.
   - In doing so, keep sterility in mind. Do not touch the septum of the media container.
   - Swab the face of the septum of the NaCl media container with 70% isopropanol alcohol.
3. Remove the spike from the park position.
4. Remove the protective cap from the spike.
   - In doing so, keep sterility in mind. Do not touch the spike tip.
5. Insert the spike centrically into the septum of the NaCl media container.
6. Turn the media container (NaCl) upside down.
7. At the (NaCl) connection point:
   - On the media holder, press and hold the lock (media container), and insert the (NaCl) media container with inserted spike and media supply tubing into the large opening in the (NaCl) media holder.
   - In doing so, ensure that the media supply tubing hangs straight down.
   - Release the lock again.

At the injector: attaching the media containers for CM

✓ Spike with holder inserted into the small opening in the media holder
✓ Spike with holder connected to swabable valve of Easy-Click-Cassette – flex

1. Remove the sterile cap from the media container.

If using an IBP media container, label the container with the date and time of the container's expiration.

- Obtain a saline tag from the XD 10754 / XD 10755 packaging.
- Label the saline tag with the date and time of the IBP media container's entry and identify the expiration date and time as 24 hours after the initial entry.
- Affix the saline tag onto the saline media container.

2. Place the media container on a suitable support.
   - In doing so, keep sterility in mind. Do not touch the septum of the media container.
   - Swab the face of the septum of the CM media container with 70% isopropanol alcohol.
3. Remove the protective cap from the spike with holder.

– In doing so, keep sterility in mind. Do not touch the tip of the spike with holder.
– Retain the protective cap by placing the cap on the tray of the injector.
– .

4. Place the media container centrically on the spike for CM with holder l or s.
5. **Max 3** only: If necessary, repeat steps (1) to (4) for the central connection point (CM).

At the control unit

This step at the control unit is **not** required if the injector has been set up starting from a completely stripped-down state.

▶ Press the **Main menu** button.
The main menu appears.

9.2.5 Configure the media

✓ Media container installed

At the control unit

This step at the control unit is **not** required if the injector has been set up starting from a completely stripped-down state.

▶ Press the **Media** status / action button.
The **Media** menu appears.

At the control unit

1. For each connection point, select the configuration of the media in the **Media Selection** and **Media List** views, and confirm each by pressing **OK**, → section 7.2.5.
   – Depending on the intended use: If wanted, use the configuration from the last used media container.
   – Typical sizes, etc. can be retained.
   The **Media** menu appears.
2. Confirm the configuration of the media by pressing **OK**.
   The safety message **"Remove tubing from patient!"** appears.
3. Ensure that the patient is **not** connected to the patient tubing. If the patient has been connected to the patient tubing:
   – Disconnect the patient tubing from the patient. Discard patient tubing.
   – Connect a new patient tubing, → section 9.2.2.

9.2.6 Fill the tubing system

DANGER! Risk of air injection due to an inadequately vented tubing system!

▶ After filling/rinsing the tubing system, visually inspect it for the absence of air bubbles.

✓ Media configured
✓ Patient tubing connected to the Easy-Click-Cassette – flex
✓ Patient **not** connected to the patient tubing

At the control unit

Step 1 at the control unit is **not** required if the injector has been set up starting from a completely stripped-down state.

1. Press the status / action button **Filling/rinsing / Vent** and confirm the message for filling the tubing system with **OK**.
2. The **Filling/rinsing / Vent** view appears. Ensure the patient tubing is connected to the Easy-Click-Cassette – flex, → section 9.2.2
   – Confirm that the drip cup is empty and the end of the patient tubing is in the patient tubing holder above the drip cup, but not contacting the drip cup.
3. Press the **Filling/rinsing** button.

➥ When the filling operation is finished, the safety message **"Check if system is free of air, vent if necessary!"** appears.

If air bubbles are detectable in the tubing system:

1. Press the **Vent** button.
   The safety message **"Remove tubing from patient!"** appears.
2. Ensure that the patient is **not** connected to the patient tubing. If the patient has been connected to the patient tubing:
   – Disconnect the patient tubing from the patient. Discard patient tubing.
   – Connect a new patient tubing, → section 9.2.2.

Next step: Vent the tubing system, → section 9.2.7.

If **no** air bubbles are detectable in the tubing system:

▶ Confirm the absence of air by pressing **OK**.

The Perform volume adjustment message appears for each new Easy-Click-Cassette – flex.

▶ Perform a volume adjustment (→ section 7.2.4)
The **Main menu** appears.

The volume adjustment can be performed individually on the same Easy-Click-Cassette – flex, if necessary (→ section 7.2.4).

Next step: Performing an injection, → section 9.3.

9.2.7 Vent the tubing system

DANGER! Risk of air injection due to an inadequately vented tubing system!

▶ After venting the tubing system, visually inspect it for the absence of air bubbles.

✓ Tubing system filled
✓ Patient not connected to the patient tubing

At the control unit

You perform the venting of the tubing system in 2 steps, → section 7.2.6.

1. Press the status / action button **Filling/rinsing / Vent**.

➥ The safety message **"Remove tubing from patient!"** appears.

2. Ensure that the patient is **not** connected to the patient tubing. If the patient has been connected to the patient tubing:
   – Disconnect the patient tubing from the patient. Discard patient tubing.
3. Connect a new patient tubing, → section 9.2.2.Press the **Vent** button.

➥ The **Vent** menu appears.

1st step: Venting media supply tubing

1. One by one, vent the media supply tubing with detectable air bubbles for each connection point.
   – Press the **Vent** button on the relevant connection point and hold it down.
   – Release the **Vent** button when all air bubbles have been conveyed out of the media supply tubing into the media channel of the Easy-Click-Cassette – flex.
2. Repeat the venting process for every connection point until there are no longer any detectable air bubbles in the media supply tubing.

➥ The **Vent (NaCl flush)** button blinks **yellow**.

2nd step: Venting and rinsing (NaCl flush)

✓ The **Vent (NaCl flush)** button blinks **yellow** when first step has been performed.

1. Press the **Vent (NaCl flush)** button.
   The **Vent** view appears. The Easy-Click-Cassette – flex is rinsed with an NaCl flush from the media channel to the exit point at the patient tubing.
   When the venting and rinsing operation is finished, the safety message **"Check if system is free of air, vent if necessary!"** appears.

If air bubbles are still detectable in the tubing system:

▶ Press the **Vent** button.
The safety message **"Remove tubing from patient!"** appears.

Next step: Vent the tubing system again, → section 9.2.7.

If there are **no** detectable air bubbles in the tubing system:

▶ Confirm the absence of air by pressing **OK**.
The **Main menu** appears.

Next step: Performing an injection, → section 9.3.

9.3 Performing an injection for the first patient of the day

9.3.1 Connect the patient

✓ Tubing system filled
✓ Tubing system vented
✓ Tubing system free of air

At the injector

▶ Remove the Luer lock connector on the patient-side end of the patient tubing from the holder over the drip cup.
   – Using aseptic technique, remove the protective cap from the Luer lock connector.
   – Using aseptic technique, connect the Luer lock connector of the patient tubing to the patient’s cannula.

At the control unit

You can optionally perform this step if the patient’s condition suggests its necessity.

1. In the main menu, press the **Vein check** application button.
   The **Vein check** menu appears.
2. In the **Flow** field, set the planned flow with the arrow keys.

3. Press the **Start** button and hold it down.
   NaCl is fed according the set flow. The vein check is performed as long as the button is pressed.
4. Release the **Start** button.
   The vein check is stopped.
5. Stopping the vein check: Press the **Main menu** button.

➥ The vein check is finished and the main menu appears.

9.3.2 Perform an injection

✓ Injector and patient connected
✓ Vein check performed if applicable

You can start the injection either **on the touch terminal** or **on the control unit** of the injector.

On the control unit, you can select an injection program in the **Favorites** menu if it has correspondingly been marked as a favorite on the touch terminal, → section 8.2.8.

If necessary, a running injection can be interrupted (paused) or in case of emergency canceled (stopped), → section 8.2.8.

Performing an injection with a new injection program:

1. Refer to section 8.3 to create and save a new injection program.

Performing an injection with an existing injection program:

On the touch terminal

1. In the main menu, in the **Program selection (Filter)** area, filter the programs using the filtering functions (e.g., **Favorites**).
2. Press the desired injection program in the programs list.

➥ The **Injection** menu appears.

3. Confirm the values of the bolus match the desired values.
   – If the values of the bolus do not match the desired values, edit the injection program, → section 8.3.2.
4. Press the **Injection** button (syringe symbol).
   The injection is prepared.
5. Press the **Start** button.

➥ The injection is started. A chart representing the injection sequence appears.

   – If an air alarm appears and the injection is aborted, confirm the message by pressing OK. If continuing the injection with the same patient, press the **Same patient** button and follow the safety messages on the Touch-Interface.
   – Vent the tubing system, → section 9.2.7
   – Resume with step 1 of performing an existing injection program.

➥ When the injection ends, the information message **"Injection completed."** appears with details regarding the injection.

Alternative approach: at the control unit

1. In the main menu, press the **Favorites** application button.

➥ The **Favorites** menu appears.

2. Press the desired injection program in the list.

➥ The selected injection program is highlighted in yellow.

3. Confirm by pressing **OK**.

➥ The main menu appears.

4. In the main menu, press the **Injection** application button.

➥ The Injection menu appears.

5. Press the **Start** button.
6. The injection is started. A chart representing the injection sequence appears.

➥ When the injection ends, the information message **"Injection completed."** appears with details regarding the injection.

9.3.3 Ending the Injection

Normally an injection runs automatically to the intended end according to the selected injection program.

✓ Injection performed
✓ Information message has appeared: **"Injection completed."**

At the end of operations:

In case of a new patient

When a new patient is treated:

▶ At the control unit / at the touch terminal: Press the **New patient** button.
– In the **"Change patient tubing"** workflow message, press the **OK** button.
The main menu appears.
▶ Strip down the injector, → section 9.6.
▶ Prepare the injection for the new patient, → section 9.4.

In case of the same patient

When the injection is repeated or a futher injection on the same patient needs to be performed:

▶ At the control unit / at the touch terminal: Press the **Same patient** button.
▶ Prepare the injection for the same patient, → section 9.5.

9.4 New patient: preparing an injection

If the service life for the Easy-Click-Cassette – flex has expired, the media containers and the tubing system must be stripped down, and the injector must be set up again, → section 9.1.

✓ Injection finished
✓ Remaining service life of the Easy-Click-Cassette – flex is adequate
✓ Filling level of the media containers is adequate

You can prepare an injection for a new patient according to the following workflows:

Filling level		Media replacement	Next workflow
OK	**Too low**	**New, compatible CM or new NaCl**	
x			▶ Workflow 1
	x	**x**	▶ Workflow 2
x		**Switch toanother, compatible CM (Max 3 only)**	▶ Workflow 3

Table 41. Workflow overview

Workflow 1:

If the injection for the new patient uses the same contrast media and the media filling level is sufficient, → section 9.4.1.

Workflow 2:

The **filling level of one (or more) media containers** is **too low**

– or –

An injection with **another, compatible contrast medium** is being performed on a new patient.

In this case the media containers and the patient tubing must be replaced and the tubing system must be rinsed, → section 9.4.2.

Workflow 3 (Max 3 only):

An injection with **another, compatible contrast medium, already installed on the injector,** is being performed on a new patient using CM Select on the Max 3. In this case the patient tubing must be replaced and the tubing system must undergo Advanced Rinsing, section 5.1.3. Case A

9.4.1 Connecting a New Patient (Workflow 1)

At the control unit / at the touch terminal

1. In the informational message **"Injection completed."** at the control unit or at the touch terminal, press the **New patient** button.
   ↪ The workflow message **"Change patient tubing"** appears on the touch terminal and on the control unit.

At the injector

2. Disconnect the patient tubing from the patient and discard it.
   – Do **not** hang the patient-side end of the patient tubing into the drip cup.
   – If applicable, set the patient-side end of the patient tubing aside in a suitable container (e.g., a trash can) until it is discarded.
3. At the control unit: Acknowledge the **"Change patient tubing"** workflow message by pressing **OK**.
4. Perform the further steps from **Workflow 1**.

Workflow 1	see
1. Connect new patient tubing to the Easy-Click-Cassette – flex	section 9.2.2
2. Fill the tubing system	section 9.2.6
3. Vent the tubing system	section 9.2.7
4. Perform an injection	section 9.3.2

Table 42. Workflow 1

9.4.2 Replacing the media containers (Workflow 2)

When replacing the media containers – unlike the usual workflow during setup – you can first connect the new patient tubing to the Easy-Click-cassette – flex and then perform the two workflow steps "Remove media containers" and "Attach media containers" together.

At the control unit / at the touch terminal

1. In the informational message **"Injection completed."** at the control unit or at the touch terminal, press the **New patient** button.
   ➥ The workflow message **"Change patient tubing"** appears on the touch terminal and on the control unit.

At the injector

2. Disconnect the patient tubing from the patient and discard it.
   – Do **not** hang the patient-side end of the patient tubing into the drip cup.
   – If applicable, set the patient-side end of the patient tubing aside in a suitable container (e.g., a trash can) until it is discarded.
3. At the control unit: Acknowledge the **"Change patient tubing"** workflow message by pressing **OK**.
4. Perform the further steps from **Workflow 2** identified below, following section 5.1.3, Case B if another compatible CM is used

Workflow 2	see
1. Connect new patient tubing to the Easy-Click-Cassette – flex	section 9.2.2
2. Remove media containers and spikes	section 9.6.1
3. Connect NaCl rinsing container and spike, if changing contrast media container to a different compatible CM type. If changing NaCl container or CM container of the same type, continue with step 6 of this workflow.	section 5.1.3, Case B
4. Rinse the tubing system	section 7.2.6
5. Remove the NaCl rinsing container and spike	section 5.1.3, Case B
6. Attach new media containers and spikes	section 9.2.4

Workflow 2	see
7. Configure the media	section 9.2.5
8. Fill the tubing system	section 9.2.6
9. Vent the tubing system	section 9.2.7
10. Perform an injection	section 9.3.2

Table 43. Workflow 2

9.4.3 Switching to different CM type on Max 3 (2 different CM types installed on CM connection point 1 and connection point 2) (Workflow 3)

At the control unit / at the touch terminal

1. In the informational message **"Injection completed."** at the control unit or at the touch terminal, press the **New patient** button.
   ➥ The workflow message **"Change patient tubing"** appears on the touch terminal and on the control unit.

At the injector

2. Disconnect the patient tubing from the patient and discard it.
   – Do **not** hang the patient-side end of the patient tubing into the drip cup.
   – If applicable, set the patient-side end of the patient tubing aside in a suitable container (e.g., a trash can) until it is discarded.
3. At the control unit: Acknowledge the **"Change patient tubing"** workflow message by pressing **OK**.
4. Perform the further steps from **Workflow 3** identified below, following section 5.1.3, Case A.

Workflow 3	see
1. Connect new patient tubing to the Easy-Click-Cassette – flex	section 9.2.2
2. Fill the tubing system	section 9.2.6
3. Vent the tubing system	section 9.2.7
4. Perform advanced rinsing	section 5.1.3, Case A
5. Perform an injection	section 9.3

9.5 Same patient: preparing an injection

If the service life of the Easy-Click-Cassette – flex has expired, the media containers and the tubing system must be stripped down and set up again, → section 9.6.

✓ Injection finished
✓ Patient connected to the patient tubing

In the following case, the same patient is treated like a **New patient**:

The **filling level of one (or more) media containers** is **too low** for the same injection on the same patient. In this case the media containers with spikes and the patient tubing must be replaced.

Filling level		Media replacement	Next workflow
OK	Too low	New, compatible CM or new NaCl	
x			1. Prepare the injection, → section 9.5.1 2. Perform the injection, → section 9.3
	x	x	▶ Perform workflow 2, → section 9.4.2

Table 44. Workflow overview

9.5.1 Preparing an injection

✓ Remaining service life of the Easy-Click-Cassette – flex is adequate
✓ Remaining service life for the patient tubing is adequate
✓ Filling level of the media containers is adequate

1. In the informational message **"Injection completed."** at the control unit or at the touch terminal, press the **Same patient** button.
2. Performing an injection, → section 9.3.2.

9.6 Stripping down the injector

At the end of the work day, or when the service life for the Easy-Click-Cassette – flex has expired, the injector must be stripped down. This includes removing the media containers and the tubing system.

✓ Injection finished

At the control unit

1. In the main menu, press the **Easy-Click-Cassette** status / action button.
   ➥ The **Easy-Click-Cassette** menu appears.
2. Press the **Strip down** button.
   ➥ The safety message **"Remove tubing from patient!"** appears.
3. Using aseptic technique, disconnect the patient from the patient tubing.
   – If applicable, place the patient-side end in a suitable container (e.g. a trash can) until it is discarded.
4. In the safety message, click the **Remove tubing system** button.
   The tubing segment for the roll pump is automatically fed out of the roll pump.
   The **Strip down** workflow message appears with the steps to be performed when stripping down the injector.

9.6.1 Remove Spikes and media containers

✓ **Strip down** menu visible on the control unit

At the injector: removing media containers (CM)

1. Close clips on the media supply tubing where a media container is connected.

2. Disconnect spike from Easy-Click-Cassette – flex via luer lock connector.
3. Press the unlock button on the media holder and remove the media container (CM) with spike with holder and the media supply tubing from the media holder.
4. Remove media container from the spike, put the protective cap on the spike and discard the media container and spike.
5. **Max 3** only:
   – Repeat steps (1) to (4) for the 2nd media container (CM).

At the injector: removing the (NaCl) media container

1. Close the clip on the media supply tubing.
2. Disconnect spike from Easy-Click-Cassette – flex via luer lock connector.
3. Press the unlock button on the media holder and remove the (NaCl) media container including spike and media supply tubing from the media holder.
4. Remove media container from the spike, put the protective cap on the spike, and discard the media container and spike

9.6.2 Remove tubing system

✓ All media containers and spikes removed

At the injector

1. Open the roll pump cover.
2. Remove the patient tubing and Easy-Click-Cassette – flex.
   – In addition, open the lock on the air sensor on the patient tubing unit and remove the patient tubing.
3. Discard the Easy-Click-Cassette – flex and patient tubing.
4. Close the roll pump cover.

9.7 Shutting down the injector system at the end of each day

9.7.1 Switch off the injector system

✓ Injector stripped down

If the connection between the injector and touch terminal is interrupted (→ section 6.6), the following steps must be performed separately on the control unit and touch terminal.

1. On the control unit **or** on the touch terminal: Briefly press the **On / Off** button.
➥ The message **"Shut down injector system. Are you sure?"** appears.
2. Confirm the message by pressing **OK**.
➥ The injector and the touch terminal will be shut down and switched off.

9.7.2 Park the injector

✓ Injector stripped down
✓ Injector system switched off

At the injector

1. Release the brakes at the injector base.
2. Move the injector out of the examination room to a suitable parking position.
3. Apply the brakes at the injector base.

– Check that the injector is in a secured condition.

9.7.3 Removing media holders (optional)

✓ Injector stripped down
✓ Injector parked
✓ Injector system switched off

At the injector

1. When a media rod is connected: Remove the media rod including the media holder.
   – For this purpose, press the lock for the media container and remove the media rod upwards.
2. Press the unlock button of the media holder, hold onto the counter holder and pull the media holder out of the connection point.

9.7.4 Cleaning

▸ Clean the injector, → section 13

9.7.5 In case of low battery charge

▶ Charge the injector’s rechargeable battery, → section 6.5.4.

10 Settings menu

10.1 System Settings

You can use the **System Settings** menu to set the language, the keyboard layout, the units for pressure, length, and volume, as well as to enable / disable software options

✓ Injector and touch terminal connected, → section 11.1.

Setting the language

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu is displayed.
2. Press the **System Settings** button.
   A dialog for setting the language, keyboard layout, and units, as well as for enabling / disabling software options appears.
3. Press the **Language** button.
4. Use the arrow symbols to scroll through the list and select the language.
   The selected language is displayed in the **Language** button.
5. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Setting the keyboard layout

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **System Settings** button.
   A dialog for setting the language, keyboard layout, and units, as well as for enabling / disabling software options appears.
3. Press the **Keyboard layout** button.
4. Use the arrow symbols to scroll through the list and select the keyboard layout.
   The selected keyboard layout appears in the **Keyboard layout** button.
5. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Setting of units

The following units can be selected.

- Pressure: bar or psi
- Length: m or inch
- Volume: mL or cc

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.

2. Press the **System Settings** button.
   A dialog for setting the language, keyboard layout, and units, as well as for enabling / disabling software options appears.
3. Select the unit for each dimension.
4. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Enabling / disabling software options

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **System Settings** button.
   A dialog for setting the language, keyboard layout, and units, as well as for enabling / disabling software options appears.
3. Enable or disable the relevant software options.
4. Confirm by pressing **OK**. Confirm the restart message.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

10.2 Injector Settings

The following settings can be made in the **Injector Settings** menu:

- Enable / disable LED indicators
- Set the default pressure limit
- Set the threshold for NaCl backup
- Enable / disable the volume adjustment for Easy-Click-Cassette – flex
- Set patient tubing length (if patient tubings without RFID recognition are used)

Enabling / disabling LED indicators

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Injector Settings** button.
   A dialog for enabling / disabling LED function, volume adjustment, for entering the default pressure limit, threshold for the NaCl backup and patient tubing length (when patient tubings without RFID are used (XD 10751 / XD 10752)) appears.
   .
3. Enabling / disabling the LED function.
4. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Setting the default pressure limit

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Injector Settings** button.
   A dialog for enabling / disabling LED function, volume adjustment, for entering the default pressure limit, threshold for the NaCl backup and patient tubing length (when patient tubings without RFID are used (XD 10751 / XD 10752)) appears.
3. Enter the value for the default pressure limit.
   – The default pressure limit can be set between 2 bar (29 psi) and 14 bar (203.1 psi) in increments of 0.1 bar (0.1 psi).
4. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

When the pressure limit is exceeded during an injection, the flow is automatically reduced until the maximum pressure limit is reached.

A warning beep sounds and the button for setting a patient-specific pressure limit is highlighted yellow, → section 8.2.6.

Setting the threshold for NaCl backup

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Injector Settings** button.
   A dialog for enabling / disabling LED function, volume adjustment, for entering the default pressure limit, threshold for the NaCl backup and patient tubing length (when patient tubings without RFID are used (XD 10751 / XD 10752)) appears.
3. Setting a specific NaCl backup threshold. The threshold can be set between 30–100%.
   – **Threshold 30%:** When the CM volume in the media containers is insufficient, up to 70% of the CM volume specified in an injection program will be substituted with NaCl.
   – **Threshold 100%:** No CM substitution is performed. If the CM volume in the media container is insufficient for the next injection program, the injection cannot be started.
4. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Enabling / disabling volume adjustment

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Injector Settings** button.

A dialog for enabling / disabling LED function, volume adjustment, for entering the default pressure limit, threshold for the NaCl backup and patient tubing length (when patient tubings without RFID are used (XD 10751 / XD 10752)) appears.

3. Enabling / disabling the **Volume adjustment**.
4. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Set patient tubing length

This setting is only available if patient tubings without RFID recognition are used. Wether RFID recognition for patient tubings is used is set by the service technician during intital system installation based on the used patient tubings.

XD 10701 / XD 10702 – patient tubings with RFID recognition

XD 10751 / XD 10752 – patient tubings without RFID recognition

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **System Settings** button.
   A dialog for enabling / disabling LED function, volume adjustment, for entering the default pressure limit, threshold for the NaCl backup and patient tubing length (when patient tubings without RFID are used (XD 10751 / XD 10752)) appears.
3. If patient tubings XD 10751 (250 cm) or patient tubings XD 10752 (320 cm) are used. choose the correct type with the drop down menu.
4. Confirm it by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request

10.3 Terminal Settings

The Terminal Settings menu can be used to perform the following settings and system tests:

- Functional test of the speaker
- Sound volume for information and warning sounds
- Display brightness of the touch terminal

Functional test of the loudspeaker

▶ Press the  button below **Error**.

Setting the volume for information and warning sounds

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.

2. Press the **Terminal Settings** button.
   The dialog for the functional test of the loudspeaker, for setting the volume of the information and warning sounds, and for setting the screen brightness appears.
3. Set the desired volume with the slider.
   The position of the slider and the displayed level value provide information on the selected volume.
4. Test the set volume by pressing the  button.
5. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

Setting screen brightness

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu is displayed.
   A dialog panel for setting and testing the terminal settings appears.
2. Set the desired screen brightness with the slider.
3. Confirm by pressing **OK**.
   – or –
   Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

The volume and brightness can be set at the same time, with no need to restart the system between these settings.

10.4 Media

The **Media** menu allows the selection of the contrast media type, and the corresponding media volumes from the media database. The selected options are presented for selection on the injector's control unit.

Symbol	Meaning
	Contrast media bottle in conjunction with a CM spike for Easy-Click-Cassette – flex

Table 45. Selection of contrast media type, media container type, and media volume

Selecting / deselecting media for display on the injector's control unit

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Media** button.
   The **Media** menu for selecting the contrast media type, and the media volume appears.
3. Select / deselect the contrast media types, the media container types and the corresponding media volumes that should appear on the injector's control unit.

Confirm by pressing **OK**. Confirm the system restart message

– or –

Discard the settings that were made by pressing **Cancel** and confirming this in the confirmation request.

For faster configuration, the **Select all** and **Deselect all** buttons can be used to select or deselect all contrast media types, all media container types, and all media volumes.

Media cannot be deselected when the injector is already set up with contrast media. To do this, the injector must first be stripped down.

10.5 Info

The following information can be displayed via the Info menu:

- Software version
- Serial numbers of the injector and touch terminal

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Info** button.

➥ The information is displayed in the dialog panel.

10.6 Help

The **Help** menu can be used to retrieve the following information:

- Display the application video for setup, operation, and strip down of the injector system
- Service contact: Contact information of your responsible service partner
- Credits: Contact information of the manufacturer
- Display error log
- Export log file

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Help** button.

➥ The information is displayed in the dialog panel, or can be retrieved there.

Viewing help videos

The following videos are available:

- Initial operation
- Setup
- Start injection
- Replacing patient tubing
- Replacing media
- Vent
- Strip down

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.

The **System Settings** menu is displayed.

2. Press the **Help** button.
3. Press the button for the intended video.
   The video starts.
4. To pause the video, press the **Pause** button.
5. The slider can be used to jump forward or backward in the video.
6. As needed, adjust the speaker volume with + or -.
7. Press the stop button to stop.

➥ The video view closes automatically at the end of the video.

Viewing system errors

1. On the touch terminal, in the **Program selection** menu or the **Injection** main menu, press the **Settings** button.
   The **System Settings** menu appears.
2. Press the **Help** button.
3. Scroll to the **Error log** area and press the **Display** button.
   System errors that occurred are displayed.

Exporting a log file

Log files can be exported to a USB storage device.

1. Connect the USB storage device to an unused USB port.
2. Specify the time period for the export (1 to 30 days).
3. Press the **Export** button.
   Log files are exported to the USB storage device.
4. Remove the USB storage medium from the USB port.

In the Help dialog panel, use the vertical scrollbar to retrieve the relevant information.

10.7 Service

The **Service** menu is only available to authorized service technicians.

11 Assembly, installation, initial configuration

11.1 Assembling / installing the injector

Assembly and installation of the injector system must be exclusively performed by ulrich medical Service or an authorized ulrich medical distributor.

Connection of injector and touch terminal

The wireless LAN connection between touch terminal and injector will be configured as part of the assembly and installation of the injector system and must be exclusively performed by ulrich medical Service or an authorized ulrich medical distributor.

11.2 Configuring initial settings of the injector system

The initial operation is part of the assembly and installation process of the injector system and must be exclusively performed by ulrich medical Service or an authorized distributor.

Initial system settings

- RFID for patient tubings on / off
- Automatic deduction of CM rinsing volume for the remaining volume indication after priming a new CM bottle (CM rinsing volume 1,5 ml per bottle)

12 Decommissioning

If the injector system is not required for a prolonged period and has to be stored in a suitable way, it can be decommissioned.

- ✓ Injector stripped down
- ✓ Disposables disposed of
- ✓ Injector system switched off

1. Disconnect the terminal from the power supply.
2. Clean the injector system and all components (→ section 13).
   – As needed, reinsert the media holders.
3. After the injector has been cleaned move it to a suitable parking position.
4. Apply the brakes at the injector base.
5. Store the touch terminal in a suitable place.
6. If necessary, protect all components of the injector system against dirt, dust, moisture and other harmful environmental influences in a suitable manner.

13 Cleaning

Risk of injuries and infections of the operator and the patient if cleaning of the injector system is not or not properly performed.

- ▶ Observe the instructions for cleaning.

13.1 Cleaning intervals

DANGER! Risk of death by electric shock and short circuit when cleaning under voltage!

- ▶ Before all cleaning tasks, disconnect the system from the power supply.
- ▶ Pull out the mains plug before pulling the power cord out of the device.

DANGER! Risk of death by electric shock and short circuit when using an excessive amount of water or cleaning agent!

- ▶ When cleaning the surfaces, do not expose them to an excessive amount of water or cleaning agent.

DANGER! Risk of death by electric shock if connectors for cables and wires or devices are wet!

- ▶ Ensure that no liquid gets into the connectors or into the housing.
- ▶ Wipe off the cables and plugs and let them dry completely before operation.

NOTE! Risk of damage to the unit due to short circuit if connectors for cables and wires or devices are wet!

- ▶ Ensure that no liquid gets into the connectors or into the housing.
- ▶ Wipe off the cables and plugs and let them dry completely before operation.

Cleaning interval	Parts	Course of action
In case of contamination with contrast media	Sensors and surfaces	▶ Clean sensors and surfaces with a soft cloth and warm water or with a mild soap solution.
Every day	Sensors, surfaces, and movable parts	**Sensors and surfaces** ▶ Clean with a soft cloth and warm water or with a mild soap solution. **Movable parts** ▶ Remove movable parts (media holders) from the injector. ▶ Clean with a soft cloth and warm water or with a mild soap solution. ▶ Completely dry the parts. **Roll pump** ▶ Clean delivery and guide rollers with a mild soap solution.. ▶ Clean the roll pump counter bearing with 70% isopropyl alcohol.

Cleaning interval	Parts	Course of action
In accordance with legal provisions and / or internal hygiene rules	Injector surfaces, touch terminal and movable parts	**Surfaces** ▶ In accordance with legal provisions and / or internal hygiene rules, disinfect using wipe disinfection. **Movable parts** ▶ Remove movable parts (media holders) from the injector. ▶ In accordance with legal provisions and / or internal hygiene rules, disinfect using wipe disinfection. ▶ Completely dry the parts.

Table 46. Cleaning intervals

13.1.1 Cleaning agents and disinfectants

Regardless of the brand, cleaning agents and disinfectants with the following ingredients may be used to clean / disinfect the injector system (incl. plexiglass parts: i.e. roll pump cover).

Type / active ingredient	Strength / concentration	Use	Cleaning agent used for testing
Water-based with alkaline additives (soap solution)	Maximum temperature of solution: 50°C	Only wipe	N/A
Alcohol-based (propan-2-ol with or without ethanol)	Any type up to max. 70% and 94% w/w	Only wipe	Isopropyl alcohol (= propan-2-ol) mikrozid® universal wipes (Schülke & Mayr GmbH)
Based on ammonium chloride (alkyl(C12-16)dimethyl-benzyl-ammonium chloride, didecyl-dimethyl-ammonium chloride and alkyl(C12-14)ethyl benzyl-ammonium chloride)	For surfaces as described by the disinfectant manufacturer	Only wipe	mikrozid® sensitive liquid (Schülke & Mayr GmbH)
Based on active oxygen (pentapotassium-bis (peroxymonosulphate-) bis(sulphate))			Perform (Schülke & Mayr – marketed by Boxal as MIKROZID PAA)

Type / active ingredient	Strength / concentration	Use	Cleaning agent used for testing
Benzalkonium chloride (2-phenoxyethanol, N,Nbis-(3-aminopropyl) dodecylamin and benzalkonium chloride)			Incidin™ Pro (Ecolab Deutschland GmbH)
Glucoprotamin® and benzalkonium chloride			ECOLAB Incidin Extra N (Ecolab Deutschland GmbH)

Table 47. Cleaning agents approved for use

- For the type of use and exposure time, see the instructions for use of the individual cleaning agent.
- In case of contamination with blood or other infectious materials, observe and comply with the legal and / or internal hygiene provisions.
- When using cleaning agents and disinfectants, observe the manufacturer's instructions (instructions for use, warnings and safety notes, etc.).

Touch terminal

- Wipe down the terminal with a soft, damp cloth. Ensure that no moisture gets inside the touch terminal.
- Only wipe the display down with a soft, damp cloth or with a specialized screen cleaning agent.
- Wipe disinfection as needed with mikrozid® universal wipes (Schülke & Mayr GmbH).

14 Technical safety check and repairs

WARNING! Injury to the operator and patient as a result of not or incorrectly performing the technical safety check and repairs on the injector system!

- Observe the instructions for the technical safety check.

The injector must be regularly tested according to the manufacturer's instructions by technical safety checks to be performed by the manufacturer or an after-sales service authorized by ulrich medical.

The inspection interval is 12 months.

After each repair a functional and technical safety check and if necessary additional accuracy checks need to be performed.
If local or internal regulations demand more frequent checks, such regulations need to be followed.

Maintenance and repair tasks must only be performed outside of the MRI room and only by ulrich medical or specialists authorized by ulrich medical. This also applies to battery replacement in the pedestal version injector.

Damage to devices and instruments or injuries to persons due to improper or insufficient cleaning or maintenance are not covered by the warranty.

15 Reporting incidents

All complaints in connection with the safety, efficacy or performance of the product must be reported by the user to ulrich medical (complaint@ulrichmedical.com) or the local distributor within 72 hours.

If one or more components of the system should have a malfunction (i.e. one or more of the performance specifications are not met the intended performance is not achieved for other reasons) or if it is suspected that this may be the case, then ulrich medical (complaint@ulrichmedical.com) or the local distributor should be notified immediately (within 24 hours).

If one or several components of the system have ever failed and possibly led or contributed to the death or severe injury of a patient, then ulrich medical or the local distributor should be notified by telephone immediately.

Please use the Medical Device Vigilance Report Form from ulrich medical to report product complaints, malfunctions or product failure. It is available at: www.ulrichmedical.com/vigilancereport.

16 System components, accessories and spare parts

16.1 Ordering address

Customers can order all listed accessories from the following sources:

- within Germany: directly from ulrich medical
- outside Germany: from your authorized distributor

Germany

ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
Telephone: +49 (0)731 9654-0
E-mail: info@ulrichmedical.com

Authorized Distributor / Customer Service

GE Pharmaceutical Diagnostics
100 Results Way
Marlborough, MA 01752
United States
Phone: 1 800 526 3593
Fax: 1 877 295 8102
Fax: 732 235 2201

16.2 Injector systems, accessories and spare parts

System components

The injector systems Max 3 and Max 2M consist of the following system components:

Catalog number	Name
XD 10150 • XD 10151 • XD 10400	Max 3 injector system • Max 3 injector • Touch terminal
XD 10140 • XD 10141 • XD 10400	Max 2M injector system • Max 2M injector • Touch terminal

Table 48. System components

Accessories

Catalog number	Name
XD 10500	Convenience pack, consisting of: • Trash can • Tray • Media rod with media holder
XD 10740	Drip cup (packaging unit: 5 units)

Catalog number	Name
XD 10741	Adapter ring (packaging unit: 100 units)
SP002887-ET	Pair of holding arms
SP001612-ET	Multiuse MRI bottle holder

Table 49. Accessories and spare parts

16.2.1 Software options

Catalog number	Name
XD 10630	**Same patient** software option
XD 10640	**CM Select** software option (**Max 3** only)
XD 10650	**Vein check** software option

Table 50. Software options

16.2.2 Software packages

Catalog number	Name
XD 10600	**Software package Max 3** comprising: • **Same patient** software option • **CM Select** software option • **Vein check** software option
XD 10610	**Software package Max 2M** comprising: • **Same patient** software option • **Vein check** software option

Table 51. Software packages

16.2.3 Measuring and testing equipment

Catalog number	Name
XD2000E-353-257	Graduated cylinder 100 ml, plastic

Table 52. Measuring equipment

17 Disposables

17.1 Easy-Click-Cassette – flex

Catalog number	Name
XD 10716	Easy-Click-Cassette 3 – flex
XD 10717	Easy-Click-Cassette 2M – flex
XD 10754	Spike for CT (CM / NaCl), MRI (NaCl)
XD 10755	Spike for MRI (CM) with holder l
XD 10756	Spike for MRI (CM) with holder s

Table 53. Easy-Click-Cassette – flex

17.2 Patient tubing

Catalog number	Name
XD 10701	Patient tubing, 250 cm (for ulrich**easy**INJECT CT / MRI Injectors)
XD 10702	Patient tubing, 320 cm (for ulrich**easy**INJECT CT / MRI Injectors)
XD 10751	Patient tubing, 250 cm without RFID (for ulrich**easy**INJECT CT / MRI Injectors)
XD 10752	Patient tubing, 320 cm without RFID (for ulrich**easy**INJECT CT / MRI Injectors)

Table 54. Patient tubing

18 Technical information

18.1 Injector

Feature	Value
MRI compatibility  **MR Conditional** – A product which does not demonstrate any deliberate hazards in the specific MRI environment	Up to 3.0 Tesla
Temperature range	
In operation	+15°C to +40°C
Storage / transport	-20°C to +60°C
Humidity	
In operation (pedestal version)	20% to 90%, non-condensing
Storage / transport (pedestal version)	20% to 90%, non-condensing
Atmospheric pressure	
In operation	700 hPa to 1060 hPa Corresponds to a maximum elevation of 3000 m above sea level
Storage / transport	700 hPa to 1060 hPa
Classifications	
Product classification according to the German Medical Device Law (MPG) 93/42/EEC	IIb
Dimensions	
Dimensions with bottle holder (L x W x H)	530 mm x 530 mm x 1372 mm
Dimensions with media rod (L x W x H)	530 mm x 530 mm x 1730 mm
Weight	Approx. 40 kg
Classifications	
Information regarding protection class according to IEC 60601-1	
Protection class against electric shock	I
Applied part type	BF
Touch protection and protection against foreign matter Protection against ingress of liquids	IP43 degree of protection against: • Solid foreign bodies with Ø 1.0 mm and above • Water spray at an angle of up to 60° on both sides of vertical in a closed state
Information regarding the fire protection class according to UL 60601-1	

Feature	Value
Particulars of the fire protection class (according to UL-60601-1)	Flammability rating V-2
Power consumption	
Electrical connection	100 V AC to 240 V AC (50/60 Hz) (automatic)
Max. power consumption in operation (measured)	200 W
Integrated rechargeable battery	
Type	Lithium-ion
Performance data	25.2 V; 11.6 Ah; 292 Wh
Charging time after deep discharge	Approx. 4 h
Operating time when the battery is fully charged	Min. 18 h
Pressure range / flow range / volume range	
Volume range	• 1–10.0 mL, increment: 0.1 mL • > 10–100 mL, increment: 0.5 mL • > 100–400 mL, increment: 1 mL Maximum CM volume is 200 mL
Flow	0.1–10.0 mL/s Adjustable in increments of 0.1 mL/s
Max. deviation from the flow	Flow 0.1 mL/s at 20 mL: ±5% Flow 10 mL/s at 100 mL: ±5% (20 gauge cannula, NaCl)
Air detector sensitivity	Max. 1 mL / patient
Detection of air bubbles	Air bubbles with a volume ≥ 50 µL are detected and summed up to a volume of 1 mL. After that the system shuts down with an air alarm.
Max. volume deviation	Volume 10–400 mL: ±5%
Max. system pressure	14 bar (203.1 psi)
Default pressure limit	11 bar (159.5 psi)
Adjustable pressure limit	2–14 bar (29–203.1 psi) in 0.1 bar (0.1 psi) increments
Media filter (particle filter) specifications	ISO 8536-4
Noise emission	
Max. noise emission (at a distance of 1 m)	71 dBA
Mechanical strength	
Permissible maximum load on tray	2 kg

Feature	Value
Installation / assembly / transport	
Max. inclination angle during operation	10°
Max. inclination angle during storage / transport	10°
Data transfer	
Between injector and touch terminal	WLAN (802.11b/g/n)
Equipment	
Contrast media (CM)	Max 3: 2 bottles Max 2M: 1 bottle
Saline solution (NaCl)	1 bottle or 1 bag (with optional media rod)
Approved bottle sizes	
Bottle sizes	CM: 10–200 mL (MRI) NaCl: 50–1000 mL
Bag sizes	NaCl: 50–2000 mL with media rod
Guidelines	
Structural safety	IEC 60601-1
EMC	IEC 60601-1-2
Radio interference suppression	EN 55011: Class B
Interference immunity	IEC 61000-3 parts 2 and 3 IEC 61000-4 parts 2–6, 8, and 11

Table 55. Technical information, injector

18.2 Touch terminal

Feature	Value
Temperature range	
In operation	+15°C to +40°C
Storage / transport	-20°C to +60°C
Humidity	
In operation	20% to 90% non-condensing
Storage / transport	20% to 90% non-condensing
Classifications	
Protection against penetration of liquids / accidental contact and foreign matter	IP30
Energy consumption and conditions	
Input to touch terminal	12–24 V DC (via external power supply unit)

Feature	Value
Input to power supply unit	100–240 V AC (50/60 Hz), 1.5 A
Output from power supply unit	12 V DC, 5 A
Ports / screen	
Ports	2 x COM (DSUB 9-pole) 1 x LAN (RJ 45, 10/100/1000 Mbit/s) 1 x HDMI 2 x USB 2.0 1 x USB OTG 1 x DC in
Screen	12" TFT LCD with PCAP multi touch
Guidelines	
Structural safety	EN 60950-1:2006 + A11:2009 + A1:2010 + A2:2013 IEC 60950-1:2005 (second edition) + Am 1:2009 + Am 2:2013
EMC	EN 55022:2010 / AC:2011, Class B EN 55024:2010 EN 61000-6-3:2007 + A1:2011 / AC:2012 EN 61000-6-1:2007 EN 61000-3-2:2014 EN 61000-3-3:2013 FCC Part 15 Class B IC ICES-003

Table 56. Technical information, touch terminal

18.3 Software settings

Adjustment ranges	Value	Description
Volume	• 1–10.0 mL • > 10–100 mL • > 100–400 mL Maximum CM volume is 200 mL	• Increment: 0.1 mL • Increment: 0.5 mL • Increment: 1 mL
Flow	0.1–10 mL/s, depending on the Easy-Click-Cassette – flex, contrast medium type and contrast medium container that are used	Increment: 0.1 mL/s

Adjustment ranges	Value	Description
Configuration of injection program	Per injection program: max. 40 boli	Including pauses / manual pauses
Elapsed time	0 s–30 min	Increment: 1 s Format: mm:ss
Timer	0 s–30 min	Increment: 1 s Format: mm:ss Up / down
Pause	0 s–30 min	Increment: 1 s Format: mm:ss
Vein check	0.1–10 mL/s	Increment: 0.1 mL/s
Maximum programmable injection volume for CM and NaCl	400 mL / patient for NaCl and CM together, with max. 200 mL CM / patient	

Table 57. Software settings

18.4 Disposables

For further information on the disposables, see the relevant Instructions for Use.

18.4.1 Easy-Click-Cassette – flex

Feature	Value
Applied part type	BF
Pressure tightness	Max. 22 bars
Material	PUR, PVC, polycarbonate (DEHP free, latex free)
Operation time	24 h

Table 58. Technical information, Easy-Click-Cassette – flex

18.4.2 Patient tubing

Feature	Value
Applied part type	BF
Pressure tightness	Max. 22 bars
Material	PVC (DEHP free, latex free)
Operation time	12 h for one patient (disposable product)

Table 59. Technical information, patient tubing

19 Combination with other devices

Combination	Standards to be observed
External devices	IEC 55011
	IEC 60601-1

Table 60. Device combinations and standards

20 FCC Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions*:*

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications made to this equipment not expressly approved by ulrich GmbH & Co. KG may void the FCC authorization to operate this equipment.

Note:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- ▶ Reorient or relocate the receiving antenna.
- ▶ Increase the separation between the equipment and receiver.
- ▶ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- ▶ Consult the dealer or an experienced radio/TV technician for help.

21 Electromagnetic compatibility (EMC)

The ulrich**easy**INJECT Max 2M / Max 3 system (called injector system below) is an electromagnetic system that consists of the injector in the MRI examination room and the touch terminal in the control room, which are connected by wireless connection (WLAN, 2.4 GHz).
The EM environment is defined according to EMC standard DIN EN 60601-1-2 05-2016 as:

Hospitals with a radiology department or radiology practices:

- Terminal in the control room
  Environment in professional health care facilities
- Max injector in the examination room
  Special environment – RF shielded room of a ME system for magnetic resonance imaging

The injector system is tested per EMC standard DIN EN 60601-1-2 05-2016. All threshold values for emitted interference according to this standard are met. All test levels for interference immunity defined in this standard are safely tolerated by the injector system, so that there is no functional restriction.

NOTE! Reduced performance and / or functional restriction due to use of non-approved accessory parts and cables!

Risk of increased EM emission, reduced interference immunity of the injector system, or malfunction.

- ▶ Only use accessories and cables that were approved by ulrich medical as spare parts for internal components.

NOTE! Reduced performance and / or functional restriction due to mobile RF communication devices!

- ▶ Keep mobile RF devices at a minimum distance of 30 cm from all device surfaces of the injector system in order to prevent reduced performance or functional restriction.

Table 1 – Electromagnetic interference emission by the injector system

The injector system is intended for operation in an ELECTROMAGNETIC ENVIRONMENT as indicated below. The customer or the user[N3)] of the injector must ensure that it is operated in such an environment.

Emitted interference measurements	**Conformity**	**Description**
Frequency fluctuations according to DIN EN 55011 / CISPR 11	Group 1 Class B	The injector uses RF energy solely for its internal OPERATION. Its RF emission is very low; thus, electronic devices in the vicinity will not be affected by interference.
Emission of harmonics according to: DIN EN 61000-3-2 / IEC 61000-3-2	Class A	The injector is suitable for use in all facilities, including those in living quarters and ones which are directly connected to a PUBLIC UTILITY GRID also supplying buildings that are used for residential purposes.
Emission of voltage fluctuations / flicker according to DIN EN 61000-3-3 / IEC 61000-3-3	Complies	

Table 2 – Electromagnetic INTERFERENCE IMMUNITY of the injector system
The injector system is intended for operation in the ELECTROMAGNETIC ENVIRONMENT indicated below. The customer or the user[N4)] of the injector must ensure that it is operated in such an environment.
INTERFERENCE IMMUNITY tests
Electrostatic discharge (ESD) according to DIN EN 61000-4-2
Radiated, radio-frequency, electromagnetic field immunity test according to DIN EN 61000-4-3
Fast transient electrical disturbance / bursts according to DIN EN 61000-4-4
Voltage surges according to DIN EN 61000-4-5
Immunity to conducted disturbances induced by high-frequency fields according to DIN EN 61000-4-6
Voltage dips, brief interruptions, and fluctuations in the power supply according to DIN EN 61000-4-11
Magnetic field at the supply frequency (50/60 Hz) according to DIN EN 61000-4-8
Frequency fluctuation according to DIN EN 60601-1

N3) N4) Nationally applicable footnote: In this context the term user refers to the "RESPONSIBLE ORGANIZATION".

22 Disposal

The system and system components can be disposed in accordance with local regulations.

- The following material components are to be taken into account:

Components / assemblies	Materials	Disposal
Rechargeable battery	Lithium-ion, plastic	▶ Electronic waste
Attachments	Aluminum, stainless steel, plastic	Metal recycling / plastic recycling
Display	Various	Electronic waste
Disposables	Plastic	▶ Dispose of disposables including packaging in accordance with the locally applicable hospital and practice provisions.
Printed Circuit Boards	Various	Electronic waste
Housing	Aluminum, plastic	Metal recycling / plastic recycling
Cables	Metal, plastic	Metal recycling / plastic recycling
Motor	Metal, plastic	Electronic waste
Power supply units	Various	Electronic waste
Switches	Various	Electronic waste
Sensors	Various	Electronic waste
Tray	Plastic	Plastic recycling
Terminal	Various	Electronic waste
Packaging	Cardboard, paper, plastic	▶ After sorting materials, separate and dispose of them in accordance with the locally applicable hospital and practice provisions.

Table 61. Disposal

23 Service

- When reporting malfunctions, provide the serial numbers of the injector and touch terminal (→ in each case, type labels are on the back side of the device), as well as the error code if applicable.

Customer service

Salus Medical Products
8123 Castleton Road
Indianapolis IN 46250
Tel: 844-467-2587 (844-GO-SALUS)

Authorized distributor / Customer services

ulrich GmbH & Co. KG | Buchbrunnenweg 12 | 89081 Ulm | Germany
Phone: +49 (0)731 9654-0 | Fax: +49 (0)731 9654-2809
injectors@ulrichmedical.com | www.ulrichmedical.com

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