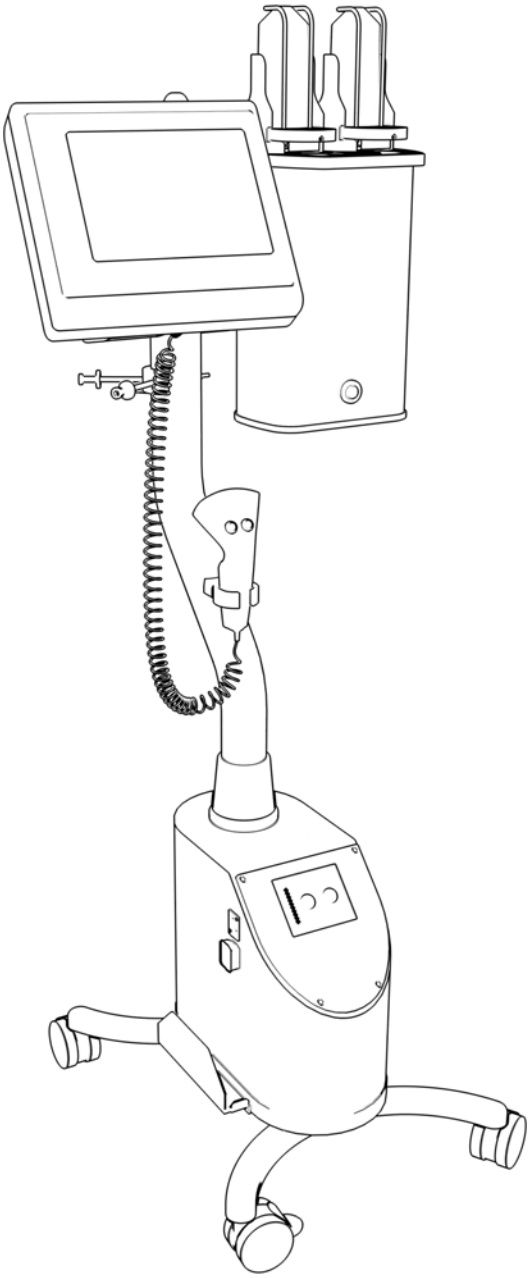
MEDTRON® AG

Accutron HP-D

Instructions for use



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These instructions for use Accutron HP-D apply to the high-pressure injector Accutron HP-D (model number 833).

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1 Introduction

This chapter contains some preliminary remarks on the use of the injector Accutron HP-D with Easy Loading Syringe (ELS) as well as explanations on the structure of these instructions for use and on the use of symbols and text markings.

Regarding these instructions for use

Read these instructions for use carefully and keep them for future reference.

These instructions for use explain how to correctly commission and operate the Accutron HP-D for your application.

It is important to MEDTRON that you operate the Accutron HP-D safely and properly.
To this end, it is essential that you read these instructions for use thoroughly before you use the injector. This manual contains important instructions designed to assist you in avoiding risks and, at the same time, increasing both the reliability and service life of the injector and its accessories.

For your own safety you should read the section *Safety instructions*. Comply exactly with all the instructions to ensure that you do not put yourself, other employees or patients at risk and prevent damage to the injector.

The user interface displays shown in these instructions for use are only for illustration purposes and may differ from the actual displays on the device.

If you have any questions concerning the handling of the Accutron HP-D not answered by these operating instructions, please contact:

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Intended use

The injector Accutron HP-D is intended exclusively for the injection of contrast media and physiological saline solution (NaCl) into patients for examinations involving angiography, intervention and computed tomography by trained and authorised staff.
The injector is intended for continuous operation for up to ten patients per hour. Any use above and beyond this scope is deemed as inappropriate. Never use the Accutron HP-D for other purposes!

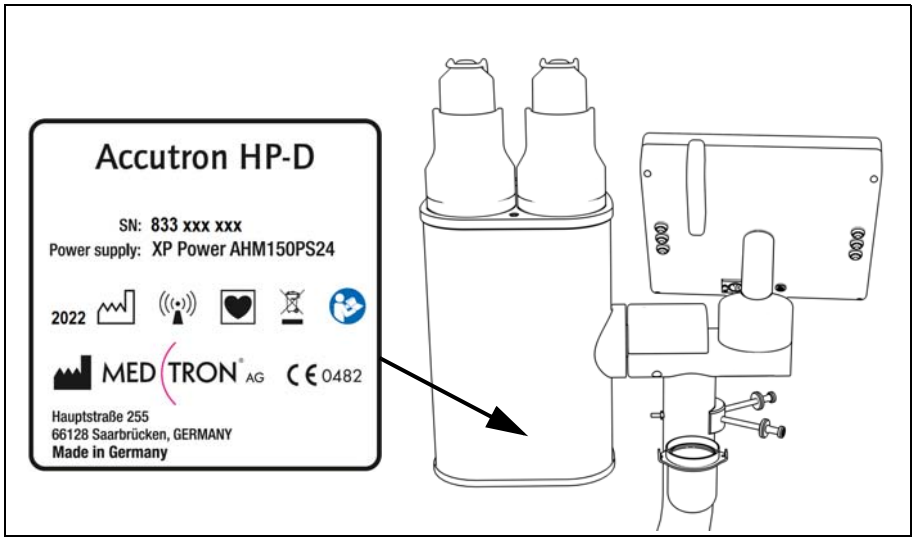
The injector Accutron HP-D may not be used in case of contrast medium intolerance.

The person responsible for the injection has to make sure before every injection that the injection parameters currently set do not endanger the patient.

The injector has to be positioned in the examination room in such a way that the connection of the consumables to the patient lying on the examination table can be established. The operator has to stand at the injector in such a way that he/she can perform all operating steps according to the instructions for use.

Manufacturer's plate

The manufacturer's plate of the Accutron HP-D bearing the model name and serial number is located on the rear of the injection unit. You will require this information if you contact the MEDTRON Customer Service, e.g. if you want to order accessories or spare parts.



Enter the model name and serial number here so that you have them at hand when required:

Model name: _____

Serial number: 833_____

Contents

This manual describes the commissioning and operation of the high-pressure injector Accutron HP-D. It consists of the following chapters:

- The chapter *Safety instructions* contains important safety instructions which are essential to observe for the safety of people and the system.
- The chapter *Product description* introduces you to the injector with its functions and controls.
- The chapter *Commissioning the injector* describes how to set the touch screen to suit your needs, how to prepare the injection unit and connect the tube system.
- The chapter *Operating the injector* explains how the contrast medium and saline solution is filled, how to deal with the injection profiles and how to perform the injection.
- In the *Annex* you will find notes on inspection and maintenance work, cleaning and storage, a table with system messages and errors and their remedy as well as the technical specifications of the injector and the declaration of conformity.
- The *Index* helps you to quickly find the desired text passages.

Symbols used on the packaging

The symbols used on the packaging have the following meanings:

This way up

Fragile; handle with care

Store in a dry place

Symbols used on the injector

The symbols on the injector have the following meanings:

SN	Serial number
	Manufacturing date
	Follow instructions for use
	Do not put old devices to the normal domestic waste
	Application part type CF
	Equipotential bonding
	Non-ionizing radiation
	Warning, risk of hand injuries
	Do not lean against the injector
	Start/stop injection with hand switch
	Alternating current
	Indoor use only
	Manufacturer

No heavy load
(Do not exceed the specified maximum permissible load)

Mass including safe working load

Environmentally friendly use period: 10 years

Symbols used in these instructions for use

You will find the following symbols identifying important safety instructions at several points in this manual:

CAUTION!
This symbol indicates risks which could involve fatal or serious personal injuries or severe damage to property.

ATTENTION!
This symbol highlights risks which could involve material damage.

The following symbol indicates tips and particularities:

Note!
This symbol indicates tips and particularities which facilitate the operation of the device.

General conventions

Bold type print

Designations and lettering of menus, menu items and buttons are printed in **bold** type.

Italic type print

Cross references to other chapters or text passages are printed in *italics*.

Inverted commas

Device functions are placed in "inverted commas".

Control steps

Control steps are identified as follows:

- Make sure that the piston is moved back.
- Push the syringe from the front into the recipient until it engages audibly.
- Remove the protective cap from the syringe.

Listings

Listings are marked as follows:

– Point A
– Point B
– Point C

2 Safety instructions

Read the following safety instructions thoroughly and adhere to them closely. They are intended to protect your own safety and the safety of colleagues and patients as well as to avoid damage to the Accutron HP-D and its accessories.

Protection of people and property

CAUTION!
Risk of fatal or serious injuries due to air embolisms!

- Do not connect the patient to the system until you have vented the syringes and the tube system.
- Vent the syringes and the tube system every time after filling the injector with contrast medium or saline solution.
- Make sure before every injection that there are no air inclusions in the syringes and in the connected tube systems.
- Only start an injection when the syringes are in the lowered position (injection position).
- Make sure before every injection that the injection parameters shown on the display do not endanger the patient.
- Maintenance and repair work may only be performed by the MEDTRON Customer Service or by persons trained and authorised by MEDTRON.
  Trained and authorised persons will receive the documents necessary for the maintenance and safety inspections from MEDTRON.
- Make sure that the injector is no longer operated when the display of the injector has only failed slightly or fails completely.

CAUTION!
Risk of uncontrolled supply of contrast medium due to hydrostatic pressure compensation!
Make sure that the patient and the syringes are at the same level.

CAUTION!
Risk of infection!

- Replace all consumables with new ones after they have been used once. Otherwise you jeopardise your patient's health.
- Do not remove the protective caps of the syringes and the tube ends until you make the connections.
- Only use consumables and accessories which MEDTRON recommends.
- Make sure that the packings of the consumables do not show any sign of damage.
- Make sure that the 'use-by' date of the consumables has not been passed.

CAUTION!
Danger from electric current!

- Make sure that no liquid can enter the injector and the peripheral equipment. Should this happen, switch off the device immediately, and secure it from being switched on again.
- Make sure that the electric connection cables are intact and cannot be bent or squeezed. If you detect any damage, pull out the mains plug and secure the remote control/the injector from being switched on again and do not continue to use the power supply unit.
- Make sure that the power supply unit of the injector is only connected to a mains supply with protective earth conductor.
- Make sure that you do not simultaneously touch the plug pins of the power supply unit and the patient when the power supply unit is connected to the mains supply.

CAUTION!
Risk of syringes bursting!
Make sure that you have installed the pressure jackets for the syringe.
Replace pressure jackets with hairline cracks, breakages or other damage immediately.

CAUTION!
Risk of crushing!
Do not touch the piston with your hand while it is moving forward or backward.

CAUTION!
Danger from injector toppling over!

- Do not lean against the injector.
- Make sure that all castors of the injector are locked when the injector is positioned on an inclined plane.
- Move the injector slowly over obstacles and steps and hold the injector firmly.

CAUTION!
Danger from modifications to the Accutron HP-D!
The injector may not be modified without the permission of the manufacturer.

ATTENTION!
Risk of malfunctions of the Accutron HP-D!
Only use syringes and consumables recommended by MEDTRON.

ATTENTION!
Risk of damage to the battery cells!
Make sure that the injector is switched off and connected to the power supply unit during non-operating periods in order to prevent damage to the battery cells.

Electromagnetic compatibility

The injector satisfies the requirements of the standard DIN EN 60601-1-2 for medical equipment in terms of the emitted interference and interference immunity.

The injector is subject to special safety precautions as regards electromagnetic compatibility.
Installation and commissioning are performed by staff trained and authorised by MEDTRON.

The emissions characteristics of the injector make it suitable for use in industrial areas and hospitals (CISPR 11, class A). If it is used in a residential environment (CISPR 11, class B) the injector might not offer adequate protection to radio-frequency communication services. If required, mitigation measures must be taken, e.g. relocating or re-orienting the injector.

Electromagnetic interference exceeding the limit values of the standard may result in a reduction in the performance characteristics of the injector and thus in an abortion of the injection.

ATTENTION!
Portable HF communications equipment (radio devices) in the immediate vicinity of the injector may result in a reduction in the performance characteristics of the injector.
Do not use such devices in a distance of less than 30 cm from the injector.

ATTENTION!
The injector may only be used with the accessories described in the instructions for use.
Operation of the injector with other accessories or equipment may result in increased emitted interference or a reduction in the interference immunity.

ATTENTION!
Using the injector next to other devices or with other devices in stacked form may result in incorrect operation.
Avoid using the injector in the way described above or observe the injector and other devices to ensure that they are working properly.

The document *Angaben zu elektromagnetischen Beeinflussungen* (Information about electromagnetic interference) can be requested from MEDTRON.

Medical-electrical system

When using the injector Accutron HP-D with the touch screen remote control Accutron HP-D and/or the interface Accutron HP-D, a medical-electrical system (ME system) is created which corresponds to DIN EN 60601-1:2013.

ATTENTION!
Risk of damage to the individual devices of the ME system!
Observe the ambient conditions and operating modes of the individual devices when installing the ME system.

CAUTION!
Danger from modifications to the ME system!
The ME system may not be modified without the permission of the manufacturer.

3 Product description

General features

The Accutron HP-D is designed for exactly dosed injections of contrast medium (CM) and physiological saline solution (NaCl). You can change between computed tomography mode (CT) and angiography mode (Angio) by pressing the corresponding button in the menu **System settings**.
You can store the injection parameters you want

- Delay,
- Volume,
- Concentration,
- Flow rate and
- Injection time

under a profile number in up to 60 profiles per mode and retrieve them at any time. The reproducibility of the injection parameters is therefore reliable and easy. A profile can consist of a maximum of 3 individually programmable injection phases which are performed automatically after the program has been started. With the parameter "Concentration", you can, if required, inject contrast medium and NaCl at the same time.

The Accutron HP-D has an injection unit with two drive units which can be controlled independently of each other and so the contrast medium can be positioned variably and accurately in the examination area with NaCl, depending on the application. This prevents tailings of the contrast medium which used to make delimitation of the examination area more difficult.
The function "Keep Vein Open" (KVO) injects the desired amount of NaCl at the time intervals set and therefore ensures that the access to the vein is retained.

The injector can be operated either cordlessly with battery cells or with the power supply unit.

Items supplied and accessories

The following elements are included in the scope of supply:

Equipment

Injector, power supply unit XP Power AHM150PS24, hand switch MEDTRON HP-D-HT, pressure jackets MEDTRON Pressure Jacket, bottle holder, cup holder, instructions for use

Optional accessories

- Interface Accutron HP-D (between injector and scanner)
- Touch screen remote control Accutron HP-D

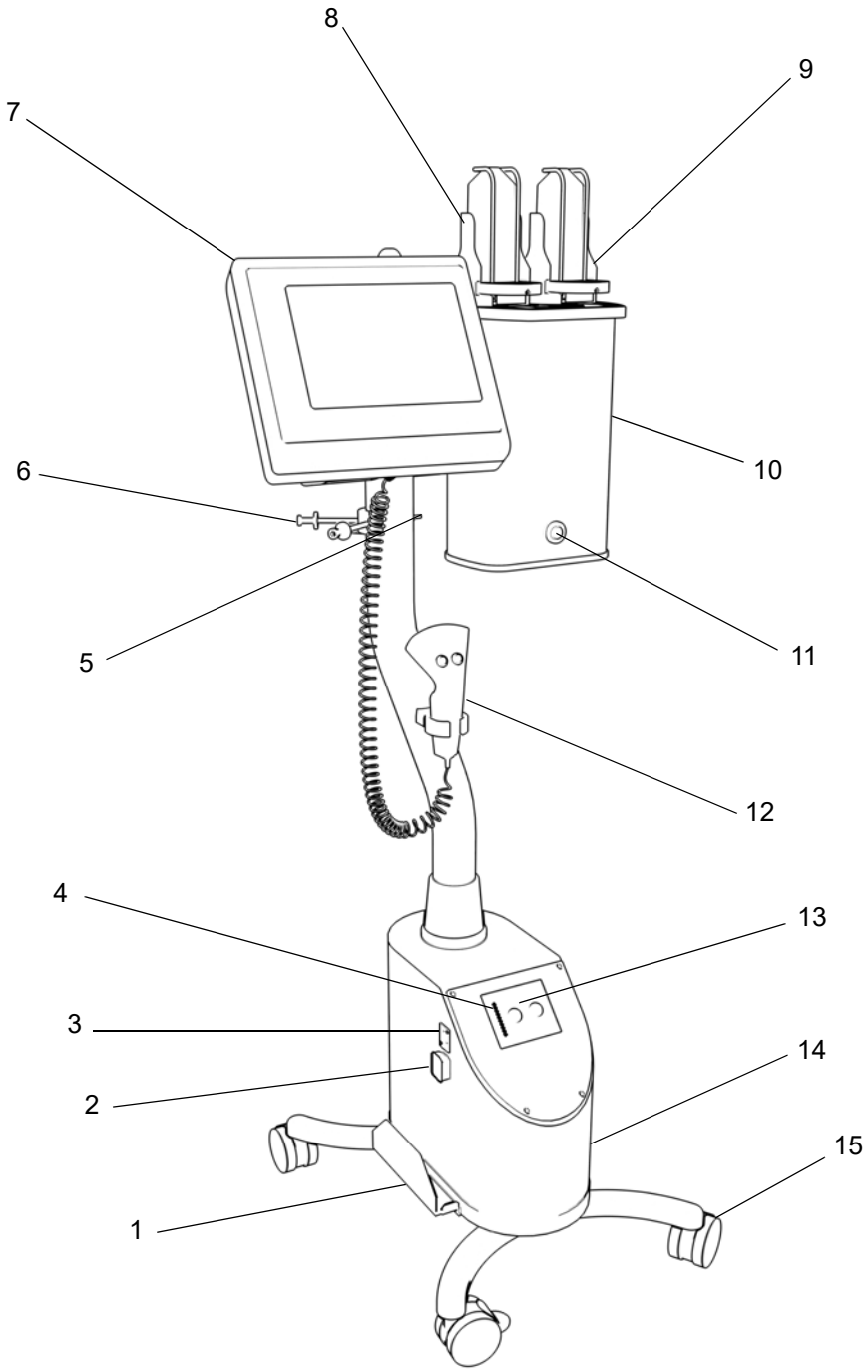
Consumables

- Syringes
- Tube system
- Patient line

Note!
For detailed information about the available consumables please refer to the MEDTRON product catalogue.

Assemblies

1 Holder for power supply unit
2 Service connection for the MEDTRON Customer Service
3 Connection for the power supply unit
4 Series of small LEDs to indicate the state of charge of the battery cells
5 Connection for the equipotential bonding cable
6 Bottle holder
7 Swivelling control unit with touch screen
8 Recipient for holding the pressure jacket with contrast medium syringe
9 Recipient for holding the pressure jacket with NaCl syringe
10 Swivelling injection unit for contrast medium and NaCl
11 Pilot light
12 Hand switch
13 Buttons for switching the injector on and off
14 Injector base with battery cells
15 Four smooth-running castors with locking brakes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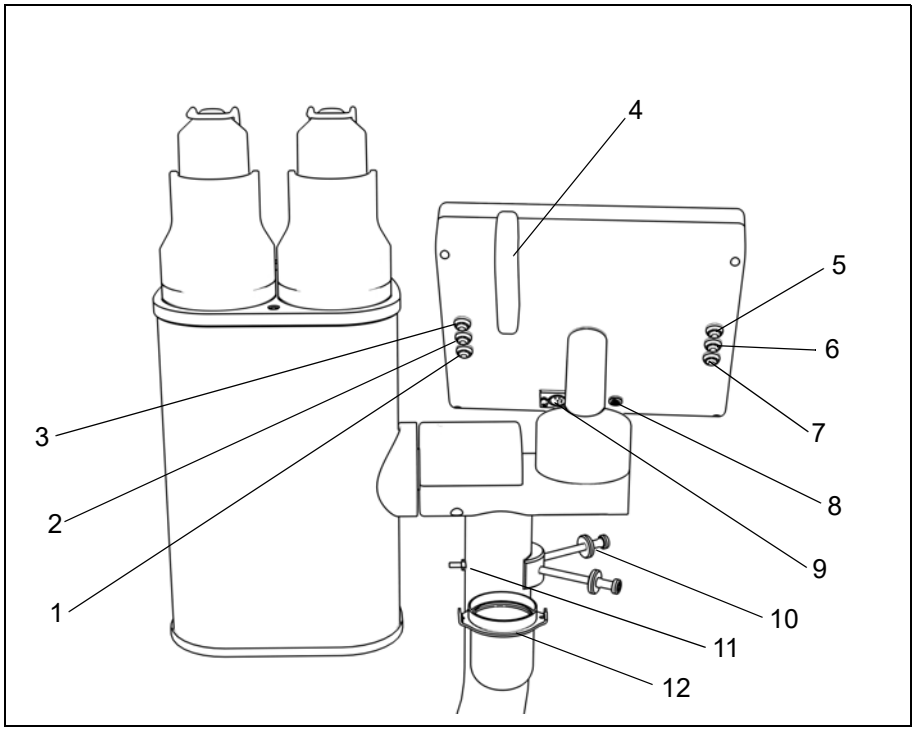
Controls

The following contains a description of the controls of the Accutron HP-D. The front side of the control panel contains a touch screen, a combination of display and entry field. The functions and operation of the *touch screen* are described from page 26.

Controls on the rear of the device

On the rear of the control unit and the device column there are the following controls:



Nr.	Symbol	Designation	Function
1	∨	Move piston NaCl back	While pressing the button the piston moves back
2	∧ ∧ ∨ ∨	Increase piston speed NaCl	The current piston speed increases with each press of the button
3	∧	Move piston NaCl forward	While pressing the button the piston moves forward
4	Antenna for the optional data transmission to the remote control and interface		

Nr.	Symbol	Designation	Function
5	∧	Move piston CM forward	While pressing the button the piston moves forward
6	∧ ∧ ∨ ∨	Increase piston speed CM	The current piston speed increases with each press of the button
7	∨	Move piston CM back	While pressing the button the piston moves back
8	Connection for service work by the MEDTRON Customer Service		
9	Connection for the hand switch		
10	Bottle holder		
11	Connection for the equipotential bonding cable		
12	Supporting ring for plastic cup to collect liquids during venting		

Pilot light

The pilot light is situated on the front side of the injection unit. It lights up yellow for a short time when switching the injector on. It stays yellow in case of an error during the starting procedure. It lights up green, when the injector is ready for injection. During the injection, the pilot light flashes green. It lights up red in the event of a fault.

Swivelling control unit

The control unit with touch screen can be swivelled horizontally by 180°. It can be operated in any position.

Touch screen

The touch screen displays messages and graphics like a normal monitor. In addition, you can make entries and call up functions by touching the buttons displayed. If a button cannot be used at the moment, it is greyed out.

ATTENTION!
Damage to the touch screen possible!
Do not strike or hit the touch screen.
Do not use any items such as pencils or tools.
Only touch the buttons lightly with your fingers.

Touch the symbol you want lightly with your finger tip. Depending on the button, you can mark or select a value or call up a function and a new window will open:

In addition to entering commands, the main window of the touch screen also serves to display the process information currently set. The profile name is located in the text field in the top and the parameters of the injection profile currently selected are in the table underneath.

The column headers for the injection parameters at the top of the display describe the following parameters for each phase:

Phase	Numbering of the individual phases
Delay (s)	Breaks between the injection phases in seconds
Volume (ml)	The amount of fluid, in millilitres, to be injected
Concentration (%)	Concentration of the injection media: – 100 % means only contrast medium – 40 % means 40 % contrast medium, 60 % NaCl – 0 % means only NaCl
Flow (ml/s)	Injection speed in millilitres per second
Inj. time (s)	Duration of the current injection phase in seconds
	Near the green syringe symbol are shown in green the remaining and total contrast medium volumes in millilitres.
	Near the blue syringe symbol are shown in blue the remaining and total NaCl volumes in millilitres.
	The green syringe symbol wobbles when you have to move the injection unit into the injection position.

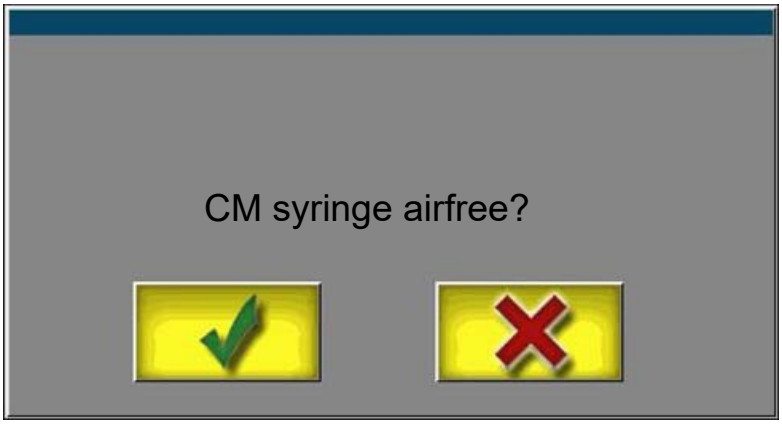
Further injection parameters are shown on three buttons at the right margin.

X-ray/Scan delay	Delay between injection start and X-ray/scan start in seconds (storable with the profile)
Pressure limit	Defined maximum pressure in bar/psi (storable with the profile)
Rise time	Time until reaching the predefined flow rate (storable with the profile)

During the injection, the touch screen also shows status information of the current injection process. There are shown:

Green ml value	Contrast medium injected so far in millilitres
Blue ml value	NaCl injected so far in millilitres
Total (ml)	Total CM volume injected so far, until you press the Reset button again
Phase time	Duration of the current injection phase in seconds
Delay	Breaks between the injection phases in seconds
Injection time	Counts the injection time from pressing the green button of the hand switch in seconds
X-ray/Scan delay	Counts back the time until X-ray/scan start in seconds
Pressure history	Curve showing the pressure graph
KVO	Indicates whether the KVO function (Keep Vein Open) is activated

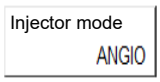
Example for dialogue messages:

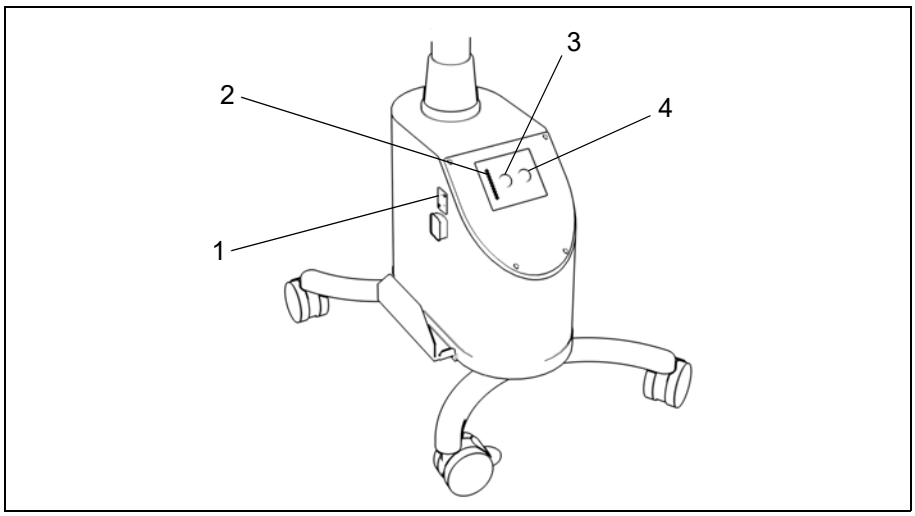


You answer dialogue messages by touching the relevant button.
In the example shown above you can either confirm the question "CM syringe airfree?" by touching the button with the green symbol **Confirm** or negate the question by touching the button with the red cross **No/Reject**.

Function of the buttons

Symbol	Designation	Function
	Call up profile	Call up an existing profile
	Save profile	Save a changed or new profile
	Confirm	Confirm inquiries and changes
	No/Reject	Negate inquiries or reject unstored entries
	Call up filling menu	Call up the filling menu in the main window
	Filling CM syringe	Enter the filling volume for contrast medium in the filling menu
	Filling NaCl syringe	Enter the filling volume for NaCl in the filling menu
	Piston forward	Move the piston forward in the filling menu
	Piston back	Move the piston back in the filling menu
	Activate injector	Prepare the injector for the injection
	Confirm venting	Confirm the previously performed venting operation
	Activate single injection	Adjust the injector to a single injection
	Activate multiple injection	Adjust the injector to several succeeding injections
	Activate interface	Activate the interface function between injector and scanner
	Deactivate interface	Deactivate the interface function between injector and scanner

Symbol	Designation	Function
	Interface not connected	No connection between injector and interface
	Add phase	Add a new phase to an injection profile
	Delete phase	Delete the last phase of a profile
	Display pressure curve	Display the pressure curve during injection
	Forward	Scroll forwards within a menu
	Back	Scroll backwards within a menu
	Calibrate touch screen	Calibrate the touch screen to suit your operating habits
	Save system settings	Save changed display settings
	Leave menu	Leave the menu back to the main window
	Reset	Reset the total CM volume to 0
	Switch heating on/off	Switch on or off the heating of the correspondent recipient
	Select mode	Change between Angio and CT mode
	Info	- In the main window: Show menu **System settings** - In the injection window: Show injection data
	KVO	Activate and deactivate the Keep Vein Open function in order to retain access to the vein
	STOP	Stop the filling process in the filling menu



State of charge display

There is a series of small LEDs (2) on the control panel on the injector base.

- When the injector is switched on, the LEDs lighting continuously indicate the state of charge of the battery cells reached so far.
- When the power supply unit is connected, the LEDs lighting continuously indicate the state of charge of the battery cells reached so far. The two following LEDs flash and thus indicate the charging process.

For further information please see section *Reading off the state of charge* on page 37.

Button ON and button OFF

There is a green button **ON** (3) on the control panel on the injector base for switching the injector on and a red button **OFF** (4) for switching it off. If you switch the injector on, the state of charge display on the injector base comes on, as well as the touch screen. If you switch the injector off, the state of charge display on the injector base goes off, well as the touch screen. If you switch the injector off when the power supply unit is connected, the state of charge display stays on in order to indicate the charging process.

Connection for the power supply unit

Two sockets are located on the side of the injector base. You can connect the power supply unit to socket (1).

Connection for the equipotential bonding cable

If required, you can order an equipotential bonding cable from MEDTRON. The equipotential bonding cable has to be connected to the equipotential bonding connection at the injector and to an equipotential busbar of the house wiring in order to avoid different potentials which could result in a fault current between injector and patient.
When using an equipotential bonding cable, please observe the requirements of DIN EN 60601-1 regarding ME systems (chapter 16).

Castors

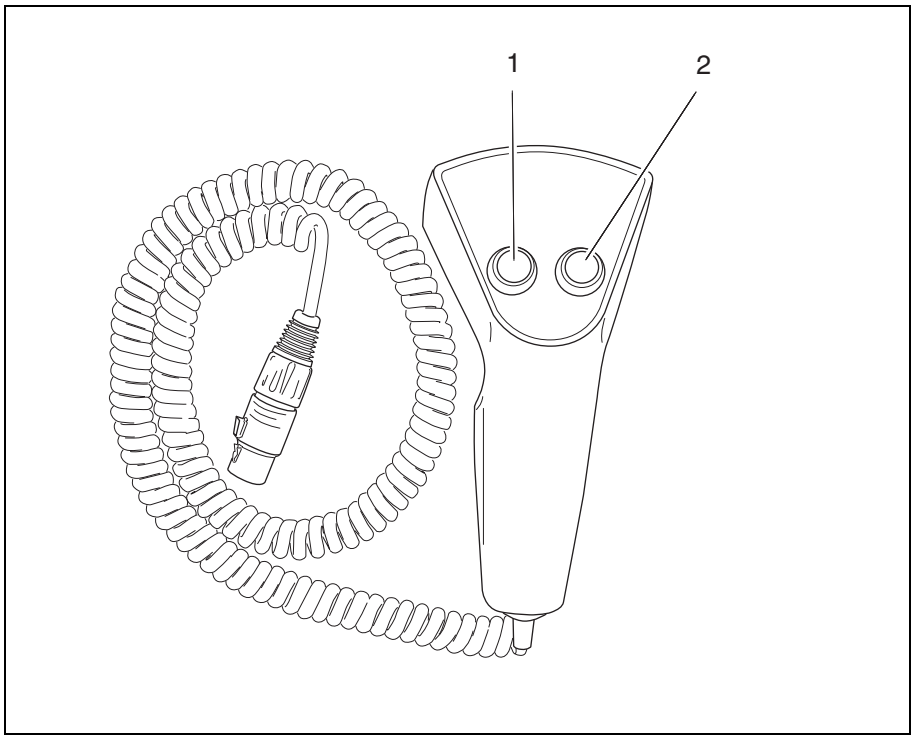
You can conveniently move the injector using the smooth-running castors to the location you want. When it is in the correct position, secure the injector using the locking castors. To this end press the locking lever downwards with your foot. When you want to release the castors, raise the locking lever slightly with your foot.

Note!
Secure the injector position using the locking castors before you swivel the injection unit upwards or downwards.

Hand switch

The hand switch has an extendible spiral cable and permits you to control the injection from a distance of up to 5 m as well as to flush with NaCl.

There are two buttons on the hand switch. By means of the green button (1) you can control the injection. By pressing the blue button (2) und keep it depressed, NaCl flushing is done.

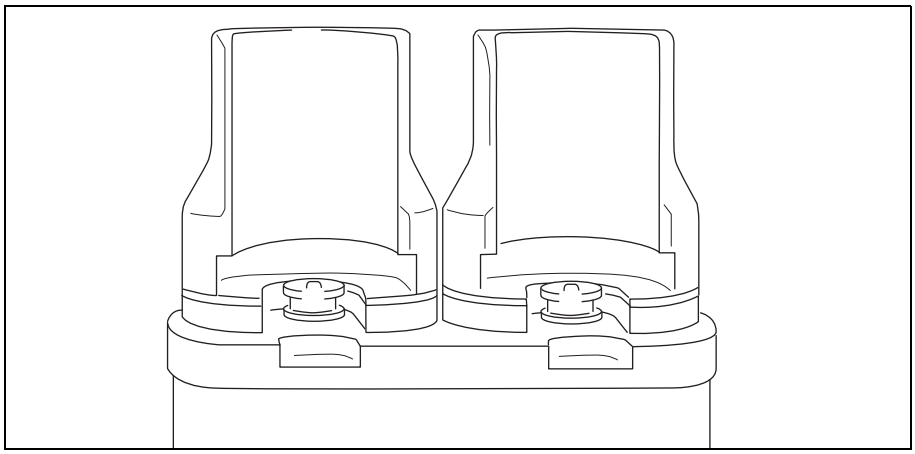


Remote control

The injector can be remotely controlled using the optional remote control. The remote control transfers the data by radio to the injector. You will find more details in the *instructions for use of the Touch screen remote control Accutron HP-D*.

Heatable recipient

The heatable recipient keeps the injection fluid at a temperature pleasant for the patient. By pressing the correspondent syringe symbol in the menu **System settings** you can switch on or off the heating of the recipients independently of each other, see page 42.



Note!
The heatable recipient is intended for injection fluid already preheated - it is not suitable for heating cold fluid.

4 Commissioning the injector

In this chapter you learn how to connect the power supply unit, charge the battery cells, set the touch screen, insert the syringes into the injection unit, and connect the tube system.

Connecting the power supply unit and charging the battery cells

The injector can be operated either cordlessly with battery cells or with the power supply unit. In both cases, you must first connect the power supply unit. For this purpose, proceed as follows:

Note!
If the unit has been out of service for a prolonged period, charge the battery cells before starting it up again.

Note!
The battery cells are maintenance-free. They are replaced when necessary exclusively by MEDTRON Customer Service.

CAUTION!
Danger from electric current!
Make sure that the electric connection cables are intact and cannot be bent or squeezed. If you detect any damage, pull out the mains plug and do not continue to use the power supply unit.

- Place the power supply unit in its holder on the injector base.
- Connect the power supply unit to the mains supply.

The green LED on the power supply unit lights up.

- Position the injector in a place where you can easily reach the mains plug and disconnect the injector from the mains supply at any time.
- Insert the connector for the power supply unit into the socket on the injector base.

The series of LEDs on the injector base lights up. The battery cells are being charged.

Note!
The charging time depends on the level of charge of the battery cells. If they are completely discharged, charging takes about 9 hours.

- As soon as the battery cells are fully charged, you can disconnect the power supply unit from the mains supply and pull the connector of the power supply unit out of the socket on the injector base.

Alternatively, you can also operate the injector with the power supply unit connected.

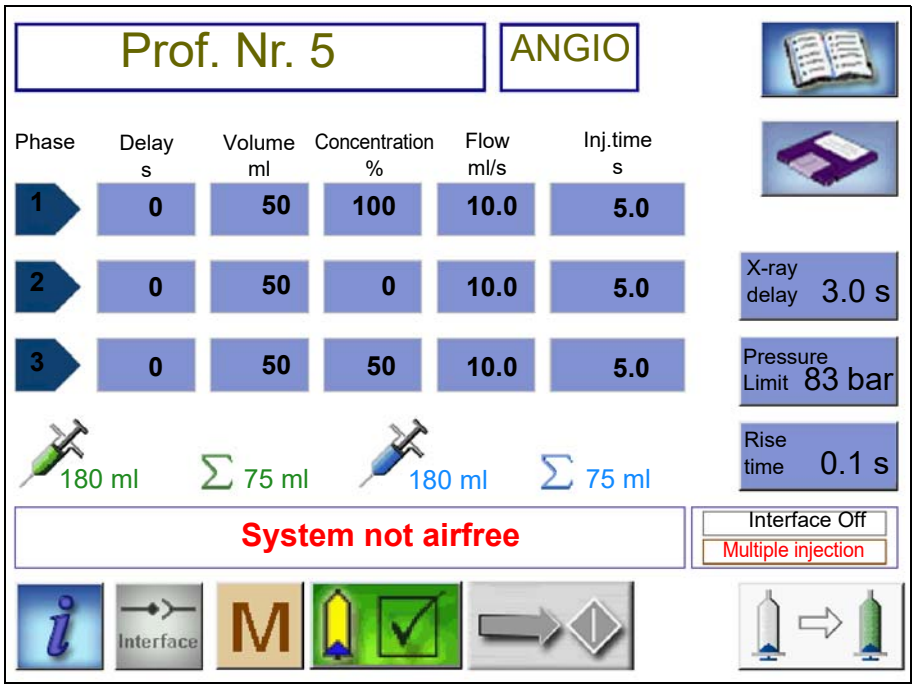
The injector is now ready to be *switched on*, see page 36.

Switching on

- Press the green button **ON** situated on the injector base to switch the injector on.

The series of LEDs on the injector base lights up.
The pilot light lights up yellow for a short time and then goes off.
The touch screen briefly displays the MEDTRON logo.

Then the touch screen immediately shows the main window from where you can call up the submenus.



Reading off the state of charge

You can read off the present state of charge of the battery cells on the series of LEDs on the injector base. The series of LEDs lights up as soon as the injector is switched on or the power supply unit is connected.

- If all LEDs light continuously, the battery cells are fully charged.
- If only the red and one yellow LED light continuously, the battery cells are almost empty. In this case, connect the power supply unit, see *Connecting the power supply unit and charging the battery cells* on page 35.
- If the red LED starts flashing, the state of charge is too low and the injector will switch off at the next opportunity. A running injection will be properly completed. Connect the power supply unit, see *Connecting the power supply unit and charging the battery cells* on page 35.

Note!
When the injector has switched off automatically, you must connect the power supply unit and press the **ON** button. The battery cells are charged.
If you want to continue working with the injector, you must press the **ON** button again. The injector switches on.
The power supply unit should be connected within 30 minutes after the injector has switched off automatically. Otherwise, a charging time of approx. 1.5 hours is required before the injector can be switched on and operated again.

Power saving mode

If you have not pressed a button for a preset period and if the main window is displayed, the display backlight switches off automatically. This saves energy. To set the stand-by time, see page 41.

You can reactivate the deactivated display at any time by pressing the display at any position.

Besides, you can save energy also when you switch off the heating of the recipients by pressing the correspondent syringe symbol in the menu **System settings 2/3** see page 42.

If you have not yet set the touch screen to your operating habits, you should make some basic settings now, see next page.

If you have already adapted the touch screen to your needs, you can continue with the section *Preparing the injection unit* on page 45.

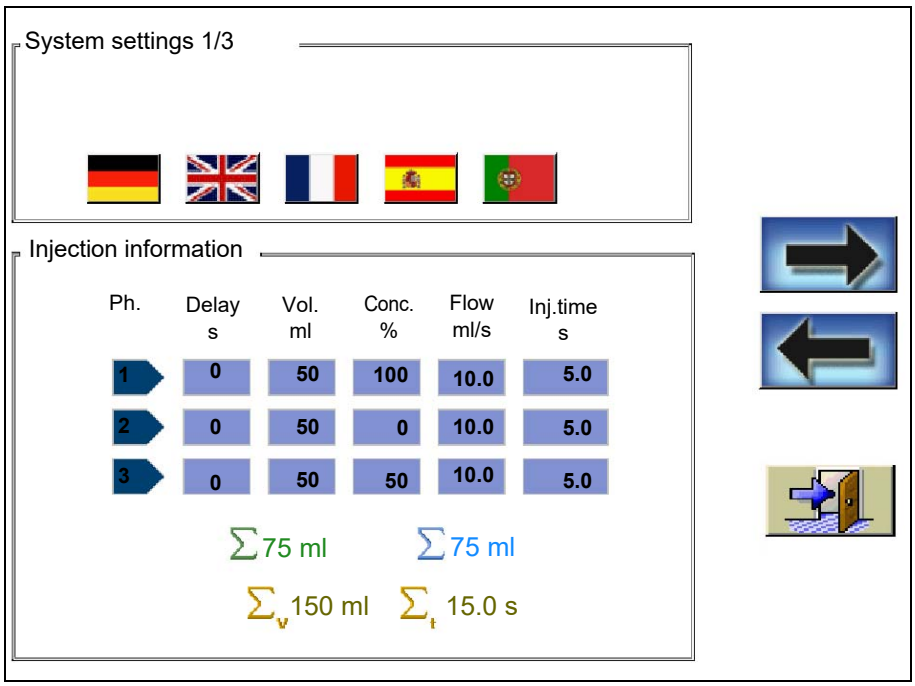
Setting the touch screen

In order to be able to use the touch screen easily and without any problems, you should set it at the outset to suit your operating habits and the environmental conditions. The menu with display settings and injection data consists of several windows where you can make the following settings:

- Selecting the language for the display texts
- Adjusting the buttons to the tactile characteristics of the operator
- Setting the idling speed of the pistons
- Setting the filling speed of the pistons
- Setting the NaCl flushing speed
- Setting the manual piston speed
- Setting the stand-by time
- Setting the KVO-volume
- Switching the heating on/off
- Selecting the mode (Angio or CT)
- Setting the interface function
- Setting the pressure unit
- Setting the KVO-time
- Setting the automatic volume adjustment
- Switching the pressure jacket detection on/off

•  Touch the button **Info** to open the **System settings**.

The first dialogue window **System settings 1/3** is displayed.



Selecting a language

In the dialogue window **System settings 1/3** you can select the language in which the texts in the touch screen are to be displayed. The following can be selected from the left to the right.

– German
– English
– French
– Spanish
– Portuguese

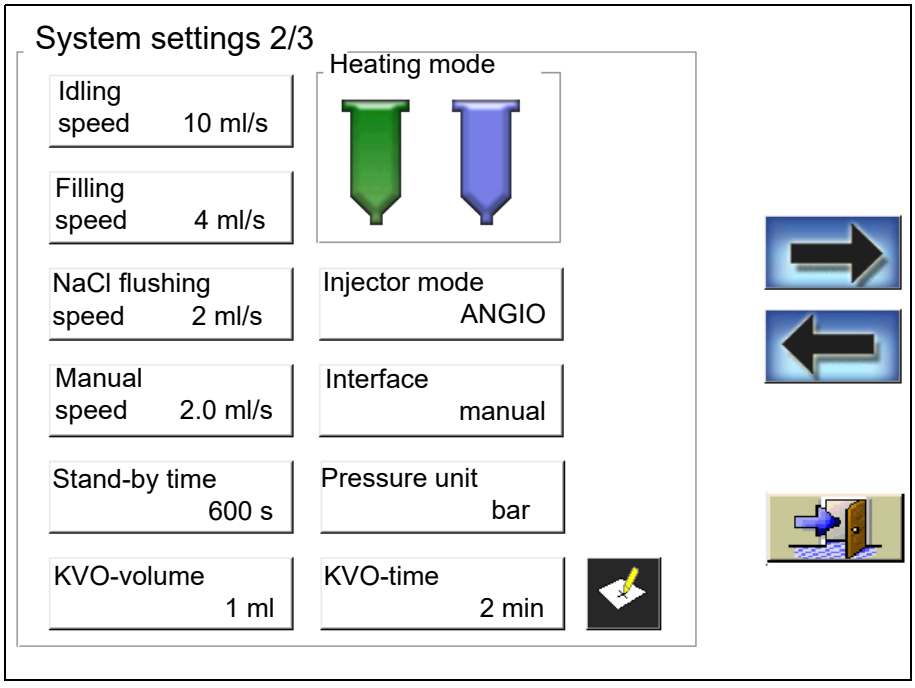
• Touch the button with the relevant flag.

Calibrating the touch screen

Everyone operates a touch screen in their own particular way. A right-handed person, for example, does not position his finger at the same place as a left-handed person. The size and angle of the fingers also play a role. To ensure that the touch screen correctly adopts your entries and commands, you must first calibrate it to your touch habits.

The first dialogue window **System settings 1/3** is displayed.

•  Call up the next dialogue window **System settings 2/3**.



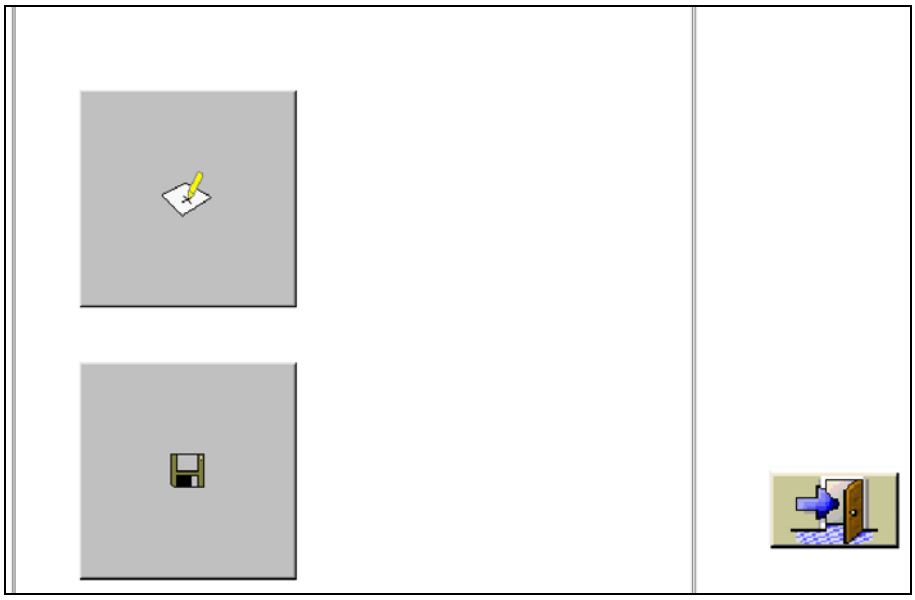
To start the calibration, you must first log into the system.

-  Press the button **Calibrating the touch screen** in the dialogue window **System settings 2/3**.

The dialogue window **Login** is displayed. You are requested to select your name.

- Touch list entry **User**.
- Enter the identification 1001 on the number buttons.
- Touch the **OK** button.

The following dialogue window is displayed.



-  Press the big button **Calibrate touch screen**.

The calibration window is displayed.
Cross-hairs are shown in the centre of the window.

- Keep your finger pressed on the cross-hairs in the centre of the screen until they disappear.

The cross-hairs are gradually displayed in each corner of the screen.

- Press each cross-hair until it disappears.
-  Save calibration.
-  Leave the menu to display the dialogue window **System settings 2/3**.

Setting the system

In the menu **System settings 2/3** you can make the following settings.

Setting the idling speed of the pistons

Here you can set at what speed the empty pistons are to be moved.
1 – 10 ml/s can be set.

Setting the filling speed of the pistons

Here you can set at what speed the liquids are to be filled. 1 – 4 ml/s can be set.

Setting the NaCl flushing speed

Here you can set at what speed the NaCl flushing is to be done. 1 – 9 ml/s can be set.

Setting the manual piston speed

Here you can set the starting speed of the manual piston movement.
0.4 – 2.0 ml/s can be set.

Setting the stand-by time

Here you can set after how many seconds the injector must switch into stand-by mode, if you don't work on the injector. 10 – 600 s can be set.

Setting the KVO-volume

Here you can set which amount of NaCl is to be injected, if the KVO function is activated. 1 – 4 ml can be set.

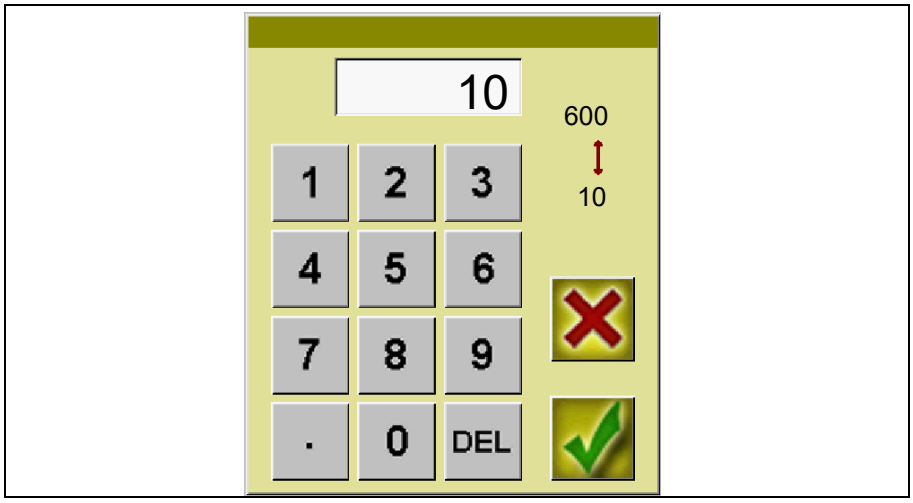
Setting the KVO-time

Here you can set the time intervals at which NaCl is to be injected, if the KVO function is activated. 1 – 4 min can be set.

Make all the above-mentioned settings as follows:

- Touch the relevant button with your finger.

A pop-up window opens.



The value currently set is displayed at the top of the window and the entry range is displayed on the right.

- Overwrite the value marked using the numeric keypad with a new value.

If you have accidentally entered the wrong number, you can delete it with the button **DEL**.

-  Confirm the new value.

The pop-up window closes.

Switching the heating on/off

By pressing the syringe symbols you can switch on or off the heating of the correspondent recipient. The green syringe symbol is for the contrast medium side, the blue one for the NaCl side. If the heating is switched on, the correspondent symbol has a red edging.

Selecting the mode

By pressing the button **Injector mode** you can select the desired mode. You can select **ANGIO** (angiography mode) or **CT** (computed tomography mode). The mode currently set is indicated on the button **Injector mode** and in the upper area of the display.

Interface

If you have selected the option "Interface", you can choose between manual and automatic function by pressing the button **Interface**. You will find more details about the interface function in the correspondent annex of the instructions for use.

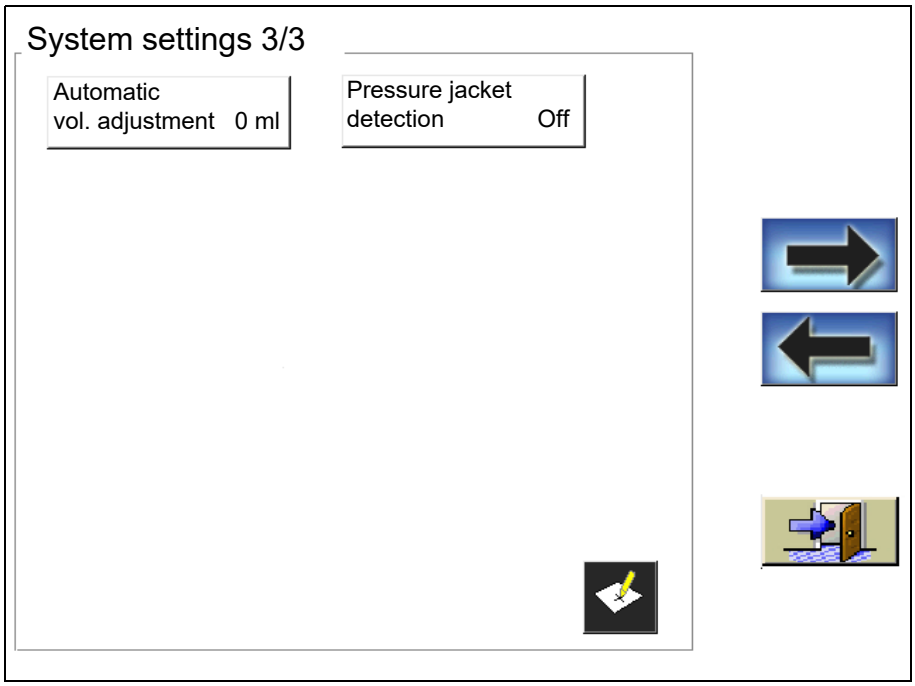
Selecting the pressure unit

By pressing the button **Pressure unit** you can select the unit for the pressure indication. The pressure is indicated in bar or in psi. There can be set 5 – 21 bar (75 – 310 psi) in CT mode and 5 – 83 bar (75 – 1200 psi) in Angio mode.

In order to make further system settings:

-  Call up the next dialogue window **System settings 3/3**.

In the dialogue window **System settings 3/3** you can make the following settings:



Setting the automatic volume adjustment

Here you can set whether an adjustment of the selected profile should be proposed automatically if the CM/NaCl volume is too low. 0 – 40 ml can be set as permitted volume tolerance.

Setting the pressure jacket detection

By touching the button **Pressure jacket detection** you can activate or deactivate the function pressure jacket detection. The current setting is displayed on the button.
If the pressure jacket detection is activated, the injector displays a warning message if the pressure jacket has not been inserted correctly.

When all settings have been made, you can now either:

-  Change to another dialogue window of the menu

or

-  Quit the dialogue window to display the main window.

When all settings have been made, you can now insert the syringe. For this purpose read the section *Preparing the injection unit* on page 45.

Preparing the injection unit

Note!
You can only insert the syringes into the injection unit when the piston of the injector is fully moved back.

CAUTION!
Risk of infection!
Do not remove the protective caps of the syringes until you make the connections.
Make sure that the packings of the consumables do not show any signs of damage.

CAUTION!
Risk of syringes bursting!
Make sure that you have installed the pressure jackets for the syringes.
Replace pressure jackets with hairline cracks, breakages or other damage immediately.

Moving the pistons back

On delivery the pistons are retracted - however, it may happen that prior to the routine change of the syringes, the pistons are advanced. In order to be able to insert new syringes, you must first move the pistons back. For this purpose:

-  **Call up filling menu** in the main window.
-  Touch left button **Piston back** for the CM piston.

The dialogue message with the confirmation prompt "Attention! Patient must be disconnected! Move piston CM back?" is shown.

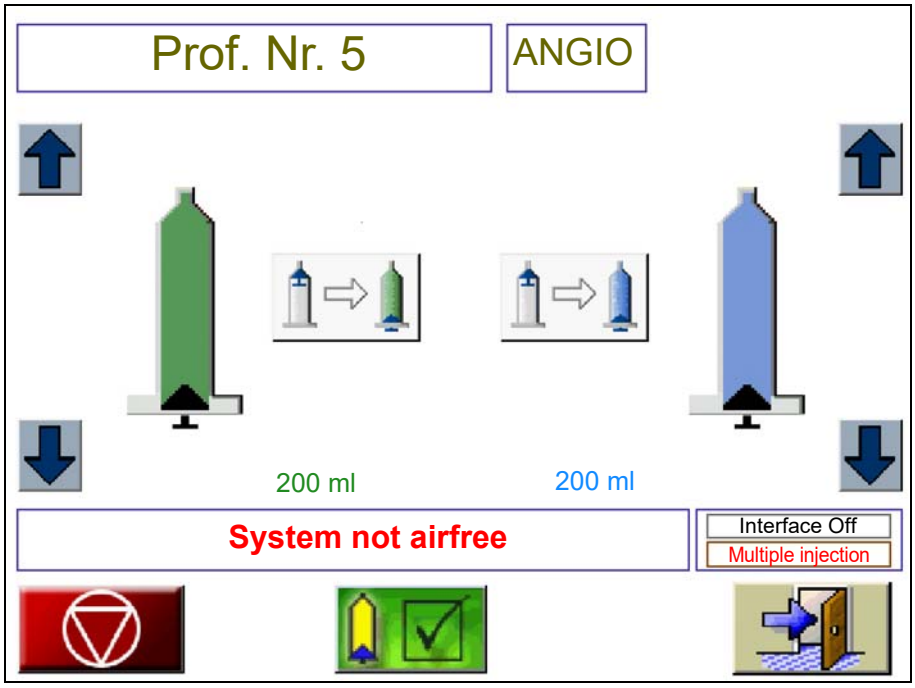
-  Confirm the message.

-  Touch right button **Piston back** for the NaCl piston.

The dialogue message with the confirmation prompt "Attention! Patient must be disconnected! Move piston NaCl back?" is shown.

-  Confirm the message.

Both pistons move back into their lowest position.



The piston is retracted when it is right at the bottom of the syringe, the syringe is completely green/blue and the remaining volume displayed is 200 ml (see diagram).

-  Return to the main window.

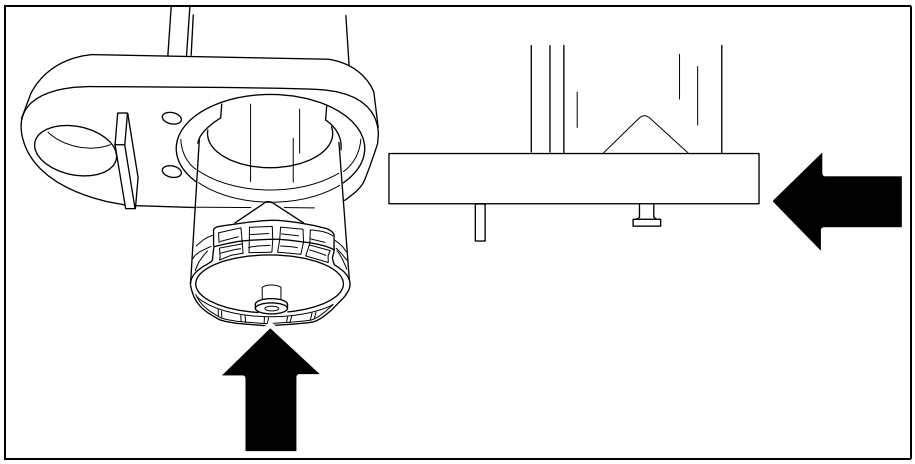
Inserting the syringes and pressure jackets

First you must insert the syringes into the pressure jackets. The pressure jacket is stuck together with a retaining ring which allows you an easier inserting into and removing from the recipient.

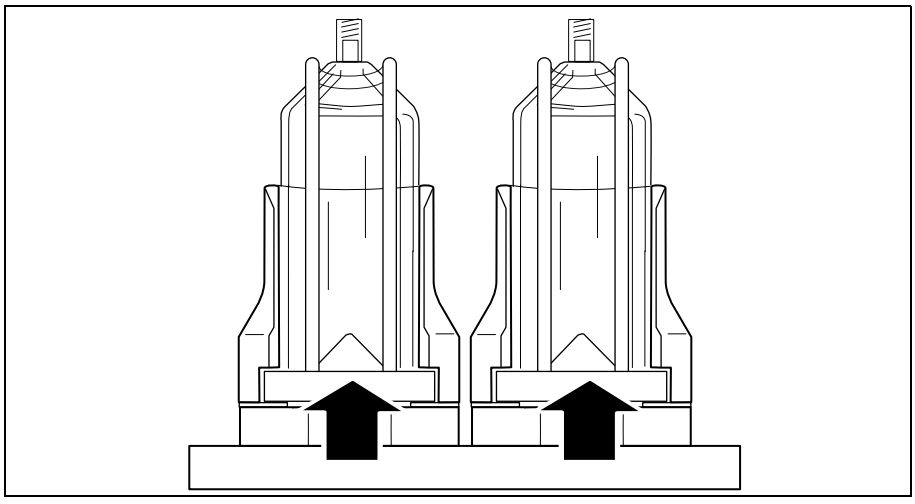
- Make sure that both pistons are moved back.

Note!
The left-hand piston is intended for the injection of contrast medium, the right-hand piston for NaCl solution.

- Insert the syringes into the pressure jackets until they are flush with the lower border of the retaining ring.



- Push the pressure jackets with syringes from the front into the recipient until they engage audibly.



Then you can connect the tube system, see next section.

Connecting the tube system

CAUTION!
Risk of infection!
Do not remove the protective caps of the tube ends until you make the connections.
Make sure that the packings of the consumables do not show any signs of damage.

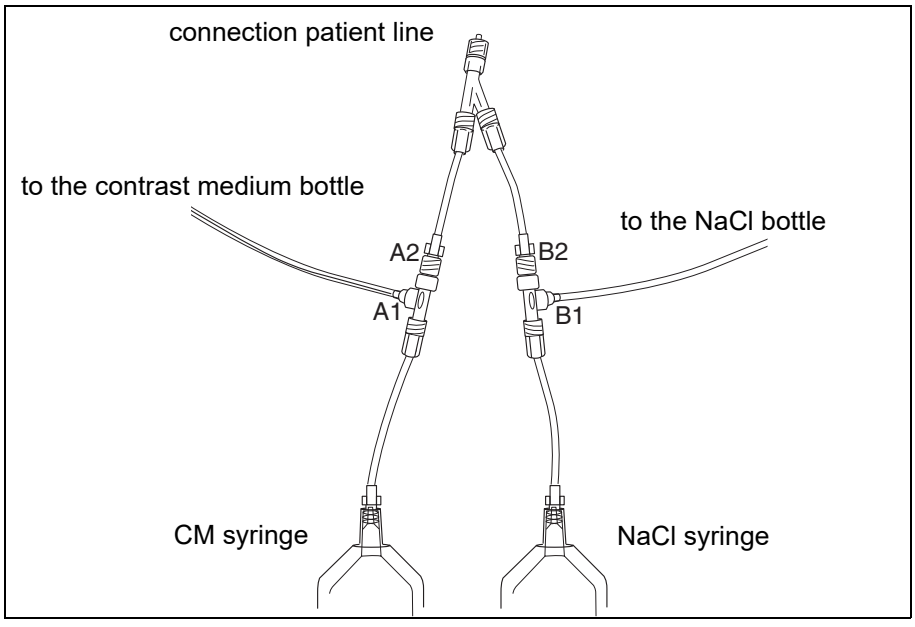
Depending on the operating mode, angiography or computed tomography, you must use different tube systems.

Note!
For detailed information about the consumables you are using, please see the separate instructions for use supplied with the product.

In the following, the way of functioning of a double head tube system with two drip chambers for angiography is described as an example.

The tube system has four valves which function as follows:

- When you fill the CM syringe with contrast medium, valve **A1** is opened and valve **A2** closed.
- When you inject contrast medium out of the CM syringe, valve **A1** is closed and valve **A2** opened.
- The valves **B1** and **B2** function in the same way.



Note!
The tube marked with a green stripe is intended for the contrast medium bottle. The tube section between valve **A2** and the Y-piece is very short in order to save contrast medium.

The tube system is connected to the syringes as follows:

- Remove the protective caps from the CM syringe and CM tube end.

ATTENTION!
Risk of damage to the syringe and tube system!
When screwing on the tube system with too much force you may damage the Luer Lock thread and therefore make the syringe and tube system unusable. Therefore do not overtighten the Luer Lock thread.

- Screw the tube system onto the CM syringe with approx. one half-turn.
- Repeat the above steps on the NaCl side.
- Hang the CM bottle and NaCl bottle with the opening downwards on the bottle holders.

In the next step connect the tube system to the bottles:

Note!
If you use a CM bag with Luer Lock connection, please use a tube system with inline drip chamber.

- Remove the protective cap from the spike of the drip chamber on the CM side and press the spike into the septum of the CM bottle.
- Open the ventilating flap on the spike of the drip chamber on the CM side.
- Briefly press the drip chamber together twice to fill it roughly half-full with contrast medium.
- Repeat the above steps on the NaCl side.

The injector is now ready to be filled with contrast medium and NaCl.

5 Operating the injector

This chapter describes how to operate the injector manually, how to work with injection profiles and how to carry out an injection.

Filling the injector with contrast medium and NaCl

Note!
Always fill the injector with contrast medium first and then with the saline solution.

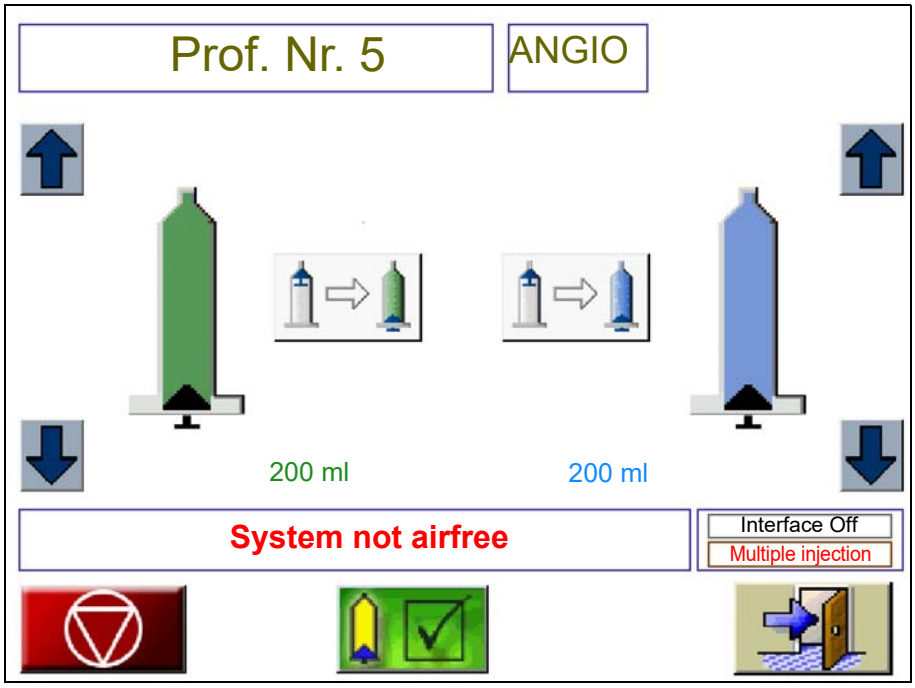
Both syringes are inserted, left for contrast medium, right for NaCl, the tube system is connected, the injector is switched on.
The main window is shown:

In order to fill the syringes, the pistons must first be moved forward.

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
Make sure that the patient is not yet connected to the system!

-  **Call up filling menu** in the main window.

The filling menu is displayed:



Moving the piston forward

-  Touch left button **Piston forward** for the CM piston.

The dialogue message with the confirmation prompt “Attention! Patient must be disconnected! Move piston CM forward?” is shown.

-  Confirm the message.

-  Touch right button **Piston forward** for the NaCl piston.

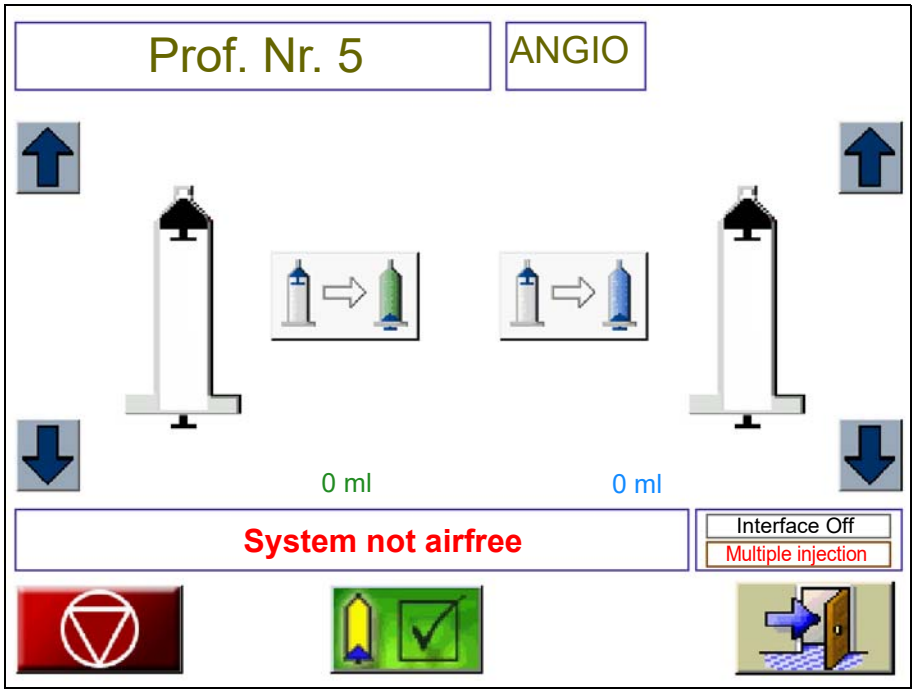
The dialogue message with the confirmation prompt “Attention! Patient must be disconnected! Move piston NaCl forward?” is shown.

-  Confirm the message.

Both pistons of the syringes move forwards into their uppermost position, the remaining volume displayed becomes lower on both sides, the two symbols for the syringes become white.

Note!
When advancing the pistons, the valves may cause a low hissing sound – this is normal.

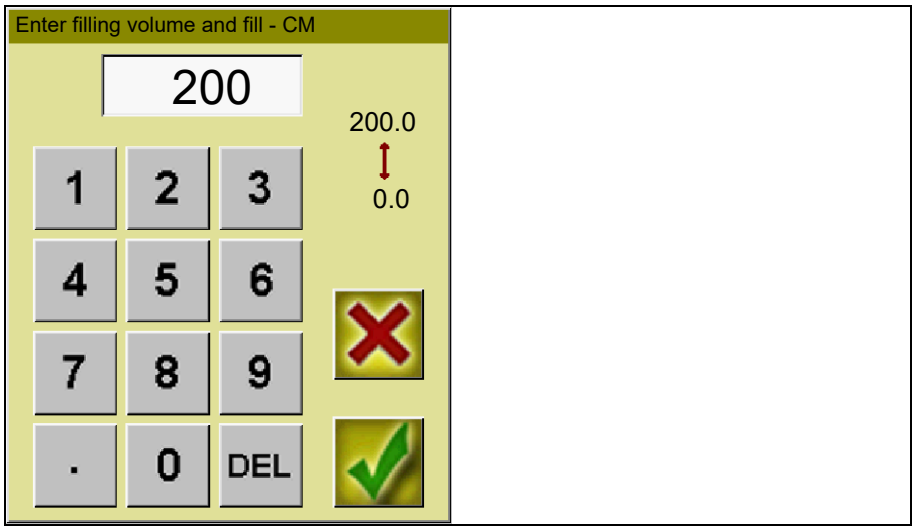
When the pistons are fully extended, the filling menu is shown like this:



Enter filling volume for contrast medium and fill

-  In the filling menu touch the green button **Fill CM syringe** in order to enter the filling volume for contrast medium.

A dialogue window with number buttons is displayed:



The range which you can enter, e.g. 0.0 – 200.0 (ml), is in the top right of the dialogue window **Enter filling volume and fill – CM**.
The current (maximum) value is already specified. You can change the value by entering the value you want on the numeric keypad. If you have accidentally entered the wrong figure, you can delete it with the button **DEL**.

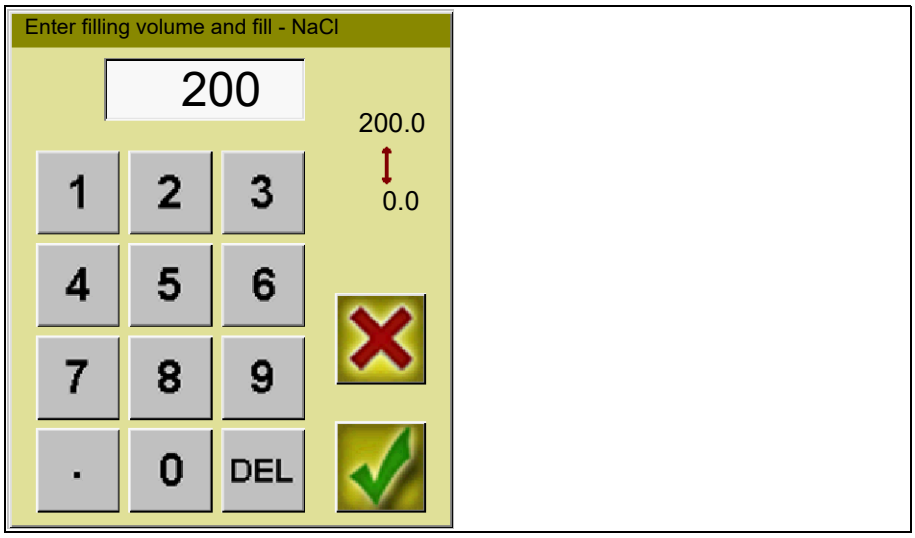
- Enter the filling volume you want.
-  Confirm entry.

The dialogue window **Enter filling volume and fill – CM** is closed. The piston of the syringe for contrast medium moves back.

Enter filling volume for NaCl and fill

-  In the filling menu touch the blue button **Fill NaCl syringe** in order to enter the filling volume for NaCl.

A dialogue window with number buttons is displayed.

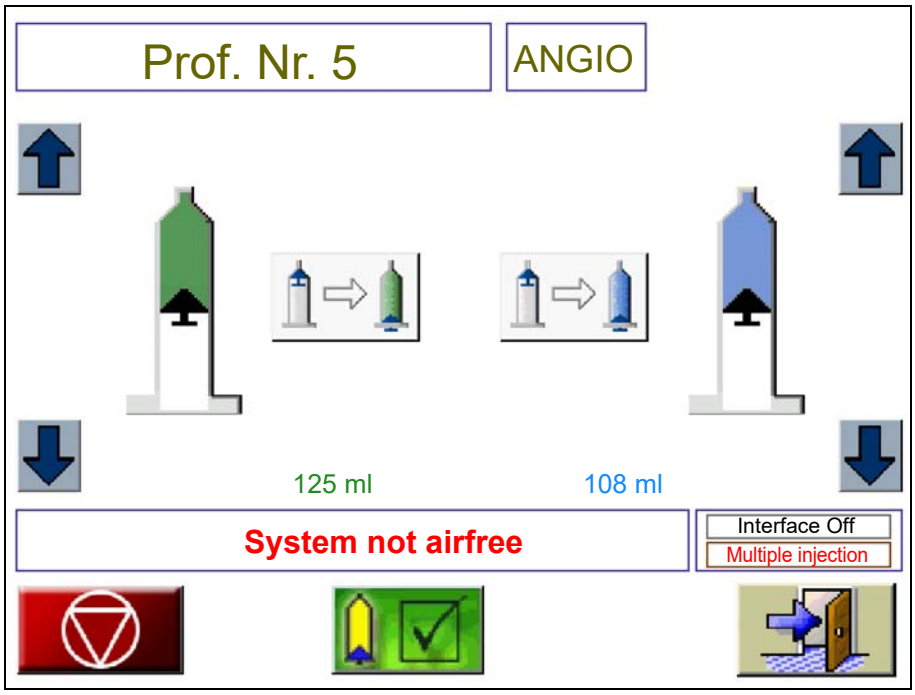


The range which you can enter, e.g. 0.0 – 200.0 (ml), is in the top right of the dialogue window **Enter filling volume and fill – NaCl**.
The current (maximum) value is already specified. You can change the value by entering the value you want on the numeric keypad. If you have accidentally entered the wrong figure, you can delete it with the button **DEL**.

- Enter the filling volume you want.
-  Confirm entry.

The dialogue window **Enter filling volume and fill – NaCl** is closed.
The piston of the syringe for NaCl moves back.

While the piston is filling the contrast medium and NaCl, you see the following display:



-  When the filling procedure is finished, return to the main window.
- Then connect the patient line to the tube system.

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
You must connect the patient line at the latest now to the tube system so that the entire system including the patient line is completely vented.

Venting the tube system

The syringes and the tube system still contain air at the moment.
You must vent the system using the buttons for the manual piston movements.

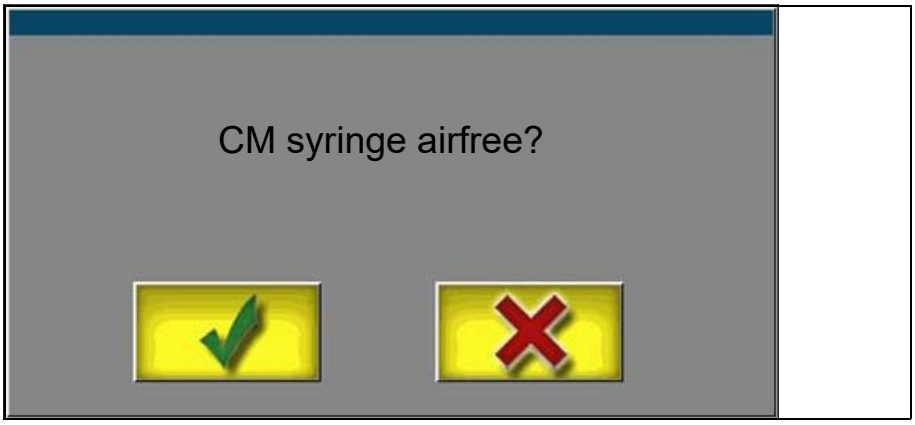
Note!
Firstly, vent the contrast medium side up to the Y-connector and only then the entire system including the patient line with the piston for NaCl.
In this way you save contrast medium.

- Make sure that the patient line is connected to the tube system.
- Swivel the injector unit into the vertical position.
- In the left hand button group on the rear of the control unit press the upper button **Move piston CM forward** and keep it depressed to advance the CM piston.
- To gradually increase the piston speed, also press the button in the middle.
- Keep venting the CM side until there are no more air inclusions just after the Y-connector.
- In the right hand button group on the rear of the control unit press the upper button **Move piston NaCl forward** and keep it depressed to advance the NaCl piston.
- To gradually increase the piston speed, also press the button in the middle.
- Vent the entire tube system including the patient line with the NaCl piston.

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
There must be no more air inclusions in the entire tube system.

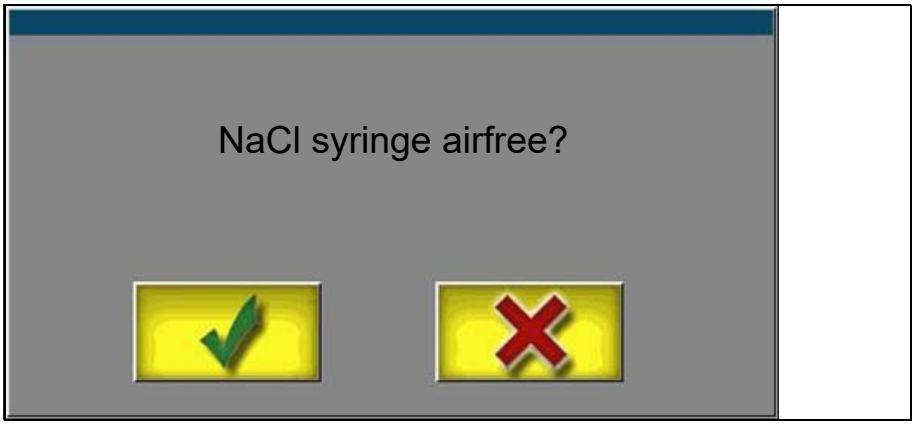
- Keep venting until there are no more air inclusions in the entire tube system including patient line.
-  On completion of venting touch the button **Confirm venting**.

The dialogue message with the confirmation prompt “CM syringe airfree?” is displayed.



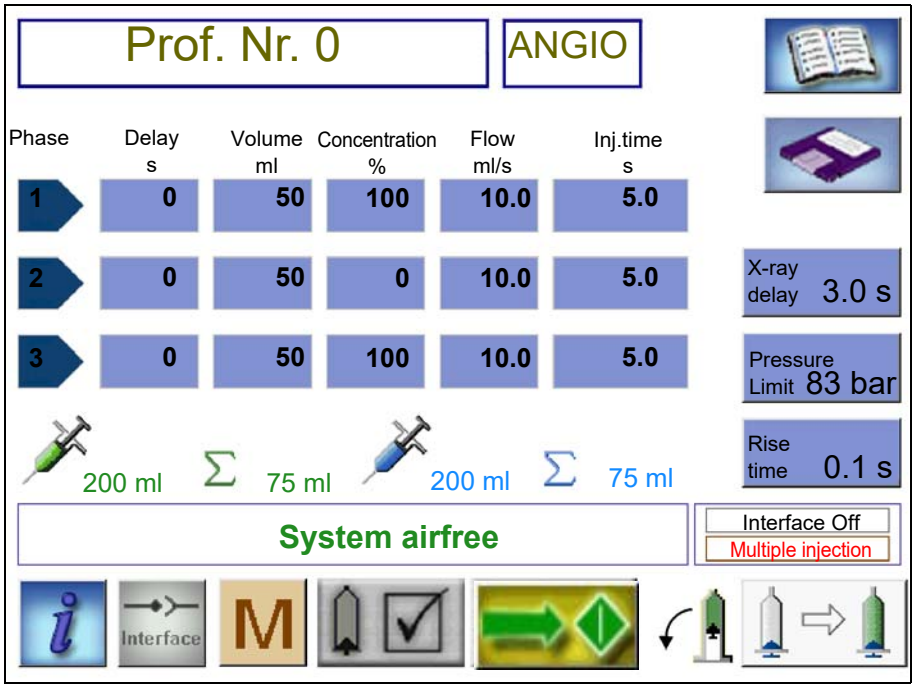
-  Confirm the message.

The dialogue message with the confirmation prompt “NaCl syringe airfree?” is displayed.



-  Confirm the message.

The parameters of the current injection profiles are displayed.
The text field indicates “System airfree” in green.
The **Activate injector** touch button is highlighted in colour and therefore active.



- Swivel the injection unit downwards into the injection position.

The injector is therefore ready for injection.

Changing the maximum operating pressure

You can set the desired injection pressure. The pressure actually reached during injection depends on a number of ambient variables such as the viscosity of the contrast medium, needle diameter of the patient access, set flow rate etc. The pressure is storable with the correspondent profile.

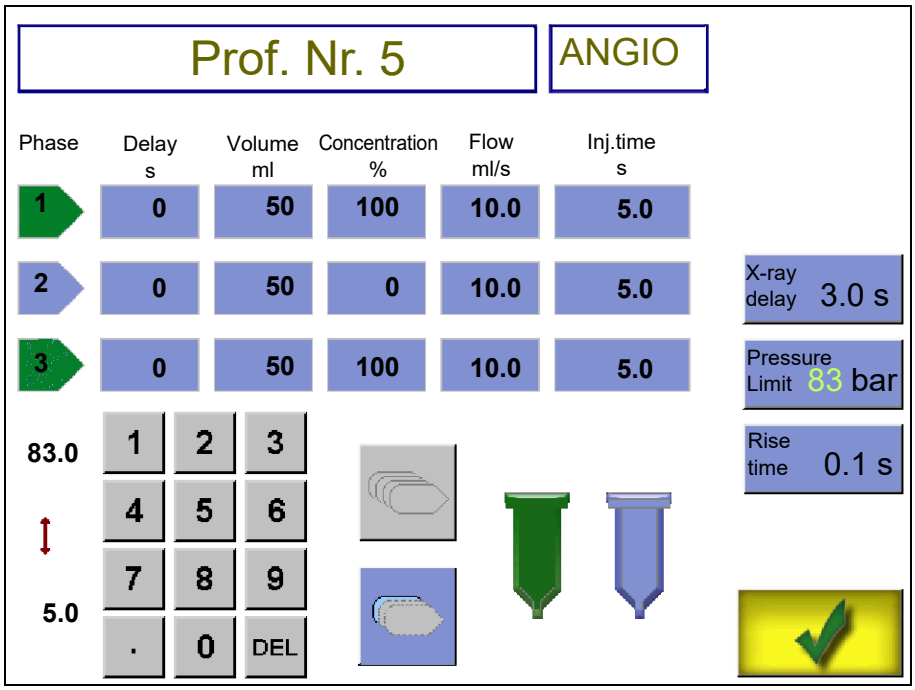
If the set maximum working pressure is reached during the injection, the flow rate is automatically reduced to keep the pressure underneath the pressure limit. If the flow rate can't be adjusted, the injection is stopped.

CAUTION!
Risk for the patient!
Make sure that the maximum pressure set does not endanger the patient.

You can change the maximum operating pressure as follows:

- Touch the button **Pressure limit** in the main window.

The dialogue window to change the injection profiles is displayed.
The current value is marked green.



- Overwrite the value marked using the numeric keypad with a new value.

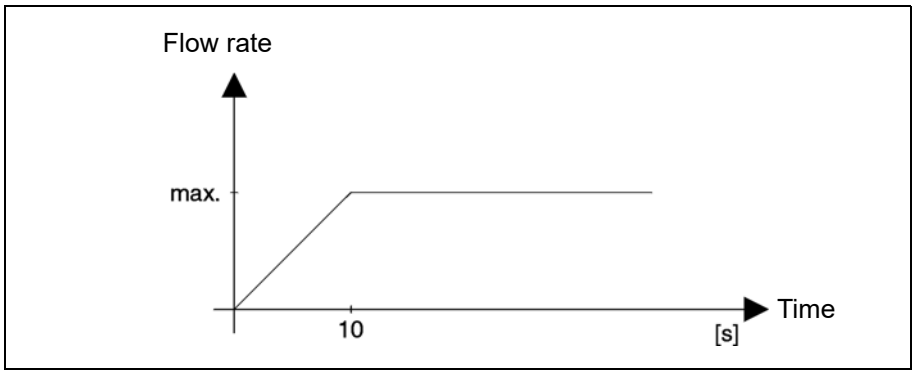
If you have accidentally entered the wrong number, you can delete it with the button **DEL**.

-  Confirm the new value.

Changing the rise time

You can set the desired rise time. The rise time represents the time, which lapses until reaching the maximum flow rate set. The entry range is 0.0 – 10.0 seconds. The rise time is storable with the correspondent profile.

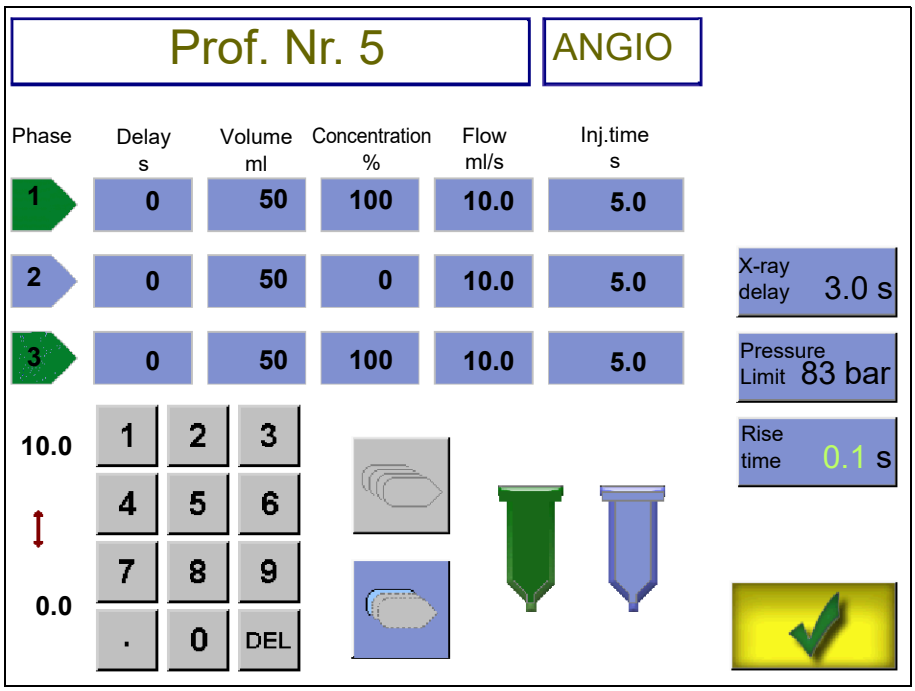
CAUTION!
Risk for the patient!
Make sure that the rise time set does not endanger the patient.



You can change the maximum rise time as follows:

- Touch the button **Rise time** in the main window.

The dialogue window to change the rise time is displayed.
The current value is marked green.



- Overwrite the value marked using the numeric keypad with a new value.

If you have accidentally entered the wrong number, you can delete it with the button **DEL**.

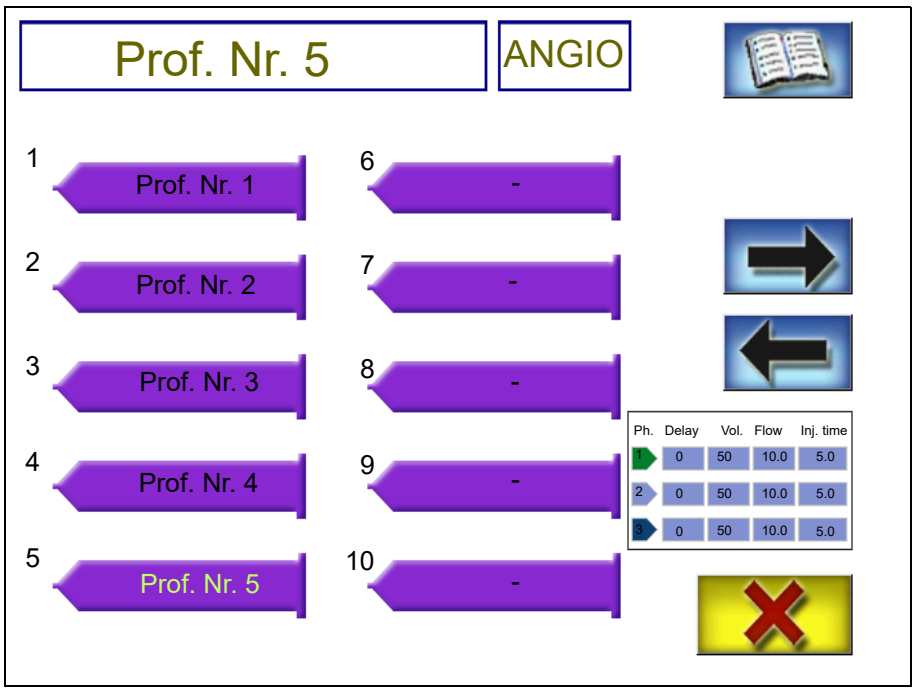
-  Confirm the new value.

Selecting an injection profile

You can create with the injector up to 60 injection profiles in each mode and save them under a profile number. Depending on the application, you call up the profile you want with the injection parameters saved and you can immediately start the injection. For this purpose proceed as follows:

-  **Call up profile** in the main window.

The dialogue window with the injection profiles already available is displayed. The profiles are numbered from 1 to 60. You can determine the profile name as you wish.



If you touch a syringe symbol, the colour of the profile name changes and in the dialogue window on the right you can view the correspondent profile data.

Using the arrow buttons, you can scroll forwards and backwards and in this way view all profile names.

- Touch the syringe symbol of the profile you want to use.
-  **Call up profile**.

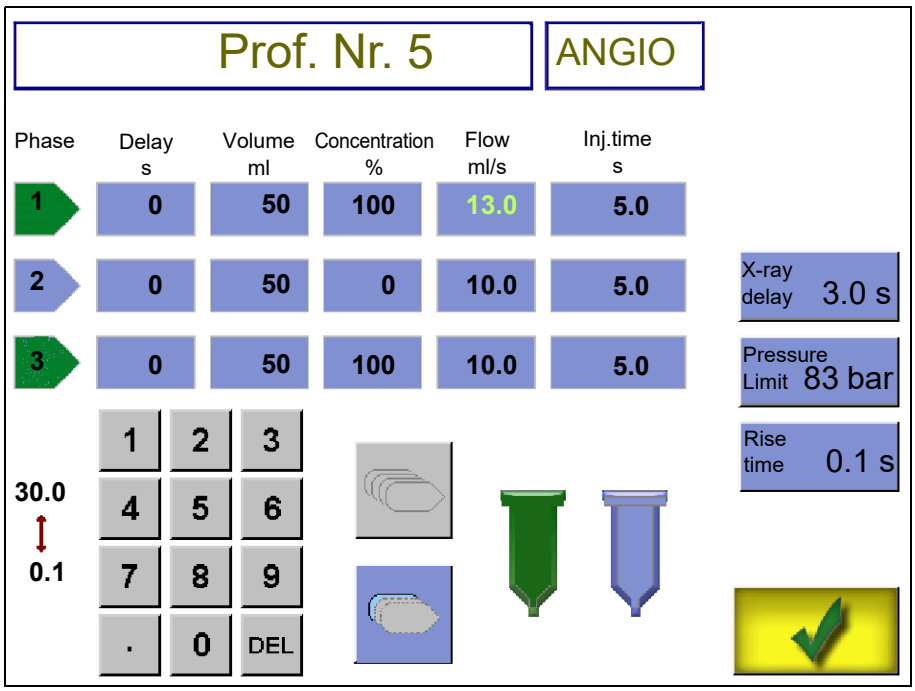
In this way you have selected a profile.
The parameters of this profile (here Prof. Nr. 5) are shown in the main window.

Changing an injection profile

You can change the parameters of an injection profile as and when required. For this, select the profile to be changed, as described in chapter *Selecting an injection profile* on the previous page.

- Touch any of the parameter values in the main window of the selected injection profile.

The dialogue window to change the injection profiles is displayed.



- Overwrite the value marked using the numeric keypad with a new value.

If you have accidentally entered the wrong number, you can delete it with the button **DEL**.

-  Confirm the new value.

Example:
The profile to be changed is displayed. You'd like to change the flow rate of a phase.

- Touch the relevant button with your finger.

The entry range of this value is indicated on the left of the numeric keypad.

- Overwrite the value marked using the numeric keypad with a new value.
-  Confirm the new value.

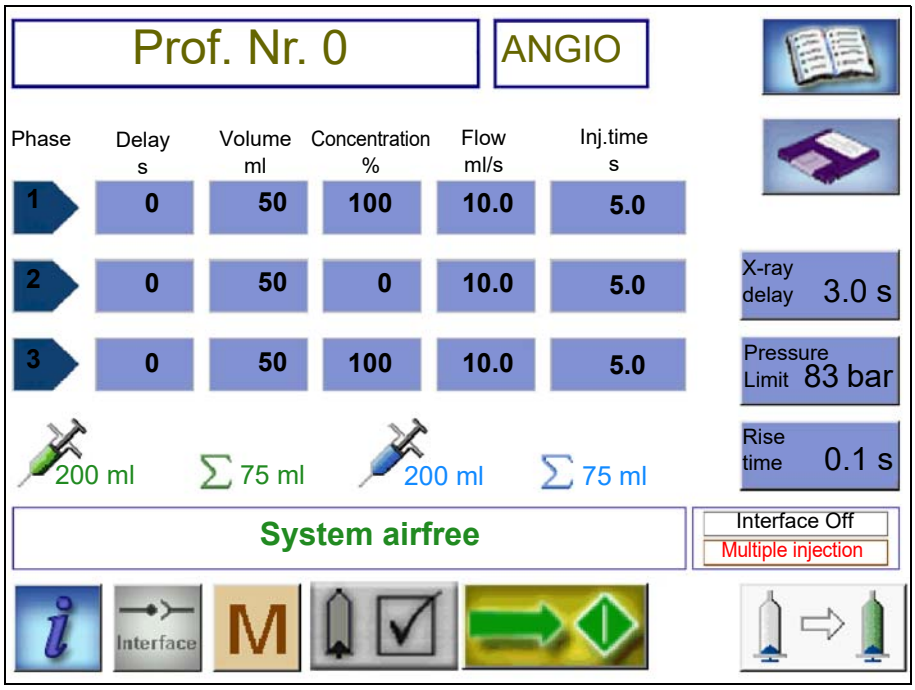
You edit the other values, such as delay, volume and concentration in the same way.

Note!
Observe the following before entering the concentration:
– 100 % means only contrast medium
– 40 % means 40 % contrast medium, 60 % NaCl
– 0 % means only NaCl

Note!
Some values have a reciprocal effect of one another.
If you change the volume value and the flow rate, the injection time of this phase changes automatically.
If you change the injection time, the flow rate is changed accordingly.
If you have not yet entered a volume value or if you reset the volume to zero, the volume will be determined automatically after you have entered the values for the flow rate and the injection time.

CAUTION!
Risk of serious injuries!
Before entering the flow rate (up to 30 ml/s possible), monitor the constitution of the patient to be examined!

The system displays the changed value in the main window. The profile name has changed automatically. **Prof. Nr. 0** is now shown in the main window.



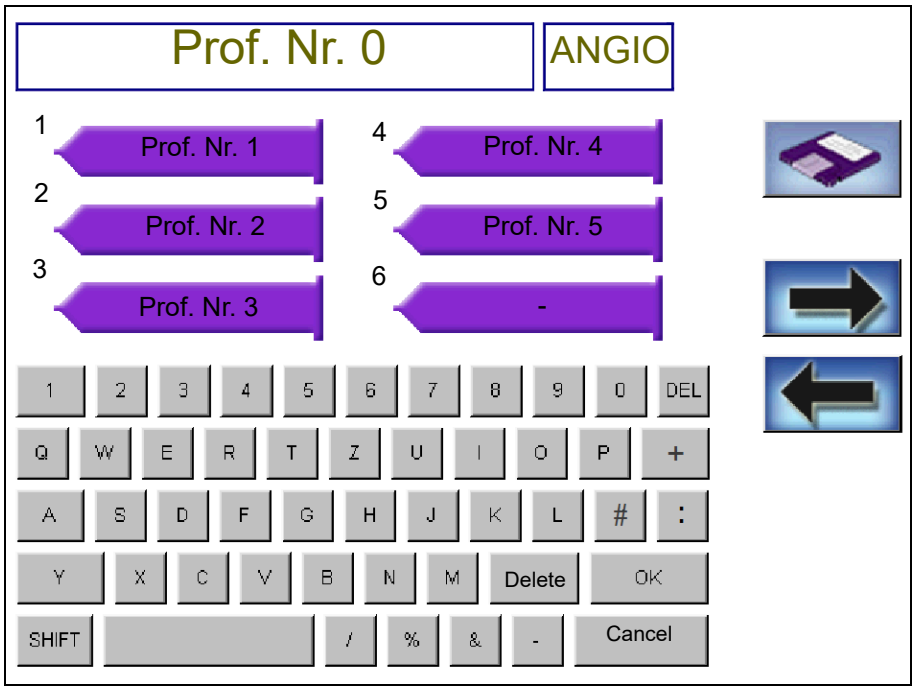
Saving changes

If you have made changes to the parameters of an injection profile, you must save the profile. However, after a change the original name of the profile is no longer on the screen but **Prof. Nr. 0**.

ATTENTION!
Risk of data loss!
Save changes to parameters under a profile number.
Otherwise the changes are lost when you switch off the injector.

-  Touch the button **Save profile** in the main window.

The dialogue window to save the injection profiles is displayed.



Using the arrow buttons, you can scroll forwards and backwards and in this way view all profile names.

Here you have two possibilities:

– *overwriting an existing profile*, see next paragraph, or
– *saving the changes under a new profile*, see page 69.

Overwriting an existing profile

If you want to overwrite an already existing profile,

- touch the appropriate syringe symbol.

The writing in the syringe symbol is green and the name of the selected profile number is now in the text field for the profile name.

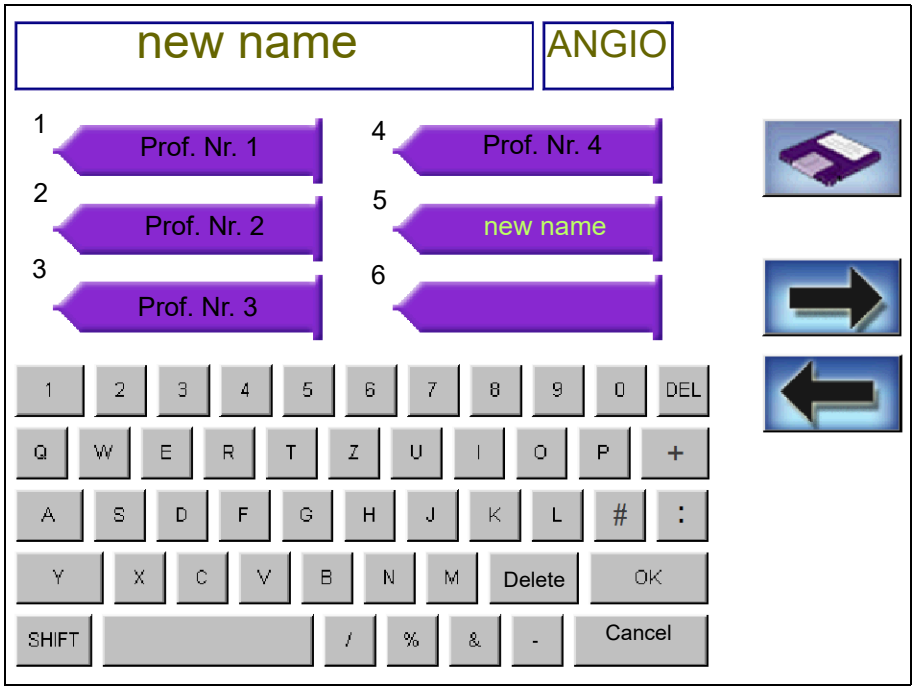
Entering a profile name

If you want to change the name of this profile:

- touch the syringe symbol with the number you want.

You can enter the new profile name using the keyboard. You can delete individual letters with the **DEL** button or delete the entire name with the **Delete button**. You can write capital letters with the **SHIFT**-button.

- Enter a new profile name.



- Touch the **OK** button on the keypad to confirm the entry.

The main window displays the changed profile.

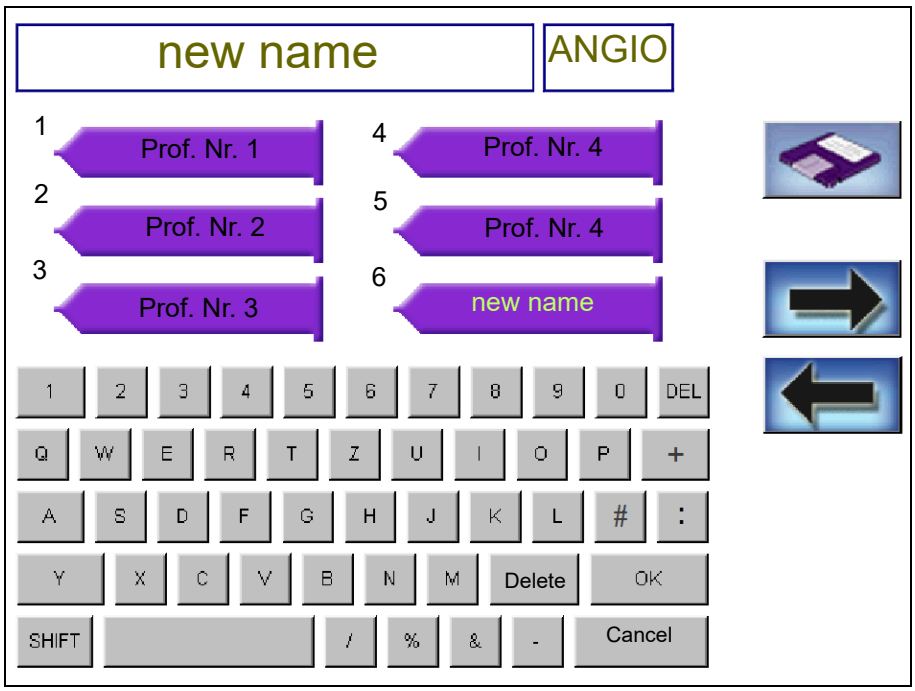
Saving changes under a new profile

If you want to save the changed profile under a new profile,

- select an empty syringe symbol.

The marking in the syringe symbol is green and is also shown at the top in the text field.

- Enter the name for the new profile with the keyboard.



- Touch the **OK** button on the keypad to confirm the entry.

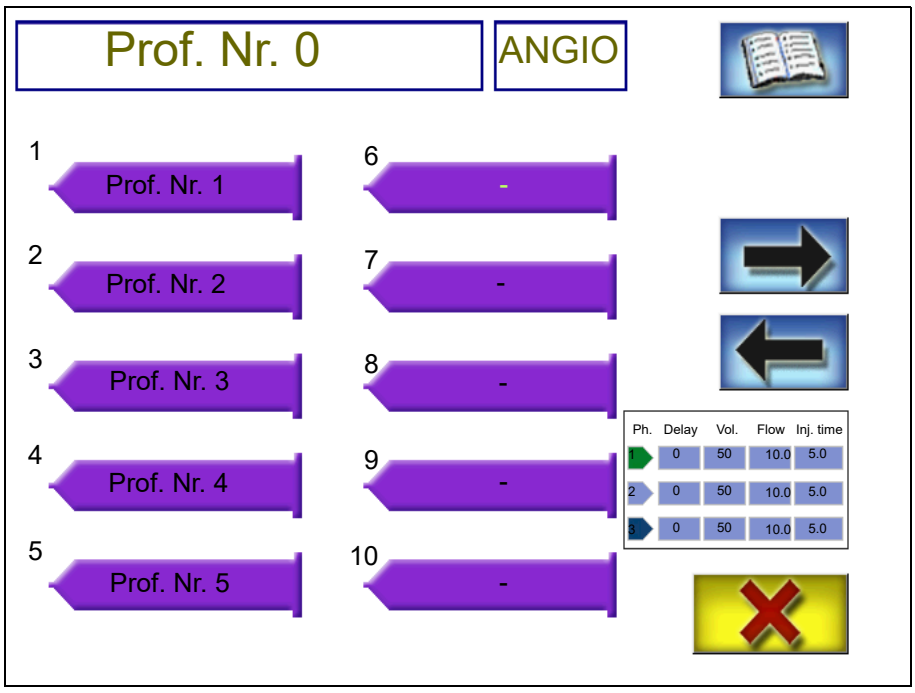
The main window displays the newly created profile.

Creating a new profile

If you want to create a completely new profile, you must first select the relevant syringe symbol. For this purpose:

-  Touch the button **Call up profile** in the main window.

The list with the profiles is displayed.



Using the arrow buttons, you can scroll forwards and backwards and in this way view all profile names.

- Choose the empty syringe symbol of the new profile and touch it.
-  **Call up profile**.

In the main window you have opened an empty profile with only one phase which you can now fill with the injection parameters you want.

- Enter all the profile data and parameters you want.
-  **Save profile**.
- Select the syringe symbol you want again.

The touch screen displays the input mask for the profile name, see page 68.

- Enter the name for the new profile with the keyboard.

- Touch the **OK** button to confirm the entry.
-  Touch the button **Save profile**, to save the new profile with the new profile name.

The main window displays the newly created profile.

Adding a new phase

You can add a new phase (a maximum of 3 are possible) to an existing profile with, for example, 2 phases.
The main window of the relevant profile is displayed.

- Touch any of the parameter values in the main window of the selected injection profile.

The dialogue window to change the injection profiles is displayed.

-  **Add a phase**.
- Touch parameter fields of the new phase.
- Enter the individual values in the input mask using the number buttons.
-  Confirm the new value.

The main window of the relevant profile is displayed.

-  Touch the button **Save profile**.
- Touch the appropriate syringe symbol.

The lettering in the syringe symbol is green and is also shown at the top in the text field.

- Touch the **OK** button to confirm the entry.
-  Save the profile under the profile name selected.

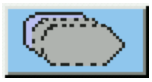
The changed profile is saved and displayed in the main window.

Deleting a phase

You can completely delete the last phase from a profile.
Proceed as follows:

- Touch any of the parameter values in the main window of the selected injection profile.

The dialogue window to change the injection profiles is displayed.

-  **Delete phase**.

The last phase is deleted.

-  Confirm changes.

The main window of the relevant profile is displayed.

-  Touch the button **Save profile**.
- Touch the appropriate syringe symbol.

The lettering in the syringe symbol is green and is also shown at the top in the text field.

- Enter a new profile name.
- Touch the **OK** button to confirm the entry.
-  Save the profile under the profile name selected.

The changed profile is saved and displayed in the main window.

Performing an injection

CAUTION!
Risk of fatal or serious injuries due to air embolisms!

- Do not connect the patient to the system until you have vented the syringes and the tube system.
- Vent the syringes and the tube system every time after filling the injector with contrast medium or saline solution.
- Make sure before every injection that there are no air inclusions in the syringes and in the connected tube systems.
- Only start an injection when the syringes are in the lowered position (injection position).
- Make sure before every injection that the injection parameters shown on the display do not endanger the patient.

The green syringe symbol at the bottom edge of the main window moves for as long as the injection unit is in the injection position.

- Swivel the injection unit out of the vertical position downwards into the lowest position (injection position).

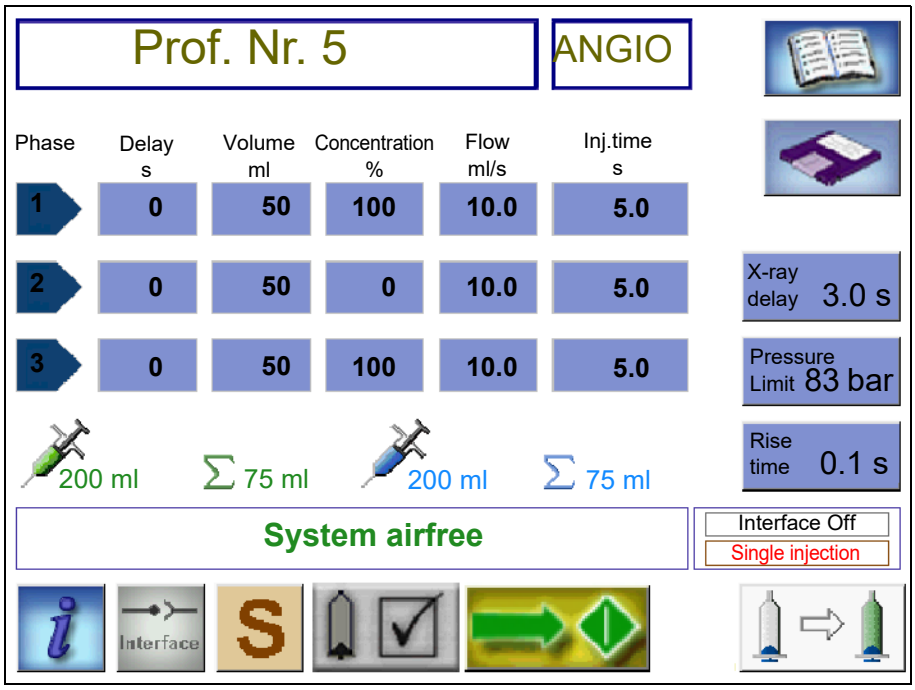
It is ensured in this injection position that possibly remaining air bubbles in the syringe rise to the piston and are not injected.

- Make sure once again that the tube system and the patient line do not contain any air inclusions.
- Remove protective cap from the patient line and connect the patient line to the patient access.

CAUTION!
Risk of uncontrolled supply of contrast medium due to hydrostatic pressure compensation!
Make sure that the patient and the syringes are at the same level.

CAUTION!
Risk of uncontrolled supply of contrast medium!
The ongoing injection is completely interrupted when you release the button!
In **Multiple injection mode** doesn't appear any message indicating the injection end. If you press the button of the hand switch again, a completely new injection process starts.

The injector is vented. On the touch screen, the button **Activate injector** is active.



Starting the injection in Angio mode

Activate single/multiple injection

M indicates, that **Multiple injection** is activated.

- 

Touch the button **M** to activate **Single injection**.

Single injection is then displayed on the right of the text field.

S indicates, that **Single injection** is activated.

- 

Touch the button **S** to activate **Multiple injection**.

Multiple injection is then displayed on the right of the text field.

- 
Activate the injector.

Maintaining vein access with the KVO function

Before performing the injection, you can now establish whether you want to activate the Keep Vein Open (KVO) function. The KVO function ensures that the access to the vein is retained during prolonged examinations.

If you activate this function, the injector injects the desired amount of NaCl at the time intervals set. In order to set the KVO-volume and the KVO-time, see page 41.

- 

If desired, activate KVO.

– If the KVO function is activated, the button is green.
– If the KVO function is deactivated, the button is grey.

To start the injection:

- press the green button of the hand switch and keep it depressed until injection end.

Note!
The injection is only performed if you press the green button of the hand switch and keep it depressed.
As soon as you release the button of the hand switch, the injection is interrupted.

The indications on the display change, see *During the injection* on page 78.

NaCl flushing function

By pressing the blue button of the hand switch in Angio mode and keep it depressed, NaCl flushing is done. In **Single injection mode** NaCl flushing is possible before the injection, in **Multiple injection mode** flushing is possible before and after the injection. For setting the NaCl flushing speed, please read chapter 4, section *Setting the touch screen* on page 38.

Starting the injection in CT mode

-  Activate the injector.

Maintaining vein access with the KVO function

Before performing the injection, you can now establish whether you want to activate the Keep Vein Open (KVO) function. The KVO function ensures that the access to the vein is retained during prolonged examinations.

If you activate this function, the injector injects the desired amount of NaCl at the time intervals set. In order to set the KVO-volume and the KVO-time, see page 41.

-  If desired, activate KVO.

– If the KVO function is activated, the button is green.
– If the KVO function is deactivated, the button is grey.

To start the injection:

- press the green button of the hand switch or of the remote control.

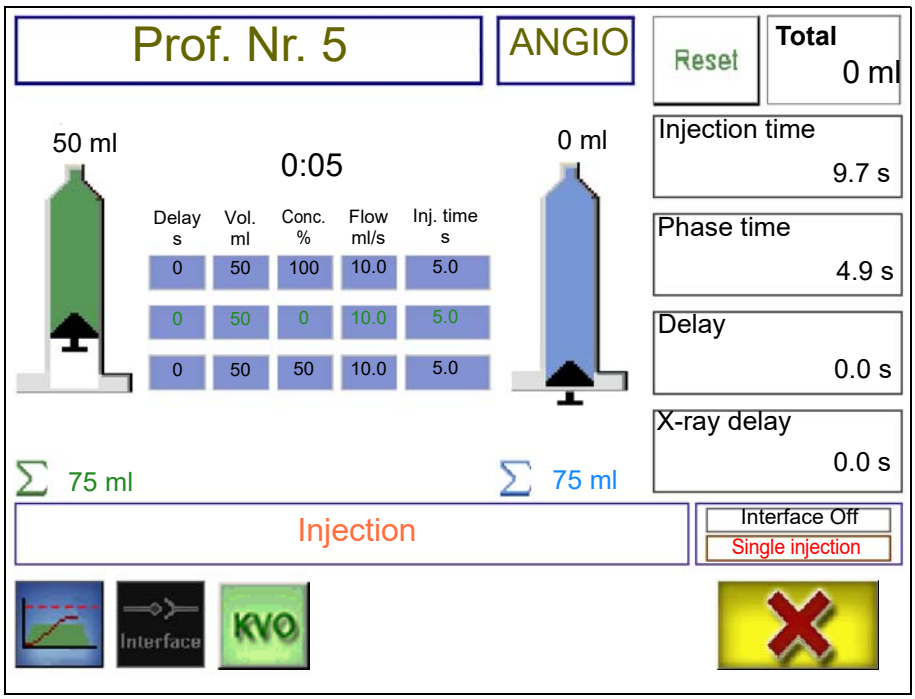
The injection starts.

The indications on the display change, see *During the injection* on page 78.

During the injection

Displaying injection data

After injection start you can follow the individual phases and information about the contrast medium and NaCl injected so far and the amount remaining, the phase time, delay and injection time. The stopwatch counts forwards. The time values of the injection on the right in the window count backwards to zero. The injected volume counts forwards. In the field **Total**, the total contrast medium volume injected so far – also throughout several injections – is displayed, until the **Reset** button is pressed.

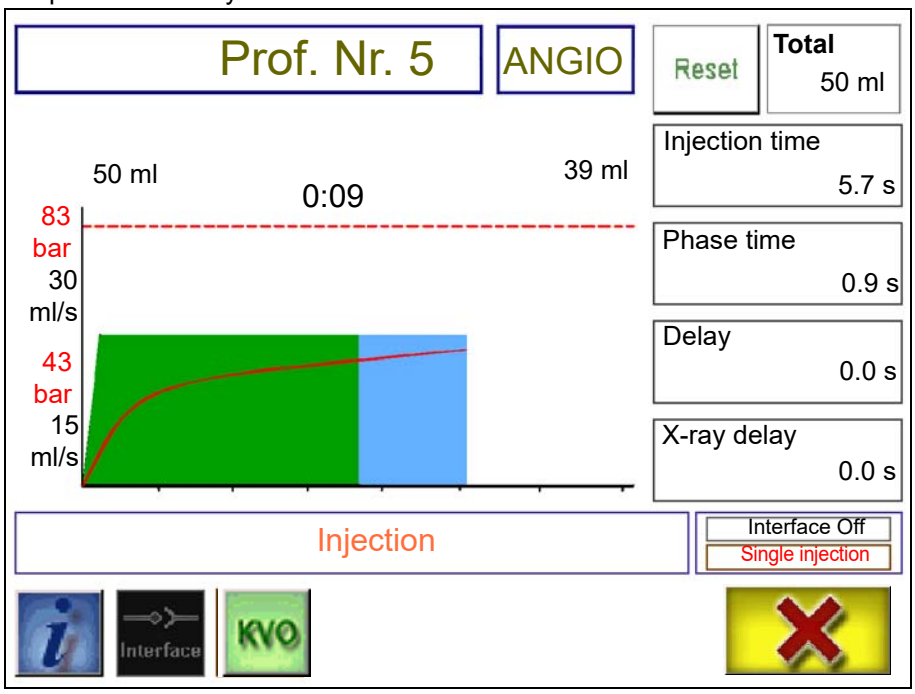


Displaying flow rate and pressure curve

During injection you can display the pressure curve. For this:

-  In the injection window, **display pressure curve**.

In the injection window you see a diagram that shows the current flow rate and the pressure history.



The flow rate is illustrated by the green field for contrast medium and by the blue field for NaCl and is running with the injection time.

In this example the flow rate is shown on a scale from 0 to 15 ml/s. If the flow rate is higher than 15 ml/s, from 0 to 30 ml/s.

The red curve illustrates the pressure history.

The dashed line shows the pressure limit.

Note!
If the pressure limit (maximum pressure) is reached during the injection, the flow rate, and thus the pressure, is reduced.

To go back into the injection window with the injection parameters:

-  Touch the button **Info**.

The injection window is displayed again.

Interrupting the injection in Angio mode

You can interrupt an ongoing injection at any time, therefore:

- Release the button of the hand switch.

The injector stops the injection.

CAUTION!
Risk of uncontrolled supply of contrast medium!
The ongoing injection is completely interrupted when you release the green button of the hand switch!
In **Multiple injection mode** doesn't appear any message indicating the injection end. If you press the button of the handswitch again, a completely new injection process starts.

Depending on the selected mode, proceed as follows:

Multiple injection

In **Multiple injection mode** you can now either

– start a new injection by pressing again the green button of the hand switch,

or

– leave the injection window by touching the button **Reject**.

Single injection

In **Single injection mode** appears the message "Injection finished".

- Confirm the message.

The main window is shown.

Interrupting the injection in CT mode

You can interrupt the injection at any time by means of the hand switch or the remote control.

- Press the green button of the hand switch or the button **Continue** on the remote control.

The injector stops the injection. You have two possibilities now:

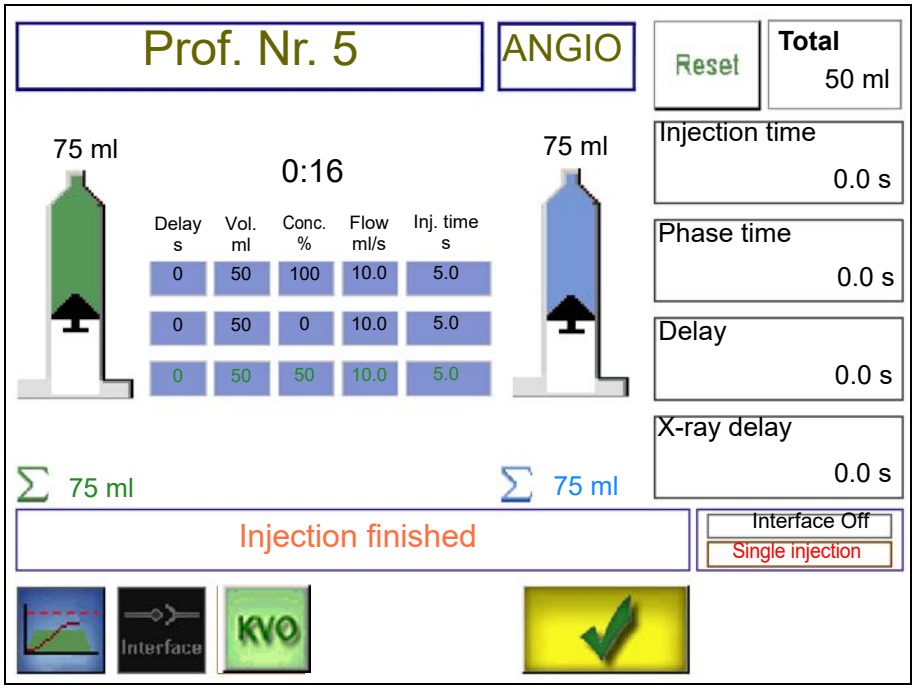
- Touch the button **No/Reject** on the injector or the remote control, if you want to interrupt the injection completely.

or

- Press the green button of the hand switch again or touch the button **Continue** on the remote control, if you want to continue the interrupted injection.
  The unit then continues the injection at the point where it was interrupted.

Injection end

After all phases have run through, the program stops.

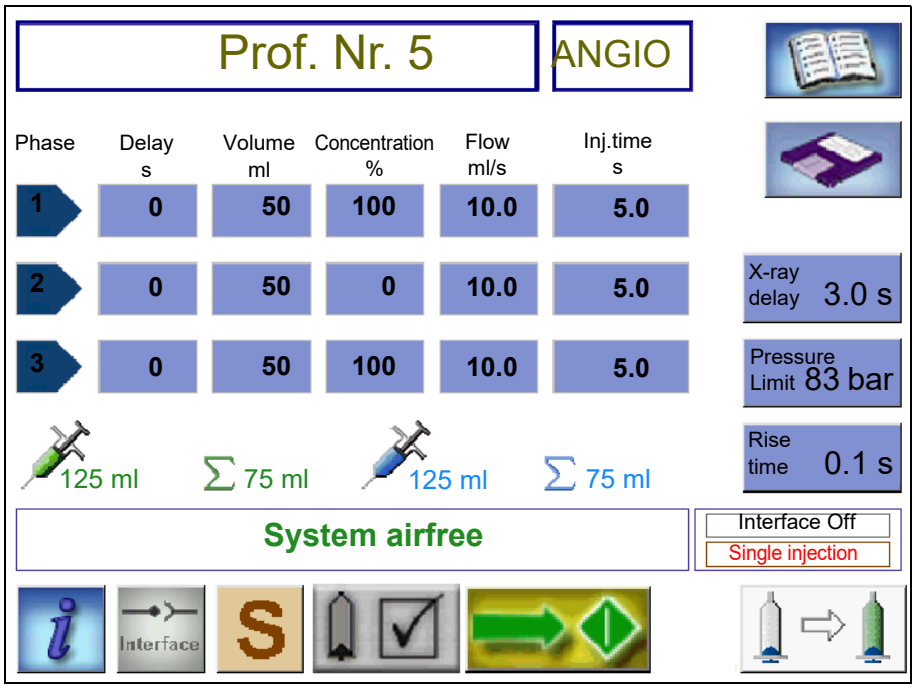


Note!
The program run stops when all phases have passed through. If the KVO function has been activated, NaCl is injected until you confirm the program end.

The message "Injection finished" appears.

- In Angio mode, release the button of the hand switch.
-  Confirm the end of the injection.

The main window is shown. You can read off the remaining quantities of contrast medium and saline solution near the syringe symbols.



- When the examination is over, disconnect the patient line from the patient access and dispose of the consumables.

CAUTION!
Risk of infection!
Replace the consumables with new ones after they have been used once. Otherwise you jeopardise your patients' health.

Observe the applicable hygiene regulations!

If you want to stop working with the injector, read and follow the instructions in the chapter *Post-examination work* on page 88.

Replenishing the injector with contrast medium/NaCl

When the contrast medium or NaCl filling of the syringes is coming to an end and you want to perform more injections or if the message “CM volume too low” or “NaCl volume too low” appears, top up the syringes.

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
Make sure that the patient is not connected to the system!

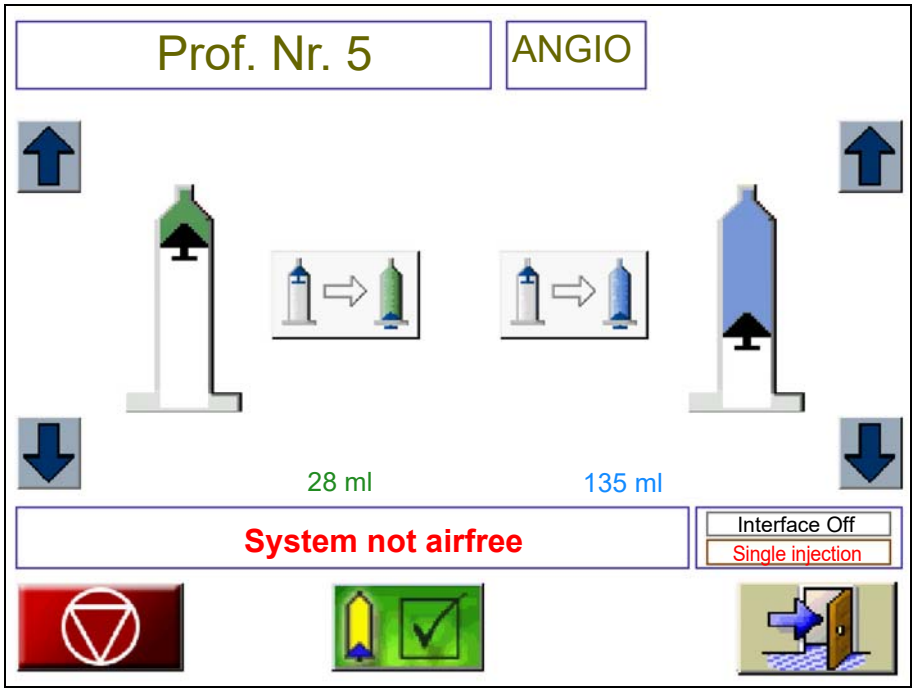
How to proceed is described here taking the example of contrast medium.

- Confirm message “CM volume too low”.

The main window of the touch screen is displayed.

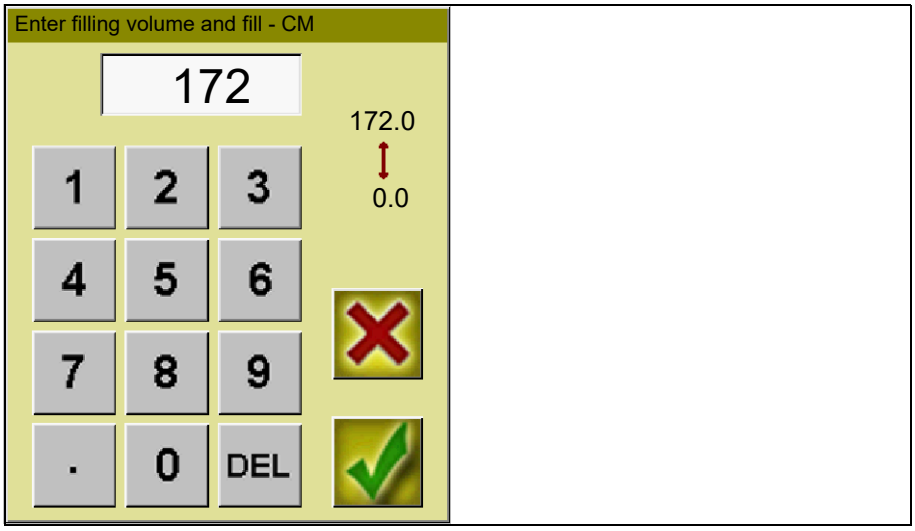
- Remove the patient line from the patient access.
-  **Call up filling menu** in the main window.

  The filling menu is displayed:



-  In the filling menu touch the green button **Fill CM syringe** in order to enter the filling volume for contrast medium.

The dialogue window **Enter filling volume and fill – CM** is displayed:



The range which you can enter, e.g. 0.0 – 172.0 (ml), is in the top right of the dialogue window.
The current (maximum) value is already specified, in this example that is 172 ml as 28 ml are available as the remaining volume. You can change the value by entering the value you want on the numeric keypad. If you have accidentally entered the wrong figure, you can delete it with the button **DEL**.

- Enter the filling volume you want.
-  Confirm entry.

The dialogue window **Enter filling volume and fill – CM** is closed.
The piston of the syringe for contrast medium moves back and draws in the contrast medium.

-  When the filling procedure is finished, return to the main window.

After filling you must vent the complete system, see next section.

Venting after replenishing

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
You must connect the patient line at the latest now to the tube system so that the entire system including the patient line is completely vented.

- Make sure, that the patient line is connected to the corresponding tube system.

The syringes and the tube system still contain air at the moment. You must vent the system using the buttons for the manual piston motions.

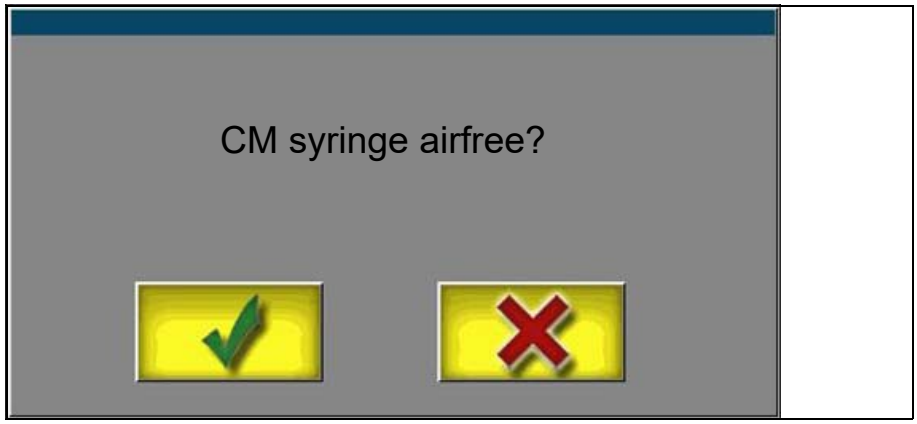
Note!
Firstly, vent the contrast medium side up to the Y-connector and only then the entire system including the patient line with the piston for NaCl.
In this way you save contrast medium.

- Swivel the injection unit into the vertical position.
- In the left hand button group on the rear of the control unit press the upper button **Move piston CM forward** and keep it depressed to advance the CM piston.
- To gradually increase the piston speed, also press the button in the middle.
- Keep venting the CM side until there are no more air inclusions just after the Y-connector.
- In the right hand button group on the rear of the control unit press the button **Move piston NaCl forward** and keep it depressed to advance the NaCl piston.
- To gradually increase the piston speed, also press the button in the middle.
- Vent the entire tube system including the patient line with the NaCl piston.

CAUTION!
Risk of fatal or serious injuries due to air embolisms!
There must be no more air inclusions in the entire tube system.

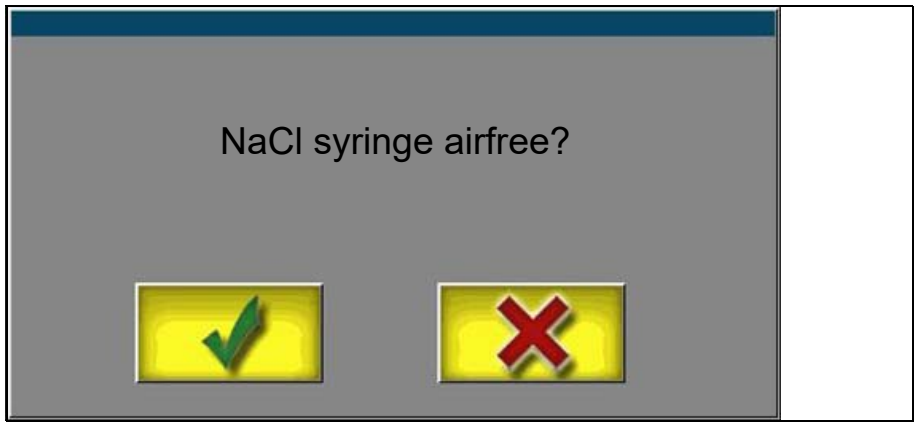
- Keep venting until there are no more air inclusions in the entire tube system including patient line.
-  On completion of venting touch the button **Confirm venting**.

The dialogue message with the confirmation prompt "CM syringe airfree?" is displayed.



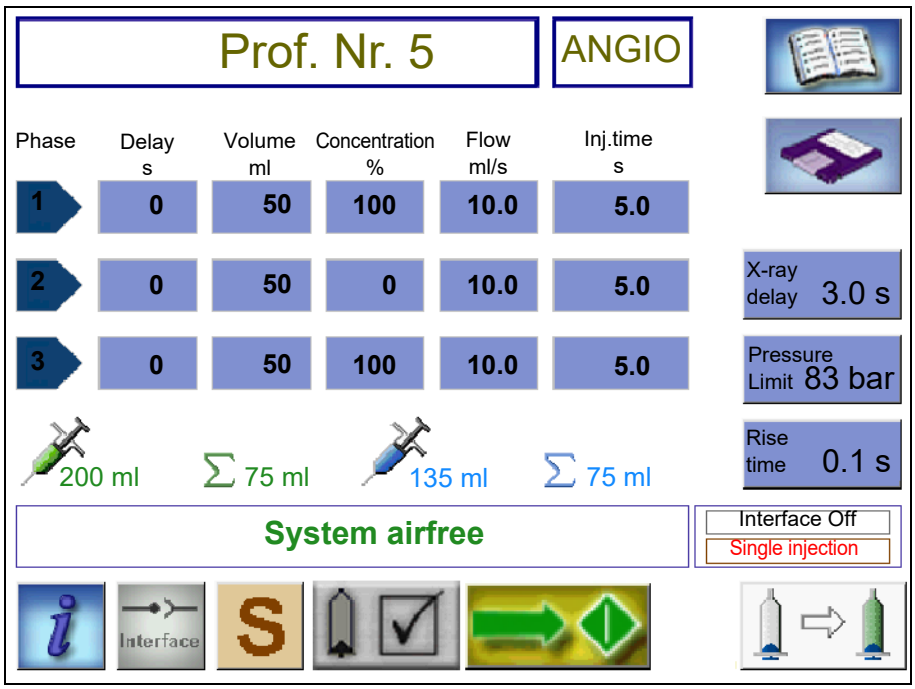
-  Confirm the message.

The dialogue message with the confirmation prompt "NaCl syringe airfree?" is displayed.



-  Confirm the message.

The parameters of the current injection profiles are displayed.
The text field indicates "System airfree" in green.
The **Activate injector** touch button is highlighted in colour and therefore active.



- Swivel the injection unit downwards into the injection position.

The injector is again ready for injection.

Post-examination work

- When the examination is over, disconnect the patient line from the patient access.
- Disconnect the tube system from the syringes.
- Dispose of the consumables.

CAUTION!
Risk of infection!
Replace the consumables with new ones after they have been used once.
Otherwise you jeopardise your patients' health.

Observe the applicable hygiene regulations!

- In the filling menu, *move both pistons back* see page 45.
- Remove the syringes with pressure jackets.
- Properly dispose of all consumables in accordance with the regulations on waste disposal and hygiene applying to the operator.
- Press the red button **OFF** to switch the injector off.
- Connect the power supply unit to the injector in order to charge the battery cells for use the next day.

Note!
MEDTRON recommends switching off the injector for 5 hours at least once a week and connecting the power supply unit in order to optimise the charging process.

ATTENTION!
Risk of damage to the battery cells!
Make sure that the injector is switched off and connected to the power supply unit during non-operating periods in order to prevent damage to the battery cells.

You can disconnect the injector from the mains supply by pulling out the mains plug.

6 Annex

Waste disposal

Do not put old devices to the normal domestic waste!
MEDTRON undertakes to take back its old devices as well as electric and electronic accessories, such as chargers, remote controls and similar in order to avoid environmental pollution caused by electronic waste.

The consumables are to be disposed of in accordance with the regulations on waste disposal and hygiene applying to the operator, in order to avoid any risk of infection.

Safety inspections and maintenance

CAUTION!
Risk of injury to operator and patient!
Maintenance and repair work may only be performed by the MEDTRON Customer Service or persons trained and authorised by MEDTRON. Trained and authorised persons will receive the documents necessary for the maintenance and safety inspections from MEDTRON.

– *FB 07.20.16 Service report injectors*

Maintenance and repair work on all parts of the injector and on all connected and attached accessories must not be performed while a patient is connected to the injector.

MEDTRON recommends annual maintenance and an annual safety inspection for the injector. The maintenance work is performed by staff trained and authorised by MEDTRON. Regular maintenance ensures the proper functioning of the injector.

Safety inspections and maintenance work should be certificated and documented in the medical devices logbook.

Cleaning and storage

Remove any consumables from the injector immediately after use and dispose of them properly. Consumables must not be sterilised and reused. Remove all dirt caused by contrast medium with warm water before the dirt dries in.

ATTENTION!
Risk of malfunctions of the Accutron HP-D!
Do not immerse the injector in water!
Do not use any aggressive cleaning agents or solvents. Warm water and a mild soap are sufficient.

To disinfect the Accutron HP-D, we recommend mikrozid AF liquid or mikrozid AF wipes from Schülke & Mayr GmbH. Do not use any aggressive disinfectant to disinfect the injector.

The front surface of the touch screen should be kept free of dirt, dust, finger prints and other materials that could degrade optical properties.

For best results, use a clean microfibre cloth and any commercially available window cleaner to clean the touch screen.

ATTENTION!
Risk of damage of the touch screen!
Do not use any abrasive to clean the touch screen.
Do not apply the cleaning solution directly to the touch screen surface but to the cloth.

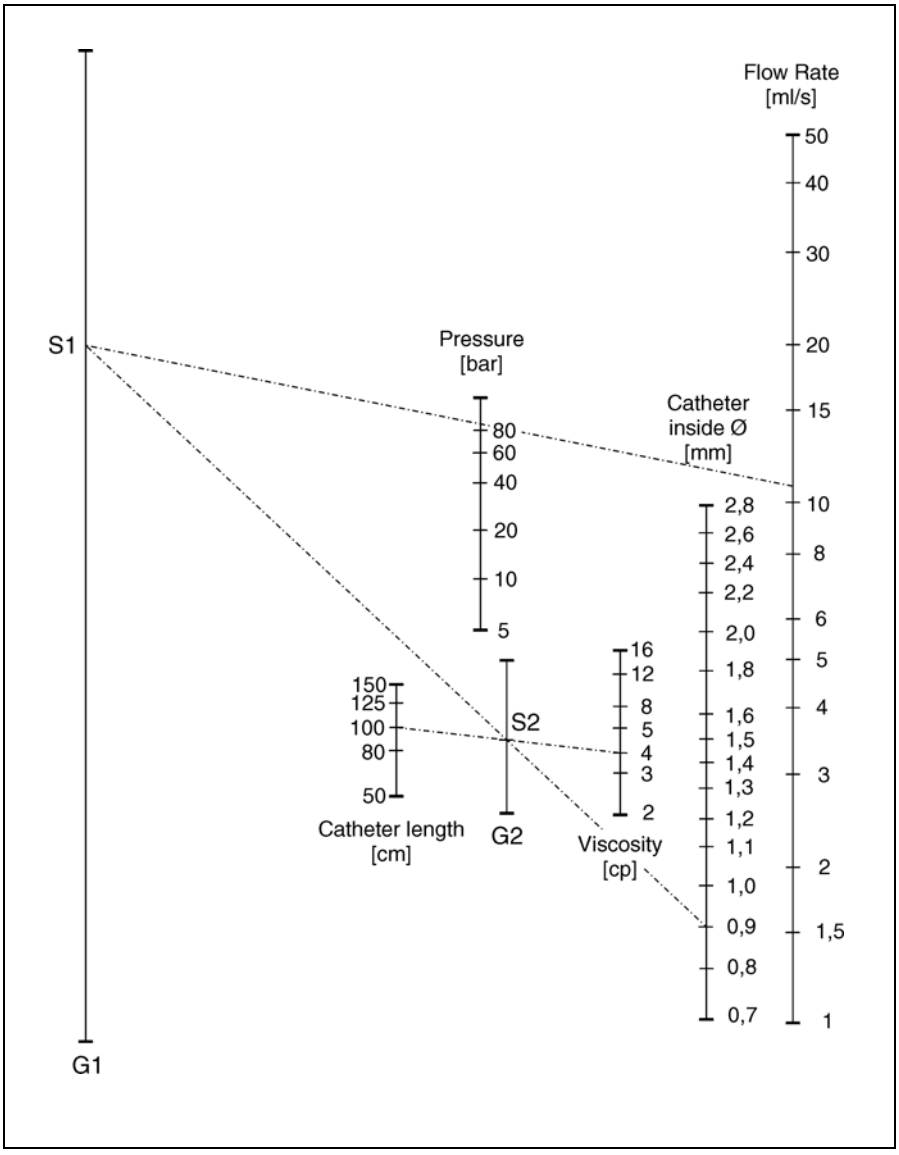
In the case of prolonged breaks in operation, store the Accutron HP-D in a safe place where it is protected against dust and moisture.

Dependence of pressure and flow rate

The pressure in the syringe, patient line and catheter depends on the following factors:

- viscosity of the contrast medium,
- length of the patient line,
- length of the catheter,
- inside diameter of the catheter and
- flow rate set

The following diagram shows the dependencies of these factors in graphic form:



Example:

The following factors are given in the previous diagram:

Viscosity:	4 cp
Catheter length:	100 cm
Catheter inside diameter:	0.9 mm

Proceed as follows to determine the maximum pressure and the corresponding flow rate:

- Using the specified values, draw a connecting line between the scales for **Catheter length** and **Viscosity**.

As a result you obtain the intersection point S2 on the line G2.

- Then draw a connecting line between the specified value on the scale **Catheter inside diameter** and the intersection point S2 and extend it to the line G1.

As a result you obtain the intersecting point S1 on the line G1.

You have now two possibilities:

- Draw a line from the intersection point S1 through the specified maximum **pressure** to the scale for the **flow rate**: As a result you can read off the maximum flow rate possible,

or

- draw a line from the intersection point S1 to the maximum **flow rate** you want: As a result you can read off the corresponding pressure required on the **pressure** scale.

In our example the given factors and a maximum pressure of 83 bar produce a maximum flow rate of 11 ml/s.

System messages

The following table contains system messages which indicate either faults in the injector or incorrect operation. Using the following table, try to eliminate the cause of the fault in question.
If the cause remains unclear and the suggestions for remedy prove unsuccessful, please contact the MEDTRON Customer Service.

Message/Error	**Possible cause and remedy**
CM volume too low	There is too little contrast medium in the syringe to implement the injection profile. Acknowledge message and *replenish contrast medium*, see page 83.
NaCl volume too low	There is too little NaCl in the syringe to implement the injection profile. Acknowledge message and *replenish NaCl*, see page 83.
CM/NaCl volume too low. Adjust profile automatically?	The amount of contrast medium/NaCl in the syringe is too low to perform the injection profile. The injector proposes to adjust the volume in order to be able to perform the injection. Acknowledge message. The profile is adjusted.
No operation possible	The value for the volume or flow rate is missing in at least one phase. Enter missing value.
Maximum pressure reached	The set maximum injection pressure was exceeded. The injector tried several times without success to adjust the flow rate to remain below the pressure limit. The injection is stopped. Acknowledge the message. Check patency of syringes, tube system and patient access.
Error syringe holder Error code: 1	The heating of the recipient is defective. Put the device out of operation and contact the MEDTRON Customer Service.
Error during the starting procedure of the injector	After having switched on the injector, an error has occurred during the starting procedure. The pilot light stays yellow. Switch the device off and on again. If the error persists, please contact the MEDTRON Customer Service.

Message/Error	Possible cause and remedy
Pressure jacket hasn’t been inserted properly! Please insert pressure jacket completely.	The pressure jacket hasn't been inserted correctly into the recipient. Insert the pressure jacket completely. Confirm the message.
Error code: […]	This message appears when a device error has occurred. Please contact the MEDTRON Customer Service and mention the displayed error code.
The injector cannot be switched on any more. The red LED of the series of LEDs on the injector base is flashing.	The state of charge of the battery cells is too low. Connect the power supply unit and switch the injector on to continue operation and charge the battery cells.

Technical data

Flow rate per unit	Angio: 0.1 ml/s – 30 ml/s, increment 0.1 ml/s CT: 0.1 ml/s – 10 ml/s, increment 0.1 ml/s
Injection volume	Contrast medium: 200 ml Saline solution: 200 ml
Partial volume which can be pre-selected	1 ml – 200 ml, increment 1 ml
Injection pressure	Angio: 5 – 83 bar / 75 – 1200 psi, increment 1 bar/psi CT: 5 – 21 bar / 75 – 310 psi, increment 1 bar/psi
Filling speed	1 ml – 4 ml/s
Manual piston movement speed (forward/backward)	0.4 ml/s (start) – 5.6 ml/s (9-time acceleration)
KVO-time	1 – 4 min
KVO-volume	1 – 4 ml
Injection profiles	60 (per mode)
Injection phases	1 – 3
Accuracy	– Volume: ± (1 % + 1 ml) – Flow rate: ± (1 % + 0.1 ml/s) – Times: ± (1 % + 0.1 s) – Pressure: ± (5 % + 1 bar) All values ≥ 0.
Power supply unit with medical approval	XP Power AHM150PS24
Input voltage power supply unit	100 – 240 V AC, 50 – 60 Hz
Power consumption power supply unit	1.8 A
Fuse	Püschel 118.000 T 2 L 250 (internal, operating unit) current: 2 A; voltage: 250 V DC; dimensions: 5 × 20 mm (Ø × L); breaking capacity: 100 A
Fuse (battery operation)	4x Littelfuse 0314020.HXP F 20 H 125 (internal, injector base) current: 20 A; voltage: 125 V DC; dimensions: 6.4 × 32 mm (Ø × L); breaking capacity: 10 kA

Battery	Varta CR 2032 3 V lithium (internal, control unit) Saft LS 14250 3,6 V lithium (internal, injection unit)	
Protection class injector	Device with internal power supply Protection class I (during mains operation and charging process)	
Operating mode	Continuous operation, ≤ 10 patients per hour	
Degree of protection against ingress of water	IPX0	
Device type	CF, identified by 	
Dimensions (H x W x D)	1520 x 550 x 535 mm in vertical position	
Weight	approx. 62 kg	
Ambient conditions during operation	– operating temperature – relative humidity – air pressure	10 °C – 40 °C 30 % – 75 % 700 hPa – 1060 hPa
Ambient conditions for storage and transport	– storage temperature – relative humidity – air pressure	- 20 °C – 60 °C up to 75 % 700 hPa – 1060 hPa
Battery cells	48 V / 14 Ah (4 x Yuasa REC14-12, injector base)	
Operating time of the battery cells	With fully charged battery cells, the operating time of the injector is at least 10 hours[1]	
Radio communication	Bluetooth	
Bluetooth class	Class 1	
Frequency	2.402 – 2.48 GHz	

The injector satisfies the requirements of the standard DIN EN 60601-1-2 for medical equipment in terms of the emitted interference and interference immunity.

[1]The operating time specified above can be extended by switching off the heating of the recipients and reducing the stand-by time.

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