CT Exprès™

Contrast Injection System

CT Exprès™ 3D Contrast Media Delivery System

Operator Manual

BRACCO

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This manual may be revised or replaced by Bracco Injeneering at any time and without notice. You should ensure that you have the most current applicable version of this manual.

While the information set forth is believed to be accurate, it is not a substitute for the exercise of professional judgment.

Nothing in this manual shall limit or restrict in any way Bracco Injeneering's rights to revise or otherwise change or modify the equipment (including its software) described in this manual.

The equipment described in this manual must be installed, operated, and serviced only by trained professionals.

You must read and understand this manual before operating the CT Exprès™ 3D device. This manual is not intended to replace a training program by personnel qualified in using the CT Exprès™ 3D.

The English Operator Manual is the source language and shall prevail.

Manufacturer / Manufactured for (USA):

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Contents

Introduction

About CT Exprès™ 3D

CT Exprès™ 3D represents a novel concept in the administration of contrast media and saline for computed tomography (CT) scans: the syringeless injector.

CT Exprès™ 3D is designed to help medical professionals work safely, quickly, and flexibly, as it manages the automatic injection of contrast media and saline in a controlled and efficient manner.

CT Exprès™ 3D is able to deliver high injection flow rates without the need for generating very high injection pressures.

CT Exprès™ 3D with temperature maintainer option actively maintains temperature of contrast media bottles prewarmed by end-user when they are installed on the device.

About This Manual

You must read and understand this manual before operating the CT Exprès™ 3D device. This manual is not intended to replace a training program by qualified personnel.

Indications for Use

The CT Exprès™ 3D Contrast Media Delivery System is indicated for controlled automatic venous-side administration of contrast media to human subjects while undergoing examination by means of a computed tomography (CT) scanner, including CT angiography (CTA).

The system consists of the CT Exprès™ 3D Instrument, the Bottle Spike, the Day Set III *HP*, the Patient Set, accessories and detachable parts.

This device is not intended for injection of contrast media for coronary arteriography, or for any other use for which the device is not indicated.

All users must be trained by a Bracco Injeneering representative on the use of the CT Exprès™ 3D. The device must be operated by or under the immediate, direct supervision of a licensed doctor or other licensed health care professional qualified to use the product and perform the procedures described in this manual. This device must to be operated only in appropriate licensed health care facility.

For Your Information

CT Exprès™ 3D units are equipped to operate at:

• 100 to 240 V AC, 180 VA, 50/60 Hz

They are designed to be in compliance with IEC 60601-1 (electrical safety), IEC 60601-1-2 (EMC).

CT Exprès™ 3D units require special precautions regarding EMC and must be installed and put into service according to the EMC information provided in *Appendix D : EMC requirements*, on page 126. Portable and mobile RF communication equipment can also affect CT Exprès™ 3D.

The CT Exprès™ 3D system is classified by IEC 60601-1 as Class I, type BF medical electrical equipment.

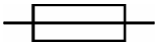
Accessory equipment connected to the analog and digital interfaces must be approved by Bracco Injeneering and certified according to the respective IEC standards. The combination must also comply with the system standard IEC 60601-1-1. If in doubt, please consult the Technical Services Department or your local representative.

Symbols and keys

Symbols used in this operator manual

Symbol	Meaning
☑	This symbol refers to the checkmark symbol ✅ (green) used on the CT Exprès™ 3D interface. ▪ Accept a prompt ("yes") ▪ Audible and visual alert off
☒	This symbol refers to the cross symbol ❌ (red) used on the CT Exprès™ 3D interface. It means: ▪ Decline a prompt ("no")

Symbols used on the injector (labels)

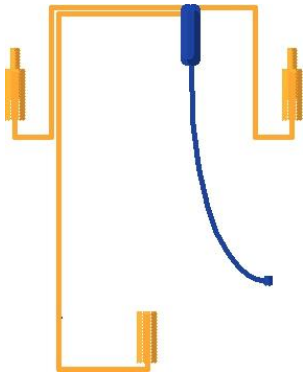
Symbol	Meaning
	Read instructions for use
	Caution, consult the accompanying documents
	Manufacturer
	Main ON/OFF switch
	Left contrast media prime
	Right contrast media prime
	Saline prime
	Fuse (for the 36 V DC)
	Separate waste collection required
	Start/Stop (for the hand switch)
CE 2797	European Union approval (CE mark)
	Do not move when the brakes are locked
MD	Medical Device

Symbols used on the injector (buttons)

Button name	Symbol	Function
STANDBY		Place the CT Exprès™ 3D in a standby mode, while retaining the current injector setup. This button wakes the injector up if pressed a second time. This function can be used for temporary locking of the display keys.
STOP		Immediately stops any function, including injection.
START		Allows the operator to start injection (hold for at least one second then release to start injection).
Prime		Button to activate manual priming of one of the corresponding three media lines.
Clamp		Button to activate (open) one of the corresponding electro clamps of the contrast media or saline lines.
Unlocking		Button to unlock the Patient Set.
Locking		Button to manually lock the Patient Set. (the Patient Set is automatically locked on insertion).

Indicators on the display

For a detailed overview on the available programming keys, refer to *Figure 4: Details of the injector status page (page 26)* and *Figure 5: Details of the injection settings page (page 27).*

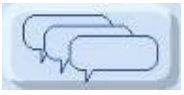
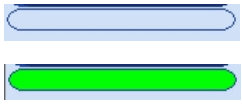
Indicator name	Icon	Function	
Timer		Symbol indicating the time since start of the injection.	
Automatic changeover		Indicates that the automatic changeover is active or inactive.	
Day-Set status Patient-Set Status		Indicates the status of the disposable:	
		White	Not filled
		Dark blue:	Filled with contrast medium
		Medium blue:	Mix of Contrast and Saline
		Light blue:	Filled with saline
		Orange:	A warning is attached to this disposable. Click it to get the warning message
		Red:	The disposable must be removed

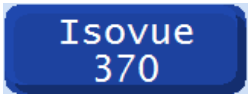
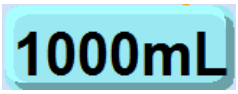
Keys in messages, keyboards or menus

Key name	Key icon	Function
Acknowledgment Positive answer (Yes)		Accept a setting. Accept a prompt (Yes)
Negative answer (No)		Decline a prompt (No)
Decline		Decline a setting. Close a keypad or menu without changing the initial value.
Forward/backward		Dedicated to go through the different pages in a menu.
Open numerical keyboard		Key to manually enter a numerical value (depending on context).
C (= Clear)		Press this key to erase a single number (e.g. volume of contrast media).
Video library		Open the video library
Bell Cancel		Audible alert off
Select Day Set III *HP* and Patient Set filling		Key to switch to filling Day Set III *HP* and Patient Set if only Patient Set filling is proposed.
Select Patient Set filling		Key to switch to only filling Patient Set if Day Set III *HP* re-filling is proposed.
Automatic prime key		Key to start an automatic priming

Keys in the status page

Key name	Key icon	Function
STOP		Stops priming and injection (the key is displayed only during priming and injection).
Prewarmed / not prewarmed status	 	Key to set contrast media prewarmed status (one key for each bottle). Red thermometer indicates prewarmed contrast media. Temperature will be actively maintained (if option is available). The crossed-out thermometer indicates not prewarmed contrast media. Temperature maintainer is switched off (if option is available).
Contextual help		Provides contextual help screens displaying information, instructions or videos.

Key name	Key icon	Function
Contextual video guidance		Provides contextual video guidance and quick access to video library.
Warning		Key indicating a technical message. Press this key to see the message.
Injector status page		Key to go to the injector status page. There, you can adjust permanent setting, bottles setting and prepare Day Set III *HP* and Patient Set. Also indication of remaining bottle volumes and selected bottle.
Injection settings page		Key to access the injection settings page. You may define the type of injection phase, the volume, the rate, and the scan delay time.
Test injection page		Key to go to the test injection page. You can initiate a saline test injection to ensure the patient's venous access is secure and stable.
Display Patient Set locking / unlocking		This key displays the Patient Set locking / unlocking buttons.
Logbook page		Key to go to the logbook page. There, you can see all actions performed on the injector during the current day or preceding day.
All logged messages		Key on logbook page. Switch to the display of all user actions (no filter)
Filtered messages		Key on logbook page. Switch to the display of all actions concerning disposables and injections
Bottle selection		This key allows the selection of the bottle for the next injection and indicate the status of the bottle.
		Blue with green bar: active and selected. Note: click on the grey bottle key (of the second bottle) if you want to unselect this bottle and select the second one.
		Empty: Disabled because empty.
		Grey: Disabled. Note: click on this key is you want to select this bottle.

Key name	Key icon	Function
Clamp		Key to activate (open) one of the corresponding electro clamps of the bottle and saline lines.
Media volume (bottles)		Key for programming the media volume of the selected bottle.
Contrast media		Key for selecting contrast media.
Needle gauge		Displays a menu that enables the operator to specify the needle gauge.
Permanent settings		Key for programming the following settings that will be stored permanently for the injector system: ▪ Automatic flushing ▪ Automatic rate reduction ▪ Video library ▪ Brightness settings ▪ Sound settings ▪ Language selection ▪ Country options ▪ Date and time setting ▪ Show software version ▪ Technical services
Phase programming		Press one of these keys to define the contrast media type, the volume, and the flow rate for the selected phase.
Saline volume		Key for programming the volume of media of the saline pouch/bottle at the third line.
Program functions		Displays the menu to set special program functions such as: ▪ Set scan delay ▪ Erase displayed program ▪ Record displayed program
Load the next program		Key to select the next program available for the same type of examination.
Load the last used program		Key to reload the most recently loaded program.
Examination type		Examination type key ("brain", "cardiovascular", "lung", …) For information about creating a program, see *section 4.8.1: Programming the CT Exprès™ 3D* on page 69.
Program preset "Brain"		Shortcut* to predefined program: "Brain" program.

Key name	Key icon	Function
Program preset "Cardiovascular"		Shortcut* to predefined program: "Cardiovascular" program.
Program preset "Lung"		Shortcut* to predefined program: "Lung" program.
Program preset "Liver"		Shortcut* to predefined program: "Liver" program.
Program preset "Abdomen"		Shortcut* to predefined program: "Abdomen" program.
Program preset "Kidney"		Shortcut* to predefined program: "Kidney" program.
Program preset "Extremities"		Shortcut* to predefined program: "Extremities" program.
Program preset "Miscellaneous"		Shortcut* to predefined program: "Miscellaneous" program.
“alphabetic” sorting key		The displayed list of injection profiles is sorted alphabetically.
“examination type” sorting key		The displayed list of injection profiles is sorted by first sub-category name and then by program name.
“concentration” sorting key		The displayed list of injection profiles is sorted by dedicated concentration first, and then by program name.
Download on USB key		Allows transfer of the daily logbook onto the USB key.

* Shortcuts are available only with a primed Patient Set and in absence of a program.

Additional keys (below) are available on the display of control panel status page in case of disabled hardware buttons:

Key name	Key icon	Function
Display manual priming		This key displays the manual priming keys on the touch screen.
Manual Prime key		Key to activate the manual priming of one of the corresponding three media lines.

Keys on the patient page

Only applicable with injectors connected to a Nexo® server. To learn more about Nexo®, refer to *section 4.12*.

Key name	Key	Function
“Incoming patient” key		To select a scheduled session from the work-list (incoming patients) or to declare a new patient.
“outgoing patient” key		To get the list of past sessions not yet sent to the PACS and the RIS.
“unknown patient” key		To associate the session of a unknown patient with a scheduled one in the hospital work-list.
“Send to PACS” key		Send patient session details to PACS and RIS.
“Clock” key		The work-list is sorted chronologically.
“examination type” key		The work-list is sorted by examination type.
“alphabetic” key		The work-list is sorted alphabetically (using patient last names).
“File” key		The work-list is sorted by patient file identifier and then by accession number.
“Room” key		The work-list is filtered by rooms.

Manual conventions

Definitions

Term	Definition
Main unit	**Combination of the injector unit with the main control panel.**
Main control panel	**Control panel which is placed on top of the injector unit. It is located in the CT scan room close to the patient, outside the CT control room (see *section 1.4.1: Installation).***
Remote control panel	**Control panel identical to the main control panel, but which is located inside the CT control room (see *section 1.4.1: Installation).***

Warnings, cautions and notes

This manual uses the following conventions:

Warning
Warnings describe a possible hazard that can cause serious injury or death.

Caution
Cautions describe a possible hazard that may result in equipment damage or personal injury.

Note
Notes provide additional information to explain the procedure.

Typographic conventions

Convention	Example	Meaning
Italic	*Structure of the CT Exprès™ 3D*	Text in italic font refers to other parts of this manual such as figures, chapters and sections. In this example, it is a part of a cross-reference.
COURIER NEW	Select the option NONE to indicate that no automatic flushing will be executed.	Courier New text style refers to text quoted from the control panel interface.

Warnings and cautions

Warning

- **Read this manual before using the CT Exprès™ 3D on a patient. Operate the device only in accordance with this operator manual to ensure safe and effective use.**
- **Bracco Injeneering cannot be held liable if the CT Exprès™ 3D is not installed, operated, and maintained in accordance with the instructions in this operator manual. No modifications of CT Exprès™ 3D are allowed.**
- **The CT Exprès™ 3D must be operated by qualified hospital personnel trained in its use. Use by unqualified, or untrained personnel can result in patient injury, personal injury and/or material damage.**
- **To avoid the risk of electric shock, CT Exprès™ 3D must be connected only to a mains supply with protective earth.**
- **Do not use CT Exprès™ 3D in close proximity to powerful sources of electromagnetic interference, e.g. near to electro-surgical equipment. CT Exprès™ 3D must not be placed in an MRI room.**
- **Switch off CT Exprès™ 3D at the power source and then on again at least once a day so that it performs all required diagnostic self-tests at start-up.**
- **Check operation of the CT Exprès™ 3D system if it has been subjected to mechanical shock or impact or has been dropped. Do not use in case of apparent breakage or cracks. In all cases of major shock, have the CT Exprès™ 3D inspected by authorized technical personnel.**
- **CT Exprès™ 3D is an electrical device. Do not use it in a potentially explosive environment (e.g. with mixtures of flammable anesthetics and oxygen).**
- **Connect the CT Exprès™ 3D to an appropriate uninterruptible power supply and place it in a safe position in order to avoid accidental disconnection of the power cables as a loss of power to CT Exprès™ 3D that can cause interruption of an injection.**
- **If a problem with CT Exprès™ 3D cannot be corrected by following the information in *section 7: Maintenance* on page 121, please report the problem to our Technical Services Department or to the Bracco Injeneering representative in your country.**
- **Installation of the CT Exprès™ 3D must be performed only by a Bracco Injeneering service engineer or Bracco Injeneering representative.**
- **Ensure that you are never in physical contact with the patient and any metallic part of the CT Exprès™ 3D at the same time.**
- **CT Exprès™ 3D is designed for accurate delivery of a variety of contrast media through different venous access devices (needles ranging in gauge from 16 to 24 G). CT Exprès™ 3D also has a built-in pressure (occlusion) sensor and can therefore deliver contrast media as long as pressure levels do not exceed the pressure alert limit. Before using CT Exprès™ 3D, we recommend ensuring that all requirements for contrast media delivery are fulfilled in consideration of the existing injection rules in your imaging suite.**
- **Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g., IEC 60950 for data processing equipment). Furthermore, all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or IEC 60601-1-2). Any person who connects additional equipment to medical electrical equipment thereby configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the Technical Services Department.**
- **If you do not hear an audible alert when the injector is switched ON, or if the start-up page is not displayed correctly, or if you see an error message, do not use the CT Exprès™ 3D. Contact our Technical Services Department or your Bracco Injeneering representative.**

- **To ensure safe and effective operation, use CT Exprès™ 3D only with disposables, components and accessories designed for it and described by Bracco Injeneering in this manual. Use of unapproved disposables, components or accessories can result in a potential hazard and or serious injuries.**
- **When the injection volume(s) is/are programmed, the CT Exprès™ 3D takes into account the volume of contrast media or saline solution in the tubing of the Patient Set. Any additional extension tubing is not taken into consideration in the volume and sequence calculation and presents a risk of severe patient injury or death due to air injection.**
- **All disposables (Bottle Spike, Day Set III *HP* and Patient Set) are made of high quality, medical grade materials. Day Set III *HP* and Patient Set contain DEHP (diethylhexyl phthalate). Although these materials are generally considered safe for use with the CT Exprès™ 3D, it is your responsibility to decide whether they may also safely be used on pediatric patients and pregnant or nursing women.**
- **Check and ensure that all disposables and packaging are suitable for use. If the packaging of any disposables is damaged or beyond its expiry date, do not use the disposables contained in this packaging. Instead, discard and replace them.**
- **Do not use the disposables beyond their intended duration of use. Re-using any disposable or using for a period exceeding the limits specified below can result in hazard and/or serious injury.**
- **A Patient Set must be used for only one patient (single use), for no more than 12 hours, and for a maximum of three injections (200 mL per injection) or 300 mL of contrast media, whichever occurs first.**
- 1.2. **A Day Set III *HP* must be used for no more than 24 hours and for a maximum of 6000 mL of contrast media injected, whichever occurs first. If removed from the injector, discard the Day Set III *HP* and change the saline bag.**
- 1.1. **A Bottle Spike must be used for no more than one bottle of contrast media or saline, and for no more than:**
  - **24 hours for installed bottles.**
  - **12 hours for stored bottles (in upright position).**
  - **The time recommended by the contrast media bottles provider, whichever occurs first.**
- **Do not re-sterilize any of the disposables.**
- **Any venous access device used must be able to withstand pressures of at least 12 bar (180 PSI) as well as the programmed flow rate.**
- **Ensure that there is no air in line warning prior to connecting the Patient Set to the patient.**
- **The disposables are all designed for aseptic use and must be used according to good clinical practices.**
- **If the Patient Set is subject to air contamination or if septic contact with the Patient Set spike or connector occurs, discard and replace the Patient Set.**
- **Discard the Day Set III *HP* in the event of suspected septic contact or air contamination of the following part:**
  - **Septum.**
  - **Spike on the saline line.**
  - **Spikes of the contrast media lines (for example by Bottle Spike contamination).**
- **Protect the Day Set III *HP* spikes on the bottle side by always inserting a bottle into the bottle holder columns (or by keeping an empty bottle in place).**
- **In the event of any possible air contamination or septic contact with the spike or the septum of the Bottle Spike, discard the Bottle Spike.**
- **In the event of accidental traction or pulling on the Patient Set tubing, the Patient Set must be discarded and replaced.**
- **Do not pour water or any other liquid over or onto the CT Exprès™ 3D at any time.**

- **The actual flow rate can differ from the programmed rate if the needle gauge is incorrectly programmed, or if the contrast media and its prewarmed condition are incorrectly entered.**
- **For optimal delivery accuracy, when selecting between prewarmed or not prewarmed contrast media, take into account that:**
  - **Not prewarmed contrast media means a contrast medium with a temperature between 20 °C (68°F) and 22 °C (71.6 °F)**
  - **Prewarmed contrast media means a contrast medium with a temperature between 35 °C (95 °F) and 37 °C (98.6 °F)**
- **Never heat contrast media above 37.5 °C (99.5°F). Injection of contrast media at a temperature higher than 37.5 °C (99.5 °F) can be harmful to the patient.**
- **With temperature maintainer option, prewarmed bottles remain at the required temperature only if the dedicated insulator is used. Without temperature maintainer option, using bottle insulators does not guarantee that the bottles remain at the required temperature over a long period of time.**
- **In the event of accidental pressure on any button (except START button) of the CT Exprès™ 3D, injection is automatically interrupted.**
- **Close and secure all tubing and connections to avoid any leaks or air injection.**
- **Ensure that the pinch clamp on the Patient Set is open before automatic filling or an injection is started. Failure to open the clamp will result in an occlusion alert and aborting of the automatic filling or injection procedure.**
- **Air initially present in the Patient Set that is distal to the air detectors (between the cassette and the vein) cannot be detected by CT Exprès™ 3D. Always make sure the Patient Set is fully primed before connecting the patient. Always make sure there is no air present before connecting a patient and starting an injection.**
- **Air detection alerts are disabled during filling or priming. To prevent accidental injection of air, ensure that the patient is not connected during filling or priming. Injection of air is hazardous and can result in serious injury.**
- **Do not allow undue time delay between setting-up an injection and the injection itself. This can result in the grouping of air bubbles which can be hazardous if injected into the patient.**
- **If you do not use the third line (saline line) of the Day Set III *HP*, some quantity of air may be aspired from the third line during normal operation, resulting in a stop due to air detection. We suggest clamping the third line near the T-connector.**
- **Never connect the CT Exprès™ 3D to a venous access device or to a vein access that is already connected to another delivery system or another line.**
- **A saline test injection must be performed to check proper positioning in the venous access before any automatic injection is initiated. The saline test injection may contain residual contrast media. Ensure that the presence of contrast media (in mL quantities) does not affect the test.**
- **Extravasation is hazardous - in particular with contrast media - and can result in serious injuries. The following conditions can result in extravasation and must be avoided:**
  - **High flow rates during venous injection with venous access not properly secured against dislodging during injection.**
  - **Misplacement within the patient's vein.**
  - **Weakness of, or leakage at, the catheterized vein.**

  It is recommended to loop back with the tubing line taped onto the patient.
- **In accordance with good clinical practice, secure intravenous access must be ensured by a physician or nurse before injection begins.**
- **During the injection, monitor the patient for signs of extravasation. If extravasation is suspected or occurs, stop the injection immediately and disconnect the patient from the CT Exprès™ 3D. Remove the intravenous needle. Treat the extravasation as per the standards of practice in your clinical area. If the injection is continued after medical advice is obtained, a new and secured intravenous access site must be established and confirmed. Refill the Patient Set before connecting the patient. Use of a new Patient Set is recommended for a new venous access device, or if appropriate aseptic manipulation cannot be ensured.**

- **Do not connect the patient to the Patient Set when the Patient Set is unlocked.**
- **Do not unlock or remove the Patient Set when a patient is connected.**
- **The Automatic Rate Reduction (A.R.R.) function adapts the maximum injection rate as a function of the injection pressure. Whereas the programmed volume of contrast media will be delivered, injections with A.R.R. may last longer than programmed, because part of the delivery is made at an injection rate that is lower than the programmed rate.**
- **If CT Exprès™ 3D is not capable of delivering the programmed volume of contrast media (e.g. because the contrast media bottle volumes were incorrectly programmed) and at least 75% of the programmed contrast media volume has been delivered, CT Exprès™ 3D will complete the injection by switching to saline delivery (rather than interrupting the injection and issuing an alert). The actually delivered volume of contrast media is displayed under «injection history».**
- **Always verify that the reservoir (underneath each contrast media bottle) is completely filled to assure the accuracy of the injected volume of contrast media.**
- **Given the possible mixing of contrast media and saline solution during the initial purge steps, even in only minute amounts, it is mandatory to ensure before each saline test injection that the patient is not susceptible to risks related to injection of contrast media. Refer to the recommended practices and safety precautions provided by the contrast media manufacturer and act in all cases, even for injection of saline solution, as if it were a contrast media injection.**
- **To avoid liquid leakage, always ensure that the pinch clamp on the Patient Set is closed before disconnection of the Patient Set from the venous access.**
- **The estimated GFR (eGFR) Calculator is intended to assist the facility in determining whether a patient's renal function allows for the administration of contrast media. It is not intended to act as a substitute of a physician's diagnosis of conditions, which may preclude the administration of contrast media or the patient's ability to accept the procedure.**
- **When using the eGFR Calculator, you should not assume that the patient does not have chronic kidney disease (CKD), until a physician confirms it. eGFR estimates may not be reliable in certain individuals as there are other factors besides CKD that can yield erroneous eGFR values. It is important that a physician is consulted if you have any concerns about a patient's kidney function or the results shown by the eGFR calculator.**
- **By utilizing the eGFR Calculator you are assuming responsibility for ensuring the accuracy of all information utilized in the eGFR calculation and making sure that all information represents the current condition of the patient.**
- **The eGFR Calculator is to be used for adults 18 years of age and older.**
- **Warning messages are displayed when the eGFR is below standard critical values of 60. These values will not inhibit the injection. It is the facility's ultimate responsibility to review the value and determine the best course of actions for the patient.**

Caution

- **Federal Law (USA) restricts this device to sale by or on the order of a physician or other licensed healthcare practitioner.**
- **All disposables and sharps must be collected and disposed of according to your hospital's procedures.**
- **It is recommended you do not re-use a contrast media or saline bottle or pouch after prolonged (more than 12 hours) storage. This is because there is a potential risk of occlusion of the Bottle Spike's air filter by the contrast media if the bottle is stored outside the injector after usage.**
- **If you wish to use the automatic changeover function of the two bottles, make sure you install two bottles of the same contrast media type and concentration.**
- **When performing a saline flush, it is necessary to program both the volume and rate of either the preflush and / or the postflush. Omitting one or both of these values automatically cancels the flush injection.**
- **A flexible intravenous access device is the recommended access for the CT Exprès™ 3D.**
- **Dispose of contrast media bottles according to the manufacturer's instructions.**
- **Do not use a saline glass bottle with the third line positioned underneath the CT Exprès™ 3D, since this area cannot be protected from shocks. Always use plastic saline bottles or pouches with the third line.**
- **Always place a bottle insulator on each bottle to protect glass bottles during use.**
- **Be aware that bottle holder top surface turns warm when prewarmed contrast media bottles are installed.**
- **It is recommended to always use the insulators to cover each bottle. The insulators protect and secure the bottles from breakage or shock or from being knocked from the bottle holder during use. The temperature of prewarmed contrast media can only be maintained if insulator is installed.**
- **Never disconnect a control panel while the CT Exprès™ 3D is powered on (make sure the mains power switch situated at the back of the main unit is switched off before disconnecting any control panel).**
- **The CT Exprès™ 3D can only be used with two control panels connected. Make sure that both control panels are connected at start-up of the CT Exprès™ 3D.**
- **To avoid fuses being tripped, make sure that the two plug connections at the rear of the device are connected and firmLy screwed into place before the device is switched on.**
- **While installation the injector unit on the stand or ceiling mount, the use of screws of length other than the screws supplied can damage the injector unit or will not guarantee correct fixing.**
- **When the injector is installed on the pedestal, lock the brakes before using the injector and release them before moving it. Move the injector with care, especially on inclined surfaces or thresholds.**
- **It is mandatory to ensure before each injection that the patient is not susceptible to risks related to injection of contrast media or saline. Refer to the recommended practices and safety precautions provided by the contrast media or saline manufacturer.**

1 Structure of the CT Exprès™ 3D

1.1 The concept

The CT Exprès™ 3D from Bracco Injeneering is an automated contrast media injector designed to enable hospital clinicians to administer contrast media in a controlled, safe and efficient manner to patients undergoing CT scan examinations.

The main elements of the CT Exprès™ 3D are shown in *Figure 1* and are described in this section.

Operating procedures and programming are described in:
- *Clinical session*, on page 45
- *Symbols and keys*, on page 9

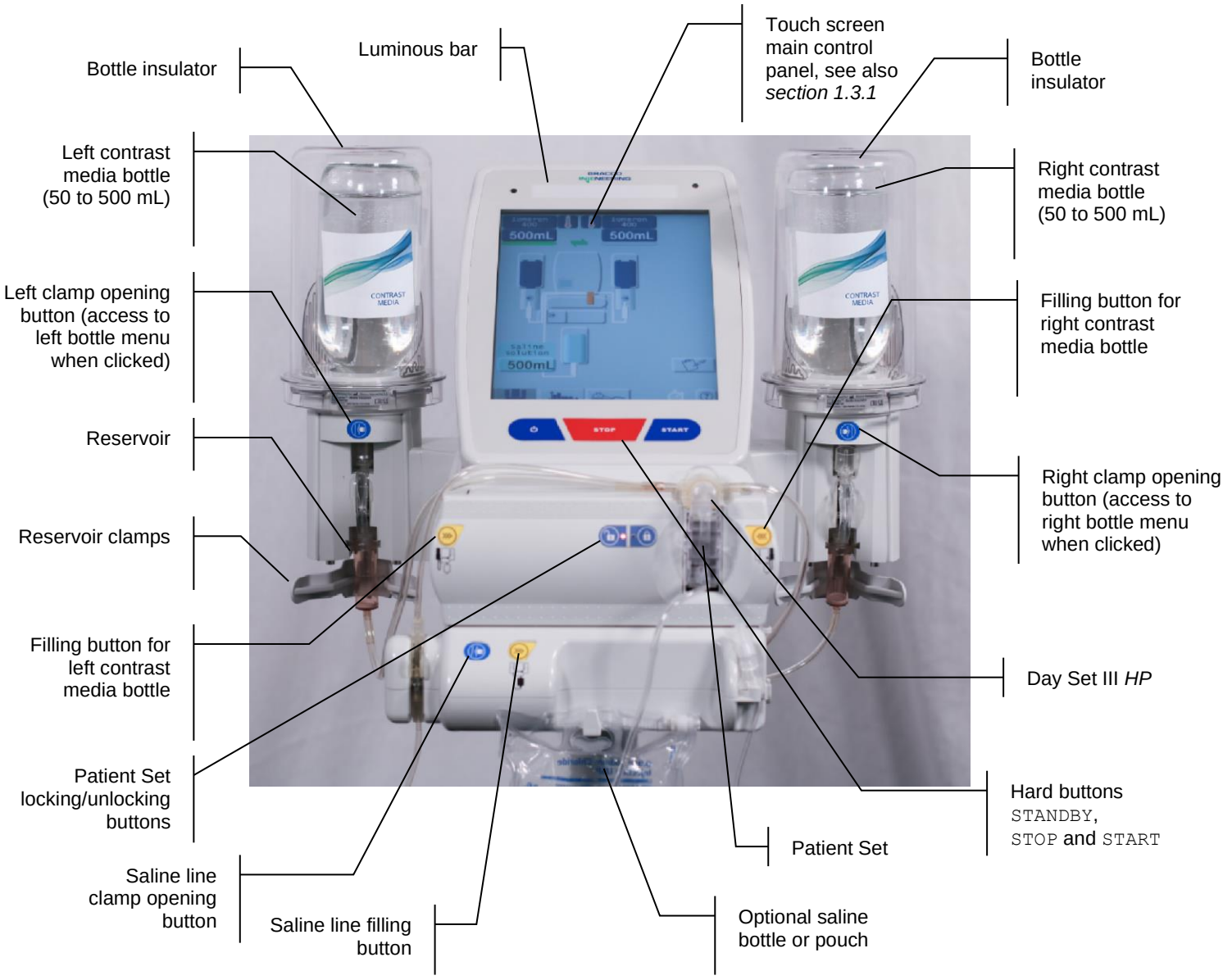


Figure 1: The CT Exprès™ 3D main unit comprising the injector unit and the main control panel.

As a unique and convenient feature, the CT Exprès™ 3D is designed in such a way that all necessary operating instructions and support for handling problems are provided through the touch screen video interface. These instructions and support are not intended to replace the operator manual and training by qualified personnel.

Overview of programming and parameters

This section contains the main description and parameters, for further and detailed info consult the specific sections.

The CT Exprès™ 3D is designed for administration of contrast media and saline. The injector has 4 built-in air detectors, two for the contrast media lines, one for the saline line and one for the Patient Set cassette. This latter air sensor is combined with a pressure detector that will interrupt injection if a maximum pressure value is reached.

The CT Exprès™ 3D has built-in applications which guide the user through the set-up and operation of the injector. In addition, the injector has a help feature which is accessed by pressing the Help key on the injector screen.

The CT Exprès™ 3D user interface is organized as three pages or screens (see below table). See *section 1.3.2 The user interface*, *1.3.3 The injector status page* and *1.3.4 The injection settings* page.

Screen / page	Short description	Long Description
Injector Status page	dedicated to the status of and interactions with system components	This is where contrast media type and volume, saline volume, needle gauge, etc. are programmed and displayed.
Injection Settings page	dedicated to programming and running injections	The CT Exprès™ 3D allows for up to 3 injections of contrast media per Patient Set (with up to 8 phases per injection and with a limit of 24 phases per patient). The first phase can consist of contrast media or saline. Subsequent phases (contrast media ,saline, diluject, pause) can be programmed with their own specified parameters. Each phase of Contrast Media or Saline or Diluject can be programmed with its own specified flow rate and volume.
Test Injection Page	dedicated to programming and running saline test injections	The CT Exprès™ 3D provides the option to program and automate the saline test injection. This page is where the saline test injection is programmed and performed. Note: the saline test injection can only be initiated once the injection program is selected on the Injection Setting page.

1.2 Main unit

The main unit consists of the main control panel and the injector unit (see also *section 1.3.1*). It contains all the electronics required to ensure safe injection, including a motor that drives the rotating peristaltic cassette of the Patient Set. The main unit has two bottle holders for two contrast media bottles, or for one contrast media bottle and one saline glass bottle. The main unit also features an integrated front part for hanging one saline pouch or saline plastic bottle.

Figure 2: The CT Exprès™ 3D main unit

1.3 Main control panel interface

1.3.1 The main control panel

The main control panel is securely mounted on top of the injector unit (see also *section 1.4*). It enables you to program the injection procedure through a touch screen interface using two main screen pages, the injection status page (*Figure 4*) and the injection settings page (*Figure 5*). It is possible to enter parameters such as contrast media type, bottle volume, injection volume, injection rate, saline flush, scan delay, interphase delay, needle gauge. The hard buttons `START` and `STOP` on the control panel permit launching and interrupting of the injection procedure.

Note

The following possibilities are available in order to deliberately stop an injection that is in progress:

- Press the `STOP` key on the main or remote control panel, or:
- Press the `STOP` key on the display of the main or remote control panel, or:
- Press the hand switch button.

To stop a saline test injection, release the `START` button.

For additional information about the display interface, see *sections 1.3.3: The injector status page* on page 26 and *1.3.4 The injection settings page* on page 27.

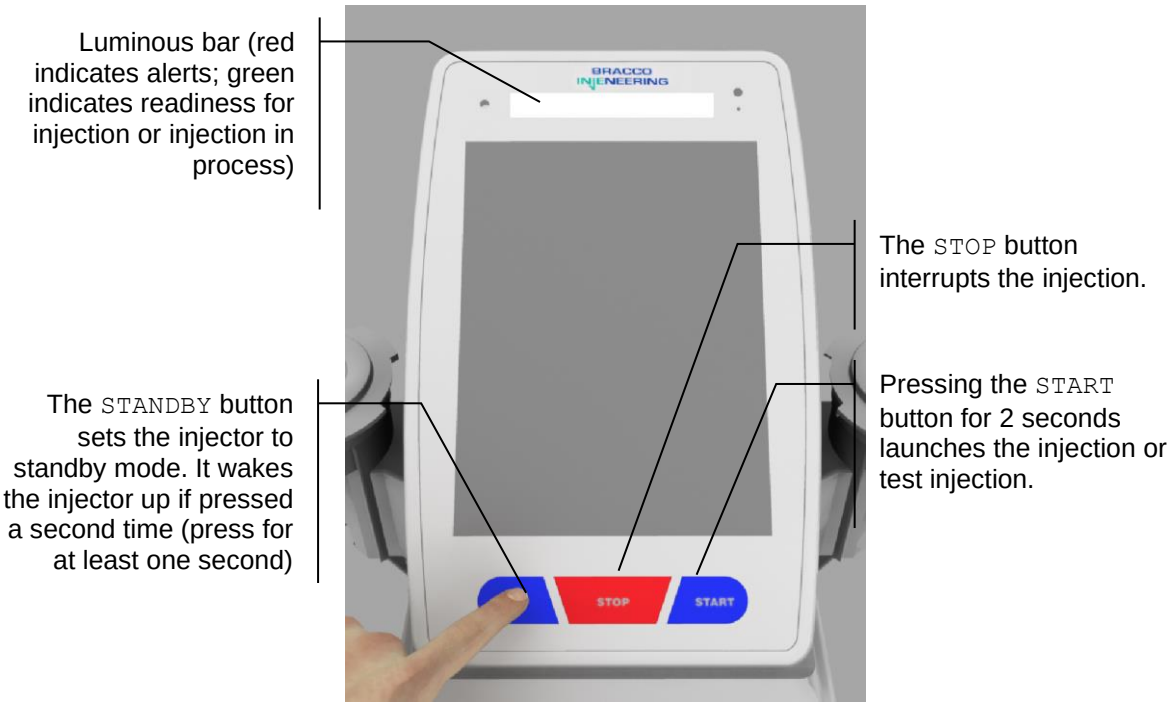


Figure 3: The main control panel

1.3.2 The user interface

Once the injector is powered on, both control panels display a welcome page. The user must wait for the completion of the progression bar before using the injector. Meanwhile, beginners may also click on the displayed help key to access a quick tour of the injector functions (review of main functions, play quick tour visit and review video library).

Once the boot process is completed, a contextual help is displayed showing the most relevant actions to do. In particular, these instructions point out the location where the user may have to interact or where the subject of interest is. These help messages are presented in blue and the user must follow recommended instructions. Except for messages requiring a validation action from the user, the instruction messages can be closed by clicking on them in order to free the display Select the help key to resume this contextual help.

All colored objects drawn with a 3D aspect are active. All disabled keys are drawn in black and white and become part of the background of a displayed message, a setting keyboard or a menu. A key shall be either active (colored) or disabled (black and white) depending on the context and program used.

In the presence of a message, a setting keyboard or a menu, the contextual help key shows a help concerning the currently displayed message, keyboard or menu respectively. In such case, the user can press and hold the help key.

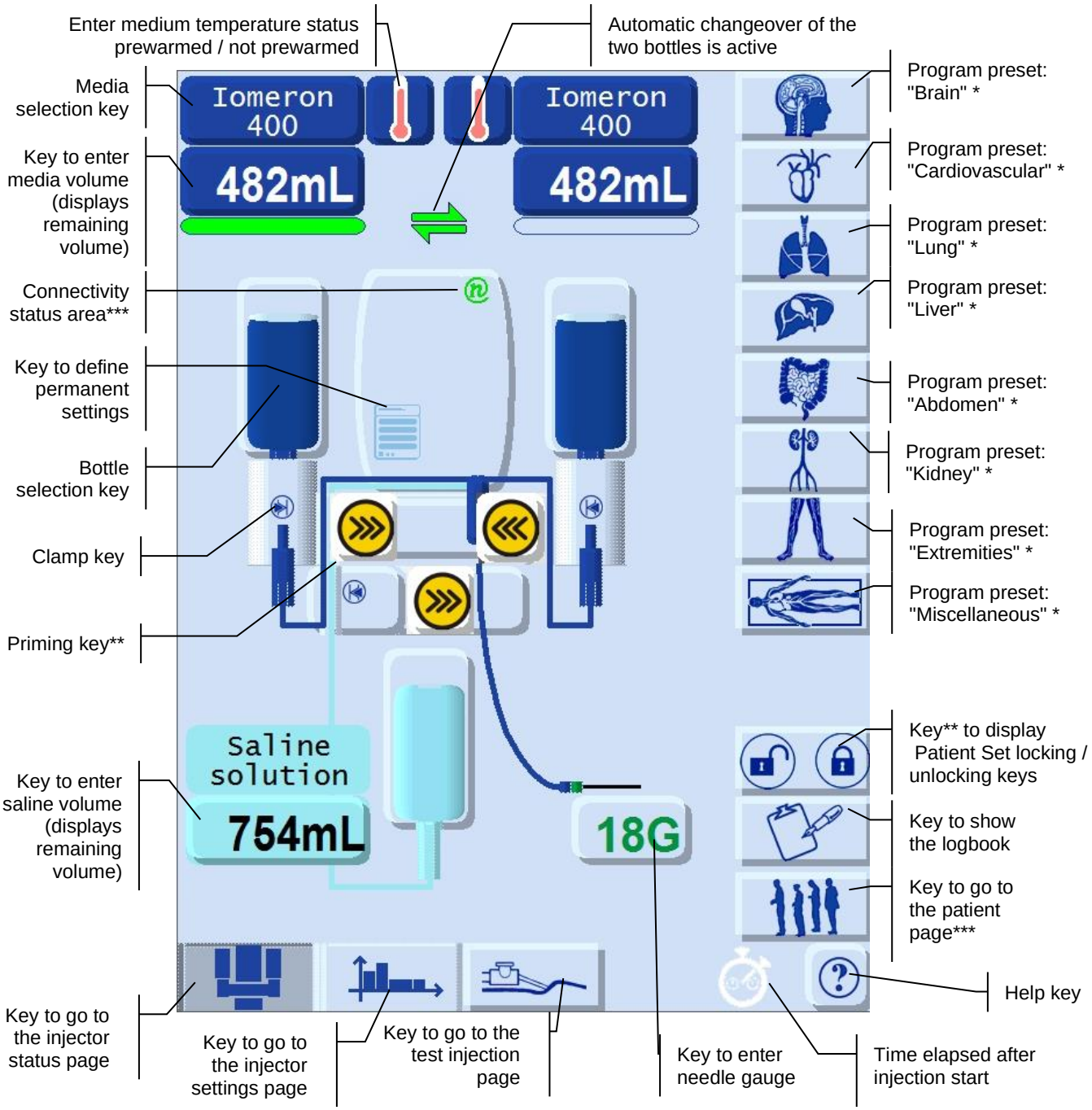
The user interface is composed of several pages where are located specific functions:

1) A status injector page is dedicated to displaying the status of the injector and interacting with it.
2) An injection setting page is dedicated to setting the injection program and starting injections.
3) A test injection page is dedicated to operating saline test injection.

The keys at the bottom of each page allow going from the current page to another.

1.3.3 The injector status page

The main control panel injector status page is designed with the following features:

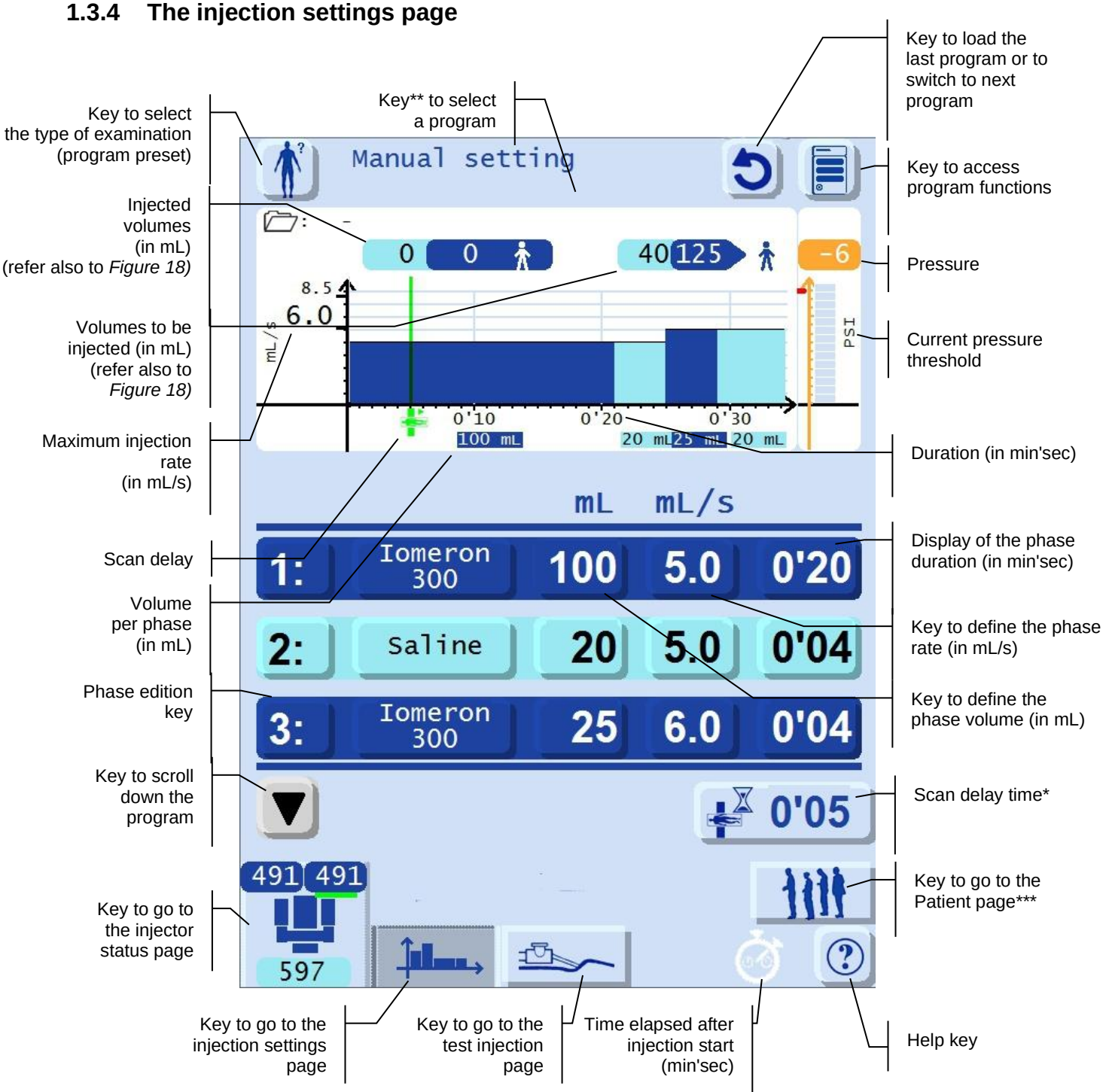


* Shown only when the Patient-Set is filled and in absence of a selected program
** Shown only when enabled (see *section 5.1.10*)
*** Indicators are shown only with system connected to Nexo® (refer to *section 4.12*) or to the scanner (refer to *section 4.13*)

Figure 3: Details of the injector status page

For an exhaustive list of the keys, see *section: Symbols and keys*, on page 9.

1.3.4 The injection settings page



* Only shown when a scan delay is programmed (See *§4.8.4.5*)
** Only shown when a saved program is loaded
*** Only shown with system connected to Nexo®, refer to *section 4.12*

Figure 4: Details of the injection settings page

For an exhaustive list of the keys, see *section: Symbols and keys*, on page 9.

Once you have correctly set up the CT Exprès™ 3D and programmed the injection phases, the luminous bar turns green to indicate the injector's readiness for the start of injection.

1.4 Installation and connections

1.4.1 Installation

Warning

- **To avoid the risk of electric shock, CT Exprès™ 3D must be connected only to a supply mains with protective earth.**
- **Installation of the CT Exprès™ 3D must be performed only by a Bracco Injeneering service engineer or Bracco Injeneering representative.**
- **Connect the CT Exprès™ 3D to an appropriate uninterruptible power supply and place it in a safe position in order to avoid accidental disconnection of the power cables as a loss of power to CT Exprès™ 3D may cause interruption of an injection.**

The injector unit is fixed on the plate of the stand or of the ceiling mount supplied with CT Exprès™ 3D by means of the supplied 4 screws combined with 4 washers.

Caution

Using screws with a different length than those supplied (M4 x 8) can damage the injector unit or will not guarantee that the device is fixed correctly.

A control panel is fixed by four dedicated pins on the upper surface of the injector unit. The control panel fixed on the injector is defined as the main control panel. The other one is the remote control panel, but both are identical and interchangeable. This automatic recognition by the CT Exprès™ 3D is driven by the cables connection (short and long connection cable).

The remote control panel is intended to be located in the CT control room, enabling you to perform all the functions you can perform on the main control panel from the radiation-shielded CT control room. The main control panel and the remote control panel are connected by cables to the injector unit. See the next section for a complete overview of the electrical connections.

If the injector is configured to run with a CANbus scanner connection (CiA 425), either the remote control panel or the main control panel must be connected to the scanner through a dedicated CANbus cable, provided by the scanner manufacturer, and a dedicated adapter provided by Bracco Injeneering. Please contact your local Bracco Injeneering representative to know if this option is available in your country.

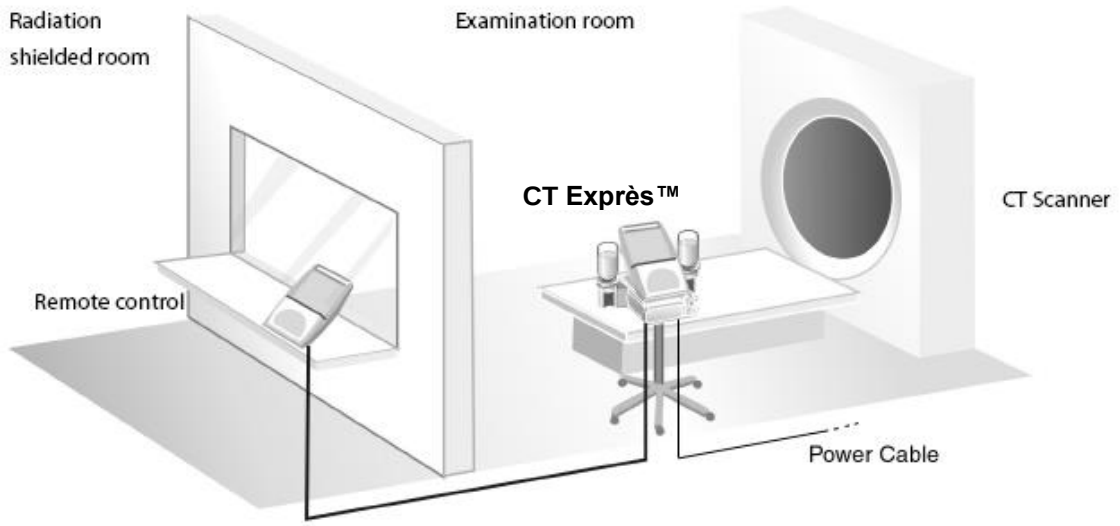


Figure 5: Typical CT Exprès™ 3D installation

Optional hardware connection with Philips scanner SAS cable is available only using a “Philips Scanner Cable Adaptor”. This accessory must be connected only on the remote control panel. Philips scanner SAS cable and remote control panel cable are connected to the Philips Scanner Cable Adaptor, see below *Figure 7*.

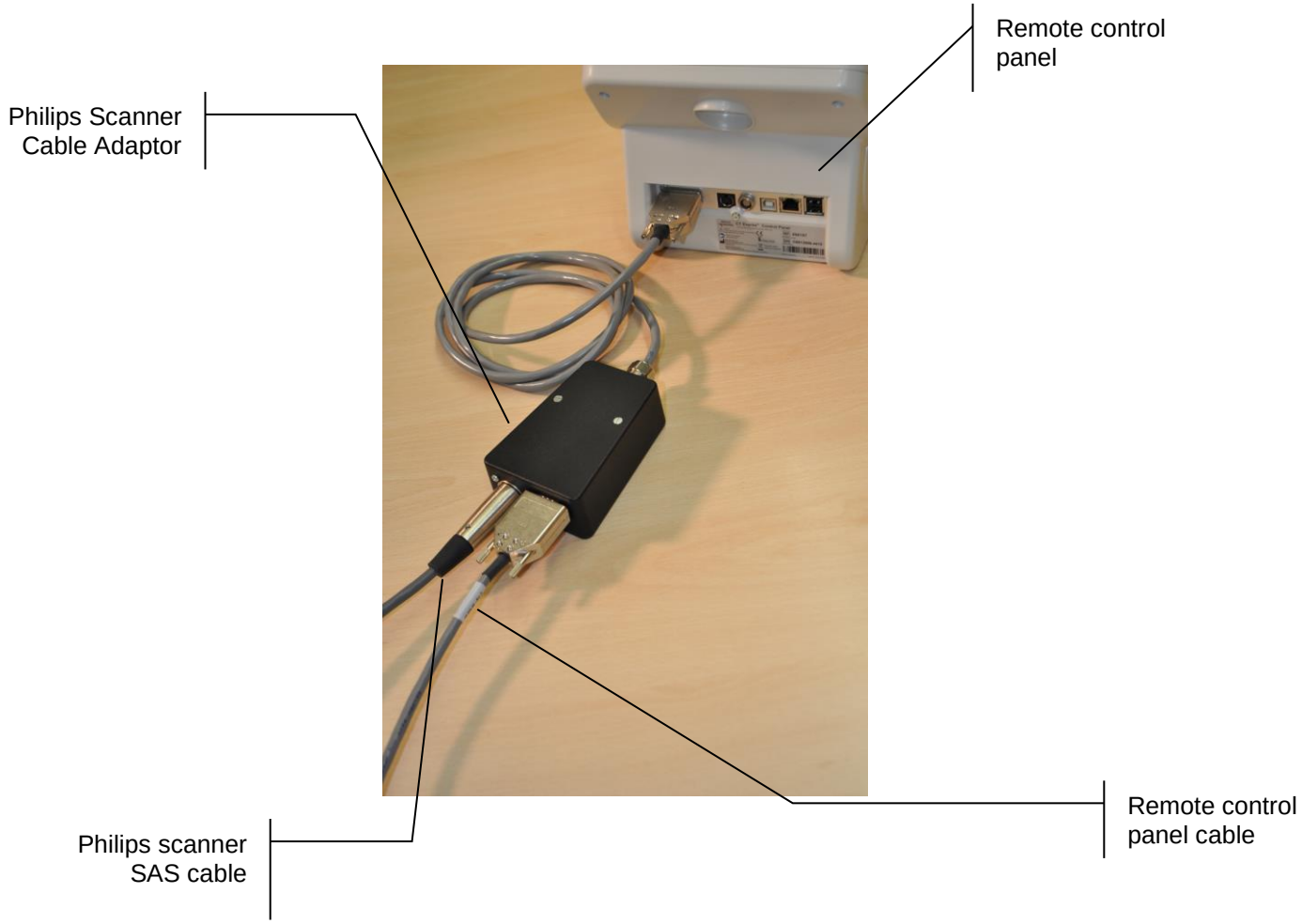


Figure 6: Philips Scanner Cable Adaptor connection

1.4.2 Main unit connections

In *Figure 7* are shown all the connections on the injector unit and on the main control panel.

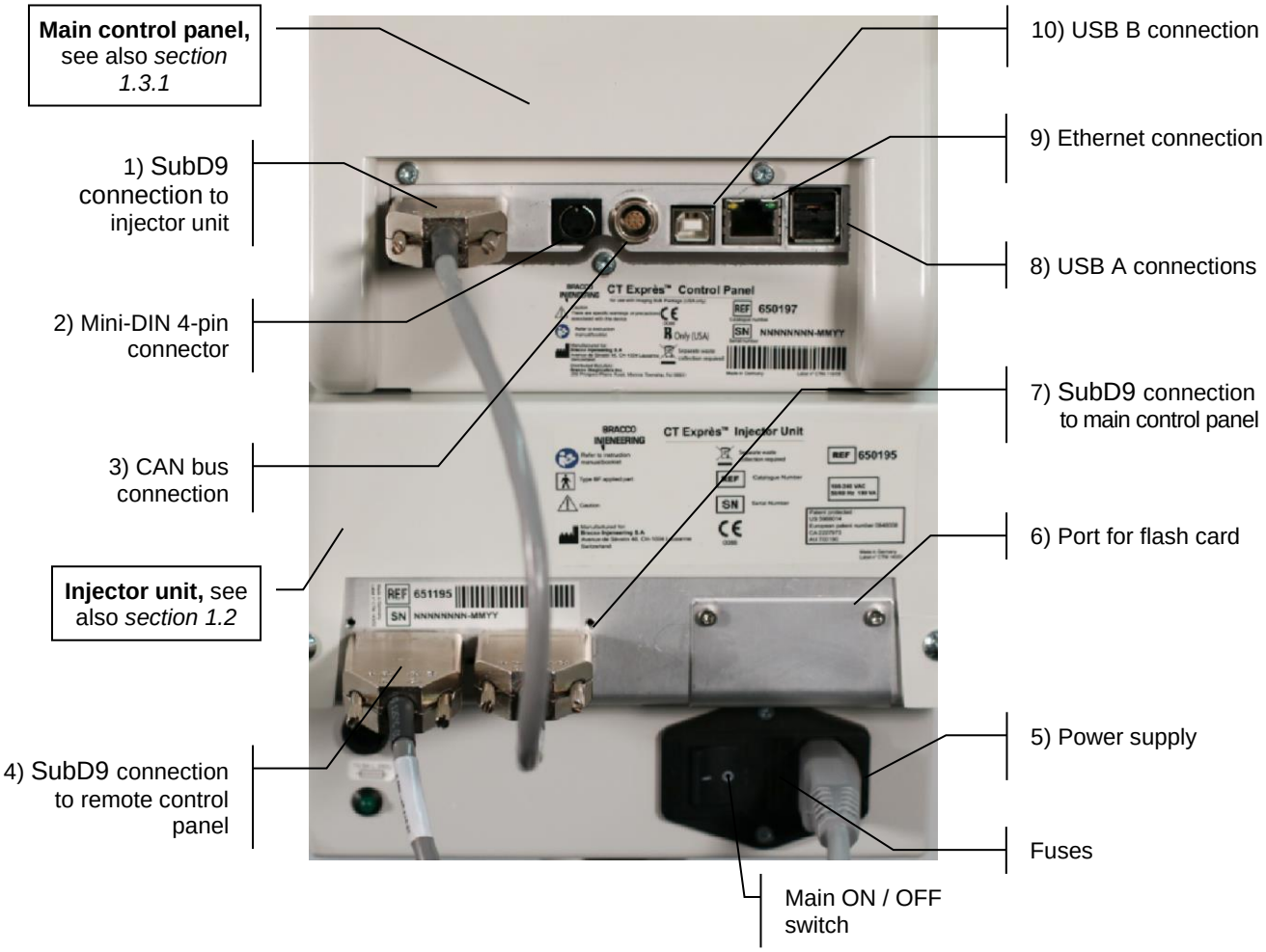


Figure 7: Rear of main unit

Warning

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (*e.g.*, IEC 60950 for data processing equipment). All configurations must also comply with the requirements for medical electrical systems (see IEC 60601-1-1 or IEC 60601-1-2).

Any person who connects additional equipment to medical electrical equipment thereby configures a medical system and is therefore responsible for ensuring that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, please consult your local representative or the Technical Services Department.

Caution

- **The CT Exprès™ 3D cannot be used with only one control panel connected. Make sure both control panels are connected at injector start-up.**
- **To avoid fuses being tripped, make sure the two plug connections at the rear of the device are connected and firmLy screwed into place before the device is switched ON.**

The following is the complete list of authorized connection devices by Bracco Injeneering:

No.	Connection type (number)	Function(s)
1	SubD9 (1 x)	Connection of the main control panel to the injector unit.
2	Mini-DIN 4-pin (1 x)	Connection of the hand switch (hand switch is dedicated to CT Exprès™ 3D and shipped with each delivery).
3	CAN bus (1 x)	Connection to and communication with CT scanner (CT scanner type and brand authorized by Bracco Injeneering). This option may not be available at the time of purchase of the equipment. Please contact your local Bracco Injeneering representative to know if this option is available in your country.
4	SubD9 (1 x)	Connection of the injector unit to the remote control panel.
5	Power supply (1 x)	Connection to local power supply (power supply cable is shipped with each delivery)
6	Port for flash card (1 x)	Port for flash card to be used for software updates approved by Bracco Injeneering. Note: it is necessary to unscrew the port cover to access the port.
7	SubD9 (1 x)	Connection of the injector unit to the main control panel.
8	USB A (2 x)	Software updates approved by Bracco Injeneering. Connection to external devices authorized by Bracco Injeneering.
9	RJ45 (Ethernet) (1 x)	E.g. internet connection for downloading software updates (for servicing, and for trouble shooting) released by Bracco Injeneering, or connecting to Nexo® server, to learn more about Nexo® , refer to *section 4.12*. This option may not be available at the time of purchase of the equipment. Consult additional instructions for use provided by Bracco Injeneering.
10	USB B (1 x)	Software updates approved by Bracco Injeneering. Connection to other devices authorized by Bracco Injeneering.

1.5 Hand switch

Figure 8: The hand switch

CT Exprès™ 3D is delivered with a small ON/OFF hand switch that you can use to start or stop an injection or perform a saline test injection. The hand switch is connected to one of the two control panels by a 3 m cable. Connected to the main control panel, the hand switch gives you the ability to be near the patient during a saline test injection or at the start of an injection.

1.6 Disposables

Warning

To ensure safe and effective operation, use CT Exprès™ 3D only with disposables, components and accessories designed for it and described by Bracco Injeneering in this manual. Use of unapproved disposables, components or accessories can result in a potential hazard and or serious injuries.

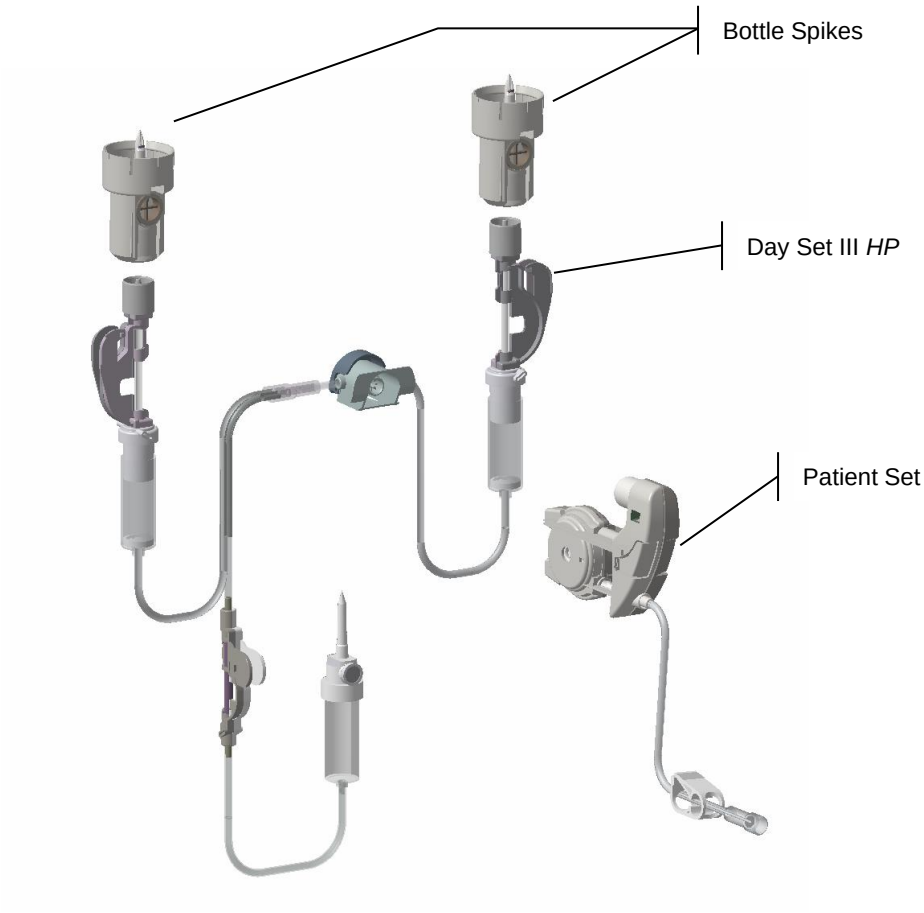


Figure 9: CT Exprès™ 3D disposables

Correct installation of the Bottle Spike, Day Set III *HP*, and Patient Set creates a completely closed fluid pathway from the fluid containers (contrast media and saline containers) to the patient.

The disposables have a number of special design features to prevent accidental re-use.

1.6.1 The Bottle Spike

Warning

- **A Bottle Spike must be used for no more than one bottle of contrast media or saline, and for no more than:**
  - **24 hours for installed bottles.**
  - **12 hours for stored bottles (in upright position).**
  - **The time recommended by the contrast media bottles provider, whichever occurs first.**
- **The Bottle Spike is made of high quality, medical grade materials.**
- **In the event of any possible air contamination or septic contact with the spike or the septum of the Bottle Spike, discard the Bottle Spike.**

The Bottle Spike is a disposable connection device for use with one single bottle of contrast media.

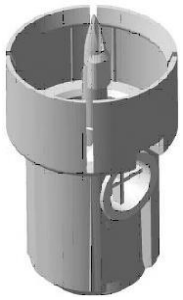


Figure 10: The Bottle Spike

On removing the Bottle Spike from the bottle, the spike tip is designed to break off and remain inside the bottle, rendering the Bottle Spike unsuitable for further use, and thereby preventing accidental re-use.

1.6.2 The Day Set III *HP*

Warning

- **A Day Set III *HP* must be used for no more than 24 hours and for a maximum of 6000 mL of contrast media injected, whichever occurs first. If removed from the injector, discard the Day Set *III HP* and change the saline bag.**
- **The Day Set III *HP* is made of high quality, medical grade materials. Some of these materials contain DEHP (diethylhexyl phthalate). Although these materials are generally considered safe for use with the CT Exprès™ 3D, it is your responsibility to decide whether the Day Set III *HP* may also safely be used on pediatric patients and pregnant or nursing women.**
- **If you do not use the third line (saline line) of the Day Set III *HP*, a quantity of air may be aspired from the third line during normal operation, resulting in a stop due to air detection. We suggest clamping the third line near the T-connector.**
- **Discard the Day Set III *HP* in the event of suspected septic contact or air contamination of the following part:**
  - **Septum.**
  - **Spike on the saline line.**
  - **Spikes of the contrast media lines (for example by Bottle Spike contamination).**
- **Protect the Day Set III *HP* spikes on the bottle side by always inserting a bottle into the bottle holder columns (or by keeping an empty bottle in place).**

Note

- It is recommended that you fit a new Day Set III *HP* when changing a contrast media type or concentration to prevent mixing of different contrast media types.
- After 12 hours of non-use, the Day Set III *HP* lines will be automatically primed with the next Patient Set filling (13 mL / line).

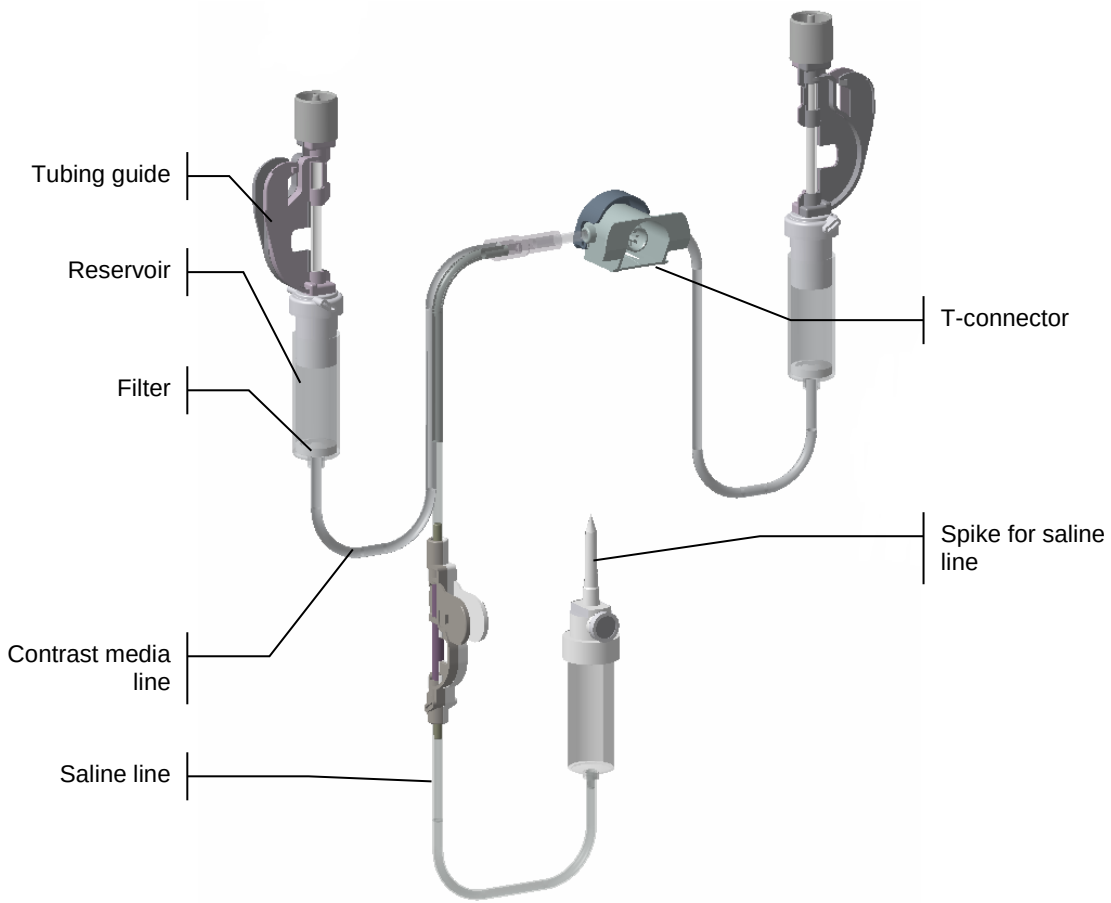


Figure 11: The Day Set III *HP*

The Day Set III *HP* consists of:

- The T-connector. This is inserted into its location on the main unit, just above the patient cassette port, as shown in *Figure 24: Inserting the Day Set III HP's T-connector* on page 52.
- Two lines with: reservoir, filter, and tubing guide. These are for the two bottles of contrast media (or one bottle of contrast media and one bottle of saline). Each tubing guide is clipped into its air-in-line detector and tubing clamp unit. Each unit is located on a bottle holder, as shown in *Figure 26: Inserting a Day Set III HP tubing guide* on page 53.
- A third line, which is for the saline line.

  The tubing guide of the saline line is clipped into its air-in-line detector and tubing clamp unit. This is located below the main part of the CT Exprès™ 3D, as shown in *Figure 27: Inserting the Day Set III HP saline tubing guide* on page 54.

  The spike is then inserted into the saline container (bottle or pouch) and the reservoir completely filled, as shown in *Figure 30: Spiking the saline container* on page 55 and *Figure 34: Filling the saline reservoir of the Day Set III HP third line* on page 55.

The logbook (see *section 5.2: Logbook* on page 110) shows the time remaining and the volume that can be injected with the installed Day Set III *HP*.

1.6.3 The Patient Set

Warning

- **A Patient Set must be used for only one patient (single use), for no more than 12 hours, and for a maximum of three injections (200 mL per injection) or 300 mL of contrast media, whichever occurs first (an alert occurs if you attempt to re-insert a used Patient Set into the CT Exprès™ 3D).**
- **When the injection volume(s) is/are programmed, the CT Exprès™ 3D takes into account the volume of contrast media or saline solution in the tubing of the Patient Set. Any additional extension tubing is not taken into account in the volume and sequence calculation and presents a risk of severe patient injury or death due to air injection.**
- **The Patient Set is made of high quality, medical grade materials. Some of these materials contain DEHP (diethylhexyl phthalate). Although these materials are generally considered safe for use with the CT Exprès™ 3D, it is your responsibility to decide whether the Patient Set may also safely be used on pediatric patients and pregnant or nursing women.**
- **If the Patient Set is subject to air contamination or if septic contact with the Patient Set spike or connector occurs, discard and replace the Patient Set.**
- **In the event of accidental traction or pulling on the Patient Set tubing, the Patient Set must be discarded and replaced.**

The Patient Set consists of the peristaltic injector cassette and tubing:

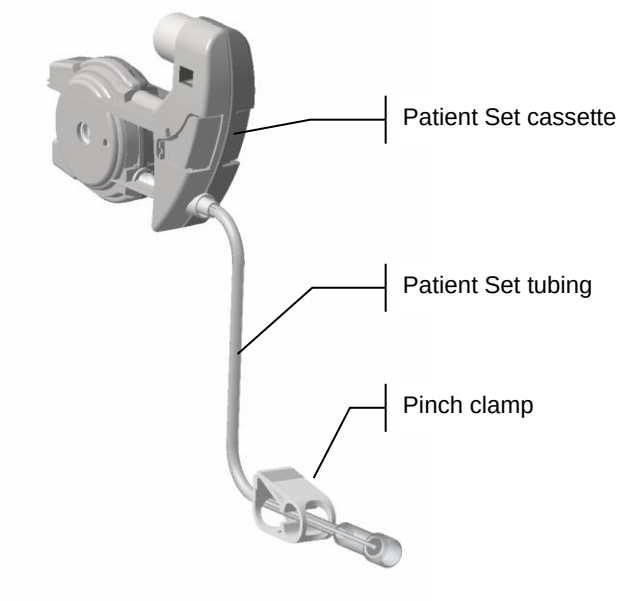


Figure 12: The Patient Set

The Patient Set is installed by sliding the patient cassette into the patient cassette port of the T-connector of the Day Set III *HP*, as shown in on page 63.

CT Exprès™ 3D is designed to prevent accidental re-use of a Patient Set that has been removed. The Patient Set allows up to 3 injections per patient, and a maximum of 300 mL of total contrast media injection.

CT Exprès™ 3D gives a warning if not used for more than 3 hours with a Patient Set installed.

The logbook (see *section 5.2: Logbook* on page 110) shows the time remaining and the volume that can be injected with the installed Patient Set.

1.7 Accessories

Warning

Use the CT Exprès™ 3D only with accessories approved by Bracco Injeneering for the device. There are potential risks if any other accessories are used.

1.7.1 Bottle insulators

The bottle insulators, specifically designed for the CT Exprès™ 3D, are provided by Bracco Injeneering.

Figure 13: A bottle insulator

Fit one bottle insulator over each contrast media bottle, as shown in *Figure 39: Inserting the bottle and fitting an insulator* on page 58.

Warning

- **With temperature maintainer option, prewarmed bottles remain at the required temperature only if the dedicated insulator is used.**
- **For optimal delivery accuracy, when selecting between prewarmed or not prewarmed contrast media, take into account that:**
  - **Not prewarmed contrast media means a contrast medium with a temperature between 20 °C (68°F) and 22 °C (71.6 °F).**
  - **Prewarmed contrast media means a contrast medium with a temperature between 35 °C (95 °F) and 37 °C (98.6 °F).**
- **Never heat contrast media above 37.5 °C (99.5°F). Injection of contrast media at a temperature higher than 37.5 °C (99.5 °F) can be harmful to the patient.**

Caution

- **It is recommended to always use the insulators to cover each bottle. The insulators protect and secure the bottles from breakage or shock or from being knocked from the bottle holder during use. The temperature of prewarmed contrast media can only be maintained if insulator is installed.**

1.7.2 Stand and wheel base (optional)

The CT Exprès™ 3D can be supplied with a stand and wheels to allow it to be positioned according to the CT procedure requirements. The wheel base has foot brakes to secure the unit in position.

1.7.3 Ceiling mount (optional)

Your Bracco Injeneering representative can supply an optional ceiling mount. Discuss this with your representative to make sure that the correct choice is made for your CT suite.

Warning

Make sure installation of any ceiling mount is performed according to the vendor's recommendation. Improper installation can be hazardous and can result in serious injuries.

2 Preparing for a clinical session

2.1 Items required

- Two bottles of contrast media or 1 bottle of contrast media and 1 glass bottle of saline.
- Two Bottle Spikes (see *section 1.6.1 The Bottle Spike* on page 34).
- Two bottle insulators (see *section 1.7.1 Bottle insulators* on page 37).
- One Day Set III *HP* (see *section 1.6.2 The Day Set III HP* on page 34).
- One Patient Set (see *section 1.6.3 The Patient Set* on page 36).
- One saline bottle or saline pouch.
- One venous access device (16 to 24 G).
- Adhesive tape to make sure patient access positioning is properly maintained.
- PDI® Super SaniCloth germicidal® disposable wipes.

2.2 Considerations for venous access

Warning

When using high flow rates of contrast media and saline:

- **The delivery volume can be higher than specified if the needle gauge used is larger (lower gauge number) than the needle programmed on the CT Exprès™ 3D.**
- **The delivery volume can be lower than specified if the needle gauge used is smaller (higher gauge number) than the needle programmed on the CT Exprès™ 3D.**

Observe the following points when connecting a patient to the CT Exprès™ 3D device:

- Connect the patient to the CT Exprès™ 3D using (preferably) a flexible means of needle access.
- Tape the Patient Set tubing securely into position on the patient, including (preferably) a loop-back. Make sure there is no risk of extravasation.
- Program the correct needle gauge in the CT Exprès™ 3D (see *section 4.8.1*: *Programming the needle gauge (size)* on page 69) and make sure that the gauge appears on the control panel display (for example, `16G`).
- To ensure proper positioning of the needle, additional saline solution other than that required for imaging purposes can be deliberately delivered to a patient during a saline test injection.

2.3 Considerations for contrast media and saline

Warning

- **Always read the contrast media bottle label before using the contrast media. Special attention must be taken to ensure that the contrast media used corresponds to the contrast media required by the injection protocol.**
- **If the Patient Set is primed with contrast media, any saline test injection or preflush is initially performed with the contrast media contained in the tubing: this might result in over-delivery of contrast media. In this case, a warning is indicated by the CT Exprès™ 3D before an injection is started. This warning will inform about patient Set content and will ask to manually prime the line with saline.**
- **Given the possible mixing of contrast media and saline solution during the initial purge steps, even in only minute amounts, it is mandatory to ensure before each saline test injection that the patient is not susceptible to risks related to injection of contrast media. Refer to the recommended practices and safety precautions provided by the contrast media manufacturer and act in all cases, even for injection of saline solution, as if it were a contrast media injection.**
- **If, after filling or priming, the Patient Set contains saline, but no saline preflush is programmed, this will result in under-delivery of contrast media during an injection. In this case, a warning is indicated by the CT Exprès™ 3D before an injection is started. This warning will inform about Patient Set content and will ask to manually prime the line with contrast media.**
- **It is necessary to be particularly vigilant if different contrast media are installed for the same Day Set III *HP*, as a mixture may form at the Day Set III *HP*'s T-connector resulting in injection of a very minute amount of the unintended contrast media.**

Caution

It is recommended you do not re-use a contrast media or saline bottle or pouch after prolonged (more than 12 hours) storage. This is because there is a potential risk of occlusion of the Bottle Spike's air filter by the contrast media if the bottle is stored outside the injector after use.

Note

Dispose of used contrast media bottles and saline containers according to the manufacturer's instructions.

2.3.1 Using contrast media

Observe the following points when preparing to use the contrast media:

- Take particular care to correctly identify the bottles during the programming process on the injector to avoid using the wrong contrast media: the properties and viscosity of contrast media depend on the type and concentration. The CT Exprès™ 3D guarantees dose accuracy only if the type and concentration are entered correctly.
- Make sure you select the correct needle gauge: viscosity affects the flow rate depending on the needle gauge. CT Exprès™ 3D can only guarantee dose accuracy if the needle gauge is programmed correctly.
- If you program a flow rate that is not compatible with the programmed contrast media type and needle, CT Exprès™ 3D will display a warning message. In this case, you will not be able to start an injection without selecting a lower flow rate or using a larger gauge (smaller gauge number) needle.
- Use only contrast media approved for intravenous injection.
- Contrast media bottle sizes that are suitable for use on CT Exprès™ 3D vary from 50 mL to 500 mL in volume.
- The CT Exprès™ 3D can operate with one empty bottle if the other bottle holds sufficient contrast media to complete the injection.
- It is recommended that you refill the Day Set III *HP* when changing a contrast media bottle to avoid blending of different contrast media types.

2.3.2 Prewarming contrast media

Warning

- **Contrast media viscosity is temperature-dependent. Using contrast media that is below or above the temperature conditions you programmed on CT Exprès™ 3D can affect the accuracy of the fluid dose delivered to the patient.**
- **For optimal delivery accuracy, when selecting between prewarmed or not prewarmed contrast media, take into account that:**
  - **Not prewarmed contrast media means a contrast medium with a temperature between 20 °C (68°F) and 22 °C (71.6 °F)**
  - **Prewarmed contrast media means a contrast medium with a temperature between 35 °C (95 °F) and 37 °C (98.6 °F)**
- **Never heat contrast media above 37.5 °C (99.5°F). Injection of contrast media at a temperature higher than 37.5 °C (99.5 °F) can be harmful to the patient.**

Observe the following points when preparing to use the contrast media:

- CT Exprès™ 3D works best with prewarmed contrast media, as this facilitates high flow rates. Using contrast media at 15 to 20 °C (59 °F to 6 8°F) cannot guarantee optimal delivery efficiency, as this lower temperature may be associated with flow rate limitations for high viscosity contrast media.
- Refer to the manufacturer's contrast media specifications for specific instructions about contrast media warming.
- If using prewarmed contrast media, make sure to program the contrast media option `PREWARMED` on CT Exprès™ 3D for each prewarmed bottle to maintain the accuracy of the flow rate.
- If option is available, CT Exprès™ 3D actively maintains temperature of prewarmed contrast media using a heater in combination with the insulator. The contrast media temperature does not exceed 37.5°C.

2.3.3 Using saline

Warning

- **Always read the label on the saline container and make sure that only saline solution intended for intravenous injection is used.**
- **Never use a saline container for more than 12 hours.**
- **It is recommended you change the saline container when you change the Day Set III *HP.***

You can perform saline injections before (preflush), after (postflush), and between (interphase) two injection phases of contrast media.

You can inject saline from its original packaging (including bottles or pouches) using the Day Set III *HP*'s third (saline) line (see *section 1.6.2: The Day Set III HP,* on page 34).

Observe the following points when preparing to use the saline:

- Use only saline approved for intravenous injection.
- When saline is present in the Patient Set after filling or priming, program a preflush to avoid the risk of:
  - Under-delivery of contrast media.
  - Delayed start of delivery of contrast media.

  These problems can take place if the Patient Set is filled with saline before a contrast media injection.

3 Dealing with status notifications and display messages (alerts, warnings)

3.1 Introduction

Section 3.2 provides information about the CT Exprès™ 3D status notifications and display messages and how to react to them:

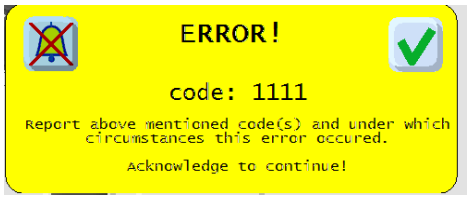
- Information display messages (untitled)
- Questions
- `WARNING` display messages
- `ALERT` display messages
- `ERROR` display messages

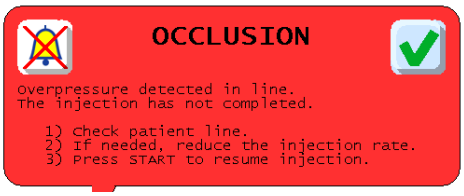
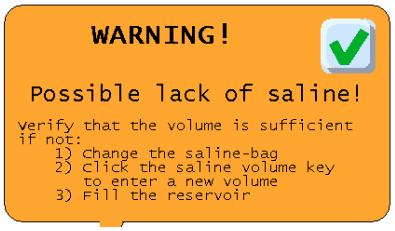
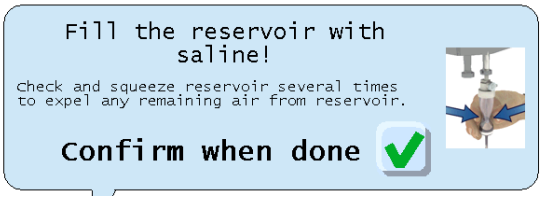
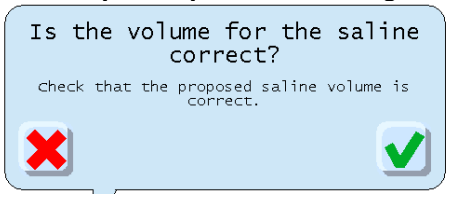
Warning

All of the above status notifications and messages require immediate attention.

3.2 Reacting to status notifications and display messages

The following table gives a general overview and examples on the visual and audible appearance of the different display messages on CT Exprès™ 3D and their acknowledgement. CT Exprès™ 3D is designed to provide adequate information and contextual help for the operator to successfully acknowledge status notifications and display messages like alerts and warnings.

Display message type	Color code of visual (alert) signal	Audible alert signal	Options for acknowledgement
ERROR This is an hard-Stop. All buttons on the injector unit are disabled as long as checkmark symbol ☑ is not pressed. No injection is possible if the source of the ERROR is not solved. If the problem is not resolved the alert will recur.	yellow message background and red luminous bar	one beep and buzzer at the same time, non-repetitive	Press ▪ the speaker symbol to permanently silence the audible signal (i.e. bell cancel). The alert will still be displayed without any sound. or ▪ the checkmark symbol ☑ to make the message disappear permanently (i.e. alert off) Note: the cause that triggered the alert continues to exist. If the instruction displayed with the ERROR is not effective, restart the injector (use the main switch on the rear). **Example display message:** 

Display message type	Color code of visual (alert) signal	Audible alert signal	Options for acknowledgement
ALERT This is an hard-Stop. All buttons on the injector unit are disabled as long as checkmark symbol ☑ is not pressed. No injection is possible if the source of the alert is not solved. If the problem is not resolved the alert will recur.	red message background and red luminous bar	one beep, or two subsequent beeps (depending on the alert type), repetitive at intervals of 10 s	Press ▪ the speaker symbol to permanently silence the audible signal (i.e. bell cancel), or ▪ the checkmark symbol ☑ to make the message disappear (i.e. alert off). **Example of alert message:** 
WARNING	orange message background	none	Press the checkmark symbol ☑ to make the display message disappear (i.e. alert off). Note: the cause that triggered the alert continues to exist. **Example of warning message:** 
Confirmation	blue message background	None	▪ Do the requested action ▪ Press the checkmark symbol ☑ to confirm the action **Example of confirmation request message:** 
Questions Read carefully displayed instructions	blue message background	none	Press ▪ the cross symbol ☒ to negatively acknowledge, or ▪ the checkmark symbol ☑ to positively acknowledge the question. **Example of question message:** 

Display message type	Color code of visual (alert) signal	Audible alert signal	Options for acknowledgement
Information display messages (untitled)	blue message background	none	Follow the instructions in the message and it will close automatically. Or, you can close the message and return to the main interface by pressing on the message itself. CT Exprès™ 3D will keep track of the message and prompt you again if needed. **Example display message:** 

4 Clinical session

4.1 Introduction and injection capabilities

The CT Exprès™ 3D enables injection of media in up to 24 phases per patient. One phase can consist of contrast media. In addition, it is possible to program a phase of saline flush before, between, and/or after each of the contrast media phases, namely preflush, interphase flush and postflush, (see also *sections 4.5.2: Programming the contrast media bottle,* on page 59 and *4.5.3: Loading and programming the second bottle,* on page 62) or an injection pause.

A simple injection program would look like the following:

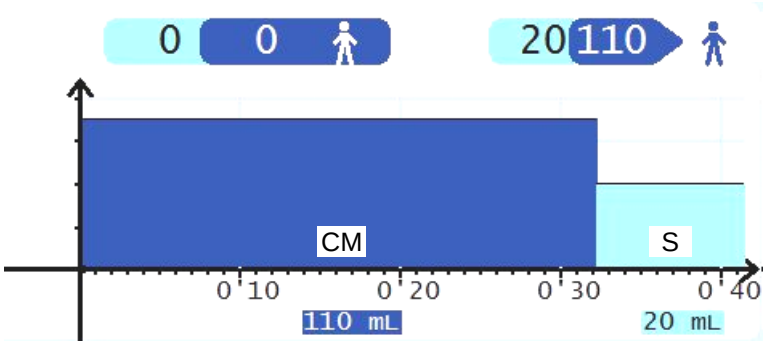


Figure 14: Simple injection program (CM = Contrast Media / S = Saline)

In the above example, 2 phases are programmed: injection of contrast (110 mL at 7.0 mL/s) followed by saline (20 mL at 4.0 mL/s).

However, the CT Exprès™ 3D also meets the needs of advanced injection requirements in programming more complex injection programs. The following graph gives an illustration of a hypothetical more complex injection profile:

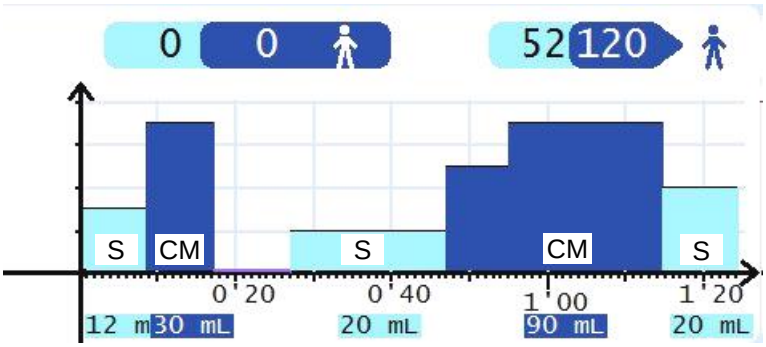


Figure 15: Complex injection program (CM = Contrast Media / S = Saline)

In the above example, 7 phases are programmed: injection of saline (12 mL) followed by injection of contrast (30 mL), pause, injection of saline (20 mL), injection of contrast (90 mL at 2 different flow rates) and finally injection of saline (20 mL).

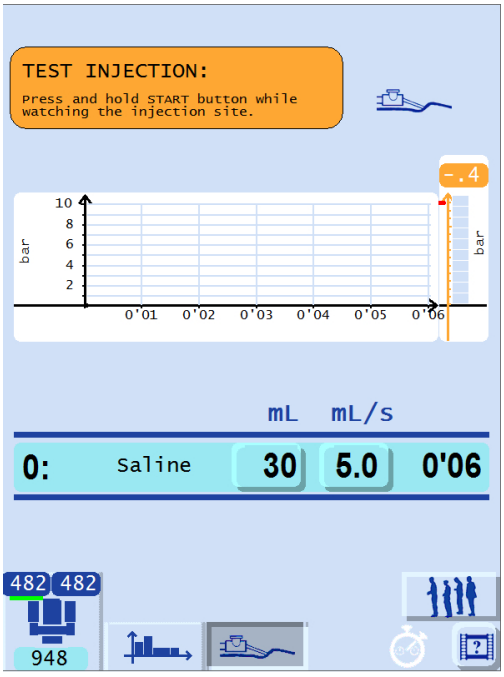
Saline phases can be added in an injection protocol before or after contrast media phase. If part of an injection protocol before the contrast media phase, it is named a pre-flush. If part of an injection protocol after the contrast media injection, it is named a post-flush. These saline phases are part of the injection protocol and should not be confused with the saline test injection as described below.

4.1.1 Programming a saline test injection

Note

- An injection must first be programmed before a saline test injection can be programmed and performed using the Test Injection page. This is because the saline test injection program will use the highest flow rate setting in the injection program as the default flow rate for the saline test injection.

The CT Exprès™ 3D provides the option to program and automate the saline test injection. The purpose of the saline test injection (also named saline test flush) is to check the quality of the venous access prior to injection, consistent with safe injection techniques. If, after a saline test injection the venipuncture site is tender or infiltrated, an alternative site should be sought. Once an injection program is selected and prior to performing the injection, a saline test injection can be programmed. A saline test injection would look like displayed below and would use the highest flow rate programmed for the injection already programmed. If a lower flow rate is desired, this must be manually entered.



4.1.2 Starting an injection or saline test injection

CT Exprès™ 3D will not start an injection if the programmed contrast media/saline injection volume is greater than the actual contrast media/saline installed volume. When programming an injection, compare the programmed contrast media and saline volume against the available volume. If the amount of contrast media or saline installed is not sufficient to meet the programmed injection protocol the CT Exprès™ 3D will display a message and prompt to install new container. If this is not performed or if the volume is still insufficient, the same message will be again displayed when trying to start the injection and the injection will not be allowed. This is applicable to both injection protocol and saline test injection.

CT Exprès™ 3D will assume that the bottles' volume is as programmed by the user. If a user incorrectly programmed a volume greater than what is effectively installed (for example programming 500 mL instead of the bottle volume of 200 mL), the CT Exprès™ 3D will authorize the start of injection. In this case, when a bottle or bag becomes empty during the course of injection, the CT Exprès™ 3D will detect it and the user will be informed.

4.1.3 Automatic changeover functionality

The automatic bottle changeover status indicator indicates whether this function is enabled. The automatic changeover function allows for automatic switching during the injection process, from an emptied contrast media bottle to the second installed bottle thereby not stopping the injection. This function is automatically enabled if the two contrast media bottles installed and programmed by the user are of the same type and, concentration. The automatic changeover function is a software function that cannot be manually activated or disabled by the user. If the user selects two different contrast media settings during the contrast media bottle installation process, then this function is automatically disabled.

4.1.4 DiluJect™ (optional)

Diluject is an optional feature available if authorized in your country. Contact your local Bracco Injeneering representative for more details.
DiluJect™ is a feature in which contrast media and saline are injected in rapidly alternating flow through the injector. As a result, contrast media and saline will blend once injected in the patient's vascular system, resulting in a combination of contrast media with saline when reaching the heart. The DiluJect™ phase parameter can be selected from 5 values, each one representing a different contrast media content expressed as a percentage of the total DiluJect™ volume injected (15%, 20%, 25%, 30% or 50% of contrast media for the total DiluJect™ volume injected).

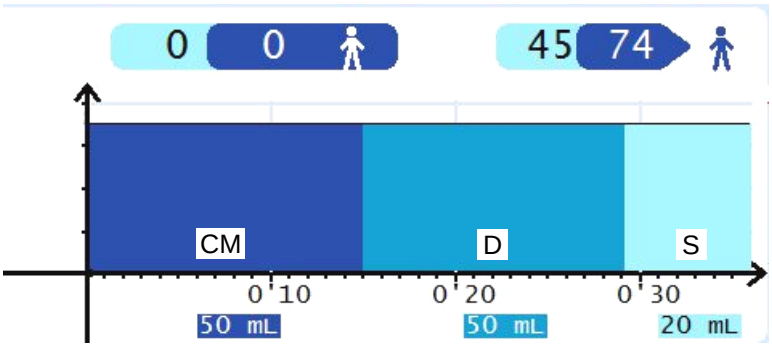
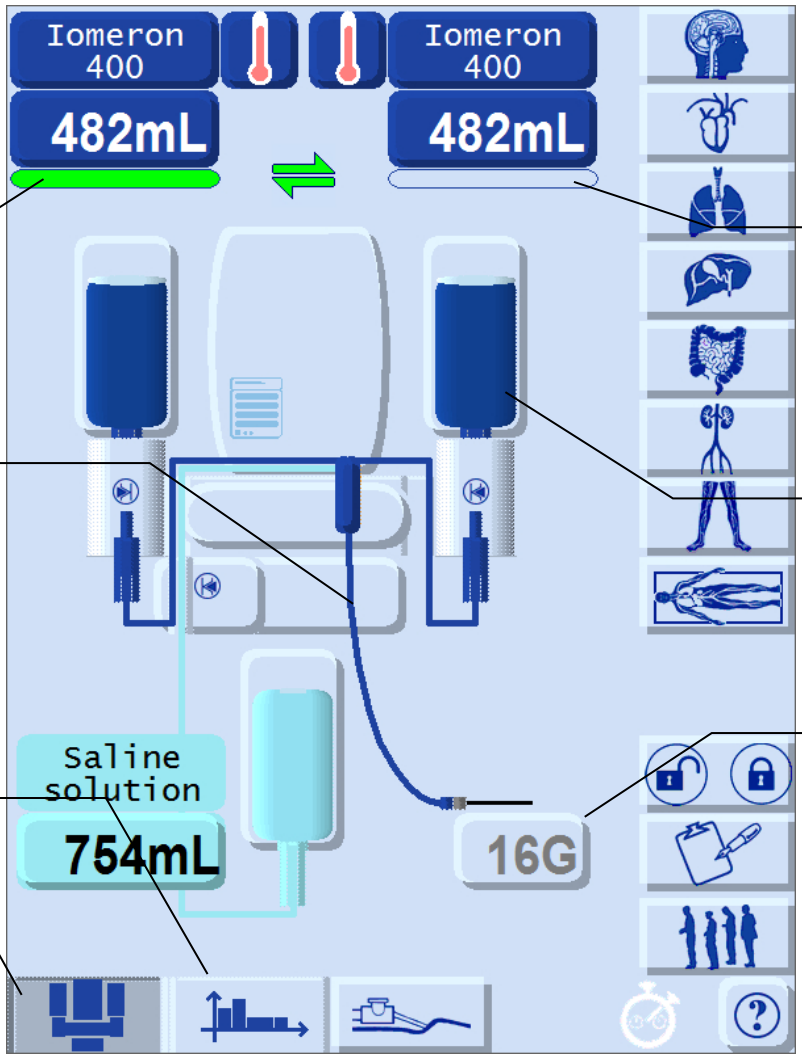


Figure 16: DiluJect™ injection program (CM = Contrast Media / D = DiluJect™ / S = Saline)

The status indicators on the control panel interface provide continuous status information about:

- The quantity of contrast media remaining in each of the two bottles mounted on top of the device (see *Figure 17*).
- The active bottle of two bottles mounted from which the delivery will start (see *Figure 17* and *Figure 18*).
- The volume of contrast media and saline already injected as well as the volume remaining to be injected into the patient (see *Figure 18).*
- The course of injection in a real-time graph (see *Figure 18*).



Green bottle display indicates this bottle is active, i.e. the injection will start with this bottle.

Patient Set tubing
White = unprimed
Blue = primed
Red = to be primed or changed

Key with light background indicates an unselected key.

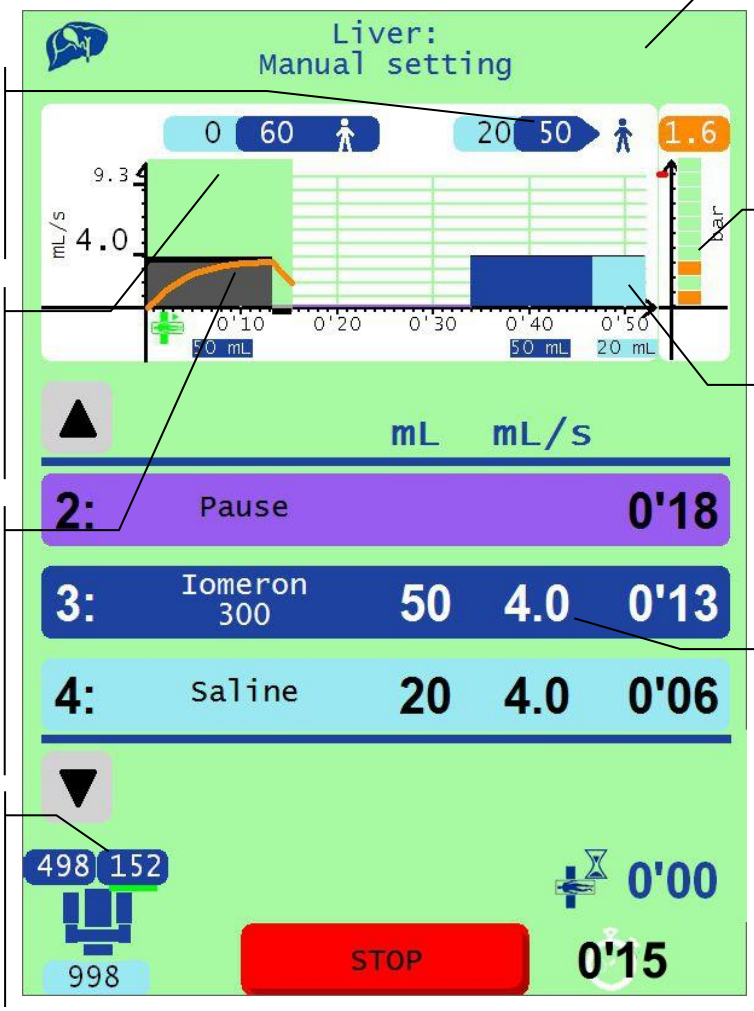
Key with dark background indicates a selected key.

Grey bottle display indicates this bottle is not active, *i.e.* injection will start with the other loaded bottle. Press the bottle selection key to activate this bottle and start the injection from here.

Dark area on bottle selection key indicates the remaining media volume (illustration is approximate).

Key with color font indicates the programmed needle gauge (see *section 4.8.1*). Grey font indicates that the needle gauge has not been chosen yet.

Figure 17: Status indicators on the Injector Status Page



Display indicating the media volume to be injected:
- saline: light blue
- contrast media: dark blue

Display indicating the injected media volume:
- saline: light blue
- contrast media: dark blue

Graph with green background indicating the phase parameters injected into the patient
- injection volume: grey box
- pressure: orange line

Green bottle display indicates that this bottle is selected. The injection will start on this bottle.

Green display background and flashing green luminous bar indicate that an injection on the CT Exprès™ 3D is in progress.

Two orange pressure bars indicating the current and max. pressure during the injection.

Graph indicating the parameters of the programmed injection phases (injection volume:
- contrast media: dark blue
- saline: light blue)

Phase key with color background indicates that the programmed phase parameters are correctly entered (contrast media phase: dark blue, saline: light blue, pause: purple).

A key with grey background indicates an inactive phase which has already been injected.

Figure 18: Status indicators on the Injection Settings Page

4.2 Starting the CT Exprès™ 3D

The CT Exprès™ 3D cannot be used with only one control panel connected. Make sure both control panels are connected at injector start-up.

1. Switch on the mains power supply with the black mains power switch at the rear of the CT Exprès™ 3D.

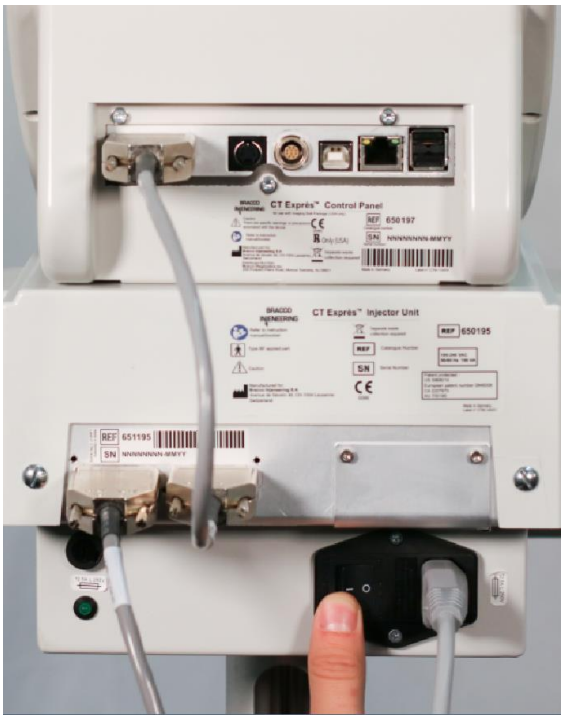


Figure 19: Switching on the mains power

2. Observe that the red and green LED of the Patient Set unlocking button light up and the luminous bar turns red, and wait for completion of the automatic self-test at start-up. If you wish to be given a brief introduction on the use of CT Exprès™ 3D, press the video quick tour key on the start-up page and follow the instructions on the display. The brief introduction and video library are also accessible at any time by clicking on the Permanent settings key.

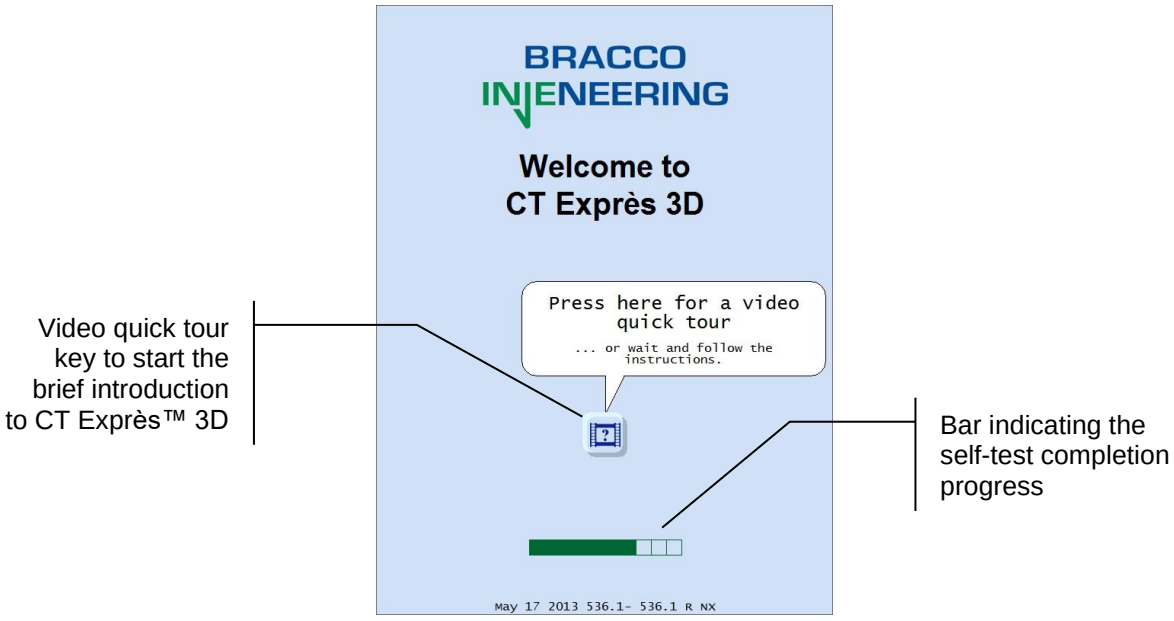


Figure 20: Start-up page

Make sure the following happens at start-up of the CT Exprès™ 3D:
- You hear an audible alert (beep).
- You see the luminous bar lit in red color
- You see the start-up page indicating the self-test completion status

This confirms that CT Exprès™ 3D is performing a self-test. Do not install any disposables during the self-test, as they could be rejected by the injector and ultimately lost.

Warning

If you do not hear an audible alert as described above, if the start-up page is not displayed correctly, or if you see an error message, do not use the CT Exprès™ 3D. Contact our Technical Services Department or your Bracco Injeneering representative.

4.3 Installing the Day Set III *HP*

Warning

Always use aseptic techniques when handling the Day Set III *HP*.

Note

- You will find details on the composition of Day Set III *HP* in the *section 1.6.2: The Day Set III HP* on page 34.
- Use of the saline line is optional. If you do not wish to use saline, then enter None when prompted to program the saline container volume.
- You can press the help key (shown in *3* on page 26 and on page 28) at any time for information and instructions.

1. After successful start-up, CT Exprès™ 3D will prompt you to install a new Day Set III *HP*:

Figure 21: New Day Set III *HP* installation message

If a Day Set III *HP* is already installed on the injector (after power failure), the CT Exprès™ 3D will display the following message:

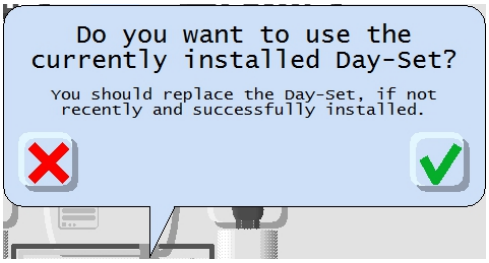


Figure 22: Day Set III *HP* already installed message

If you wish to use the already installed Day Set III *HP*, confirm the message by pressing ☑ and continue with the instructions given in *section 4.4: Installing and programming the saline container*. If you wish to change the Day Set III *HP*, decline the message by pressing ☒, remove the current Day Set III *HP* and follow the instructions given below.

2. Place the new Day Set III *HP*'s saline spike in its holder to keep it clean.

Note
Leave the cover on the spike. Remove it prior to piercing the septum of the saline container.

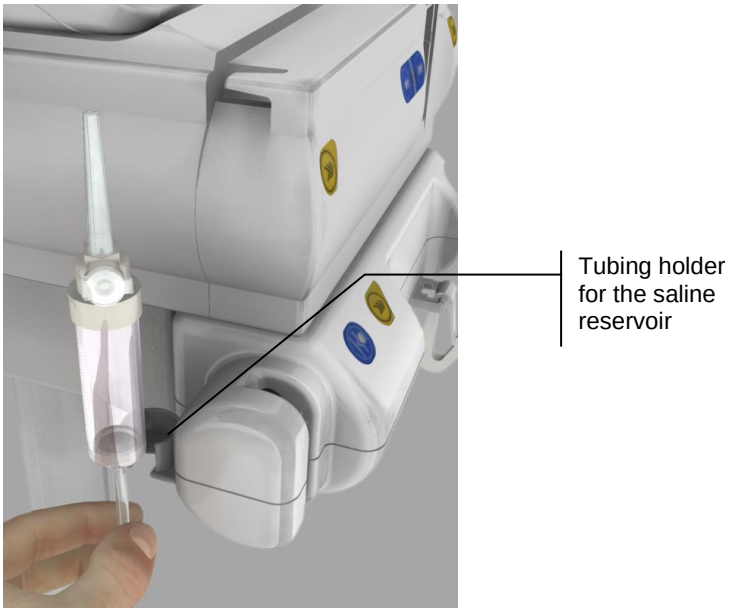


Figure 23: The Day Set III *HP*'s saline spike in its holder

3. Insert the Day Set III *HP*'s T-connector until it "clicks" into place.

Figure 24: Inserting the Day Set III *HP*'s T-connector

Note
When the T-connector is correctly inserted, the Day Set III *HP* will appear in grey color on the control panel display

4. Once the T-connector is in place, the three clamps of the three lines open automatically for easy insertion of each tubing guide. These clamps will stay open, allowing you to finish installing the Day Set III *HP*. A display message will prompt you to verify correct insertion of the Day Set III *HP* lines in their respective slots on the CT Exprès™ 3D (see
5. *Figure 25: Day Set III HP correctly installed* message). Please follow the instructions below without confirming the verification message (confirmation is at step 8 of the procedure, on page 54).

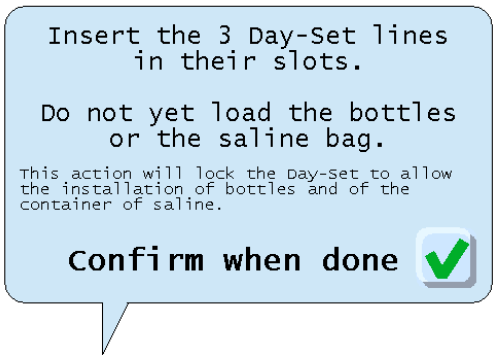


Figure 25: Day Set III *HP* correctly installed message

Note

- When you accept the verification message *(Figure 26: Day Set III HP correctly installed message*), the clamps will automatically close. If tube supports are not already installed, then remove the T-Connector to open again each clamp.
- Do not insert any bottle or pouch before all clamps are closed as this may result in a Day Set III *HP* alert during filling.

6. Insert the tubing guide of each of the two contrast media lines into the correct position on its respective bottle holder. To do this, first slide the angled tabs at the bottom of the tubing guide all the way into the tracks near the bottom of the bottle holder. Then rotate the tubing guide upward into position.

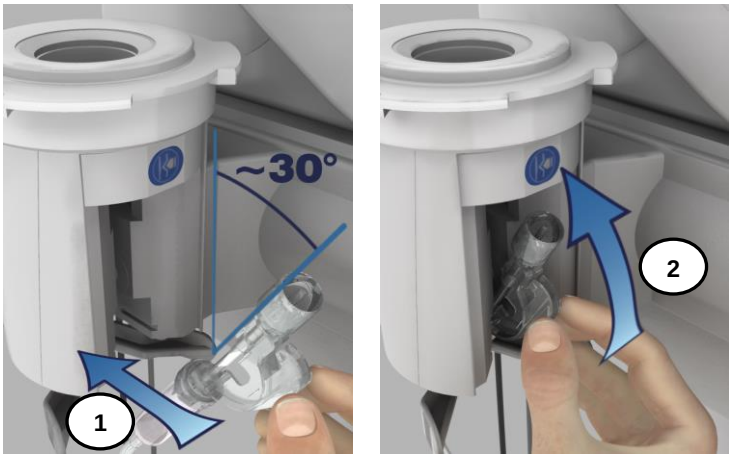


Figure 26: Inserting a Day Set III *HP* tubing guide

Warning

Before rotating the tubing guide, make sure the bottom of the tubing guide is fully inserted. After rotating the tubing guide, check that the top of the tubing guide is properly inserted and pushed in up to the stop.

7. Repeat the procedure for the second contrast media line.
8. Insert the third line (saline) tubing guide in a similar manner.

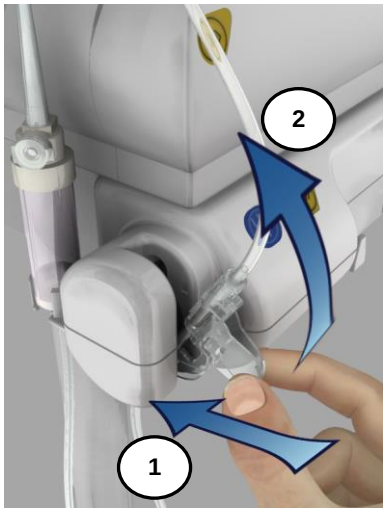


Figure 27: Inserting the Day Set III *HP* saline tubing guide

Warning

Before rotating the tubing guide, make sure the bottom of the tubing guide is fully inserted. After rotating the tubing guide, check that the top of the tubing guide is properly inserted and pushed in up to the stop.

9. Once you have completed the installation of the Day Set III *HP*, confirm the message (*Figure 26: Day Set III HP correctly installed message)* by pressing ☑. This will subsequently close the clamps of all three lines.
10. The CT Exprès™ 3D will now ask you to install the saline container. Please follow the instructions given in *section 4.4: Installing and programming the saline container*.

4.4 Installing and programming the saline container

4.4.1 Connecting the third line to the saline container

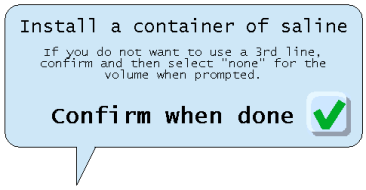


Figure 28: Saline container installation message

1. Remove the protective cover seal of the saline container.
   You may clean the rubber under the aluminum part with an appropriate disinfecting agent.

Figure 29: Removing the aluminum seal from the saline container (example given for rigid bottle)

2. Using aseptic techniques, remove the saline spike from its holder, remove the protective cover from the spike, and pierce the saline container (bottle or pouch).

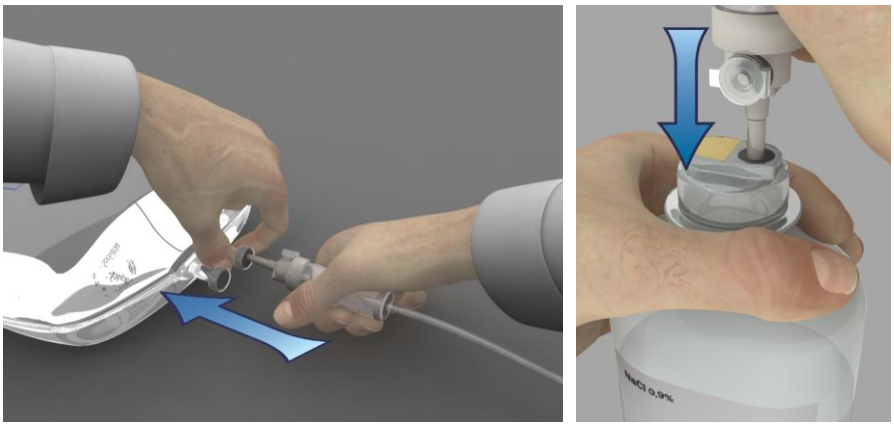


Figure 30: Spiking the saline container (left: pouch; right: rigid bottle)

3. Make sure that the air vent on the reservoir chamber is open if you are using a rigid plastic bottle. This is necessary to allow fluid movement from the saline rigid bottle. The air vent may be closed if using a saline pouch.

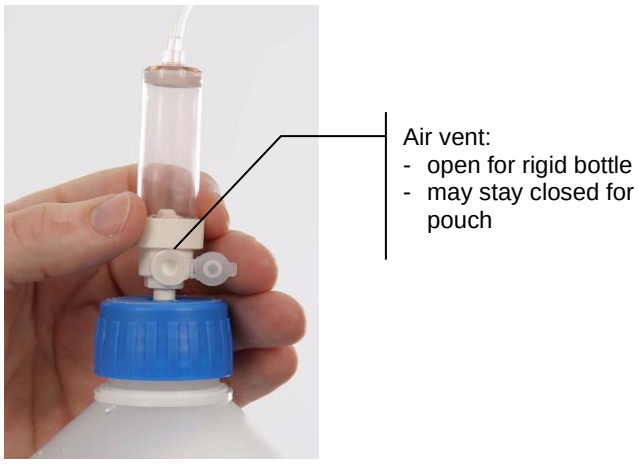


Figure 31: The air vent on the saline reservoir (shown open)

4. Hang and secure the saline container (pouch or plastic bottle) on either of the hooks at the front of the CT Exprès™ 3D, (the left hook is for the quickest possible attachment. The right hook is for enhanced attachment security).

Figure 32: A saline container in place (left: pouch; right: plastic bottle)

5. Now confirm by pressing the ☑ key of the display message (see *Figure 29: Saline container installation message* on page 54) that you have connected the saline bag to the saline line

4.4.2 Programming CT Exprès™ 3D for the saline container

1. Choose between the different volumes proposed or press the key to manually program a volume using the keypad. Confirm the value by pressing the ☑ key.

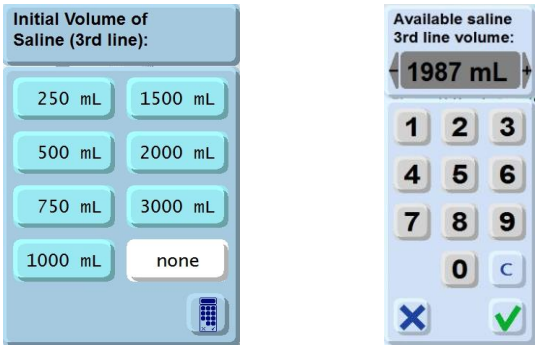


Figure 33: Volumes proposed (on the left) and keypad to enter a new volume (on the right)

2. If the volume proposed is correct acknowledge by pressing the ☑ key, then fill the reservoir (as described below) and acknowledge the message. If the volume proposed is not correct, press the red ☒ key and follow the instructions in step 1.
3. If the saline third line path is used (a volume has been selected), ensure that the reservoir of the saline line is entirely filled. Check the reservoir, squeeze it repeatedly and press ☑ on the displayed message.

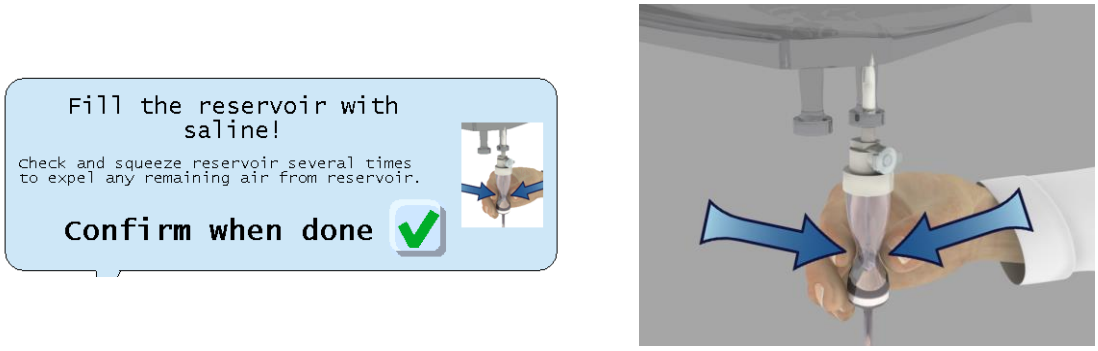


Figure 34: Filling the saline reservoir of the Day Set III *HP* third line

Note

Failure to entirely fill the reservoir can result in air alerts later.

Note

- The screen "Volume of saline 3rd path" can be displayed at any time by briefly clicking the saline line clamp-opening button or by selecting the corresponding zone on the touch screen.
- You may opt to use one of the following settings:
- two contrast media bottles (no saline container), no third line container or
- one contrast media bottle and one saline glass bottle, no third line container.

  In this configuration (i.e. using two bottles, but no third line container) you must program None as the volume of the third line container.

Warning

- **Unintentional combination of saline and contrast media can occur in the tubing.**
- **Given the possible mixing of contrast media and saline solution during the initial purge steps, even in only minute amounts, it is mandatory to ensure before each saline test injection that the patient is not susceptible to risks related to injection of contrast media. Refer to the recommended practices and safety precautions provided by the contrast media manufacturer and act in all cases, even for injection of saline solution, as if it were a contrast media injection.**

4.5 Installing a contrast media bottle

The following message is displayed in absence of a bottle:

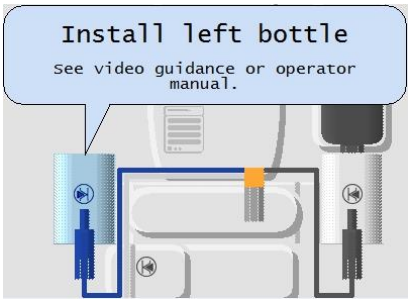


Figure 35: Install Left Bottle Message

4.5.1 Loading the contrast media bottle

Warning

Always use aseptic techniques while handling contrast media.
To guarantee asepsis, follow the procedure described.

1. If necessary, remove the protective cover seal from the contrast media bottle. Do not remove the aluminum rim.

Figure 36: Removing aluminum cover seal from contrast media bottle. Do not remove the aluminum rim.

2. Open the blister package containing the Bottle Spike, making sure not to touch the spike directly or to exert any pressure on the tip of the spike even indirectly (the spike is designed to break off after use).

Figure 37: Opening the Bottle Spike blister package

3. Using the packaging to hold the Bottle Spike. Pierce the bottle seal, making sure not to touch any part of the spike. Make sure that the spike is fully inserted into the bottle and that the Bottle Spike body is fully pushed into place on top of the bottle.

Caution

- **Using the Bottle Spike packaging, push the spike down precisely in the center and perpendicularly so that you do not damage the bottle seal.**
- **Once inserted, rotate the Bottle Spike ¼ of a turn in order to secure it in position.**

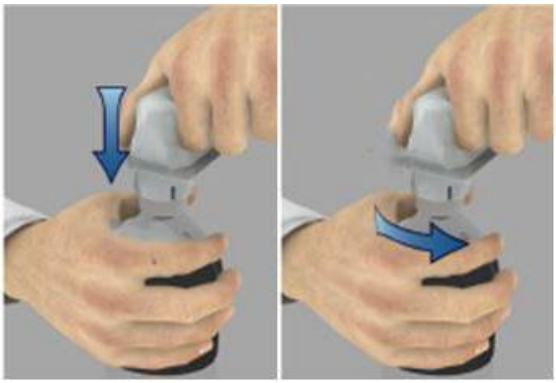


Figure 38: Piercing a contrast media bottle seal.

4. Position the flat surface of the Bottle Spike containing the air filter facing the front, and insert the bottle fully into a bottle holder. The insulators, specifically designed for the CT Exprès™ 3D, are provided by Bracco Injeneering. Secure the bottle by fitting an insulator on top of it, and turn the insulator clockwise (1/8 turn) to lock it in place.

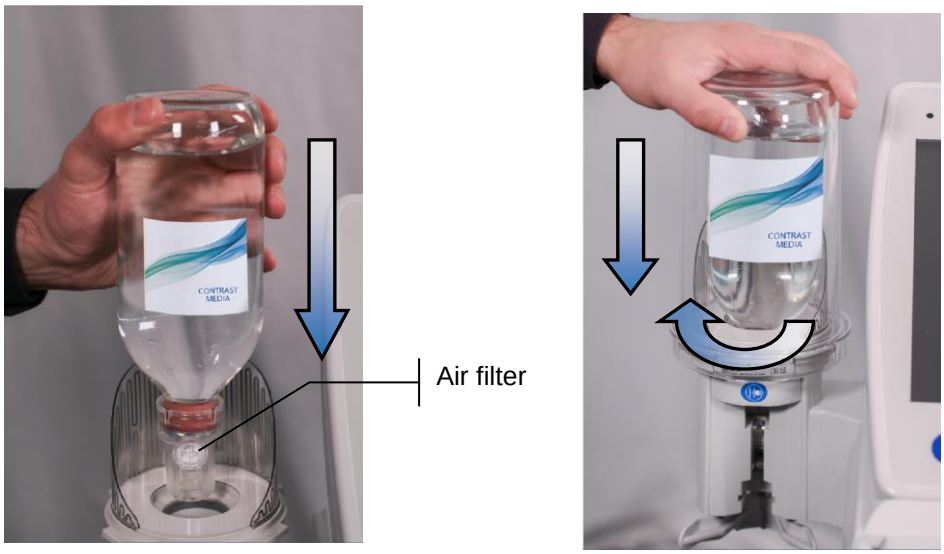


Figure 39: Inserting the bottle and fitting an insulator

Caution

It is recommended to always use the insulators to cover each bottle. The insulators protect and secure the bottles from breakage or shock or from being knocked from the bottle holder during use. The temperature of prewarmed contrast media can only be maintained if insulator is installed.

4.5.2 Programming the contrast media bottle

At the insertion of a bottle, the CT Exprès™ 3D bottle inventory display on the CT Exprès™ 3D control panel prompts you to select the installed bottle type.

1. Select the latest bottle installed or a product of your inventory by pressing on the corresponding button. The last four bottle type entries are saved in the inventory.

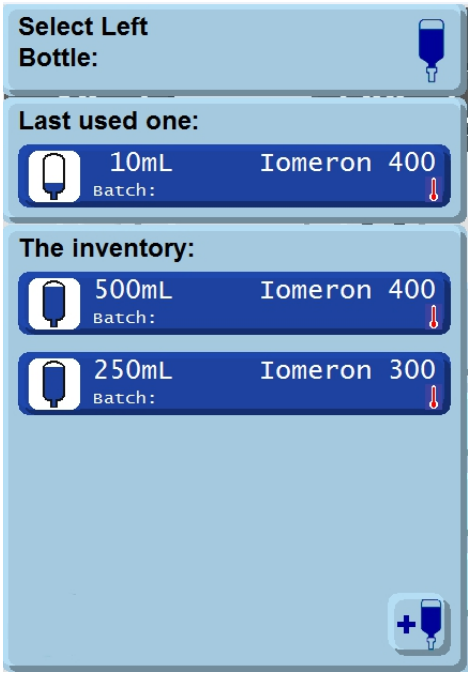


Figure 40: Bottle inventory display

2. If the bottle type is not in the inventory, press  to define the new bottle type, then select the new product by pressing on the corresponding key. Use the left and right arrows to change the page.

Note
Only the contrast media present in the new product selection menu can be used on the CT Exprès™ 3D.

3. Select the contrast media of the installed bottle

Figure 41: New product selection menu

4. Choose whether prewarmed contrast media ( ) or non-prewarmed contrast media ( ) is used. CT Exprès™ 3D will automatically actively maintains temperature of prewarmed contrast media (if option is available).

Figure 42: Prewarmed/non-prewarmed product selection

Warning

- **Be aware that bottle holder top surface turns warm when prewarmed contrast media bottles are installed (and temperature maintainer option is activated).**
- **Prewarmed bottles remain at the required temperature only if the dedicated insulators are used.**

5. Define the volume in the bottle by pressing a proposed volume key or manually enter the available volume by pressing the key: enter the value in the “Available volume windows”, then accept by pressing ☑.

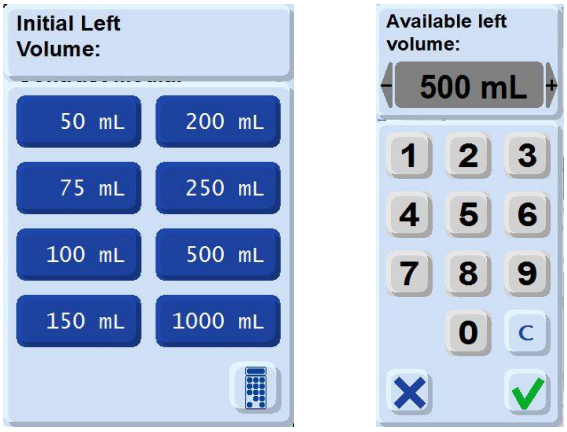


Figure 43: Volume selection

Note
Programming the wrong volume can result in the injection stopping before the required volume is delivered and lead to a sub optimal injection.

6. If the option "batch number" is active (see *section 5.1.8 Country options,* on page 107), it is also necessary to enter the bottle batch number at this step.

7. Once you have entered the settings (and if temperature maintainer option is activated), the system will prompt a message asking to install a bottle insulator. In all cases, and even if the bottles are not prewarmed, it is recommended to install a bottle insulator.

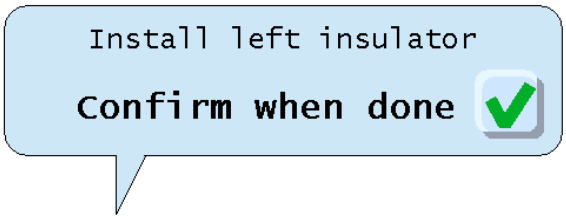


Figure 44: Installation of Bottle Insulator

Warning

- **Do NOT use the CT Exprès™ 3D without bottle insulators secured. Using uncovered contrast media bottles exposes them to heat loss, bumping and potential breakage, and can lead to unreliable imaging for multiple patients.**
- **Using bottle insulators without temperature maintainer feature does not guarantee that the bottles remain at the initial temperature over a long period of time.**

Note

- The contrast media settings menu can be displayed at any time by pressing the contrast media name above the displayed bottle.
- CT Exprès™ 3D will assume that the bottles are full by default. If a bottle becomes empty during the course of injection, this will be detected and displayed by the following message:

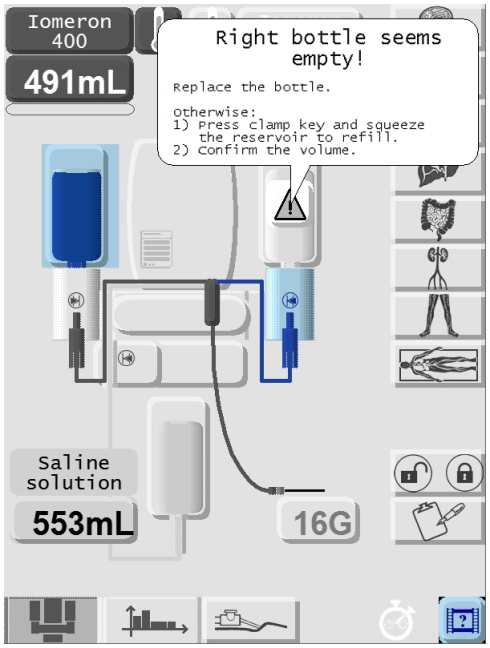


Figure 45: Bottle empty message

To replace an empty bottle, follow the instructions given in *section 4.5: Installing a contrast media bottle*, on page 57.

4.5.3 Loading and programming the second bottle

1. Repeat the procedure in *section 4.5.1,* on page 57, for loading the second bottle of contrast media or saline.

2. Repeat the procedure for programming the bottle described in *section 4.5.2: Programming the contrast media bottle,* on page 59, making sure that the information you enter corresponds to the first bottle of contrast media with respect to type, volume, and prewarmed condition.

Note
The green indicator close to the LEFT BOTTLE/RIGHT BOTTLE keys will lights up (after automatic filling) to show which bottle will be used first during the injection. Note that the first bottle installed will be the first one used at the start of injection. This selection can be changed by pressing the LEFT BOTTLE or RIGHT BOTTLE key corresponding to the bottle you wish to select.

4.6 Installing a new Patient Set

Warning

- **Always use aseptic techniques when handling the Patient Set.**
- **Discard the Day Set III *HP* in the event of suspected septic contact or air contamination of the septum.**

Note
You can see the Patient Set in *section 1.6: Disposables* on page 33.

The CT Exprès™ 3D will prompt you to install a new Patient Set with the following message:

Figure 46: Message to install a new Patient Set

Follow the procedure below to correctly install the Patient Set:

Insert the patient connector into its holder without removing its protective cap in order to keep it clean.

Figure 47: Insertion of patient connector in its holder

2. Make sure that the pinch clamp is open. This is necessary later during the automatic filling so that you can fill the reservoirs and prime the system:

Figure 48: Pinch clamp in open position

3. Insert the Patient Set Cassette firmly into the port situated in the front of the main unit. Slide it along the guides until it **'Clicks'** in place. Firmly introduce the Patient Set spike into the Day Set septum. Only release after seeing the green confirmation light, the motor is now engaged into the Patient Set Cassette.
   The Patient Set Cassette is automatically locked in place when inserted correctly.

Figure 49: Incorrect introduction of the Patient Set cassette

Figure 50: Correct introduction of the Patient Set cassette

The CT Exprès™ 3D will now ask you if you want to perform automatic filling of the Day Set III *HP* and Patient Set. Go to next section for more information.

4.7 Filling the Day Set III *HP* and Patient Set

4.7.1 Automatic filling of Day Set III *HP* and Patient Set

Warning

Always make sure that the patient is not connected during the filling process. Having a patient connected during filling can result in serious patient injury or death due to unintended injection of large volumes of air and contrast media.
Do not use extension tubing with the Patient Set. Any additional extension tubing is not taken into consideration in the volume and sequence calculation and presents a risk of severe patient injury or death due to air injection.

After a Day Set III *HP* installation, CT Exprès™ 3D will prompt you to perform automatic filling of the Day Set III *HP* and Patient Set by displaying the following message:

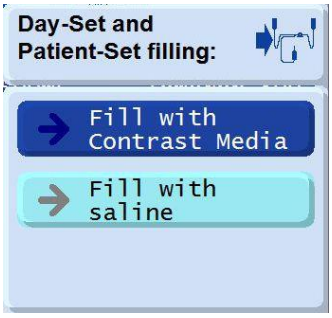


Figure 51: Message for Day Set III *HP* and Patient Set filling

If the Day Set III *HP* is already filled (next patient), a shorter filling process for the Patient Set only is proposed.

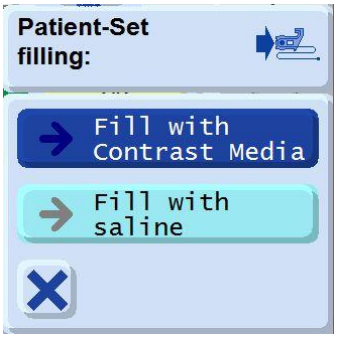
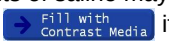
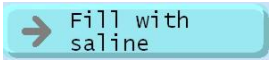


Figure 52: Message for Patient Set only filling

Note

- You must perform automatic filling now, as there is no option to do later.
- To cancel the automatic filling menu and go to the manual priming menu (see *section 4.7.2: Performing manual priming,* on page 67) press the ☒ key on the display message shown above.

As displayed on the control panel you can choose between
- Filling the tubing with saline
- Filling the tubing with contrast media

Screen	Comment
	At the end of filling, the tubing will essentially be filled with contrast media. Trace amounts of saline may nevertheless also be present. Select  if you do not require a preflush before contrast media injection and if you do not want to perform a saline test injection. Note: saline test injection is recommended before an injection
	At the end of filling, the tubing will essentially be filled with saline solution. Trace amounts of contrast media may nevertheless also be present. Select  only if you require a preflush before contrast media injection or if you wish to perform a test injection with saline. It is recommended to fill with saline in order to perform a saline test injection.

Warning

If you fill the Patient Set with contrast media and then program an injection with a saline preflush, the CT Exprès™ 3D will display a message requesting a manual prime with saline.
If the Patient Set contains saline but neither a saline test injection nor a saline preflush is programmed, the CT Exprès™ 3D will automatically program and display a saline preflush to account for the volume of saline in the Patient Set line. This saline pre-flush can be deleted. In this case, a software message will prompt a manual prime with contrast media.

Note

If a program preset has been defined, the CT Exprès™ 3D will propose the preferred setting for automatic filling. You have the option to accept this setting for automatic filling by pressing the ☑ key or to change it if necessary.

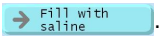
1. Make sure that the pinch clamp on the Patient Set is open (see *Figure 49*). Activating automatic filling with the pinch clamp closed results in interruption of the filling process and an OCCLUSION alert message on the control panel screen.

2. Make sure that the safety cap (*Figure 49*) of the Patient Set is removed.

3. Make sure that the Patient Set connector is over a receptacle to prevent spillage. At this point it is still possible to select the bottle where the automatic filling should start.

Note

- Automatic filling is performed at a high flow rate. The CT Exprès™ 3D always minimizes the volume of contrast media used during such automatic filling by using saline as much as possible.
- Automatic filling requires two bottles to be inserted into the bottle holders (both bottle detectors must be activated).

4. Activate automatic filling by pressing  or  .

5. A warning is given on the control panel to make sure that no patient is connected. Press the left ☒ key to decline automatic filling and continue with manual priming of each line. Press the right yellow arrow key to start filling the fluidic pathway (Day Set III *HP* and Patient Set). During the first 10 seconds after pressing the right arrow key, no fluid should flow into the Day Set III *HP*.

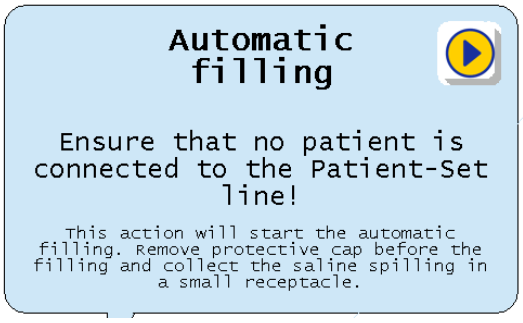


Figure 53: Automatic filling message

Warning

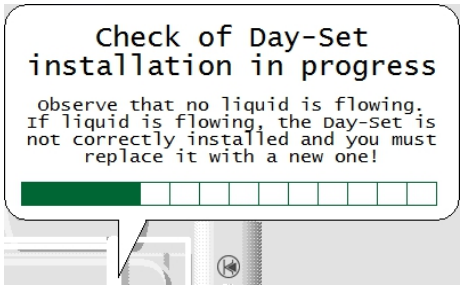
If fluid flows into the Day Set III *HP* during this first 10 seconds, a message stops priming requests you to change the Day Set III *HP*. If you observe fluid flowing, you can anticipate the message stopping the automatic priming process (press STOP on the display or on the control panel or on the hand switch). Then:

- **remove and discard the Patient Set**
- **remove and discard the Day Set III *HP***
- **install a new Day Set III *HP* and a new Patient Set and repeat all operations, as necessary, starting from *section 4.3: Installing the Day Set III HP* on page 51.**

Note

- Do not try to re-use the Day Set III *HP*, since it will always result in the same alert conditions as liquid is present in the Day Set III *HP* at insertion. Replace the Day Set III *HP* with a new one and make sure it is properly installed at each location where a tubing guide is to be inserted.
- Automatic filling is mandatory for installation of the Day Set III *HP.*

6. Day set III *HP* filling is done in two steps. Firstly when the vacuum is in action:



7. Then, when lines are filled with the appropriate liquid:

8. Automatic filling ends with a message on the control panel display saying that you should check the absence of air in the lines.

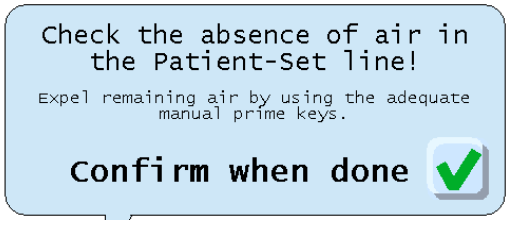


Figure 54: Verification after filling

Warning

Always make sure that no air bubbles are present in any of the tubing after filling is complete. If air bubbles are still present, perform manual priming, as described in *section 4.7.2: Performing manual priming*, to remove all the air before the patient is connected.

9. If there are no bubbles in any of the lines:
   a. Press the ☑ key on the control panel display.
   b. Close the pinch clamp. Fit a protective cap (see *section 4.6: Installing a new Patient Set* on page 62), if a patient is not connected right away.

10. When installing the Day Set III *HP*, a message is displayed requesting to expel all residual air in reservoir by pressing and holding the blue clamp opening button while squeezing the reservoir clamps located beneath each contrast media bottle. This has to be performed for left and right reservoirs.

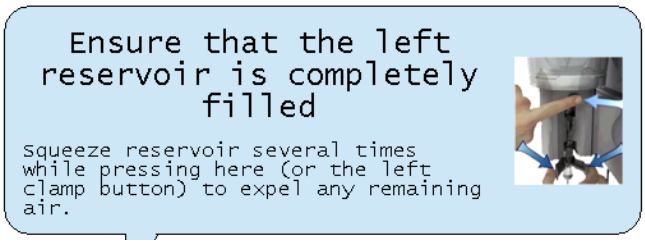


Figure 55: Reservoir filling message

11. If a patient is not connected right away, fit a protective cap (see *section 4.6, Installing a new Patient Set*, on page 62).

Warning

- **If the Patient Set indicator flashes, this means that the automatic test is in progress. Wait until the flashing stops (end of test) before connecting the patient.**
- **In case of filling with saline trace amounts of contrast media may be present in the Patient Set. Manually purge the saline line, if it is suspected that such residue may adversely affect the examination in progress.**

4.7.2 Performing manual priming

Warning

Always make sure that the patient is not connected during the priming process. Having a patient connected during priming can result in serious patient injury or death due to unintended injection of large volumes of air and contrast media.

Note

Manual priming (by using any of the yellow priming keys) is limited to 12 mL for each continuous activation. Manual priming stops automatically as soon as this limit is reached. If you wish to continue manual priming, release the priming key and then press it again. Manual priming is not possible upon installation of a new Day Set III *HP*.

1. Separately prime each contrast media line and the saline line by pressing the corresponding yellow priming key on either the control panel touch screen or on the injector unit until any air bubbles present in the line have passed through the Patient Set.

There are three different priming buttons, all which are yellow.

- The first two are located at the same height on the top portion injector unit, on either side. These two buttons allowing priming of contrast from the Left bottle and Right bottle respectively.
- The last button is located at the bottom of the injector unit, and is used to prime with saline.

1. Left contrast media line priming button
2. Right contrast media line priming button
3. Saline line priming button

Figure 56: The three manual priming buttons on the injector unit

Press the yellow priming button on the injector unit corresponding to the line you want to prime. A warning message requests you to check that no patient is connected. After ensuring that no patient is connected, press the yellow priming button again and prime the tubing until all air is in the Day Set III *HP* or Patient Set.

2. Prime the entire line using either contrast media or saline as required until there is no longer any air in the Patient Set.

3. Finish manual priming of the Patient Set only with the product (contrast media or saline) that you intend to inject first (for example: saline in case of preflush or saline test injection).

Warning

- **When the Patient Set is primed with contrast media and that a saline test injection or saline pre-flush is programmed, a potential over-delivery of contrast media would occur. In this case, before the saline test injection or injection is started, a message is indicated by the CT Exprès™ 3D requiring to manually prime with saline (see below message).**

- **When the Patient Set is primed with saline and that a first phase of contrast injection is programmed (without saline test injection), a potential under-delivery of contrast media would occur. In this case, a preflush is automatically programmed and displayed to account for the volume of saline in the Patient Set line. This pre-flush can be deleted. If the pre-flush is deleted, a manual prime with contrast media is required before the injection can be started (see below message).**

- **When the Patient Set has been manually primed and contains both saline and contrast media, a message is indicated by the CT Exprès™ 3D requiring to manually prime with the solution that corresponds to the first liquid to be injected.**

4. Replace the safety cap if a patient is not connected right away.

4.8 Programming the CT Exprès™ 3D

4.8.1 Programming the needle gauge (size)

Warning

The actual flow rate may differ from the programmed rate if the needle gauge is incorrectly programmed, or if the contrast media and its prewarmed condition are incorrectly entered.

1. CT Exprès™ 3D will prompt you to enter the needle gauge by displaying the following message:

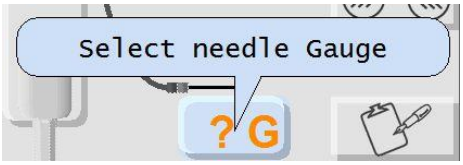


Figure 57: Selection of needle gauge

Note
You can access the needle gauge program at any time by pressing the NEEDLE GAUGE key on the display (see *Figure 3: Details of the injector status page* on page 26).

2. Enter the gauge of the needle by pressing the corresponding key in the menu:

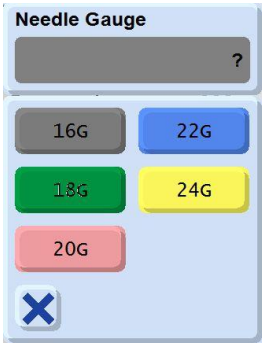


Figure 58: Needle gauge menu

Note
For needle gauge corresponding to 17, 19, 21 and 23G, it is necessary to select 16, 18, 20 and 22G respectively.

4.8.2 Programming an injection

CT Exprès™ 3D will not start an injection if the programmed contrast media/saline injection volume is greater than the actual contrast media/saline installed volume. When programming an injection, compare the programmed contrast media and saline volume against the available volume. If the amount of contrast media or saline installed is not sufficient to meet the programmed injection protocol the CT Exprès™ 3D will display a message and prompt to install a new container. If this is not performed or if the volume is still insufficient, the same message will be again displayed when trying to start the injection and the injection will not be allowed.

Make sure that the display now shows the following information for the bottle:

- The contrast media type and concentration
- The volume of contrast media in the bottle.
- The contrast media status (prewarmed or not prewarmed)

The display will now show the following message:

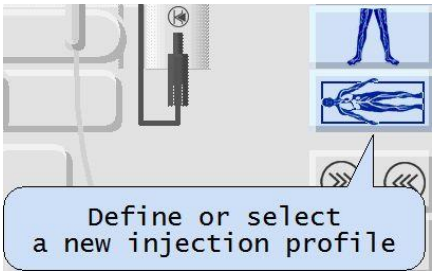


Figure 59: Definition or selection of a new injection profile

Note
If the injector status page does not show a display similar to this, you have probably made a mistake in the programming process. Press the help key, which will then guide you in the programming process.

4.8.3 Defining a new profile or loading a program

You can program the CT Exprès™ 3D in either of two ways:

- By defining a new injection profile, as detailed in *section 4.8.4: Defining a new injection profile (define phase parameters)*

or

- By using a predefined program, as detailed in *section 4.8.6: Loading a predefined injection program.*

4.8.4 Defining a new injection profile (define phase parameters)

4.8.4.1Programming the first phase of media for injection

- Go to the injector settings page (see on page 27). The page title is "manual setting".
- Press one of the "phase 1" keys and follow the procedure to enter the phase parameters. It is possible to enter the parameters for a phase of saline, or DiluJect™ or contrast media.

- Enter the first phase programming menu by pressing one of the "phase 1" keys on the screen.

Figure 60: Entering the first phase programming menu

- Select between either a saline phase, or DiluJect™ phase or contrast media phase. Press ☒ to decline

Figure 61: Type of phase menu

- Enter the volume using the keypad. Press ☑ to confirm. Press ☒ to decline.

Figure 62: Volume menu

- Enter the flow rate using the keypad.
  Select next to set the rate of the current phase as identical to the rate of the next phase. Select previous to set the rate of the current phase as identical to the rate of the previous phase (not applicable for first phase). Press ☒ to decline.

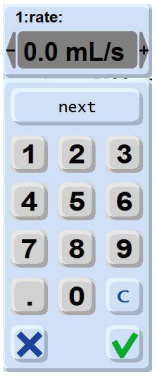


Figure 63: Flow rate menu

4.8.4.2Programming a DiluJect™ phase for injection

When a DiluJect™ phase is selected (step 4 in *section 1.1.11.1.1*), a choice is provided indicating the resulting contrast media content (expressed as a percentage of contrast media for the total volume injected) during the DiluJect™ phase injection using the DiluJect™ method, which is schematically shown on the keys.

1. Select the percentage of contrast media ranging from 0% (all saline) to 100% (all contrast media). Press ☒ to decline.

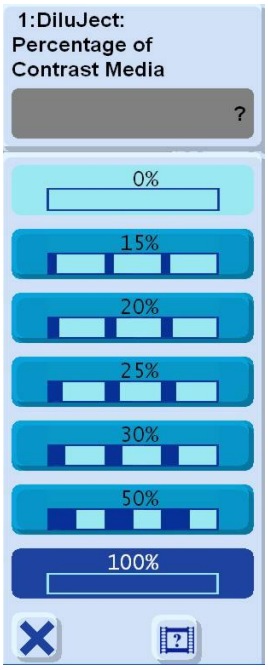


Figure 64: DiluJect™ - Percentage of contrast media menu

2. Enter the volume using the keypad. Press ☑ to confirm the volume entered. Press ☒ to decline.

Figure 65: Volume display

3. Enter the flow rate using the keypad.
   Select next to set the rate of the current phase as identical to the rate of the next phase. Select previous to set the rate of the current phase as identical to the rate of the previous phase (not applicable for first phase). Press ☒ to decline.

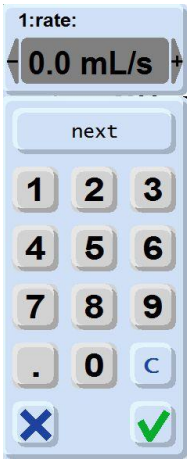


Figure 66: Flow rate display

Warning

Before using a DiluJect™ phase, always ensure that all three reservoirs are completely full to ensure the accuracy of the resulting contrast media percentage in relation to the total DiluJect™ volume injected.

4.8.4.3Programming the second phase and further media phases (if required)

Note
You can enter up to 24 phases for one patient. One phase can consist of contrast media, saline or an injection pause.

If you require an additional phase for the injection, press the corresponding line key and repeat the procedure described in *section 1.1.1* for this phase. It is now possible to program saline interphase and post-flushes, further phases of contrast media, and injection pauses, as required.

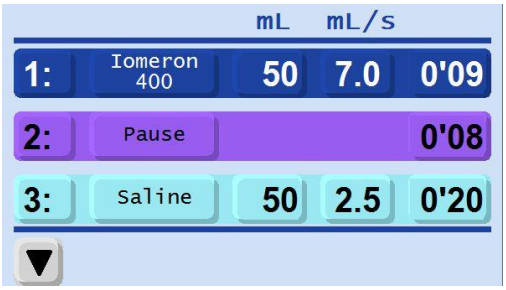


Figure 67: Injection program with contrast media phase, pause, and saline phase

Note
- If an automatic post-flush has been previously programmed, you can overwrite it with another type of phase: the post-flush will be then automatically placed as the last phase. For more information on saline flush options, *see section 5.1.3* on page 104.
- A preflush is automatically loaded when automatic filling is chosen with saline or when you program a second injection and the first one has ended with postflush.

4.8.4.4Cancelling or inserting a phase

First, click the phase number key of the phase you wish to select.

Three options are then available:

- select the key if you wish to cancel the selected phase
- select the key to insert a new phase before the selected one
- or select the ☑ key to accept the selected phase as it is.

4.8.4.5Programming the scan delay (if required)

Note
When coupled to the scanner through the CANbus scanner interface, the setting of the scan delay is not available on the injector. In that case, the delay can be managed through the scanner only.

You can program a scan delay to display a count-down for the scan start combined with an audible alert by using the key.

1. Go to the Injector Settings Page (see on page 27) and press the key in the upper right corner.
2. Press the Set Scan Delay key or quit the menu by pressing the ☒ key.

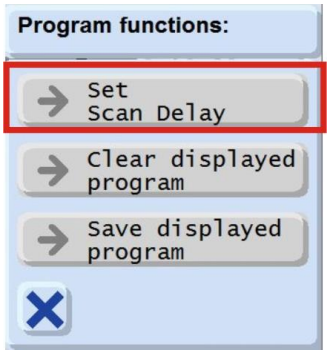


Figure 68: Program functions menu

3. Enter the delay in seconds using the displayed keypad. Confirm with the ☑ key. Quit the menu by pressing the ☒ key.

Figure 69: Scan delay display

Note
The programmed scan delay is visually indicated in the status graph (green indicator) on the Injection Settings page.
When a scan delay has been programmed, CT Exprès™ 3D will emit one (audible) beep 2 seconds before the end of the scan delay and a second (audible) beep at the end of the scan delay and you may start your CT scan.

4.8.5 Saving a new injection program for further use (optional)

Injection programs are saved in a local program library that is organized by examination types. Examination types are classified as follows:

Body part icon	Examination type
	Brain
	Cardiovascular
	Liver
	Abdomen
	Thorax
	Kidney
	Extremities
	Miscellaneous

Optionally, the user is able to create additional subcategories in order to refine examination types. For instance:

Body part icon	Examination type
	Abdomen / Biliary Tree
	Abdomen / Peritoneum
	Abdomen / Prostate
	Abdomen / Small Bowel
	Abdomen / Spleen

Each injection program is saved with a dedicated name, as for example:

Body part icon	Examination type	Program name
	Abdomen / Small Bowel	Tumor (GIST)
	Abdomen / Small Bowel	Crohn's Disease

Optionally, each program can be optimized with a given contrast media concentration, as for example:

Body part icon	Examination type	Program name	Iodine mg/mL
	Abdomen / Small Bowel	Tumor (GIST)	300 mg/mL
	Abdomen / Small Bowel	Tumor (GIST)	400 mg/mL

To save a program, it must be entered manually at first. If you have not yet programmed an injection profile for the specific PROGRAM key you selected, CT Exprès™ 3D will display the following on the injector settings page (see on page 27):

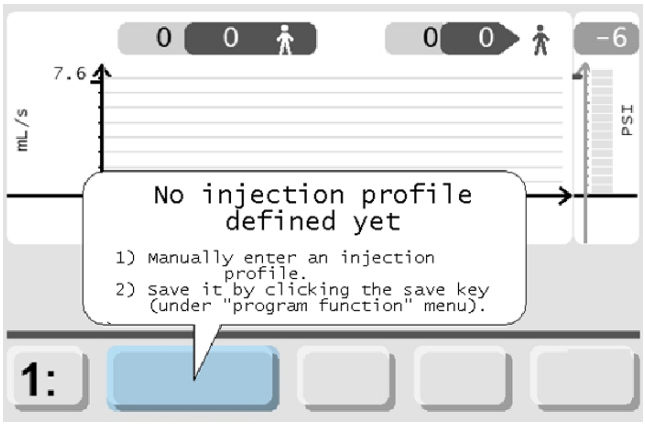


Figure 71: “No injection profile defined” message

1. Confirm the screen message and enter the program parameters such as media type, phase volume and rate according to the procedure described in *section 4.8.4.1: Programming the first phase of media for injection*, on page 70.

2. Press the key in the top right display corner and select Save displayed program.

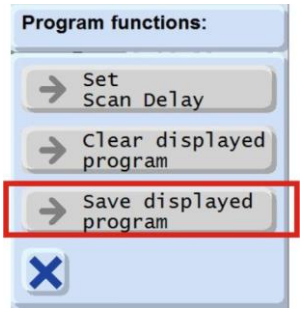


Figure 70: Program functions menu

3. The following keyboard appears (if the examination type is not yet selected):

Figure 71: Record menu

4. Select an examination type (if not yet already selected while entering/modifying manually the program)

5. Optional: enter a subcategory of the examination type using the keypad (by default, the subcategory has the name of the type of examination type). First, clear the name entered by default (function key “c”) and enter a subcategory name using the keypad. Validate the subcategory name when completed.

6. Enter the program name using the keypad and validate when completed.

Figure 72: Entering name of program

Note
The program name length is limited to 16 characters.

7. Select the contrast media concentration for which the saved program is dedicated (by default, the concentration of the contrast media currently in use is selected):

Figure 73: Selecting the concentration of iodine

Once the program has been saved, its name will appear at the top of the screen.

8. Go to *section 4.9: Connecting and injecting the patient* on page 81.

Note

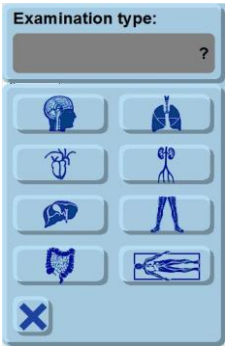
- Several programs can be stored by means of the EXAMINATION TYPE key. If you wish to change the program settings, press the respective program key and follow the procedure described above.
- To erase a recorded program, load the program, press and select Clear displayed program. Then press again and select Delete last loaded program.
- To rename a program, press the respective EXAMINATION TYPE key. Select the option Save displayed program, select the key of the respective program again and rename it using the keypad. Validate with the ☑ key.

4.8.6 Loading a predefined injection program

This feature is to access a program that has been saved previously.

From the injection setting page:

1) Click the examination type key on the top left of the injector setting page (on page 27). The examination type menu is then displayed:



For injectors connected to the Nexo® server, protocols can be remotely managed. This is indicated by the additional key ( ) displayed at the bottom of this menu. To learn more about Nexo®, refer to *section 4.12*.

Figure 74: Selecting the examination type

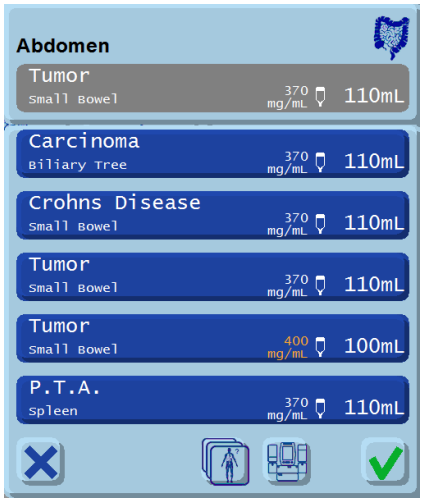
2) Select the examination type of interest.
3) In the absence of any program, an invitation to manually enter a program will be displayed. If only one program is available, this program is directly loaded and displayed. If several programs are available, this opens the list of programs saved for this examination type. Programs can be sorted alphabetically, by subcategories or by concentration.
4) Select the program.

The CT Exprès™ 3D now displays the injection parameters saved under the selected program.

From the injector status page:

1) Select one of the examination type shortcut keys displayed on the injector status page *(see figure 4 on page 26).* If these keys are not yet available, go to the injection setting page.
2) If only one program is available, this program is directly loaded and displayed. If several programs are available, this opens the list of programs saved for this examination type. Programs can be sorted alphabetically, by subcategories or by concentration.
3) Select the program.

The CT Exprès™ 3D now displays the injection parameters saved under the selected examination type:

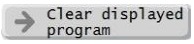


Note

- You can only access a predefined program if one or more programs are already written and stored in CT Exprès™ 3D.
- When you use a predefined program, no further programming is required unless you want to modify the predefined program
- If the program is saved for a dedicated contrast media concentration, this concentration is shown in orange, in the case it does not match the one of the installed contrast media.

4.8.7 Deleting, Renaming or modifying saved programs

To delete a recorded program:

5) Load the program to delete
6) Press  and select 

7) Press again  and select 

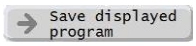
8) Validate with the ☑ key.

To rename a program:

1) Load the program to rename
2) Press  and select the option  .

3) Save the program with a new name.

To modify a program:

1) Load the program to modify
2) Modify impacted information
3) Press  and select the option 

4) Save the modified program by validating its initial name.

4.8.8 Quick reload of the last used injection program

When a series of identical and consecutive examinations are scheduled, it is possible to quickly reload the last used injection profile. Once a predefined injection program is loaded and used, this one can be reloaded by clicking the quick reload key (), which is displayed on the top of the injection setting page.

Note
The quick reload key ():

- is available only after having used a predefined injection program
- is no more available once a new program is loaded. Clear it to get back the reload key
- will not appear after having switched off the injector
- is no more available if the injection profile has been modified between two examinations.

4.9 Connecting and injecting the patient

Caution

- **It is mandatory to ensure before each injection that the patient is not susceptible to risks related to injection of contrast media or saline. Refer to the recommended practices and safety precautions provided by the contrast media or saline manufacturer.**

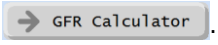
4.9.1. The eGFR calculator

Warning

- **The estimated GFR (eGFR) Calculator is intended to assist the facility in determining whether a patient's renal function allows for the administration of contrast media. It is not intended to act as a substitute of a physician's diagnosis of conditions, which may preclude the administration of contrast media or the patient's ability to accept the procedure.**
- **When using the eGFR Calculator, you should not assume that the patient does not have chronic kidney disease (CKD), until a physician confirms it. eGFR estimates may not be reliable in certain individuals as there are other factors besides CKD that can yield erroneous eGFR values. It is important that a physician is consulted if you have any concerns about a patient's kidney function or the results shown by the eGFR calculator.**
- **By utilizing the eGFR Calculator you are assuming responsibility for ensuring the accuracy of all information utilized in the eGFR calculation and making sure that all information represents the current condition of the patient.**
- **The eGFR Calculator is to be used for adults 18 years of age and older.**

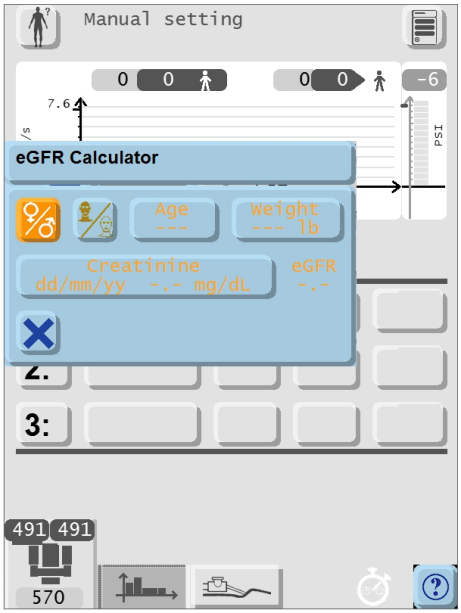
The Glomerular Filtration Rate (GFR) is a measure of how well the kidneys are filtering metabolic waste products from the blood. Creatinine is a waste product formed by the normal breakdown of muscle cells. Healthy kidneys filter creatinine from the blood into urine to be excreted from the body. When the kidneys are not working well, creatinine builds up in the blood.

The eGFR is calculated from a routine measurement of creatinine in the blood and other factors like age, weight, gender,… depending on the selected equation for calculating eGFR. The 3 main equations for calculating eGFR are available (CKD-EPI, MDRD or Cockcroft-Gault, refer to *section §5.1.8* for their definition). The equation can be selected from the permanent settings menu (see *section §5.1.8*).

To open the eGFR calculator, click the  key in the top right corner of the injection setting page and select 

.

Then, enter/select all orange fields required by the selected GFR equation by clicking the respective fields. The estimated GFR is displayed as soon as all required data are entered. When the injector is connected to RIS through a Nexo® server, these fields (but Creatinine) are also directly accessible from the patient page and filed from the selected patient session in the work-list of the hospital. To learn more about Nexo® , refer to *section 4.12*.



Warning

- **Warning messages are displayed when the eGFR is below standard critical values of 60. These values will not inhibit the injection. It is the facility's ultimate responsibility to review the value and determine the best course of actions for the patient.**

4.9.2. Performing a saline test injection

Warning

- **A saline test injection will always be performed with saline.**
- **Unintentional combination of saline and contrast media can occur in the tubing.**
- **Given the possible mixing of contrast media and saline solution during the initial purge steps, even in only minute amounts, it is mandatory to ensure before each saline test injection that the patient is not susceptible to risks related to injection of contrast media. Refer to the recommended practices and safety precautions provided by the contrast media manufacturer and act in all cases, even for injection of saline solution, as if it were a contrast media injection.**

After having installed the disposables and programmed the CT Exprès™ 3D (the injector is ready for injection), a saline test injection can be performed to ensure that the patient's venous access is secure and stable. Please follow the instructions given below:

1. Make sure you have entered an injection profile using the injection status page (see *section 4.8.2*: *Programming an injection*).

2. Go to the test injection page *(Figure 5 page 27)*. The default volume is displayed as 10 mL. The default injection rate is the highest injection rate of the injection profile (the following is an example for a Patient Set prefilled with saline; see also the note below):

3. Select the volume key.

Figure 75: Volume key selection

4. Program the volume for the saline test injection phase using the keypad. The CT Exprès™ 3D allows a maximum volume of 30 mL for the saline test injection. Press the ☒ key to quit the menu.

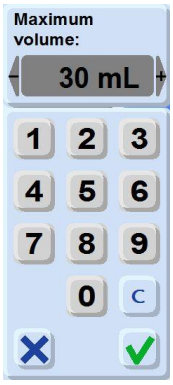


Figure 76: Volume display

5. Program the flow rate for the test injection phase using the keypad. The CT Exprès™ 3D allows a flow rate of between 0.5 and 9.8 mL/s.
Press the ☒ key to quit the menu.

Figure 77: Flow rate for saline test injection display

6. The volume and flow rate for the saline test injection are programmed. To start the saline test injection, press and hold the START key while watching the injection site.

Figure 78: Programmed volume, flow rate and injection time

Note

- The saline test injection rate is by default set to the highest rate programmed in the injection profile. The saline test injection volume parameter sets a volume limit for the saline test injection. The volume you program is the limit permitted by CT Exprès™ 3D for a saline test injection while you press and hold down the START key or the hand switch button.
- After this limit is reached, the CT Exprès™ 3D stops, and the operator must release the key and press it again to restart a new saline test injection sequence with the same new limit.

4.9.3. Starting an injection

Warning

Always use aseptic techniques when connecting the patient

1. Make sure the pinch clamp on the Patient Set is open.
2. Remove the protective cap on the patient connector, and connect the patient using aseptic techniques.

Note

You can perform a saline test injection now, if required (see *section 4.9.2,* on page 82).

3. Go to the injection settings page and ensure that the status bar is green.
   If not, press the help key and read displayed instructions.

4. Start the injection by doing either one of the following:
   - Press and hold the START key on the main or remote control panel (for at least for two seconds) until the screen turns green and then release it.
   - Press and hold the hand switch button (for at least for one second) until the screen turns green and then release it.

   The injection procedure that you programmed takes place automatically and the luminous bar flashes.

Note

- If the screen does not react to the pressure on the START key after two seconds (display looks frozen), then press the STOP key and retry from the other control panel.
- To deliberately stop an injection that is in progress, do one of the following:
  - Press the STOP button on the main or remote control panel, or
  - Press the STOP key on the display of the main or remote control panel, or
  - Press the hand switch button

Following completion of the injection, the injection history is displayed on the CT Exprès™ 3D Injection Settings Page (use the up and down buttons to scroll).

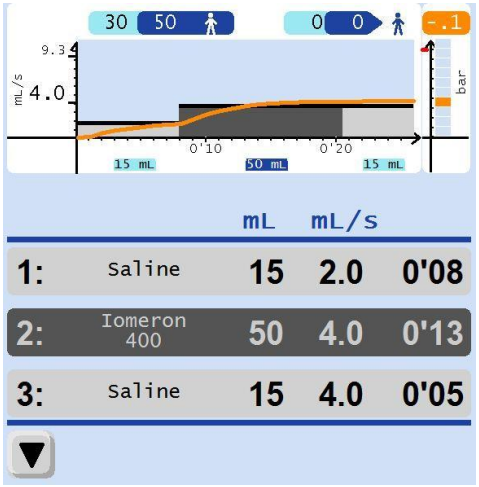


Figure 79: Example of injection history

Note

In the event of multiple injections per patient, the phases of new injections will be added to the injection history, starting from phase 1 and onwards.

4.10 Disconnecting the patient

Warning

- **To avoid liquid leakage, always ensure that the pinch clamp on the Patient Set is closed before disconnection of the Patient Set from the venous access.**
- **Do not unlock or remove the Patient Set when a patient is connected.**

1. Close the pinch clamp on the Patient Set.
2. Disconnect the patient from the Patient Set according to your hospital procedure.
3. Unlock the Patient Set by twice pressing the blue unlock key near the Patient Set port. A red light is displayed on the unlock button when the cassette is unlocked.

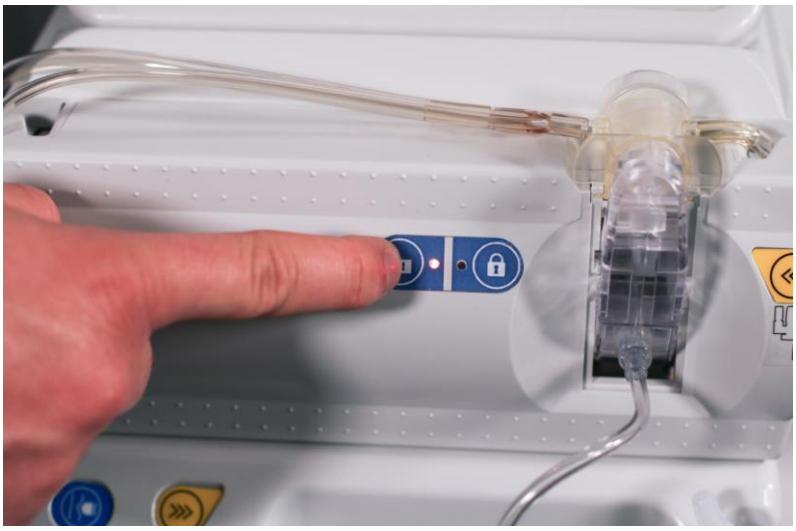


Figure 80: Unlocking the Patient Set

Warning

Remove the Patient Set immediately after the cassette is unlocked.

Note

- Note that you can also use the locking / unlocking keys on the screen (see *Symbols used on the injector (buttons) on page 9*).
- If the Patient Set is not removed immediately after unlocking it, an alert message will be displayed. Remove the Patient Set and press ENTER to reset the alert condition before inserting a new Patient Set. CT Exprès™ 3D will not accept a new Patient Set before the alert condition is acknowledged by pressing ENTER.

4.11 Preparing for the next patient

4.11.1 Normal workflow

Warning

- **You must use a new Patient Set for each patient. The CT Exprès™ 3D displays an alert if you re-insert and lock a previously used Patient Set.**
- **Always use aseptic techniques when handling a Patient Set**

1. Insert a new Patient Set as described in *section 4.6: Installing a new Patient Set,* on page 62.
2. Prime the Patient Set as described in *section 4.7.1*: *Automatic filling of Day Set III HP and Patient Set*, on page 64. Because the Day Set III *HP* is already filled, a shorter filling process for the Patient Set only is proposed.

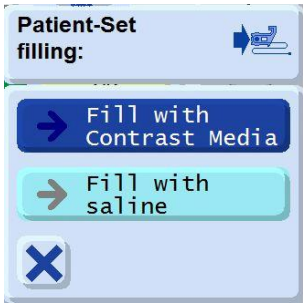


Figure 81: Message for Patient Set only filling

Note
You must perform `AUTO FILLING` now, as there is no option to do so later.

3. Program the CT Exprès™ 3D according to *section 4.8: Programming the CT Exprès™ 3D*, on page 69.
4. Perform injection as described in *section 4.9: Connecting and injecting the patient* on page 81.
5. Disconnect the patient as described in *section 4.10: Disconnecting the patient*, on page 85.

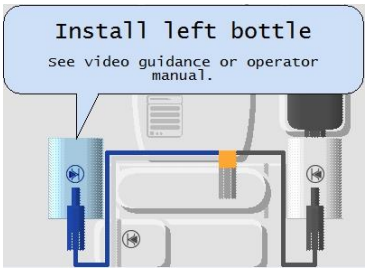
4.11.2 Preparing a new contrast media bottle

Warning

- **When a contrast media bottle is empty, keep it installed on the injector until you install a new bottle. This protects the Day Set III *HP* spike from possible contamination. Contamination of the Day Set III *HP* spike presents a risk of serious injury to multiple patients due to infection.**
- **The Day Set III *HP* can be for a maximum of 24 hours or a maximum of 6000 mL of contrast media injected, whichever occurs first; after this the Day Set III *HP* must be replaced.**

1. Remove the bottle insulator.
2. Remove the empty bottle.

The following message is displayed in absence of bottle:



3. Follow all instructions in *section 4.5.1 Loading the contrast media bottle* and in *section 4.5.2 Programming the contrast media bottle* to load and program a new contrast media bottle.

4. When the bottle has been defined, check the reservoir and, if necessary, use the reservoir clamps to fill it completely (see *Figure 82: Reservoir filling message and procedure*).

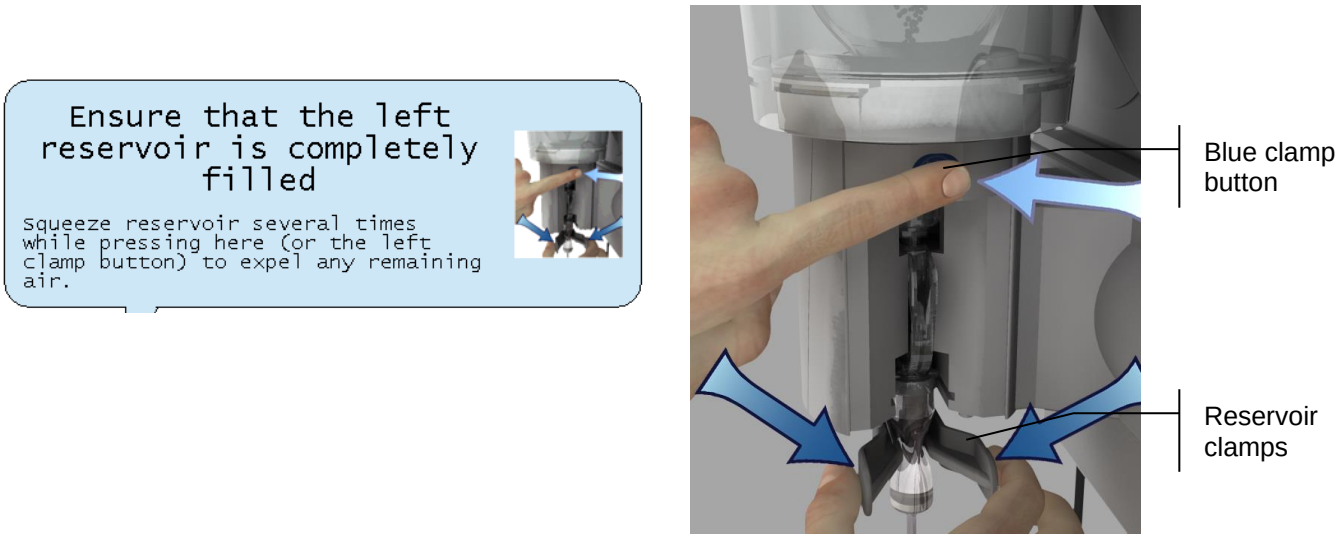


Figure 82: Reservoir filling message and procedure

Warning

- **Entering an incorrect contrast media type, or an otherwise incorrect setting can result in inaccurate dosing.**
- **If you wish to use the automatic changeover function of the two bottles, make sure that you install two bottles of the same media type and concentration.**

5. Now you have programmed the first bottle of contrast media on CT Exprès™ 3D. To install and program the second bottle of media, see *section 4.5.3: Loading and programming the second bottle* on page 62.

6. Once you have entered the settings (and if temperature maintainer option is activated), the system will prompt a message asking to install a bottle insulator. In all cases, and even if the bottles are not prewarmed, it is recommended to install a bottle insulator.

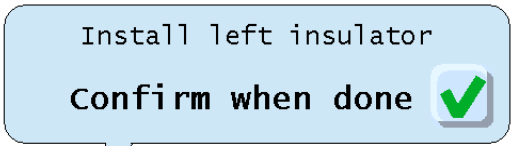


Figure 83: Bottle insulator message

7. If the option "batch number" is active (see *section 5.1.8: Country options*, on page 107), it is also necessary to enter the bottle batch number at this step.

Note

The contrast media settings menu can be displayed at any time by pressing the contrast media name above the displayed bottle.
CT Exprès™ 3D will assume that the bottles are full by default.

Warning

- **Do NOT use the CT Exprès™ 3D without bottle insulators secured. Using uncovered contrast media bottles exposes them to heat loss, bumping and potential breakage, and can lead to unreliable imaging for multiple patients.**
- **Using bottle insulators without temperature maintainer feature does not guarantee that the bottles remain at the initial temperature over a long period of time.**

If the contrast media in the new bottle does not match the contrast media that is currently in the Day Set III *HP* (for example, different type or concentrations of contrast media), expelling the residual air from the reservoir is not an option. A procedure for liquid replacement is automatically triggered with the following message when you select a new contrast media (immediately, if a Patient Set is already installed, or later, when a Patient Set is installed).

Figure 84: Full Day Set III *HP* filling recommended message due to possible contrast media mix-up.

Warning

Automatic filling with a new contrast media does not ensure full contrast media replacement. Traces of the previous contrast media may remain after execution of this procedure.

Note

Declining the full Day Set III *HP* filling will result in injecting 13 mL of the old contrast media into the patient. Replacement of liquid consumes about 18 mL per changed line. It is possible to skip this procedure by pressing the key  , although this is not recommended because of the resulting contrast media mixing in the Day Set III *HP* lines.

8. If the Patient Set is already installed, to fill the Day-Set III HP acknowledge the message. If the Patient Set is not already installed, then, first install the Patient Set. The system prompts the following instructions.

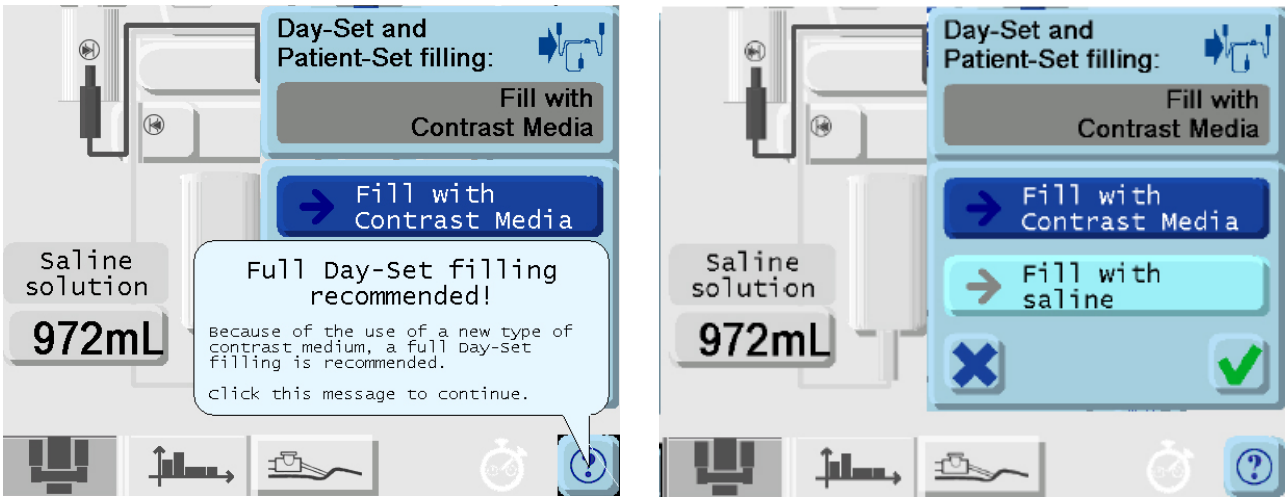


Figure 85: Full Day-Set III HP and Patient Set filling recommended message

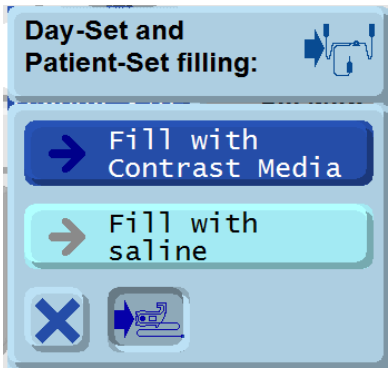


Figure 86: Day Set III *HP* and Patient Set filling

9. To fill only the Patient Set (if the full Day Set III *HP* filling is declined), press the  key. To fill the Day Set III *HP* and Patient Set, press the  key. To decline filling the Day Set III *HP* and Patient Set, press the ☒ key.

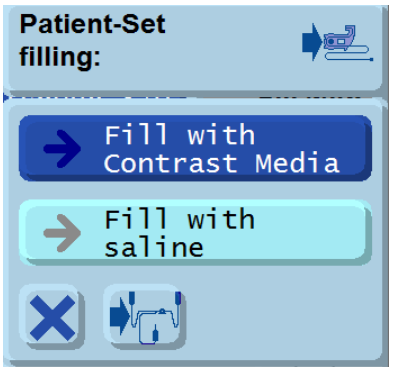


Figure 87: Patient Set filling

10. After that a message is displayed requesting to expel all residual air (from previous bottle) by pressing and holding the blue clamp opening button while squeezing the reservoir clamps located beneath each contrast media bottle.

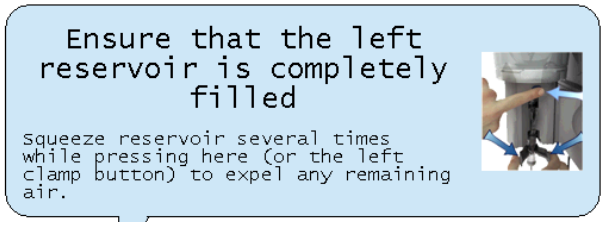


Figure 88: Reservoir filling message

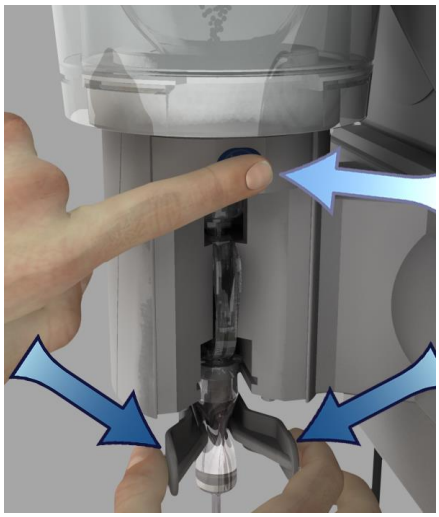


Figure 89: Fill the reservoir using the clamps while pressing the blue clamp button

11. A warning is given on the control panel to make sure that no patient is connected. Be sure you have a small receptacle to catch the saline or contrast media that will come out of the line during filling. Press the automatic filling key to start filling the fluidic pathway (Day Set III *HP* and Patient Set).

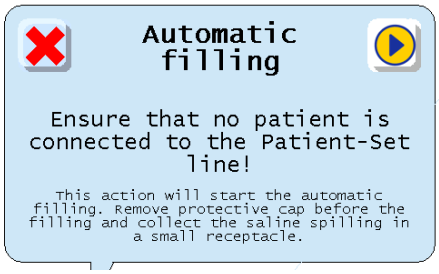


Figure 90: Automatic filling message

12. Automatic filling ends with a message on the control panel display saying that you should check for the absence of air in the lines.
If there are no bubbles in any of the lines, press the ☑ key on the control panel display.

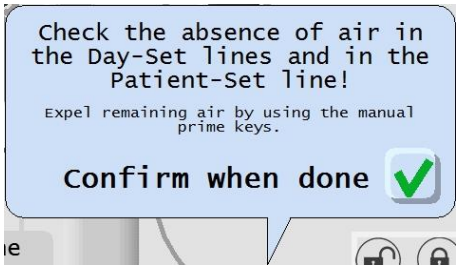


Figure 91: Check the absence of air message.

4.11.3 Changing a saline container

If the system determines that there is not enough saline solution in the saline bag for next injection, a message will be displayed, asking for confirmation of the volume.

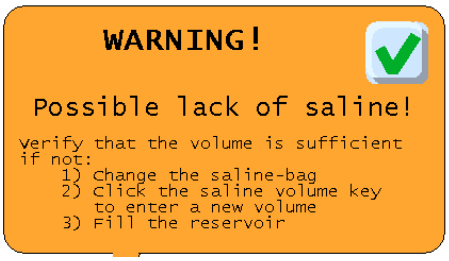
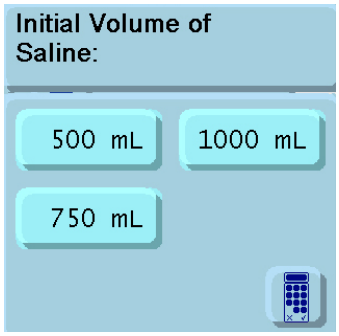


Figure 92: Change saline bag recommended message

1. Install the saline bag as per instruction in *section 4.4 Installing and programming the saline container*

2. Press the SALINE VOLUME key.

3. Choose between the different volumes proposed or press the key to manually program a volume using the keypad. Confirm the value by pressing the ☑ key.



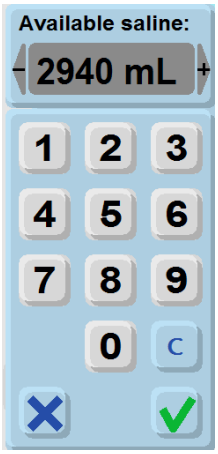
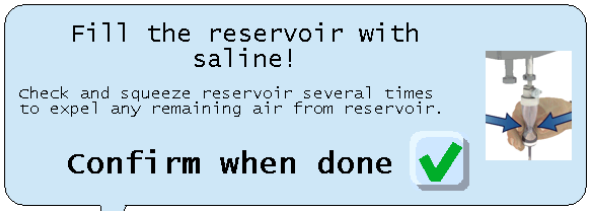


Figure 93: Volumes proposed (on the left) and keypad to enter a new volume (on the right)

4. Ensure that the reservoir of the saline line is entirely filled. Check the reservoir, squeeze it if necessary and press ☑ on the display message.



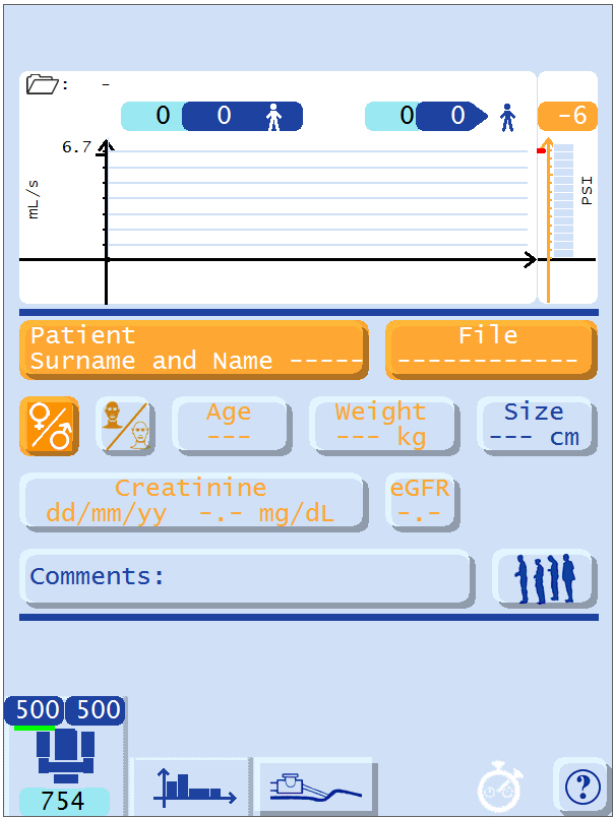
Note
If air is found in any of the lines, or if you wish to prime the Patient Set with a different fluid than was filled in automatic filling, you can manually prime any of the lines using the yellow manual priming buttons. Please refer to *section 4.7.2 Performing manual priming*, page 67.

4.12 Programming the CT Exprès™ using the Nexo® server

This section concerns CT Exprès™ injection systems connected to a Nexo® server.

NEXO® is a self-contained software package distributed by Bracco Injeneering, aimed to network Bracco Injectors and add connectivity to RIS/PACS to them. NEXO® can be enabled on Bracco Injectors as an additional software option. For more information on NEXO® please contact your local representative.

The status of the connection to a Nexo® server is shown on the status page in the connectivity status area (See page 26). The connection is established only once the correct TCP/IP addresses are defined in the permanent settings of the injector (see *§5.1.10* Ethernet network). The connectivity symbol is red (ⓝ) when it is not yet established, green (ⓝ) when is it open on the current control panel and blue (ⓝ) when it is open on the other control panel.

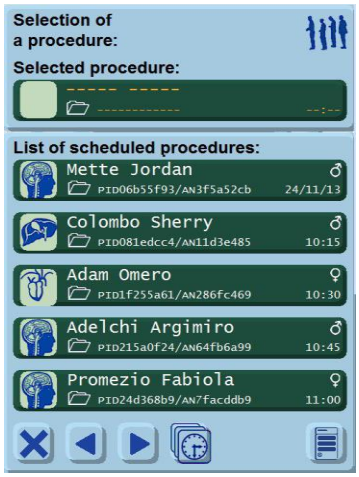


4.12.1 Hospital Work-list and shared patient data

Injectors connected to a Nexo® server have an additional page (patient page) where are managed patient data. This page can be reached by selecting the “incoming patient” page ( ) that is available on all other pages.

4.12.1.1 Calling the hospital work-list

In the absence of a specific patient selection, the current hospital work-list in the RIS is loaded onto the injector through the Nexo® server and then displayed. This can take a few minutes depending on the network current performances.



The patient name, patient file identifiers, accession number, sex, expected scheduled time and examination type are displayed for each patient entry in the work-list. The entries can be sorted by patient name, scheduled time, patient identifier or by examination type, depending on the sorting method chosen (or respectively). Nexo® setting also allows to filter the list by CT-rooms, when clicking the room key ( ) displayed on the top of the display.

Two cases are then possible:

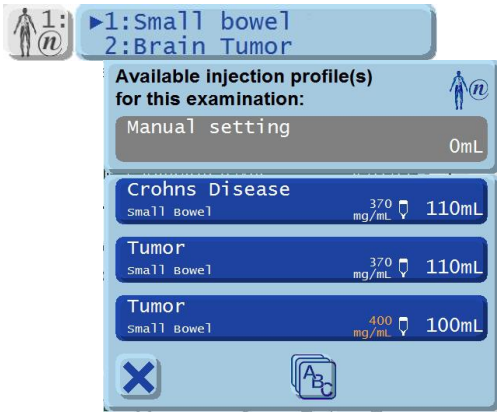
4.12.1.2 The current patient is not yet declared in the hospital work-list

In that case, it is possible to create a new patient from the injector (this will not update RIS). Click the menu key ( ) at the bottom right of the display work-list to start the declaration of a new patient. It is then asked to fill the mandatory items (orange keys) that are patient name, patient file identifier, scheduled time (if any, by default it is set to the time of the declaration) and sex.

Then prepare the injection. The association of this new patient session with the effective work-list will be synchronized thereafter, after the injection is finished.

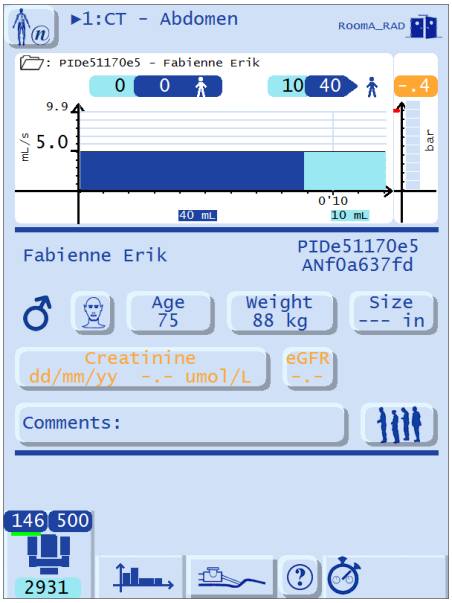
4.12.1.3 The current patient is already declared in the hospital work-list

Select a patient by clicking the associated key in the work-list. This immediately loads the data for the selected patient onto the patient page. A new menu is then displayed and shows all injection protocols which have been loaded from Nexo® and which match with the injection protocols related to the selected patient.



Proceed as with the injection profile library to select the adequate injection profile (*section §4.8.6 Loading a predefined injection program*). If this menu is not displayed (no proposal from Nexo® library) or no adequate injection profile is proposed then enter manually an injection profile (see *section §4.8.2 Programming an injection*). In the case where several examinations are requested, then these are listed on the top of the page. Click this list to modify the selected examination and find the adequate injection profile.

The patient page is then filled:



On top is shown the name (or the list of names) of scheduled examinations as stated in RIS. The key allows to search through the injection profiles that are available by the Nexo® server and that match the best with the selected scheduled examination.

When provided by RIS, patient name, surname, sex, patient file and accession number are displayed and frozen. Enter all fields needed for a GFR calculation to get it calculated and displayed (see *section §4.9.1*).

4.12.1.4 Selecting another patient from the hospital work-list

In the case of a patient already been selected, but with no injection performed yet, it is then possible to select another patient by clicking on the “incoming patient” key ( ). Selecting a new patient will overwrite all patient data with the newly selected one and previous injection profile will be cleared.

In the case of a patient already selected, and the injection having been performed, the user must close the session with the current patient, in order to be able to select a new patient. In that case the “incoming patient” key ( ) is not available.

4.12.2 Closing a patient session scheduled in the hospital work-list – sending patient session to PACS and RIS

There are two ways to close a patient session once the examination is complete: Removing the Patient-Set or sending the session details to PACS and RIS. In both cases the “incoming patient” key ( ) is again displayed to access the current hospital work-list for the next patient. Meanwhile, the previous patient session remains displayed.

It is also possible to report a special comment about the session, before its closure. To do so, click the Comments: key present on the patient page and enter a comment. This comment will be maintained in the Nexo® database and can be remotely retrieved by consulting the Nexo® web page of the hospital through the recommended web browser from any computer.

4.12.2.1 Close the session by removing the patient-Set

Once the patient-Set is removed, all patient data are frozen. The only allowed actions are to enter a comment if needed (*§4.12.2*), and to send the session details concerning this closed session to PACS and RIS by clicking the key on the patient page.

4.12.2.2 Close the session by sending the patient session data to PACS and RIS

In that case, it is possible to send the session details concerning the closed session to PACS and RIS by clicking the key on the patient page. It will then be asked to remove the Patient-Set.

4.12.3 Closing a patient session not scheduled in the hospital work-list – sending patient session to PACS and RIS

This concerns the cases when the patient is not yet declared in the hospital work-list and is locally declared, or if the patient has been examined before to search information in RIS.

In these cases, it is not possible to immediately send session details to PACS and RIS. The procedure association of the current session with a scheduled one in RIS must be done prior to closing the session. Hence the key is not available and is replaced by the "patient matching" key ( ).
First, if needed, enter a comment concerning the current session by clicking the Comments: key present on the patient page and enter a comment. This comment will be maintained in the Nexo® database and can be remotely retrieved by consulting the Nexo® site of the hospital through the recommended web browser from any computer.
Then a click on the key leads to a dedicated menu which allows a procedure association between the current patient session and the scheduled ones in RIS.

The first procedure presented is the entered data for the current executed session, while the second procedure shown is the scheduled procedure, selected from the hospital work-list. This work-list is also displayed in the second part of the displayed menu.
Select the correct scheduled procedure from that list. Then validate the association between this scheduled procedure and the current session by clicking the key.

Close this menu if the association is not yet possible. The session can be closed by removing the Patient-Set and switching to the next patient. The association of a past session is then postponed. In such case, the "outgoing patient" key ( ) appears: by clicking on it, you can access the list of past sessions which are not already sent to PACS and RIS, or which are not yet associated (see next section).

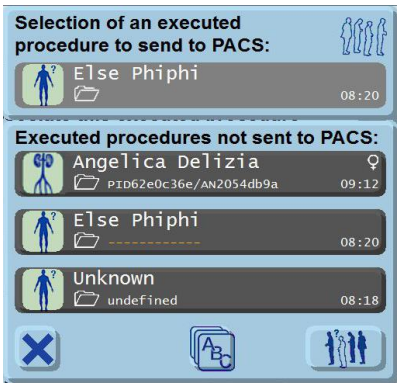
4.12.4 Postponed patient session association with a scheduled session in the hospital worklist

When the “outgoing patient” key ( ) is present on the patient page, this means that some past patient sessions have not yet been sent to the PACS and the RIS. Click on this key to display the list of such sessions. Then click an already executed procedure to select it.

Two cases are possible after having selected an already executed procedure:

a)

b)



a) When selecting a past session (executed procedure) that has been already attached to a scheduled session from the hospital work-list, the key appears at the bottom right of the list. Clicking on this key sends the selected session details to the PACS and the RIS.

b) When selecting a past session (executed procedure) that has not already been attached to a scheduled session from the hospital work-list, the key appears at the bottom right of the list. Clicking on this key opens the menu allowing the association between the past session and a scheduled session in the hospital work-list (as described in *section §4.9.3*). Once the association is performed, the key appears to send the selected session details to the PACS and the RIS. If the association is not possible, it can be done thereafter. The key is then available to definitively delete these past session details.

These actions can be performed during another active patient session.

Warning

- **Past patient sessions not yet send to PACS remain encrypted in the injector’s permanent memory. They are definitively deleted and consequently lost if the injector is powered on in absence of connection to Nexo®.**
- **Sessions successfully sent to PACS and RIS are immediately deleted from the injector’s permanent memory.**

4.12.5 Summary of available keys concerning patient session management

“Incoming patient” key		To select a scheduled session from the work-list (incoming patients) or to declare a new patient.
“outgoing patient” key		To get the list of past sessions not yet sent to the PACS and the RIS
“unknown patient” key		To associate the session of a unknown patient with a scheduled one in the hospital work-list
“Send to PACS” key		Send patient session details to PACS and RIS
“Clock” key		The work-list is sorted chronologically
“examination type” key		The work-list is sorted by examination type
“alphabetic” key		The work-list is sorted alphabetically (using patient last names)
“File” key		The work-list is sorted by patient file identifier
“Room” key		The work-list is filtered by rooms

4.13 Programming the CT Exprès™ 3D using the scanner interface

The scanner interface offers connectivity to approved scanners using the CiA425 communication protocol. It allows bi-directional interactions (class 4) between scanner and CT Exprès™ 3D. This interface can be enabled on Bracco Injectors as an additional software option. Please contact your local Bracco Injeneering representative to know if this option is available in your country.

The status of the connection to a scanner through the CANbus is shown on the injector status page in the connectivity status area (See *Figure 4*). The connection is established only when the CANBus node identifiers are defined in the permanent settings of the injector (see *§5.1.10* CANbus setting). The connectivity symbol is red ( ) when it is not yet established, yellow ( ) when not yet operational, green ( ) when is it open on the current control panel, or blue ( ) when it is open on the other control panel.

CT Exprès™ 3D supports two modes of operation, which can be selected from the scanner user interface:

- The “not coupled” mode: injection data are transmitted from the injector to the scanner but no additional communication is possible.
- The “coupled” mode: the scanner can download injection programs, as well as start injections along with the scanning; the injector can upload injection programs from the scanner and start the scanning along with the injection.

4.13.1 Programming and starting an injection when the injector is not coupled to the scanner

In that mode, injection data are transmitted from the injector to the scanner, which is only visible through the scanner. The injector cannot start the scanning and the scanner is not able to start the injection remotely.

Programming an injection:

In the “not coupled” mode, a program entered on CT Exprès™ 3D or loaded from the internal program library is uploaded to the scanner interface. It is then possible to switch to the coupled mode to modify it remotely from the scanner.

Start an injection:

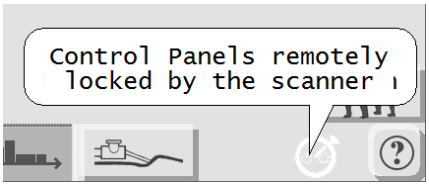
In that mode, a start of injection will not trigger the scanner.

4.13.2 Programming and starting an injection when the injector is coupled to the scanner

In that mode, additional features are available on the CT Exprès™ 3D.

Programming an injection:

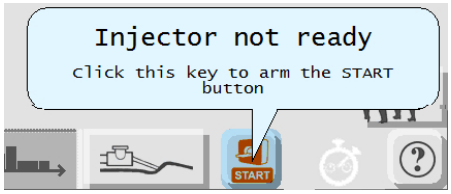
In the “coupled” mode, injection programs cannot be locally programmed on the CT Exprès™ 3D. Any attempt of modification will return the following message:



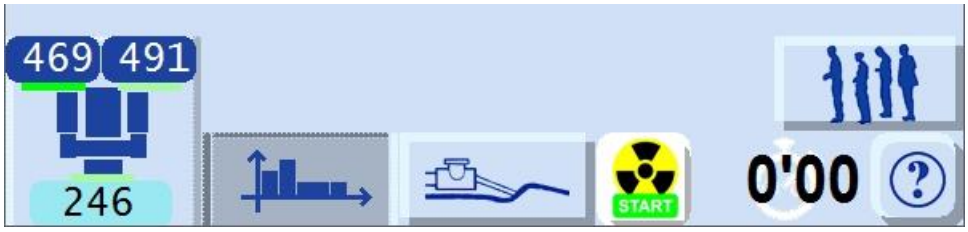
An injection program entered through the scanner will be downloaded to the injector. It is then possible to switch to the “not coupled” mode to modify the injection program locally on the injector.

Start an injection:

In the “coupled” mode, a start of injection will also trigger the scanner. To authorize such a start, the scanner must be set as ready from the scanner user interface and the injector must be set as ready as well from the injector interface (see below “injector ready keys”). If not yet set, the following message is displayed when pressing the Help key or the START button:



By clicking on the “injector ready” key, this will enable the injector. Clicking a second time on this key, or any other selection on the injector, will disable the injector. This key is present at the bottom of the injection setting page only when all required parameters are set on CT Exprès™ 3D to perform an injection.



The “injector ready” keys:

The “injector ready” key indicates both the status of the scanner and of the injector:

Key	Description	Action
	The scanner is not ready The injector is not ready	Prepare the scanner. Click the key to enable the injector.
	The scanner is not ready The injector is ready	Prepare the scanner.
	The scanner is ready The injector is not ready	Click the key to enable the injector.
	The scanner is ready The injector is ready	Press the key and release it when the display becomes green in order to trigger the injector and the scanner.

4.14 End of session and general cleanup procedures

4.14.1 End of session procedure

At the end of each daily clinical session, after the last patient has been disconnected, perform the tasks in the following sections, observing the warnings and cautions in the *section: Warnings and cautions*.

4.14.1.1 Removing contrast media bottles

Warning

- **Use each Bottle Spike only once. When removing the Bottle Spike from the contrast media bottle, the tip of the spike will remain in the contrast media bottle. Discard any bottle containing such a spike tip; do not re-use the contrast media.**
- **Each Bottle Spike has to be disposed of according to your institutional procedures.**
- **Handle contrast media in accordance with the manufacturer's instructions**

Remove both contrast media bottles from the bottle holder by pulling them from above.

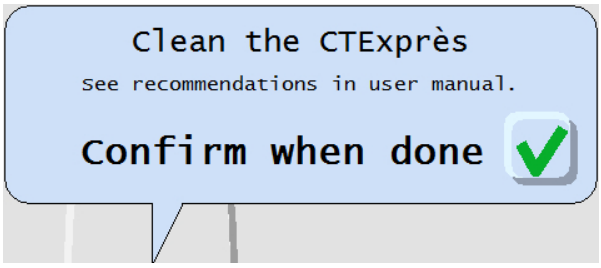
4.14.1.2 Removing the Day Set III *HP* and saline container

Caution

- **Before continuing, make sure that both contrast media bottles have been removed.**
- **Day Set III *HP* and saline container have to be disposed of according to your institutional procedures.**

Note
To avoid fluid spillage, hold reservoirs upright after removing them from the CT Exprès™ 3D.

1. Remove the T-connector from above the Patient Set port. The T-connector on the screen is now shown in orange and the CT Exprès™ 3D shows the message "Presence of Day Set not detected".



2. Begin by taking out the reservoir of the saline line, then take out those located under the bottle holders. In this way, fluid siphons into the saline container and spillage of product contained in the lines is avoided.
3. Press and hold the blue clamp-opening button on each bottle holder and remove the reservoirs under the two bottle holder columns. Hold them at their original position and height to prevent spillage.
4. Remove the saline pouch or bottle.

4.14.2 General cleanup procedure

Warning

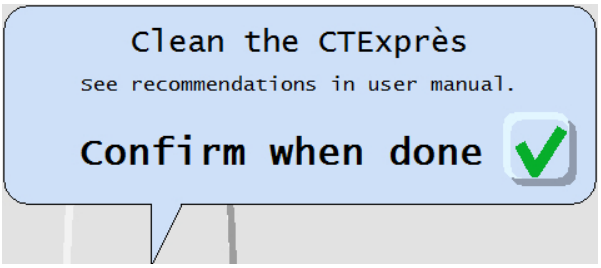
- **Do not put water or any other liquid over or onto the CT Exprès™ 3D at any time.**

Caution

- **During cleaning of control panels and injector unit, the CT Exprès™ 3D stays in STANDBY mode to ensure that no function will be activated accidentally. At the end of the cleaning process, please confirm the message on the control panel.**
- **Use only PDI® Super SaniCloth® germicidal disposable wipes to clean the CT Exprès™ 3D.**
- **NEVER use the following chemicals with the CT Exprès™ 3D for any purpose (as any of these substances can result in permanent damage to the device):**
  - **Acetoaldehyde**
  - **Acetone or acetone based solution**
  - **Ammonia**
  - **Benzene**
  - **Hydroxytoluene**
  - **Methylenechloride**
  - **Ozone**
- **Be aware that bottle holder top surface turns warm when prewarmed contrast media bottles are installed.**

4.14.2.1 Upon removal of an expired Day Set III *HP*; or at end of day; or in case of visible contamination:

1. Remove all the disposables (if any) as per the instruction in *section 4.14.2*. The software automatically disables the functions of injector and the buttons to allow the cleaning.



2. Use a cleaning wipe to remove visible soil from the entire surface of the injector unit, main and remote control panels, and Hand Switch. Use a clean wipe and thoroughly wet the surface. The surface should remain wet for a full two (2) minutes to disinfect. If necessary, additional wipes can be used to ensure that the surface remains continuously wet for 2 minutes. Follow the specific wipe manufacturer's instruction for specific warnings or restriction.
3. Inspect the surface for visible soil. If there is visible contamination, remove the visible contamination and repeat step before as many times as necessary until no visible soil is detected.
4. Allow to air dry and confirm the end of the cleaning process by acceptance of the software message (refer to figure above). Install new disposables.

4.14.2.2 In case of contrast media or saline spills:

1. Remove all the disposables (if any) as per the instruction in *section 4.14.2*. Remove all the disposables (if any) as per the instruction in *section 4.14.2*. The software automatically disables the functions of injector and the buttons to allow the cleaning.
2. Wipe off any visible saline or contrast media thoroughly with a damp cloth using warm water, paying particular attention to the areas shown in *Figure 94*.

Warning

- **When cleaning the system, do not remove the silicon layer added on the Day Set sensor, as displayed on the below picture.**

3. Use a cleaning wipe to remove visible soil from the entire surface of the injector unit, main and remote control panels, and Hand Switch. Use a clean wipe and thoroughly wet the surface. Follow the specific wipe manufacturer's instruction for specific warnings or restriction. The surface should remain wet for a full two (2) minutes to disinfect. If necessary, additional wipes can be used to ensure that the surface remains continuously wet for 2 minutes. Follow the specific wipe manufacturer's instruction for specific warnings or restriction.
4. Inspect the surface for visible soil. If there is visible contamination, remove the visible contamination and repeat step 2 and 3 before as many times as necessary until no visible soil is detected.
5. Allow to air dry before turning on the CT Exprès™ 3D. Install new disposables.

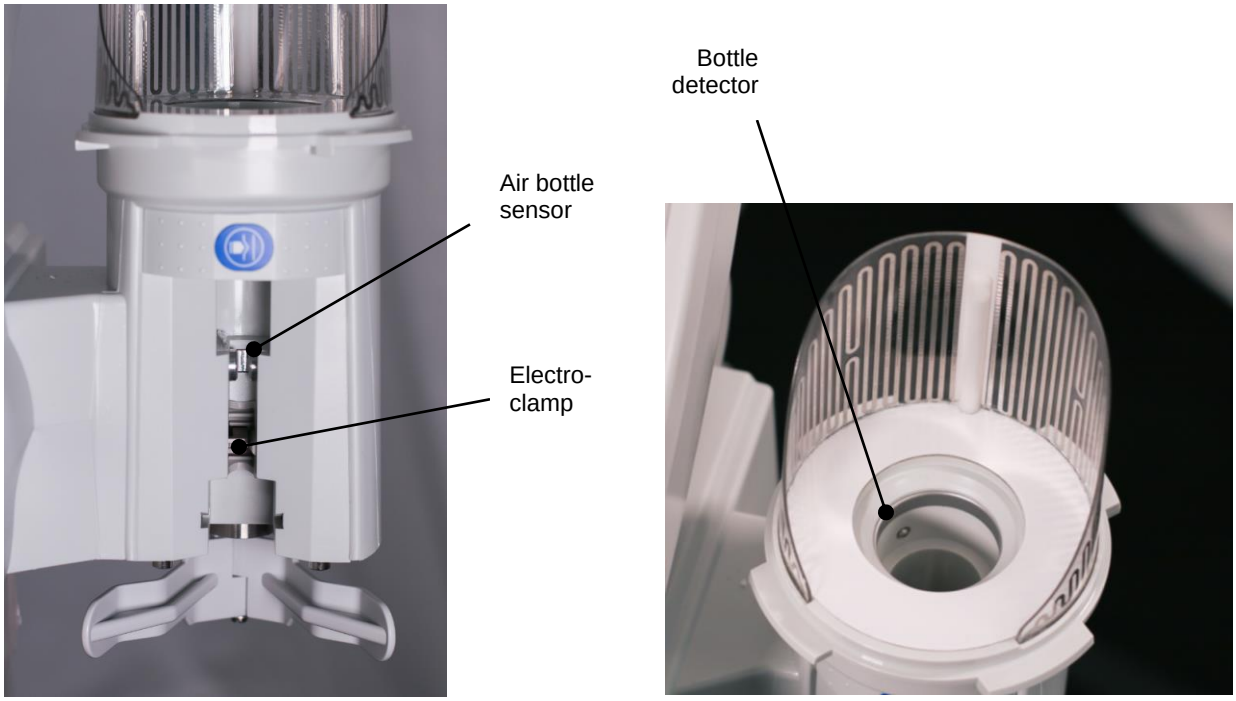


Figure 94 : Bottle holder points to be cleaned

Caution

Use the cleaning cassette in the event of recurrent "Patient Set defect" detection, entering the menu described in the *section 5.1.12 Cleaning cassette*, page 109.

5 Permanent settings menu

5.1 General

The CT Exprès™ 3D Permanent Settings Menu enables you to permanently modify options or parameters on system level. In order to go to the Permanent Settings Menu:

1. Make sure that no patient is connected to the CT Exprès™ 3D.

2. Make sure that no process (for example, flushing or injection) is taking place.

3. Go to the Injector Status Page (see *Figure 3*) and press the `PERMANENT SETTINGS` key to display the menu. Use the arrow keys to scroll down and up the different menu options:

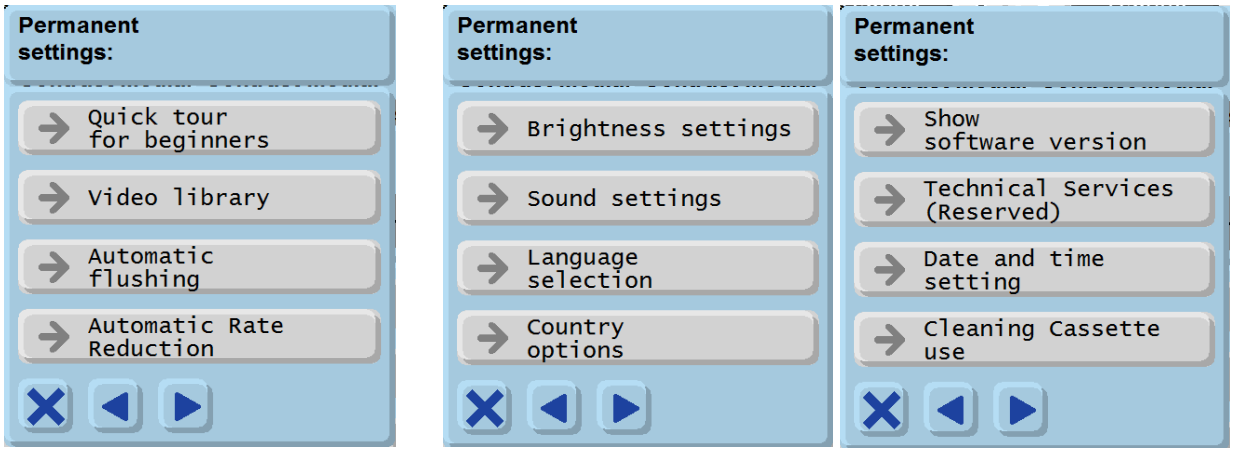


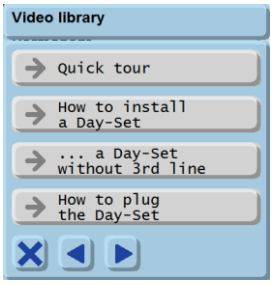
Figure 95: The three screens of the permanent settings menu

4. Press the key of the option you wish to modify and following the displayed instructions. Refer to the following *sections 5.1.1* to *5.1.11*.

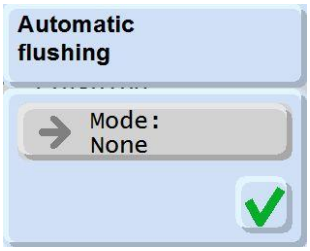
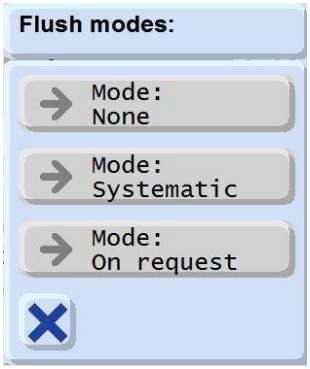
5.1.1 Quick tour for beginners

Screen Display	Comment
	This starts the review of main control panel keys. It ends by playing a quick tour video and finally opens the video library.

5.1.2 Video library

Screen Display	Comment
	This allows access to all available video presentations. ▪ Select a video presentation for viewing. ▪ Press the ⏸ button to pause or the ☒ key to quit the video presentation. ▪ Select another video presentation for viewing or press the ☒ key to quit the video library.

5.1.3 Automatic flushing

Screen Display	Comment
 	Use the automatic flushing option to set saline flushes (preflush, postflush) as a standard program to be used with each patient injection program. 1. Select the key mode to access the automatic flushing mode menu. 2. Select one of the following flush modes: ▪ None: No automatic flushing will be executed during an injection. ▪ Systematic: Saline flushing is systematically performed for injections. Set the following options, as applicable: - Preflush: programs the preflush volume, the rate is the rate of the next contrast media phase - Postflush: programs the postflush volume, the rate is the rate of the previous contrast media phase ▪ On request: CT Exprès™ 3D will ask you whether you wish to use the automatic flushing options prior to each injection. Set the following options, as applicable: - Preflush: programs the preflush volume, the rate is the rate of the next contrast media phase - Postflush: programs the postflush volume, the rate is the rate of the previous contrast media phase Note: if you set NONE for the preflush or postflush option, this will deactivate the option. Press ☑ to save the settings. Press ☒ to leave the saline flush option screen.

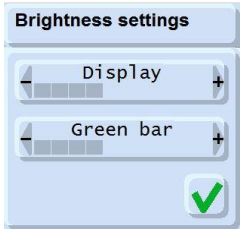
Caution

If “systematic flushing” is detected, the post-flush parameters only apply to manually programmed injections. Stored injection profiles will be loaded as they were saved.

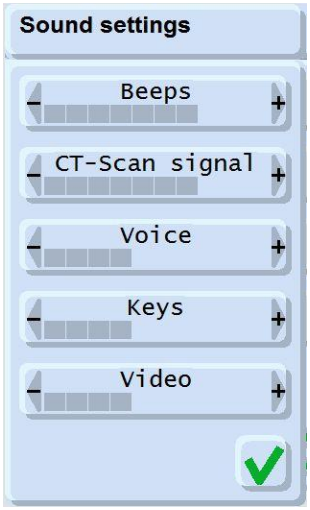
5.1.4 Automatic rate reduction

Screen Display	Comment
	This Automatic Rate Reduction adjustment enables you to determine the behavior for CT Exprès™ 3D if it detects excess pressure. By default, CT Exprès™ 3D stops injecting if it detects excess pressure. However, you can choose to have the device reduce the flow rate, instead of aborting the injection. For appropriate occlusion detection, even if the Automatic Reduction Rate, A.R.R., is set at 0%, a Forced Automatic Reduction Rate, F.A.R.R., will be automatically performed by the CT Exprès. It is not possible to disable this functionality, as it is part of the occlusion detection algorithm and cannot be set by the user. For example, if you select a Maximum Rate Reduction value of -30%: • If, during an injection, the pressure reaches the occlusion detection limit, the flow rate will be automatically decreased up to 80% (F.A.R.R.) of the flow rate programmed during a short period of time. This Forced Automatic Reduction Rate is used by the CT Exprès to determine if the excessive pressure is related to a complete or partial obstruction of the Patient Set, patient moving obstruction, needle used, etc. • If the pressure does not decrease proportionally after the flow rate reduction, the system will stop the injection with an occlusion detection alert message displayed on both control panels. • In case of proportional pressure decrease, the system will increase the flow rate until the maximum pressure limit. If this new flow rate is included in the range of the A.R.R. % programmed by the user (-30% in this example), the injection is continued at this reduced rate. • If not, the injection is stopped with an occlusion detection alert message displayed on both control panels. In summary, after the initial temporary F.A.R.R., the CT Exprès™ 3D reduces the flow rate as little as possible, but in any case by no more than 30% below the programmed rate, providing that the pressure remains under the pressure limit. However, if the pressure exceeds the pressure limit despite a 30% reduction in flow rate, the injection will be aborted. When using Automatic Rate Reduction, CT Exprès™ 3D will deliver the programmed volume of contrast media (however, the injection duration will be prolonged as delivery proceeds at a lower than programmed injection rate). This function is useful, since it can be preferable to reduce the injection speed rather than abort the injection in cases such as when: ▪ The selections of speed and needle and/or contrast media type are not completely compatible. ▪ There is a partial occlusion of the vein access. Action: ▪ Enter the A.R.R. value (0 to - 50%). Note: the "0" value disables this A.R.R. option (but not the F.A.R.R. that is automatic). ▪ Press the ☑ key to confirm and save, or quit the menu by pressing ☒. The A.R.R. is displayed during injection while the injection rate is reduced (see *Injection Settings Page*: Graphic showing rate vs. time and pressure vs. time. The latter will become yellow if A.R.R. is activated).

5.1.5 Brightness settings

Screen Display	Comment
	▪ Displays the current screen brightness. ▪ Increase or decrease the screen brightness by pressing - and +. ▪ Press the ☑ key to complete the task and save.

5.1.6 Sound settings

Screen Display	Comment
	With this menu you can select the sounds settings of: • Beeps: sound for minor warnings and information messages • CT-scan signal: sound at start of injection or after the scan delay (see the note below) • Voice: sound for voice guidance • Keys: sound for operation of the display buttons • Video: sound for help videos Press - and + to adjust the settings. Then press ☑ to save.

Note

- Two seconds before the end of the scan delay, the CT Exprès™ 3D outputs a single tone. At the end of the scan delay, it outputs a tone twice, indicating that you must start the scan.
- The alert settings cannot be changed. The alert volume on the remote control panel is at maximum; at the main control panel near the patient it is lower.

5.1.7 Language selection

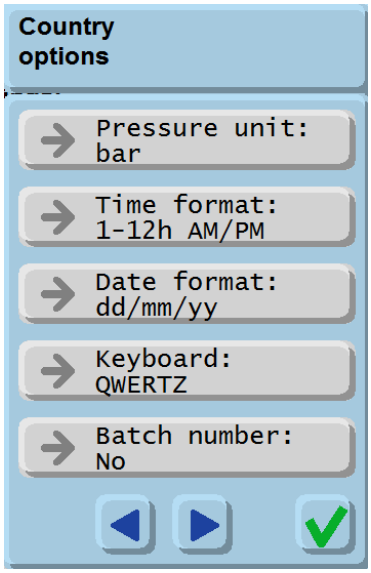
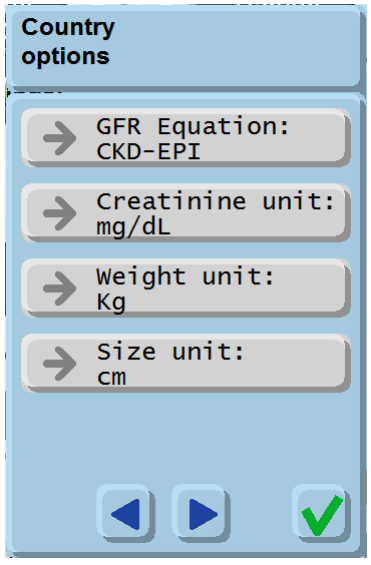
Warning

Do not access or change this function in routine operation.

Screen Display	Comment
	With this menu you can select the language for the CT Exprès™ 3D system: ▪ English ▪ Français (French) ▪ Deutsch (German) ▪ … Press the ☑ key to save the settings or the ☒ key to quit the menu.

5.1.8 Country options

This menu is composed of two pages.

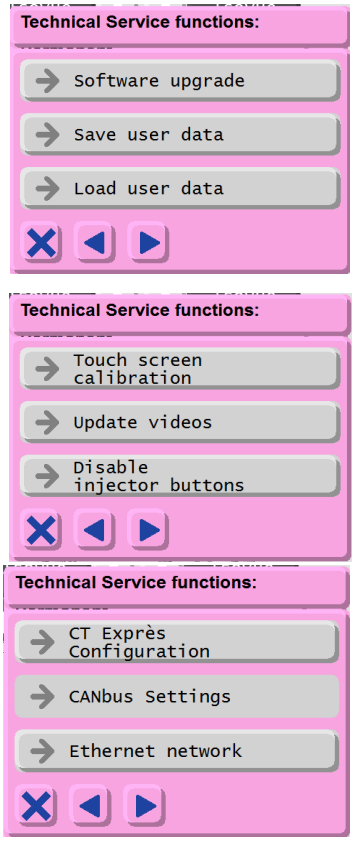
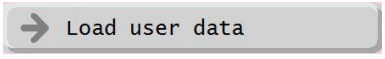
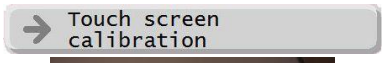
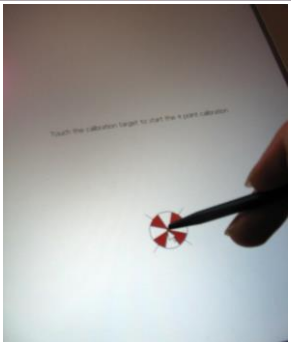
Screen Display	Comment
	First page: you can set the following options: • Pressure unit: bar or PSI • Time format: 0-23h or 1–12h AM/PM • Date format: dd/mm/yy or mm/dd/yy (d for day, m for month, y for year) • Keyboard type: Sets the keys of the display keyboard to QWERTZ, QWERTY or AZERTY • Batch number: Enables the function bottle batch number: If you set YES, the batch number is asked during new bottle entry (see *section 4.5.2: Programming the contrast media bottle* on page 59). Bottles of same product can thus be distinguished by their batch numbers. Press ☑ to save.
	Second page: You can select the equation used by the GFR calculator (CKD-EPI, MDRD or Cockcroft-Gault equation): CKD-EPI equation[1]: GFR = 141 x min(Scr/κ,1)$^{\alpha}$ x max (Scr/κ, 1) $^{-1.209}$ x 0.993^{Age} x 1.018 (if female) x 1.159 (if African type) Where Scr is serum Creatinine rate (mg/dL), κ = 0.7 (females) or 0.9 (males) , α = −0.329 (females) or −0.411 (males) MDRD equation[2]: GFR = 186 x (Scr)$^{-1.154}$ x age$^{-0.203}$ x 0.742 (if female) x 1.21 (if for African type) Where Scr is serum Creatinine rate (mg/dL) Cockcroft-Gault equation[3]: GFR = (140 – age) x weight (kg) x κ / 72 / Scr Where Scr is serum Creatinine (mg/dL) κ is (0.85 if female) or (1 if male) The units used on the user interface can also be selected: • Creatinine rate unit: uMol/L or mg/dL • Weight unit: Kilogram (kg) or Pounds (Lbs) • Size unit: Centimeters (cm) or inches (in). Press ☑ to save.

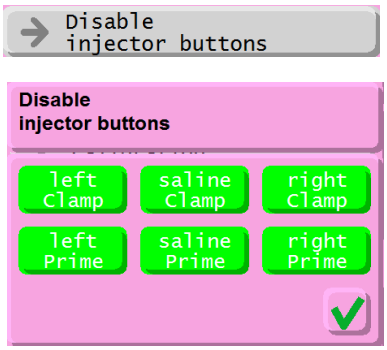
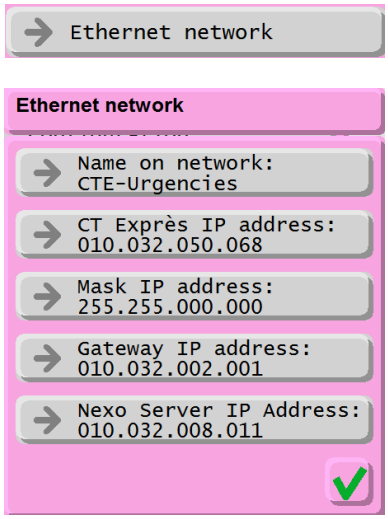
[1] Levey *et al.* Ann Intern Med 2009 ; 150 : 604-12 ;
[2] Levey *et al.* Ann Intern Med 2003 ; 139 : 137-147 ;
[3] Gault *et al.* Nephron 1992 ; 62 :249-256.

5.1.9 Show software version

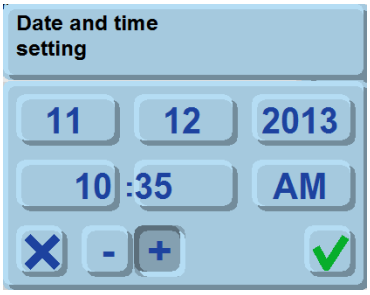
Comment
This menu shows you the software version currently installed on the CT Exprès™ 3D system.

5.1.10 Technical services functions

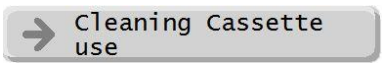
Screen Display	Comment
	This part of the permanent settings menu is for Technical Services staff only. A limited number of functions are nevertheless accessible to the user by means of the Bracco Injeneering user USB key. Install the Bracco Injeneering user USB key in its slot on the back of the Control Panel and wait for the screen to turn pink. Select the “Permanent Settings” key, then select the “Technical Services” key. Only shaded keys are active. Available functions : ▪ Software update ▪ Saving and downloading of user data ▪ Touch screen calibration ▪ Injector button activation / reactivation tests ▪ Show current injector configuration ▪ Change CAN network settings for CiA 425 communication protocol with scanners (Enabled only on injectors configured to run the scanner interface CiA425) - Enter requested Injector node ID (typically 24) - Enter the scanner node ID (typically 1) - Enter communication speed only on the connected control panel (always 250kBaud) ▪ Change Ethernet network settings for use with the Nexo® server (Enabled only on injectors configured to run the scanner interface CiA425) Enter requested IP addresses as provided by your IT service
	Your Bracco Injeneering representative may propose that you perform a software update. This procedure allows this update to be performed and must be applied to both control panels. Follow the instructions of your Bracco Injeneering representative to initialize your Bracco Injeneering USB key for this procedure.
	This function allows the user data (current injector status and list of saved injections profiles) to be saved onto you Bracco Injeneering USB key.
	This function allows for previously saved user data (current injector status and list of saved injection profiles) to be copied into a new Control Panel or the Control Panels of another injector.
 	Touch screen calibration : If the touch screen appears to function incorrectly, call your Bracco Injeneering representative for replacement of the Control Panel. Until then, you may solve the problem by selecting the touch screen calibration key. Select the aforementioned key on the Control Panel that functions correctly. On the defective Control Panel you now have 15 seconds to press the red target with a stylus as shown in the picture. Once the target has disappeared, you have to press four successive new targets until all have disappeared. Finally, press the “Accept” key.

	Injector key activation / deactivation test Your Bracco Injeneering representative may request you to test the injector keys. Select the key to be activated or deactivated (green or red) as requested. Confirm selection.
	Enter the name on the network. This defines the injector name for Nexo® server system. This name must be unique and kept in the case the injector is replaced with another one. Enter the IP addresses required for your Nexo® server system. Contact your IT representative to get the relevant addresses. Confirm selection.

5.1.11 Date and time setting

Screen Display	Comment
	With this menu you can set the operating date and time of the CT Exprès™ 3D system. The time is not automatically updated upon changeover from winter time to summer time and vice versa. Click on the keys to change their value. Then, click - or + keys to select a decrementing or an incrementing mode. Press ☑ to save (this updates the settings for both control panel). For injectors connected to the Nexo® server, this setting is automatically updated at power on and cannot be modified by the user.

5.1.12 Cleaning cassette

	This option allows insertion of the cleaning cassette as described in the cleaning kit.

5.2 Logbook

You may access the logbook by pressing the  key on the injector status page.
Two pages become accessible. The first contains the installation of the disposables and the injections. The second contains the principal user actions and all displayed messages. Data concerning limits of use for disposables are shown at the top of these pages.

You can toggle between the pages by pressing the  and  keys.

5.2.1 Sending the logbook to your Bracco Injeneering representative

Your Bracco Injeneering representative may ask you to forward him/her the logbook so he/she is in a better position to answer your questions.

To do so:

- Connect your Bracco Injeneering USB key on the rear of the Control Panel. The screen must become pink and display a new key :

  This key allows transfer of the daily logbook onto the USB key.
- Select the page with the messages to be forwarded (as described on the screenshot). Click on the  key.
- Select the date of a possible problem to be reported.
- Select the  key to transfer the data. Repeat for each day of interest.
- Remove the USB key and wait until the screen becomes blue again. You may be requested to repeat the operation on the other Control Panel.
- Install the Bracco Injeneering USB key on your PC and e-mail the contents of “logfiles” directory to your Bracco Injeneering Representative. You must then delete the contents of the “logfiles” directory.

6 Troubleshooting

Note

You can press the help key or video guidance at any time for information and instructions. (Always at the bottom of the main screen).

6.1. Setup

Backing up; moving to a different step or page

If you want to "back up" or change previous settings while the CT Exprès™ 3D is prompting you to perform the next step:

1. Press directly on the prompt message to close it.

2. Press the key or interface element for the setting you want to access (e.g. contrast media bottle; saline bag).

3. When you are ready to continue, press the HELP key. CT Exprès™ 3D will prompt you again for the next step needed.

Inserting Day Set III *HP* T-connector

If the CT Exprès™ 3D does not respond when you insert the Day Set III *HP* T-Connector:

- Make sure the T-connector is inserted with the septum facing you. There should be two lines on the left side of the T-connector, and one line on the right.

- Press the HELP key to view a video of T-connector installation.

Day Set III *HP* and Contrast Media bottle(s) displayed as always present, even if it's not the case

As already mentioned, in case of contrast media spills, particular attention has to be paid to certain areas of the system: air bottle sensors, clamps and particularly to the bottle detectors. If not correctly cleaned, the system might permanently detect a contrast media bottle.
After reaching one of the Day Set III *HP* limitations, time (12h or 24h) or volume (4L or 6L), or when restarting the system, the user might experience the following issue:

- Day Set III HP displayed in red, even when not installed, asking to be replaced. If the user tries to install a new Day Set III HP, the system does not recognize it.
- One or both contrast media bottles are also displayed on screen, even if not present.
- Restarting the system will not have any impact on the problem

To solve the issue: using a damp cloth and warm water, clean both bottle detectors. This should release them, solving the issue (Day Set III *HP* displayed in red should disappear from the screen, as well as the contrast media bottles(s)).

Automatic filling not prompted

If the CT Exprès™ 3D does not prompt you for automatic filling after you insert the Patient Set:

- Make sure the Day Set III *HP* is not expired, defective or already used. This would be indicated by a red Day Set indicator shown on the Injector Status page.
- Make sure the contrast media bottles are correctly installed and detected by removing and immediately replacing each bottle.
- Make sure the Patient Set is locked. This should be indicated by a green light on the Patient Set locking button.

Figure 96: Patient Set locked

Patient Set does not lock automatically

If the CT Exprès™ 3D does not automatically lock the Patient Set after you insert it (neither the green LED on the lock button nor the red LED on the unlock button is lit):

1. Press the Patient Set lock button . The Patient Set should lock, and the green LED on the locking button should light (see *Figure 96: Patient Set locked*).
2. Contact your Bracco Injeneering representative. Failure to automatically lock the Patient Set indicates hardware failure which should be repaired, as it can interrupt injection.

Warning

If you see the following message, contact your Bracco Injeneering representative as directed.

If you need to stop an injection or saline test injection, you must use the STOP key on-screen or the Hand Switch button. Attempting to use the hard button will not stop the injection and could result in severe patient injury.

Contrast media bottles crooked or Bottle Insulators do not attach correctly

If the contrast media bottle looks crooked when you insert it in the bottle holder, or if the Bottle Insulator will not close:

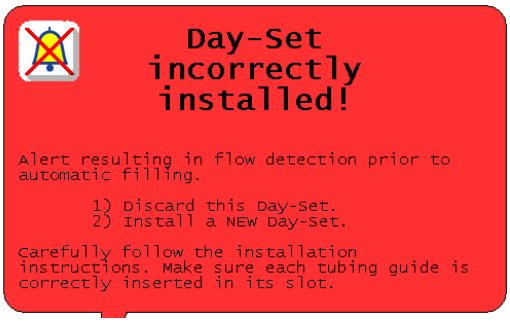
1. Remove the bottle, remove the bottle spike from it, and discard both according to your hospital's procedures.
2. Use a new bottle of contrast media and a new bottle spike, starting from *section 4.5: Installing a contrast media bottle.*

Check after inserting the bottle that all three reservoirs are completely filled.

6.2. Filling/Priming

Filling/priming is interrupted by an Alert

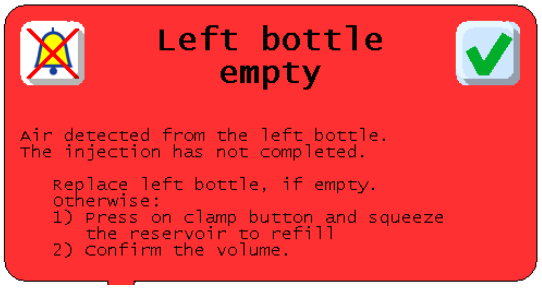
If the CT Exprès™ 3D stops filling/priming and sounds and displays an Alert, locate the Alert title below and follow the steps to address it.

Alert Title	Instructions
Day Set incorrectly installed	This alert appears when there is fluid presence in Day Set III *HP* before filling. 1. Remove and discard both the Day Set III *HP* and Patient Set. 2. Install a new Day Set III *HP* and Patient Set (see *section 4.3: Installing the Day Set III HP* and *section 4.6: Installing a new Patient Set*. Do not try to re-insert the Day Set III *HP*; it will cause the same alert repeatedly. 

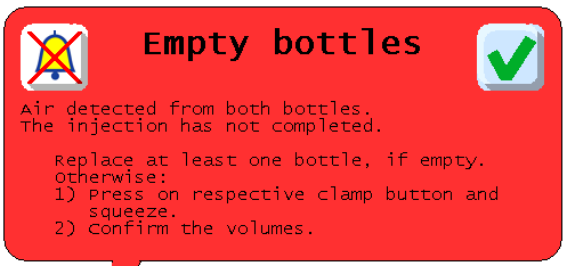
<table>
<tr><th>Alert Title</th><th>Instructions</th></tr>
<tr><td>Empty bottles</td><td>
1. Replace the empty bottle and Bottle Spike with new ones, following the procedure in section 4.5: Installing a contrast media bottle.

2. Fill the reservoir beneath the new bottle as shown in Figure 88: Reservoir filling message.

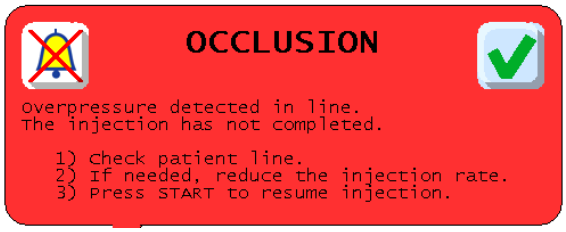
If the left bottle is empty, the alert shows as follows (with an identical message for the right bottle):



If both bottles are empty, the alert shows as follows:



</td></tr>
<tr><td>Occlusion</td><td>
1. Silence the alert by pressing the  key.
2. Make sure the pinch clamp is open.
3. Make sure that the safety cap (Figure 48: Pinch clamp in open position) on the end of the patient connector has been removed.
4. Once you have corrected the occlusion, press the ☑ key to acknowledge and clear the Warning.



</td></tr>
</table>

Note
If air is found in any of the lines, or if you wish to prime the Patient Set with a different fluid than was filled in automatic filling, you can manually prime any of the lines using the yellow manual priming buttons. Please refer to *section 4.7.2: Performing manual priming* p 67.

Empty Reservoir Alert after automatic filling:

If the CT Exprès™ 3D detects air after filling the Day Set III *HP* and you see that a Day Set III *HP* reservoir is still empty:

The contrast media line with the empty reservoir may not be correctly installed.

1. Remove the contrast media bottle from above the empty reservoir.
2. Press and hold the blue clamp opening button above the tubing guide and remove the tubing guide.
3. Continuing to hold the blue clamp opening button, re-install the tubing guide carefully as shown in *Figure 26: Inserting a Day Set III HP tubing guide*.
4. Immediately place the contrast media bottle back in the bottle holder.
5. Fill the reservoir using the clamps while pressing the blue clamp button.
6. Manually prime the line to expel air as shown in *section 4.7.2: Performing manual priming.*

Air bubbles in line after filling; manual priming:

If at any point you see air bubbles in the contrast media lines or the saline line:

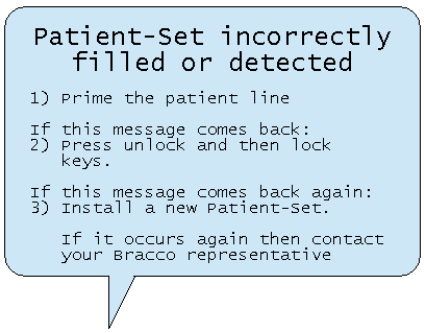
1. Make sure you are not connected to a patient.
2. Manually prime the line in which you see bubbles, by pressing the yellow priming button corresponding to that line as shown in *Figure 56: The three manual priming buttons on the injector unit.*
3. Make sure there is no air in the contrast media reservoirs and the saline reservoir. If necessary, squeeze the reservoirs to expel air as shown in *Figure 34: Filling the saline reservoir of the Day Set III HP third line.*

Patient Set blinking after filling:

If after filling the Patient Set is shown blinking on the Injector Status page:

The CT Exprès™ 3D is still checking the Patient Set, and will not allow an injection to start, but you can continue programming your injection as normal.

- If the check is successful, the Patient Set will stop blinking and you can run your injection as normal.
- If you see the following message, follow the instructions to re-run the Patient Set test:



1. Press the Patient Set unlocking key and then the Patient Set locking key to unlock and re-lock the Patient Set. This will re-start the test.
2. Install a new Patient Set.

6.3. Programming and running an injection

Injection does not start; display remains blue

If the injection does not start when the START button is released, and the display background remains blue:

The START button was likely released too early, before the display background turned green.

1. Press and hold START button or hand switch.
2. Continue holding button until display background turns green, then release.

Injection does not start and Error is displayed

If the CT Exprès™ 3D displays an error message when you try to start an injection, locate the error number below and follow the steps to address it. If this happens during an injection, the injection may have not been successfully completed.

Error number	Instructions
1178 or 1182 START button not fully pressed	Retry and press START button more firmLy. If this error is frequent: ▪ Contact your Bracco Injeneering representative for control panel repair. ▪ Use other control panel to start injections.
1183	1. Reinstall bottles (remove from bottle holders and immediately replace, and select "last used" from bottle selection menu). 2. Clear the current program and program it again. 3. Start the injection. If you receive the same error a second time: 1. Clamp the Patient Set. 2. Disconnect your patient. 3. Unlock and remove the Patient Set. 4. Plug the technical service USB memory stick into the main control panel. 5. Switch the CT Exprès™ 3D off and back on. 6. Select "save user data" and wait for completion. 7. Remove the USB memory stick and plug it into the other (remote) control panel. 8. Select "load user data" and wait for completion. 9. Turn off the CT Exprès™ 3D and remove the USB memory stick. 10. Turn on the CT Exprès™ 3D and prepare your injection again.
1187 Reinstall bottles	1. Reinstall bottles (remove from bottle holders and immediately replace, and select "last used" from bottle selection menu). 2. Start the injection.
Other error numbers	1. Retry START button. If you receive the error again: 2. Clamp the Patient Set. 3. Disconnect your patient. 4. Change the Patient Set and prepare your injection again.

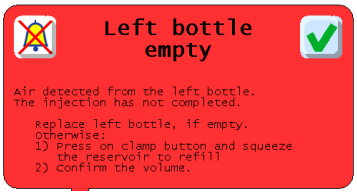
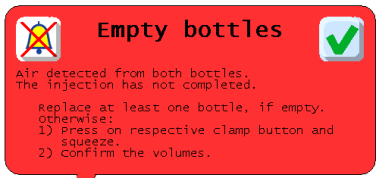
Display frozen while trying to start injection:

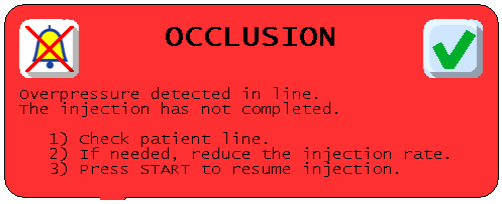
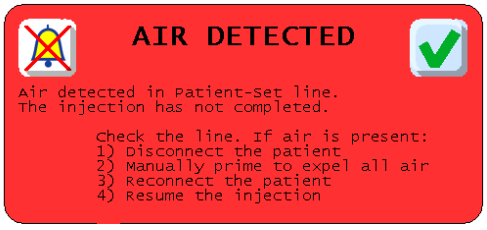
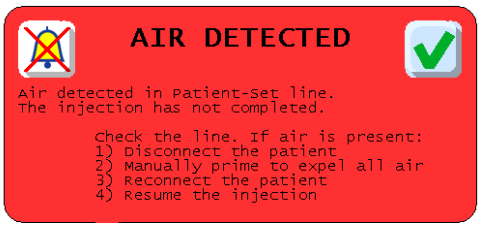
If the screen does not react to the pressure on the START button after two seconds (display looks frozen):

1. Press the STOP button.
2. Retry starting the injection from the other control panel.

Injection is interrupted by Alert

If the CT Exprès™ 3D stops your injection and sounds and displays an alert, locate the alert title below and follow the steps to address it.

Alert Title	Instructions
Stop requested by the user	It is likely that you pressed or bumped the START button or hand switch a second time. To restart the injection: 1. Acknowledge the alert by pressing the ☑key. 2. Press and hold the START button or hand switch again until the screen and luminous bar turn green. 3. Release the switch or button to restart the injection. For safety, CT Exprès™ 3D does not start the injection when you press the START button or hand switch-- you are required to hold the key or button for one or two seconds respectively until the Screen and luminous bar turn green. Then, the injection begins when the key or button is released. If the button is pressed again after that, the injection is stopped. 
Empty bottles	1. Acknowledge the alert by pressing the ☑key. 2. Clamp the Patient Set. 3. Disconnect your patient. 4. Open the clamp on the Patient Set (liquid may be expelled from the line because of the residual pressure). 5. Remove at least one empty bottle and follow instructions (open day-set line clamp and squeeze reservoir to expel air from reservoir to bottles, manually prime air in day-set line if any). 6. Reconnect your patient and continue your injection. the left bottle is empty, the alert shows as follows (with an identical message for the right bottle):  If both bottles are empty, the alert shows as follows: 

Occlusion	1. Search for the source of occlusion (bad connection, clamped line, bad injection site). 2. Acknowledge the alert by pressing the ☑key. 3. Clamp the Patient Set line. 4. Disconnect your patient. 5. Open the clamp on the Patient Set line (liquid may be expelled from the line because of the residual pressure). 6. Fix the source of the occlusion (if none is visible, reduce the injection rate). 7. Reconnect your patient and continue your injection. 
Air in Patient Set (and air is visible in one or more lines)	1. Acknowledge the alert by pressing the ☑key. 2. Clamp the Patient Set. 3. Disconnect your patient. 4. Open the clamp on the Patient Set (liquid may be expelled from the line because of the residual pressure). 5. Manually prime air from lines as necessary (see *section 4.7.2, Performing manual priming*). 6. Reconnect your patient and continue your injection. 
Air in Patient Set (during saline phase, and no air is visible)	If no air is visible in the lines, the source of the alert may be outgassing. 1. Acknowledge the alert by pressing the ☑key. 2. Clamp the Patient Set. 3. Disconnect your patient. 4. Open the clamp on the Patient Set (liquid may be expelled from the line because of the residual pressure). 5. Manually prime the Patient Set (see *section 4.7.2, Performing manual priming*). 6. Reduce the flow rate of the interrupted phase. 7. Reconnect your patient and continue your injection. 

Removing Patient Set:

If you encounter difficulty removing the Patient Set after the injection:

1. Make sure the Patient Set is unlocked by pressing the Unlock button **twice**.

You should see a red light on the Unlock button, indicating that the Patient Set is unlocked.

2. If you see the red light, it is safe to pull the Patient Set out of its port.

If you do not see the red light, do NOT pull on the Patient Set as this could damage the CT Exprès™ 3D.

6.4. Shutting Down and cleanup

Removing Day Set III *HP*:

If you encounter difficulty removing the Day Set III *HP* tubing guides from the CT Exprès™ 3D:

- Make sure the contrast media bottles have been removed from the bottle holders. If bottles are present, they lock the Day Set III *HP* in place.
- Press and hold the Clamp button above or next to the respective tubing guide while pulling on the guide.

Power failure

In case of power failure, the CT Exprès™ 3D will restart from startup page as soon as the power is reestablished.

1. If the Patient Set was installed before the shut-down, a message will prompt you to remove it.

2. Once the automatic tests are completed, a message will prompt you to confirm that the currently installed Day Set III *HP* can be used.

3. The settings of the already installed bottles and saline bag will have to be confirmed. The CT Exprès™ 3D will propose settings (bottle volume, concentration and temperature) at the time of the power failure.

4. Any already programmed protocol is lost and will have to be entered again. The CT Exprès™ 3D might be unable to display the amount already delivered if the power failure occurs during an injection. As a consequence it is end-user responsibility y to repeat or modify the programmed protocol.

Fuse failure

- In case of fuse failure, the CT Exprès™ 3D will not restart. If this happens during an injection, the injection may have not been successfully completed.
- Refer to Appendix B on how to replace a fuse.
- If this fuse replacement does not solve the issue, please contact your Bracco Injeneering representative.

7 Maintenance

Note
In the event of recurring problems or problems that you cannot solve by following the display messages on the CT Exprès™ 3D, please call your service representative.

7.1 Preventive maintenance

Caution

Preventive maintenance must be performed every 12 months.

Service, quality control, and periodic maintenance must be carried out, in consultation with the hospital, by a technical service representative authorized by Bracco Injeneering.

7.2 Corrective maintenance

For any corrective maintenance, i.e. repair in case of injector defects, please contact a technical service representative authorized by Bracco Injeneering.

8 Disposal of CT Exprès™ 3D

8.1. Disposal of disposables: Bottle Spike, Day Set III *HP*, Patient Set

Discard all disposables as biohazard waste according to your institutional procedures.

8.2. Disposal of electrical and electronic parts

At the end of their useful lifetime, you must return to the authorized representative of Bracco Injeneering the following parts for recycling in accordance with local requirements:

- Electrical and electronic parts: main unit, control panels, hand switch, cables
- Other parts such as: accessories and insulators

Warning

Do not dispose of electrical and electronic parts as unsorted municipal waste, as they contain substances that could have hazardous effects on the environment and human health.

8.3. Packaging material

The CT Exprès™ 3D standard set (see *Appendix A: : Standard*) packaging material consists of:

- Secondary packaging (box): cardboard
- Primary packaging (inner packaging): polystyrene, plastic bag or wrapping paper

Product type	Packaging dimensions (approx.)	Packaging weight (approx.)
Box of Injector	40 x 40 x 60 cm	2 kg
Box of control panels	30 x 35 x 40 cm	2 kg
Box of pedestal pole	80 x 60 x 15 cm	1 kg

In the event that you must return CT Exprès™ 3D to the manufacturer, always do so using the original packaging materials. For the complete shipment weight, please refer to *Appendix E: : CT Exprès™ 3D specifications,* on page 135 .

At the end of their useful lifetime, recycle the packaging materials in accordance with your local requirements.

Appendix A : Standard scope of delivery

Warning

CT Exprès™ 3D must always be assembled and installed by an authorized representative of Bracco Injeneering.

Note
Operators are requested to inspect the packaging and the delivered items before installation.

Every precaution is taken to ensure that the CT Exprès™ 3D is delivered in perfect condition. However, damage can result from transportation. Therefore, please check the packaging on arrival for signs of damage.

The standard package includes:

- 1 CT Exprès™ 3D injector unit
- 2 control panels (remote and main, identical)
- 2 connection cables (one short, one long)
- 1 power cable
- 1 hand switch
- 2 bottle insulators
- 1 operator manual
- 1 cleaning kit
- 4 screws M4 x 8 and 4 washers M4
- 1 Allen key
- 2 fuses

After unpacking, please check that all components listed are present and that none appear damaged. If any item appears damaged, report this immediately to the appointed Bracco Injeneering representative or the designated service representative who will install your CT Exprès™ 3D.

Note
Retain all the original packing materials in case you must return CT Exprès™ 3D to the manufacturer (see also *section 8.3: Packaging material* on page 122).

Appendix B : Replacing fuses

Pump rear panel

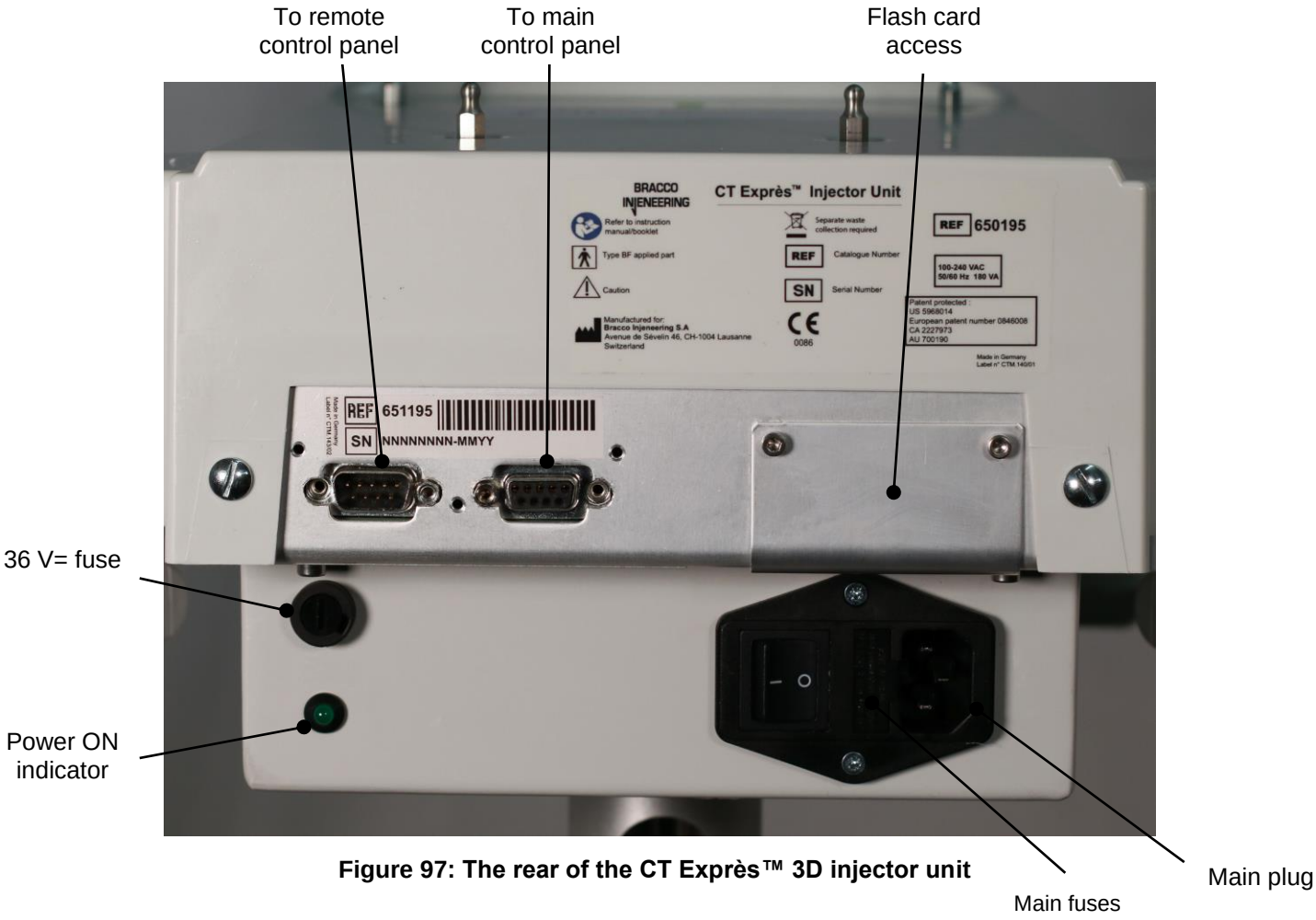


Figure 97: The rear of the CT Exprès™ 3D injector unit

B.1 Replacing the 36 V DC (T3.15A) fuse

1. Switch off the CT Exprès™ 3D using the mains power switch at the rear and disconnect the mains power cable (*Figure 97*).
2. Unscrew the 36V DC fuse cover.
3. Replace the fuse. Fuse type and rating must be: 3.15 A slow blow.
4. Replace the fuse cover.
5. Plug in the mains power cable and switch on the CT Exprès™ 3D using the mains power switch.

B.2 Replacing the main fuses

1. Switch off the CT Exprès™ 3D using the mains power switch at the rear, and disconnect the mains power cable (*Figure 97*).
2. Open the housing for the main fuses.
3. Replace the fuses. Fuse types and ratings must be: 250V, 2x 3.15 A slow blow
4. Replace the main fuse housing.
5. Plug in the mains power cable and switch on the CT Exprès™ 3D using the mains power switch.

Appendix C : Order codes for parts and accessories

	Product Description	Item No.
	Bottle insulator	640131
1.1.	Bottle Spike type A, 30 mm (60/box, sterile)	640058
	Bottle Spike type B, 25 mm (60/box, sterile)	640059
	Ceiling Column SHORT – Mobile Arm	640180
	Ceiling Column MEDIUM - Mobile Arm	640181
	Ceiling Column LONG - Mobile Arm	640182
	Ceiling Column Var. SHORT - Mobile Arm	640183
	Ceiling Column Var. LONG - Mobile Arm	640184
	Ceiling Column SHORT - Fixed Arm	640185
	Ceiling Column MEDIUM - Fixed Arm	640186
	Ceiling Column LONG - Fixed Arm	640187
	Ceiling Column Var. SHORT - Fixed Arm	640188
	Ceiling Column Var. LONG - Fixed Arm	640189
	Cleaning Kit	640077
	Connection cable, short	640072
	Connection cable, long (25 m)	640073
1.2.	Day Set III *HP* (15/box, sterile)	640060
	Hand switch	640080
1.3.	Patient Set (25/box, sterile)	640057
	Pedestal pole (= stand and wheels)	640076
	Philips Scanner Cable Adaptor	640283
	Power cable, CH, 5 m	640079
	Power cable, hospital grade, EU, 5 m	640082
	Power cable, hospital grade, US/CANADA, 25 ft (7.62 m)	640078
	Reservoir clamp	640153
	Spare fuse set (T 3.15 A L 250 V)	640497
	SUB-D15 CAN-Bus Adaptor	640093
	User USB key	640069

Appendix D : EMC requirements

Caution

- **Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.**
- **Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.**
- **Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CT Exprès™ 3D, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**

CT Exprès™ 3D is suitable for professional healthcare facility environment. The CT Exprès™ 3D is a medical equipment with essential performance and the operator can expect to have the phenomena and operation listed below due to electromagnetic disturbances.

Examples of professional healthcare facility environment intended use: Physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near HF SURGICAL EQUIPMENT, outside the RF shielded room of an ME SYSTEM for magnetic resonance imaging).

Declaration:
Essential performance for Equipment Under Test (EUT) CT Exprès™ 3D are the following:

- **Safe state**

  If the Injector is stopped during injection, the user shall be informed:
  The under-dose resulting from the injector being stopped shall not present the risk of missing a lesion on the CT imaging radiography, as long as the user is informed.

- **Specific safety goal**

  The injector shall detect the air injection and inform the user when the limit is reached (within specified tolerances):
  Due to the high flow-rate used during the injection of Contrast Media, the injection of air is the major risk of this type of devices.

  The injector shall prevent environmental and cross-contamination:
  Due to the multi-dose and multi-patient claims for the CT Exprès ™, the contamination of the fluidic pathway by a patient (which could potentially contaminate the following patients) is a Major risk of the CT Exprès ™.

Compliance criteria:
(other than the essential performance*)

- The Philips Signal relay must remain closed during an injection
- No change of parameters, no errors during an injection
- All ping requests must be acknowledged
- The injected volume of liquid difference should be under ±6%

* Essential performance = performance necessary to achieve freedom from unacceptable risk.

D.1 Cables, transducers and accessories

The following tables list all cables and maximum lengths of cables, transducers and other accessories with which Bracco Injeneering claims compliance with the requirements of IEC 60601-1-2, §5.2.2.1.

D.1.1 Cables

Identification	Connectors type	Length	Remarks
Main control panel cable	▪ Female Sub-D, 9-pin ▪ Male Sub-D, 9-pin	30 cm	Cable specifically manufactured for Bracco Injeneering.
Remote control panel cable	▪ Male Sub-D, 9-pin ▪ Male Sub-D, 9-pin	25 m	Cable specifically manufactured for Bracco Injeneering.
Power unit cord	CE plug for Europe	5 m	Or cord approved for medical applications in the specific country (hospital grade).
Philips Scanner Cable Adaptor	▪ Female, 4-pin ▪ XLR-4-12C	20 cm	Adapter specifically manufactured by Bracco Injeneering.
RJ45 (Ethernet)	▪ RJ45	10 m	Category 6 SF/UTP, off-the-shelf
SUB-D15 CAN-Bus Adaptor	▪ Male 10-pin round connector LEMO FB ▪ Male SUB-D15P connector	150 cm	Adapter specifically manufactured by Bracco Injeneering.

Table 1: Cables

D.1.2 Other accessories

Identification	Connectors type	Length	Remarks
Hand switch	Male mini-DIN, 4-pin	3 m	Accessory specifically manufactured for Bracco Injeneering.

Table 2: Accessories

D.1.3 Equipment to be used with cables, transducers and accessories

The following table lists all equipment and systems with which the accessories, transducers or cables may be used, and that are claimed by Bracco Injeneering to be in compliance with the requirements of IEC 60601-1-2, §5.2.2.1 when used with the accessory, transducer or cable.

Cables and accessories Identification	Equipment that are claimed by Bracco Injeneering to be in compliance with the requirements of IEC 60601-1-2, §5.2.2.1 when used with the accessory, transducer or cable
Main control panel cable	CT Exprès™ 3D
Remote control panel cable	CT Exprès™ 3D
Power unit cord	CT Exprès™ 3D
Philips Scanner Cable Adaptor	Philips Scanner
RJ45 (Ethernet)	Nexo® 1.2 manufactured by Bracco Injeneering
SUB-D15 CAN-Bus Adaptor	CT Scanner CAN-Bus cable
Hand switch	CT Exprès™ 3D

Table 3: Equipment for use with cables, transducers and accessories

D.2 Equipment for use with cables, transducers and accessories

The following table lists all equipment and systems with which the accessories, transducers or cables may be used, and that are claimed by Bracco Injeneering to be in compliance with the requirements of IEC 60601-1-2, §36.201 and §36.202 when used with the accessory, transducer or cable.

D.2.1 Electromagnetic emissions

Warning

The CT Exprès™ 3D is intended for use in the electromagnetic environment specified below. The customer or the user of the CT Exprès™ 3D must ensure that it is used in such an environment.

Note

The CT Exprès™ 3D is defined as CISPR 11 equipment. The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

The following table shows guidance and the manufacturer declaration for electromagnetic emissions for all equipment and systems.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The CT Exprès™ 3D uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The CT Exprès™ 3D is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 4: Electromagnetic Emissions

D.3 Electromagnetic immunity IEC60601-1-2:2007 Edition 3.0 (manufacturing release before 1st January 2019)

The following table shows guidance and the manufacturer's declaration for electromagnetic immunity for all equipment and systems.

Guidance and manufacturer's declaration – electromagnetic immunity			
The CT Exprès™ 3D is intended for use in the electromagnetic environment specified below. The customer or the user of the CT Exprès™ 3D must ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	• ± 6 kV contact • ± 8 kV air	• ± 6 kV contact • ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	• ± 2 kV for power supply lines • ± 1 kV for input/output lines	• ± 2 kV for power supply lines • ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• ±1 kV differential mode ▪ ±2 kV common mode	• ±1 kV differential mode • ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	• <5% UT[1] (>95% dip in UT[1]) for 0.5 cycle • 40% UT[1] (60% dip in UT[1]) for 5 cycles • 70% UT[1] (30% dip in UT[1]) for 25 cycles ▪ <5% UT[1] (>95% dip in UT[1]) for 5 seconds	• <5% UT[1] (>95% dip in UT[1]) for 0.5 cycle • 40% UT[1] (60% dip in UT[1]) for 5 cycles • 70% UT[1] (30% dip in UT[1]) for 25 cycles ▪ <5% UT[1] (>95% dip in UT[1]) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CT Exprès™ 3D requires continued operation during power mains interruptions, it is recommended that the CT Exprès™ 3D be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	• 3 A/m	• 3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 5: Electromagnetic immunity

[1] AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity			
The CT Exprès™ 3D is intended for use in the electromagnetic environment specified below. The customer or the user of the CT Exprès™ 3D should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Conducted disturbances induced by RF fields **IEC 61000-4-6 (Immunity to conducted disturbances induced by RF fields)**	**3 Vrms** **150 kHz to 80 MHz**	**3 Vrms**	**Portable and mobile RF communications equipment should be used no closer to any part of the CT Exprès™ 3D, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter** **Recommended separation distance :** $d = 1.2\sqrt{P}$
Radiated RF EM fields **IEC 61000-4-3 (Immunity to radiated radio frequency electromagnetic field)**	**3 V/m** **80 MHz to 2.5 GHz**	**3 V/m**	$d = 1.2\sqrt{P}$ **80 MHz to 800 MHz** $d = 2.3\sqrt{P}$ **800 MHz to 2,5 GHz** **where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m)** **Field strengths from fixed RF transmitters, as determined by an electromagnetic site[1] survey, should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol :** 

Table 6: Electromagnetic Compatibility

1. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CT Exprès™ 3D is used exceeds the applicable RF compliance level above, the CT Exprès™ 3D should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CT Exprès™ 3D.

2. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note

- At 80 MHz and 800 MHz, the higher frequency range applies
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

D.4 Recommended equipment separation distances Edition 3.0 (manufacturing release before 1st January 2019)

Warning

The CT Exprès™ 3D is intended for use in an electromagnetic environment in which radiated radio frequency disturbances are controlled. The customer or the user of the CT Exprès™ 3D can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (transmitters) and the CT Exprès™ 3D as recommended below according to the maximum output power of the communications equipment.

The following table shows recommended separation distances between portable and mobile radio frequency communications equipment and the CT Exprès™ 3D for equipment and systems that are not life-supporting.

Rated maximum output of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 7: Recommended Equipment Separation Distances

Note

- For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

D.5 Electromagnetic immunity IEC60601-1-2:2020 Edition 4.1 (manufacturing release after 1st January 2023)

The following table shows guidance and the manufacturer's declaration for electromagnetic immunity for all equipment and systems.

Guidance and manufacturer's declaration – electromagnetic immunity			
The CT Exprès™ 3D is intended for use in the electromagnetic environment specified below. The customer or the user of the CT Exprès™ 3D must ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	• ± 8 kV contact • ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	• ± 2, ±4 ,± 6, ± 8 kV contact • ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrostatic transient / burst IEC 61000-4-4	• ± 2 kV for power supply lines • ± 1 kV for input/output lines 100 kHz repetition frequency for both combination	• ± 2 kV for power supply lines • ± 1 kV for input/output lines 100 kHz repetition frequency for both combination	Mains power quality should be that of a typical commercial or hospital environment. *Not applicable for DC and I/O if cable < 3 m
Surge IEC 61000-4-5	• ±0.5 kV, ±1 kV line(s) to line(s)* • ±0.5 kV, ±1 kV, ±2 kV line(s) to earth*	• ±0.5 kV, ±1 kV line(s) to line(s)* • ±0.5 kV, ±1 kV, ±2 kV line(s) to earth*	Mains power quality should be that of a typical commercial or hospital environment. *Not applicable for DC and I/O if cable < 3 m
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT: 1 cycle At 0° 0% UT: 250/300 cycles At 0° 70% UT: 25/30 cycles At 0°	0% UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% UT: 1 cycle At 0° 0% UT: 250/300 cycles At 0° 70% UT: 25/30 cycles At 0°	Mains power quality should be that of a typical commercial or hospital environment. *Not applicable for DC and I/O if cable < 3 m. If the user of the CT Exprès™ 3D requires continued operation during power mains interruptions, it is recommended that the CT Exprès™ 3D be powered from an uninterruptible power supply or a battery. UT is the a.c. mains voltage (100-240) prior to application of the test level.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	• 30 A/m 50/60 Hz	• 30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 8: Electromagnetic immunity

<table>
<tr><th colspan="4">Guidance and manufacturer’s declaration – electromagnetic immunity</th></tr>
<tr><th colspan="4">The CT Exprès™ 3D is intended for use in the electromagnetic environment specified below.
The customer or the user of the CT Exprès™ 3D should assure that it is used in such an environment.</th></tr>
<tr><th colspan="4">Portable and mobile RF communications equipment should be used no closer to any part of the CT Exprès™ 3D, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</th></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment Guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz outside ISM bands and radio amateur band *

6 Vrms
150 kHz to 80 MHz in ISM bands and radio amateur band *</td><td>6 Vrms
150 kHz to 80 MHz outside ISM bands and radio amateur band *

6 Vrms
150 kHz to 80 MHz in ISM bands and radio amateur band *</td><td rowspan="3">If the measured field strength in the location in which the CT Exprès™ 3D is used exceeds the applicable RF compliance level, the CT Exprès™ 3D should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CT Exprès™ 3D.
Minimum separation distance shall be calculated by following equation:

E is the immunity test level in [V/m]
d is the minimum separation in [m]
P is the maximum power in [W]

RF wireless equipment maximum output power and separation distance tested (at 30 cm) :
TETRA 400: max 1.8 W
GMRS 460, FRS 460: max 2 W
LTE Band 13 and 17; max 0.2 W
GSM 800/900: max 2 W
TETRA 800: max 2 W
iDEN 820: max 2 W
CDMA 850: max 2 W
LTE Band 5: max 2 W
GSM 1800/1900: max 2 W
CDMA 1900: max 2 W
DECT: max 2 W
LTE Band 1, 3, 4 and 25: max 2 W
UMTS: max 2 W
Bluethooth: max 2 W
WLAN 802.11b/g/n: max 2 W
RFID 2450: max 2 W
LTE Band 7: max 2 W
WLAN 802.11 a/n: max 0.2 W

Interference may occur in the vicinity of equipment marked with the following symbol:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz

80% AM at 1 kHz</td><td>3 V/m
80 MHz to 2.7 GHz

80% AM at 1 kHz</td></tr>
<tr><td>Proximity fieldfrom RF wireless communication equipment
IEC 61000-4-3</td><td>27 V/m
380-390 MHz
50 % PM 18 Hz

28 V/m
430-470 MHz
FM }5 kHz deviation,
1kHz sine

9 V/m
704-787 MHz
50 % PM 217 Hz

28 V/m
800-960 MHz
50 % PM 18 Hz

28 V/m
1700-1990 MHz
50% PM 217 Hz

28 V/m
2400-2570 MHz
50% PM 217 Hz

9 V/m
5100-5800 MHz
50% PM 217 Hz.</td><td>27 V/m
380-390 MHz
50 % PM 18 Hz

28 V/m
430-470 MHz
FM }5 kHz deviation,
1kHz sine

9 V/m
704-787 MHz
50 % PM 217 Hz

28 V/m
800-960 MHz
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28 V/m
1700-1990 MHz
50% PM 217 Hz

28 V/m
2400-2570 MHz
50% PM 217 Hz

9 V/m
5100-5800 MHz
50% PM 217 Hz</td></tr>
<tr><td colspan="4">*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz.</td></tr>
<tr><td colspan="4">If the measured field strength in the location in which the CT Exprès™ 3D is used exceeds the applicable RF compliance level above, the CT Exprès™ 3D should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CT Exprès™ 3D</td></tr>
</table>

Table 9: Electromagnetic immunity

D.6 Recommended equipment separation distances Edition 4.1 (manufacturing release after 1st January 2023)

Warning

The CT Exprès™ 3D is intended for use in an electromagnetic environment in which radiated radio frequency disturbances are controlled. The customer or the user of the CT Exprès™ 3D can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile radio frequency communications equipment (transmitters) and the CT Exprès™ 3D as recommended below according to the maximum output power of the communications equipment.

The following table shows recommended separation distances between portable and mobile radio frequency communications equipment and the CT Exprès™ 3D for equipment and systems that are not life-supporting.

The **CT Exprès™ 3D** is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **CT Exprès™ 3D** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **CT Exprès™ 3D** as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz outside ISM and radio amateur bands* $d = 2.0\sqrt{P}$	150 kHz to 80 MHz In ISM and radio amateur bands* $d = 1.0\sqrt{P}$	80 MHz to 2700 MHz (for define RF Wireless transmitters see table before) $d = 2.0\sqrt{P}$
0.01	0.20	0.10	0.20
0.1	0.63	0.32	0.63
1	2.0	1.0	2.0
10	6.3	3.2	6.3
100	20	10	20
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.			
*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 –54.0 MHz.			

Table 10: Recommended Equipment Separation Distances

Note

- At 80 MHz the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Instructions for maintaining BASIC Safety and Essential performance for the expected Service life

Do not change the once installed final application due to EM DISTURBANCE. If the environment doesn't correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the **CT Exprès™ 3D**.

The presence of transmitters near the **CT Exprès™ 3D** could affect its performances. The distances mentioned in the tables prepared by manufacturer could help to prevent any disturbances of the equipment in normal operation.

Appendix E : CT Exprès™ 3D specifications

Equipment Type	Automated Contrast Media Injector
Classification	
• Type of electrical insulation:	Class I
• Degree of electrical insulation:	BF (body floating)
• Protection against water ingress:	Ordinary equipment
• Mode of operation:	Continuous
• Pollution degree:	2
• Overvoltage category:	II
Power requirements	
• Rated voltage:	100 to 240 V AC
• Rated power:	180 VA
• Rated frequency:	50/60 Hz
Fuses	
• Mains power fuse:	3.15 A slow blow
• 36V DC fuse:	3.15 A slow blow
Display	
• Type:	Color LCD with touch screen
• Resolution:	800 x 600 pixel
• Technology:	TFT (Thin Film Transistor)
Cleaning instructions:	See *section 4.14.2* on page 101.
Programming:	Phases of: ▪ Contrast media ▪ Saline pre-flush ▪ Saline interphase flush ▪ Saline post flush ▪ Pause ▪ DiluJect™ Scan delay Needle gauge Contrast media type / concentration, prewarmed state Saline flush preset option
Operating conditions	
• Temperature:	15 to 25 °C
• Relative humidity:	30 to 75% (no condensation)
• Barometric pressure:	700 to 1060 mbar
Programming limitation:	Max. 300 mL of contrast media or 3 injections per Patient Set, at maximum 8 phases per injection.
Injection rates for phases of contrast media:	0.5 to 9.7 mL/s (in steps of 0.1 mL/s, maximum flow rate depending on type of contrast media, prewarmed state and needle size).
Injection rates for phases of saline:	0.1 to 9.8 mL/s depending on needle size.
Volume injected per injection / phase:	1 to 200 mL (in steps of 1 mL). As an exception, the first phase volume is at least 10 mL.
DiluJect™ phase:	Contrast media contents: 15%, 20%, 25%, 30% or 50% of undiluted contrast media concentration.
Pause:	0 to 400 s (in steps of 1 s)
Scan delay:	0 to 400 s (in steps of 1 s)
Needle gauge:	16 to 24 G (in steps of 2 G)

Accuracy	
• Injection rate:	± 10% ± 0.1mL/s for a volume injected between 1mL and 9mL ± 6% for a volume injected between 10mL and 200mL
• Volume to be injected:	± 10% ± 1mL for a volume injected between 1mL and 9mL ± 10% for a volume injected between 10mL and 59mL ± 6% for a volume injected between 60mL and 200mL
• DiluJect™:	± 5 percentage points of selected contents, i.e., (15 ± 5) %, (20 ± 5) %, (25 ± 5) %, (30 ± 5) % or (50 ± 10) %.
Note:	The specified accuracy may not be reached if the needle gauge, the contrast media type, or its warming status are incorrectly set
Filling/priming rate:	Approximately 1.5 mL/s for manual priming. Approximately 6.0 mL/s for automatic filling. Warning: the air-in-line alert is disabled during filling or priming.
Saline test Injection rate:	0.5 – 9.8 mL/s in steps of 0.1 mL/s
Saline test injection volume:	Max. 30 mL
Storage conditions	
• Temperature:	0 to 40 °C
• Relative humidity:	10 to 90% (no condensation)
• Barometric pressure:	500 to 1060 mbar
Product Weight / Dimensions	
• Injector unit (without pole):	Approximately 11 kg / 44 x 32 x 27 cm
• Control panel:	Approximately 2.1 kg / 30 x 20 x 22 cm
• Bottle insulator:	Approximately 0.25 kg / 19 x Ø 12 cm
• Pedestal pole:	Approximately 11 kg / 110 x Ø 55 cm
Shipment Weight	(for dimensions, refer to *section 8.3: Packaging material* on page 122)
• Standard package injector	Approximately 13 kg
• Standard package 2 control panels:	Approximately 4 kg
Protection against air injection:	The patient is protected against air injection by a fail-safe air detector.
Air detector	
• Detection principle:	Ultrasound
• Technical detection limit:	0.04 mL
• Air alert (air sensor volume threshold):	If contrast media volume ≤ 35 mL: 1.25 mL If contrast media volume > 35 mL: 1.25 mL in case of fragmented air volume, otherwise an additional air volume of 0.75 mL is tolerated. The Patient Set contains a minimum volume of 8 mL after the air detection system.
Occlusion detection	
• Detection principle:	Fail-safe piezo-resistive pressure sensor
• Alert limit (average):	9.1 bar ± 1.2 bar
Auditory alert sound pressure level:	approximately 60 dBA
Software version:	548 and approved modifications (higher versions) thereof.
Containers:	2 contrast media bottles (of 50 to 500 mL) and 1 saline container (third line) or 1 contrast media bottle (of 50 to 500 mL), 1 saline glass bottle and 1 saline container (third line) Bottles are individually selectable.
Log (operator's and servicing log):	Continuous unrestricted storage of programming and injection history.

Memory	
• Size:	2 GB (quasi unlimited storage of injection profiles)
• Retention time after switch off:	Infinite
Electrical interfaces:	For connections restricted for use with the CT Exprès™ 3D by Bracco Injeneering only.
• Remote control:	RS 422
• Hand switch:	MiniDIN 4-pin connector
• Connection to CT scanner through CANbus interface :	CAN bus 10-pin round connector LEMO FB.
• Software updates via flashcard:	Flashcard port
• Software updates & connection to external devices authorized via USB A:	USB A port
• Software updates via USB B:	USB B port
• Ethernet connection:	RJ45
Communication delay between control panel and injector unit:	Typically 0.2 s, in any case less than 0.5 s
Reliability	
• Injector usage lifetime	300 hours of injection For example, provided the procedures are as follows: • 200 days / year, 15 injections/day and 1 min/ injection : this is equivalent to 6 years of usage • 200 days / year, 20 injections/day and 1 min/ injection : this is equivalent to 4.5 years of usage

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