EmpowerCTA®+

Contrast Injection System

EmpowerCTA®+ Injector System

User's Guide • software version 10

Bracco Group

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BRACCO INJENEERING

Innovative Injection Technology

Proprietary Information Notice

Main Contact Information

Manufacturer:

Bracco Injeneering S.A.
Avenue de Sévelin 46
CH-1004 Lausanne
Switzerland

Web site (worldwide): http://imaging.bracco.com

Distributor/Distributed by (USA):

Bracco Diagnostics Inc.
259 Prospect Plains Road
Building H
Monroe Township, NJ 08831
USA

Contents

1 Introduction

The EmpowerCTA®+ Injector System

The EmpowerCTA®+ Injector System is used to intravenously administer iodinated contrast medium followed by a saline flush into human patients who are undergoing diagnostic exams for computed tomography (CT). Refer to page 3 for the Intended Use and Contraindications.

℞Only *Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.*

About this User's Guide

This User's Guide provides instructions for setting up and using the EmpowerCTA®+ Injector System. It includes the following sections:

Section	Purpose
1. Introduction	Identifies the purpose and structure of this user's guide.
2. Warnings, Cautions, and Symbol Definitions	Users must read and understand this section thoroughly before using the EmpowerCTA®+ Injector System.
3. Basic Operating Procedures	Provides instructions for preparing and using the EmpowerCTA®+ Injector System for computed tomography diagnostic exams.
4. Advanced Programming Procedures	Provides instructions for modifying and managing programs using the Program screen.
5. Using EmpowerCTA®+ with Nexo®	Provides instructions for managing programs, patients and injections when the EmpowerCTA®+ Injector System is connected to Nexo® system.

About this User's Guide (continued)

Section	Purpose
6. System Configuration	Provides instructions for reviewing system information and changing system settings. It also explains how to use the Help feature.
7. Understanding Extravasation Detection	Provides instructions for using the Extravasation Detection Accessory (EDA)
8. Using the IRiSCT® Utility	Provides instructions for using the IRiSCT® Viewer Application.
9. CT Scanner Interconnect	Describes the EmpowerSync®, the CT scanner protocol that allows signals to be transmitted and coordinated between the CT scanner and the EmpowerCTA®+ Injector System.
10. Limited Warranty	Provides warranty information.
Appendix A: Glossary	Provides definitions of terms.
Appendix B: Troubleshooting	Provides answers to frequently asked questions. Also provides a reference for system alert messages.
Appendix C: Technical Specifications and EMC Tables	Provides technical specifications for the Injector, Remote Control, and Extravasation Detection Accessory.

Manual Conventions

This manual uses the following conventions:

Note

Notes are used to highlight important information from the rest of the text.

CAUTION

Cautions alert the user to a possible hazard that may result in equipment damage or personal injury.

WARNING

Warnings alert the user to a possible hazard that could cause serious injury or death.

2 Warnings, Cautions, and Symbol Definitions

Read this First!

Before using the EmpowerCTA®+ Injector System, be sure to read this entire section and be certain you understand it fully. Failure to do so may result in serious injury to the patient, to the user, or may result in damage to the EmpowerCTA®+ Injector System or other equipment. If you have any questions after reading this section, contact a local Bracco Injeneering S.A. representative.

Intended Use

The EmpowerCTA®+ Injector System is indicated for the vascular administration of contrast and flushing media in conjunction with computed tomography (CT) scanning of the body with an optional interface to a CT scanner and an optional calculator for glomerular filtration rate (GFR).

The Extravasation Detection Accessory (EDA) is an optional accessory and is indicated for the detection of extravasations of ionic and nonionic contrast during CT procedures using a power injector.

Contraindications

The EmpowerCTA®+ Injector System is not intended for use as a long-term infusion pump, nor is it intended to be used to inject any agents other than contrast or flushing media. Do not attempt to use the Injector for any other purpose (such as chemotherapy or drug infusion). The EmpowerCTA®+ Injector System should not be used to inject substances into nonvascular body cavities. Any applications of the EmpowerCTA®+ Injector System other than those described in this User's Guide are inappropriate and should not be attempted.

Warnings

The following warnings refer to hazards that can cause serious injury or death. Read this section carefully.

- Rx only: Federal law (USA) restricts this device to sale by or on the order of a physician.
- When operating the EmpowerCTA®+ Injector System, you must put only contrast medium in the contrast syringe and saline in the saline syringe. Failure to do so may lead to inadequate diagnostic results and potential injury to the patient.
- This equipment is not for use in chemotherapy, drug infusion, or any other application for which it is not indicated.
- The EmpowerCTA®+ Injector System must be used properly to prevent the risk of an air embolism. Always fill the syringe with the Injector pointing fully upward. When the syringe has been filled to the desired volume, all the air should be purged from the syringe and coiled tubing with the Injector still in the fully vertical position. Failure to do so may lead to serious injury and/or death.
- Never use any buttons on the EmpowerCTA®+ Injector Controller when the Injector Head is tilted upright (in the Load position) while the EmpowerCTA®+ Injector System is connected to the patient.
- In the event of a system malfunction, immediately turn off the EmpowerCTA®+ Injector System and quickly disconnect the patient from the unit. Confirm that the system malfunction has been repaired before reconnecting the patient. Turn the system on, arm the Injector and perform a test injection. If the system shows no further malfunction, reconnect the patient. If a fault message still exists and cannot be corrected and/or the Injector is still malfunctioning, DISCONTINUE USE of the EmpowerCTA®+ Injector System until the problem is properly identified and solved. Contact a local Bracco Injeneering S.A. representative.
- Exercise extreme caution when setting the flow rate on the Remote Control and/or the Injector Controller so as not to create an inadvertently high flow rate injection. PATIENT INJURY CAN RESULT FROM HIGH FLOW RATE VENOUS INJECTIONS. Be sure to review all program parameters and injection settings prior to arming and running the Injector.
- The EmpowerCTA®+ Injector System is not MRI compatible and must not be used in magnetic resonance imaging (MRI) studies. Portions of the EmpowerCTA®+ Injector System will respond dangerously to the very high magnetic fields associated with MRI scanners.

Warnings (continued)

- A risk of explosion exists if the EmpowerCTA®+ Injector System is used in the presence of flammable anesthetics. It should never be operated when any flammable gases are present. This equipment is not suitable for use when a FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE is present.
- The EmpowerCTA®+ Injector System works properly with Bracco Injeneering S.A. supplies. To prevent the risk of incompatibilities and equipment failures during procedures, use only syringes and connecting tubes supplied directly by Bracco Injeneering S.A. or its authorized distributors. Failure to use Bracco Injeneering-approved syringes and/or connecting tubes with the EmpowerCTA®+ Injector System constitutes misuse of the system and may result in voiding the warranty.
- After the FastLoad™ syringe has been filled with contrast medium, it should be used within the maximum time recommended by the contrast medium manufacturer. Always follow the contrast medium and saline manufacturers' labeling for handling, loading, use, storage and disposal of the product.
- To prevent transmission of infection, observe aseptic techniques when handling contrast medium, saline, or any equipment or materials that contain or conduct the contrast medium or saline, including syringes, fill tubes, and intravenous administration sets. Never reuse any of these single-use items. Discard these disposable items using proper procedures for biohazardous waste.
- To assure sterility, as well as to prevent spills or damage to the equipment, always inspect the packaging of the connecting tube and the syringe itself to verify that there are no broken seals or other signs of damage. If such conditions exist, do not use the syringe.
- Spilled fluid can result in the possibility of electrical shock. Do not allow contrast medium, saline, or other fluids to spill over the EmpowerCTA®+ Injector System. Do not immerse any parts of the EmpowerCTA®+ Injector System when cleaning. This could create a conductive path between metallic parts of EmpowerCTA®+ Injector System and the patient.
- Use the EmpowerCTA®+ System only when connected to a proper electrical source. Plug the EmpowerCTA®+ Injector and Remote Control directly into a grounded, hospital-grade electrical outlet. Do not use an extension cord. Do not use an adapter to plug the EmpowerCTA®+ Injector System or Remote Control into a two-pronged, non-grounded outlet. Replace any worn or frayed wires immediately.
- The EmpowerCTA®+ Injector System, as well as any other electrical equipment attached to the patient and/or catheter must be electrically isolated or properly grounded to prevent possible electrical shock.

Warnings (continued)

- Attempting to open any component of the EmpowerCTA®+ Injector System can also result in electrical shock. Do not attempt to repair or modify any portion of the system. These units contain no user-serviceable parts. Only local, authorized Bracco Injeneering S.A. representatives should perform servicing of internal parts.
- The use of non-approved mounting equipment can cause injury. Mount the EmpowerCTA®+ Injector System using only mounting assemblies approved by Bracco Injeneering S.A.
- Administering intravenous contrast medium or saline with an Injector poses the risk of extravasation. As with any procedure that involves intravenous injection of a substance, proper technique can substantially reduce the incidence of extravasation. While the attending physician must always establish the specific technique, suggested precautions when using the EmpowerCTA®+ Injector System can be found in Section 6.
- Always instruct the patient to immediately notify the CT personnel of any pain or change in feeling that is experienced during the procedure.
- Respond appropriately to all system messages. If the message cannot be cleared, contact a local Bracco Injeneering S.A. representative.
- No modification of this equipment is allowed.
- To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
- The EmpowerCTA®+ Injector System may only be interfaced with CT equipment certified to the appropriate EN/IEC 60601-1 standard.
- Do not touch the patient while making connections to the Injector Head or to the power supply.

Cautions

⚠ The following precautions refer to hazards that could result in injury or damage to the EmpowerCTA®+ Injector System or other equipment. Read this section carefully.

- For proper operation and to ensure equipment compatibility, use only accessories and options provided or specified by Bracco Injeneering S.A. for use with the EmpowerCTA®+ Injector System.
- Ensure all consumable kits are installed properly. Ensure all kit connections are secure to prevent leaks, disconnections, air introduction, or component damage.
- Do not over-tighten connections or use tools to assist in the installation or removal of consumable kits.

Cautions (continued)

- Connect the EmpowerCTA®+ Injector System only to an electrical source of the proper voltage and frequency as specified in Appendix C. If an incorrect voltage is used, the Injector System or the Remote Control may be damaged when it is plugged into electrical mains.
- The Remote Control must be shut down with the proper procedure to avoid loss of data and/or function.
- When retracting the syringe plunger with the EmpowerCTA®+ Injector System during contrast medium or saline filling, or after the end of an injection, do not let a vacuum build in the syringe by leaving the EmpowerCTA®+ Connecting Tube attached to the end of the syringe. In addition, do not allow the tubing pathway to occlude the J-tube (fill tube) or patient coiled tubing to the syringe. When connecting the syringe with a spike, do not over tighten the spike onto the syringe luer lock in order to prevent from damage and occlusion to the fluid path. Failure to let the syringe properly vent when retracting the syringe plunger can cause the plunger to recoil forward when the Injector ram reaches the Replace Syringe position. If needed, contact the local Bracco representative.
- Dried contrast medium may make removal of Luer fittings difficult. Do not let contrast medium dry. Make sure the Luer connection is not over-tightened.
- In the event of a loss of communications between the Injector and the Remote Control, the Injector System will go to Monitor mode. An acknowledgement message will be displayed to denote the fault occurrence.
- To prevent unintentional movement of the EmpowerCTA®+ System, lock the wheels.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
  - Use of the accessory in the patient vicinity.
  - Evidence that the safety certification of the accessory has been performed in accordance to the appropriate EN/IEC 60601-1 harmonized national standard.
- Use only the supplied medical grade power converter with the Remote Control supplied by Bracco Injeneering to ensure safe operation of the EmpowerCTA®+ System.

Symbol Definitions

Symbol	Definition
	Patient Applied Part, Injector Head, Degree of protection against electric shock, Type BF
	Potential equalization
	Alternating current
	Protective earth (ground)
	Consult instructions for use
	On (power connection to line power)
	Off (power disconnection to line power)
	Patient Applied Part, Extravasation Detection Accessory, Degree of protection against electric shock, Type CF applied part
	Manufacturer
	Date of manufacture
	Serial number
	Catalog number
	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Warning: dangerous voltage
	Explosion hazard
	Contact for service

Symbol Definitions (continued)

Symbol	Definition
	This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419). Disposables will be disposed of in accordance with all applicable laws and standards. If required by EU directives, a Bracco Injeneering S.A. local representative may be contacted to retrieve this product at the end of its lifetime. In accordance with European Union WEEE Directive 2002/96/EC, Bracco Injeneering S.A. will be fully responsible for the coordination, logistics, and costs of the WEEE process.
	With respect to electrical shock, fire, mechanical, and other specified hazards, only in accordance with EN/IEC 60601-1.
	Complies with European Directive 93/42/EEC, Medical Device Directive
	Use by (expiration date)
	Sterilized using ethylene oxide
	Lot code
	Temperature limitation
	Humidity limitation
	Pressure limitation
	Keep dry
	Do not use if packaging is damaged

Symbol Definitions (continued)

Symbol	Definition
	Quantity enclosed.
	Fragile
	Contains DEHP
	Non-pyrogenic
	Do not reuse
	Do not resterilize
IPX0	Environmental enclosure rating, Injector Head
	Refer to instruction manual
	Do not use in the presence of flammable anesthetics
	Caution
	Keep upright

3 Basic Operating Procedures

System Components

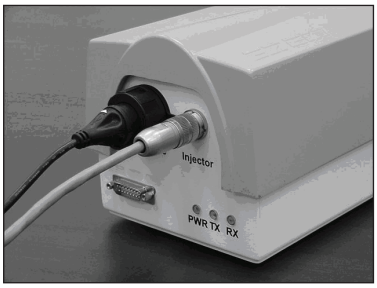
The EmpowerCTA®+ Injector System has three primary components:

- Injector
- Remote Control
- Power Supply

For instructions on the use of your particular scanner and its other related equipment, consult the manuals provided with those devices or contact their respective manufacturers.

Injector

Remote Control



Power Supply

System Installation

Only a local, authorized and trained Bracco Injeneering S.A. representative may install the EmpowerCTA®+ Injector System.

Injector Components

The Injector (shown below) includes the Injector Head with the Injector Controller touch screen, pendant, EDA, connection cables and contrast syringe warmer. The Injector Controller touch screen enables you to initialize, fill, and purge the syringes. It also provides EDA status information and controls for starting/stopping the injection once parameters are defined using the Remote Control.

Notes

- *Replacement of the battery inside the Injector housing requires a specialized tool and can be done by local Bracco Injeneering S.A. representatives only.*
- *The USB port on the Injector Controller is for use by local Bracco Injeneering S.A. representatives only, for the purpose of loading software and downloading data.*

Remote Control

The Remote Control runs the REMOTE software application of the EmpowerCTA®+ Injector System. From the Remote Control touch screen, you can do the following:

- Use the Bracco Protocols to select or review predefined injection parameters (if enabled)
- Select a predefined program (if available)
- Enter and save a new program
- View the EDA status (if available)
- View the syringe status
- Arm the system for injecting
- Run a test injection (if enabled and programmed)
- Run an injection
- Pause an injection
- Adjust the flow rate during an injection
- Jump to the saline phase (if available) during the last contrast medium injection
- Print a label for the study (if enabled)

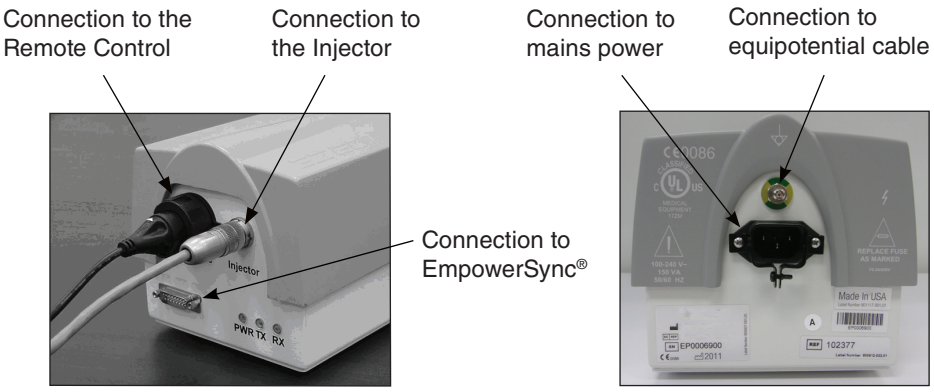
Power Supply

The power supply unit provides power for the Injector. It also provides communications between the Injector and the Remote Control, and between the Remote Control and CT scanner if EmpowerSync® is enabled.

The power supply must be positioned to provide easy access to either or both ends of the line power cable for disconnection from mains power.

In order to prevent voltage differential between medical equipment, an equipotential cable may be required. Ground equalization can be established by connecting the equipotential cable to the equipotential lug on the power supply.

The other end of the equipotential cable must be attached to the appropriate location on the patient table. The connection on the power supply is in compliance with EN/IEC 60601-1 3rd Edition, clause 8.6.7.



Label Printer

The label printer is an optional component that connects to the Remote Control and prints a label that contains the following information:

- Patient ID
- Date
- Time of injection
- Contrast medium brand
- Contrast medium lot number
- eGFR value and unit
- Serum creatinine (SCr) value and unit
- The amount of contrast medium injected
- The injection protocol (injection parameters for each phase)

Note

Bracco Injeneering has validated the use of the DYMO LabelWriter 450 with EmpowerCTA®+ remote control panel.

EmpowerCTA®+ System Configurations

The EmpowerCTA®+ System, as delivered, operates as a stand-alone unit. Both floor and ceiling mounting options are available for the EmpowerCTA®+ System. Extravasation monitoring during contrast medium injections, scanner interconnect options, and Injector connectivity solutions are available as options to your EmpowerCTA®+ system.

Contact your local Bracco Injeneering S.A. representative for more information.

Overview of Basic Operating Procedures

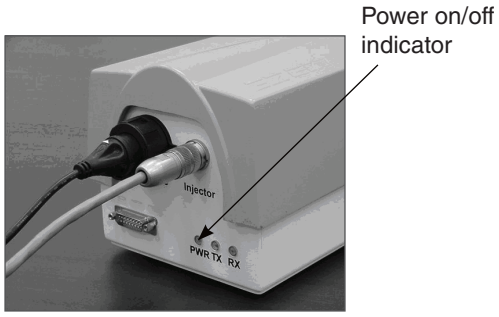
To perform an injection using the EmpowerCTA®+ Injector System you must know how to perform the following steps. These steps are described in more detail in the following subsections.

1. Turn on power to the system components.
2. Review the features of the Injector Head and Injector Controller touch screen.
3. Prepare the patient.
4. Load the syringes and fill them with contrast medium and saline (if using saline).
5. Remove all air from the syringes and tubing.
6. Program the Remote Control.
7. Optionally, use the Saline Advance feature before arming the Injector for an injection procedure.
8. Arm, and then run the injection, or optionally arm the Injector, run a test injection, and then run the injection.
9. Use the Saline Jump feature during the injection (optional).
10. Optionally, print a label for the study.
11. Disconnect the patient and unload the syringes.
12. Shut down the Remote Control (using the SHUTDOWN function on the Setup screen) and turn off power to the Injector.

Power On

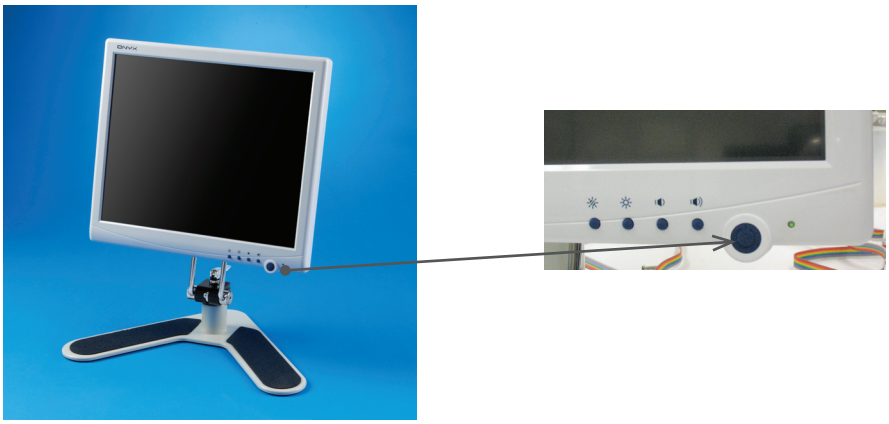
Power Supply

Ensure the power supply is connected to the main power source and that the connecting cables to the Remote Control and to the Injector are secure. Verify that the PWR indicator light on the power supply is green.



Remote Control

The push button power switch for the Remote Control is on the front of the Remote Control in the lower right corner. When you turn on power to the Remote Control, it will start up automatically, display a series of screens, and then display the Main screen.



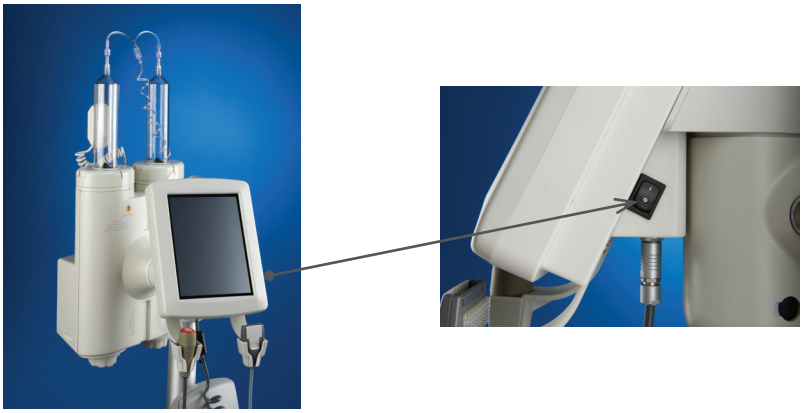
CAUTION

The Remote Control must be shut down with the proper procedure to avoid loss of data and/or function.

For the proper shutdown procedure, see page 111.

Power On (continued)

To turn on power to the Injector, ensure that the Injector power cord is plugged into the Power Supply unit and that the Injector Controller is connected to the Remote Control. Then flip the rocker switch on the right underside of the Injector Controller touch screen to turn on power. After startup, the touch screen displays setup instructions.



Injector Features

Syringe Identification

The syringes are clearly marked CONTRAST (orange LED indicator light) and SALINE (yellow indicator light) to reduce any confusion as to the content or purpose of the syringe selected.

Injector Features (continued)

Injector Head Positions

Position	Purpose
Load Position (Upright)	In the Load position (tilted upright), the Injector Controller can be used to initialize syringes, fill syringes, and purge air from the syringes and tubing. When the procedure is complete, the patient is disconnected and the Injector Head is tilted upright to remove the syringes.
Run Position (Tilted down)	In the Run position (tilted down, either to the left or right), you can use the Saline Advance feature, arm the Injector, run the injection, or pause or stop the injection.

Load Position

Run Position

Injector Features (continued)

Injector Controller Functions

The Injector Controller has a touch screen that enables you to do the following:

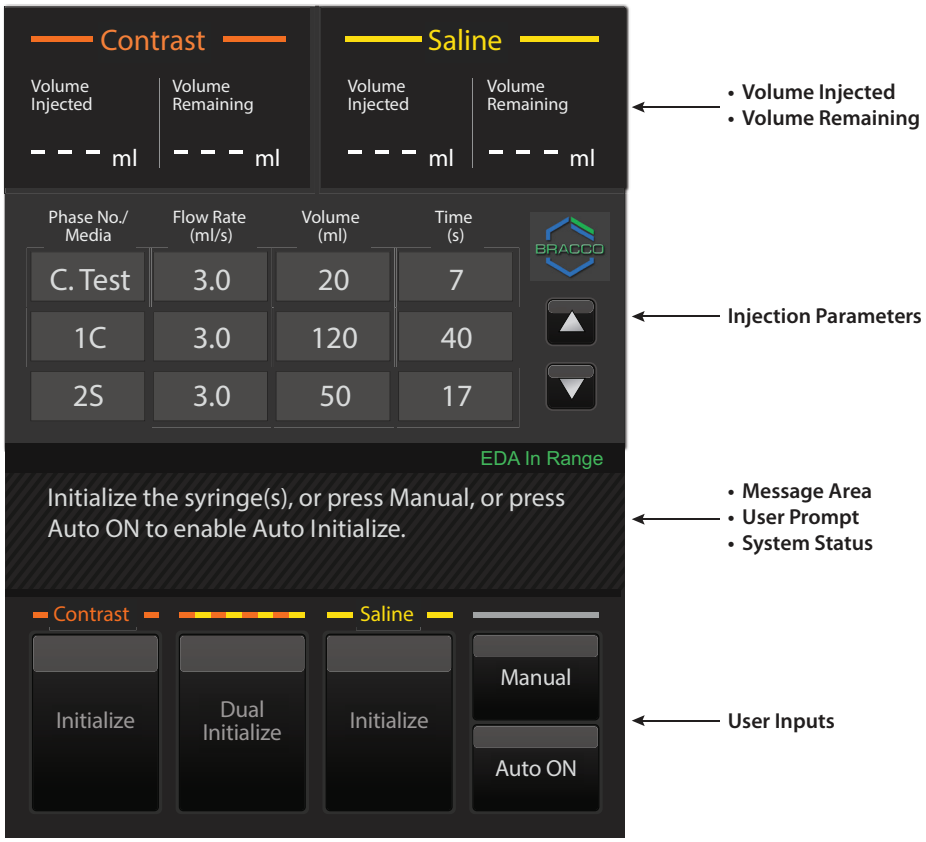
- Initialize syringes
- Fill the syringe
- Purge air from syringes and tubing
- Inject saline prior to arming (using the Saline Advance feature)
- Arm the Injector
- Run the injection
- Pause or stop the injection
- Adjust the flow rate during an injection
- Replace a syringe

Notes

- *The Injector Controller beeps when it recognizes the selection of a button. You must press **and hold** the following buttons before the Injector Head will respond: Single (replace syringe), Dual (replace syringe), Initialize, Dual Initialize, and Protocol Fill.*
- *If the Injector Controller touch screen does not respond, or a selection does not give the desired response, the touch screen may need to be calibrated. See page 56 for instructions on calibrating the Injector Controller touch screen.*

Injector Features (continued)

The Injector Controller Touch Screen User Interface



Injector Features (continued)

Initialize Syringe Options

To initialize syringes, the Injector rams advance each syringe plunger to the distal end of the syringe. When initialization is completed, the Volume Remaining parameter displayed on the Injector and Remote Control shows 0 ml for each initialized syringe. The Injector Controller offers four initialization options: Auto ON, Initialize, Dual Initialize, and Manual.

Initialize Option	Description
Auto ON	The Auto ON mode is the most efficient way to prepare the syringes for filling. In this mode, you program the Remote Control, select **Auto ON**, open the contrast (and saline) syringe door(s), insert the syringes using an aseptic technique, and close the syringe doors. The system then automatically prepares the syringes for filling by advancing the Injector rams to the 0 ml position. ***Important*** *At least one contrast phase must be programmed at the Remote Control to use this option. If no contrast phases have been programmed, the button will still appear, but will not be functional. Also, if a saline phase is not programmed, the saline syringe will not be initialized unless the SA DOOR/FILL option is set to Enabled on the Remote Control's Setup screen.*
Initialize	To prepare a single contrast or saline syringe for filling, open the appropriate syringe door, insert the syringe using an aseptic technique, and close the syringe door. Press and hold **Initialize** until the Injector responds.
Dual Initialize	The Dual Initialize mode saves a few steps. To prepare both syringes, insert a contrast syringe and a saline syringe using aseptic technique, and close the syringe doors. Press and hold **Dual Initialize** until the Injector responds.
Manual	Insert one or both syringes using an aseptic technique, and then select **Manual.** Use the slow forward and fast forward arrow keys under each syringe to advance the Injector ram for that syringe. Note that if you are using both a contrast syringe and a saline syringe, selecting **Manual** requires both syringes to be initialized manually.

Injector Features (continued)

Fill Syringe Options

The Injector Controller offers four fill modes. Except for the Protocol Fill and Manual fill options, you must select how much fluid will be added to each syringe before filling begins. For specific instructions, see page 33.

Fill Option	Description
Protocol Fill	Protocol Fill is the most efficient way to fill a single syringe or both syringes simultaneously. It requires you to set up the injection protocol in the Remote Control before initiating the Protocol Fill mode. Press and hold **Protocol Fill** until the Injector responds. In Protocol Fill mode, the Injector will do the following: • Sum the total volume of contrast medium to be used in the programmed protocol. If a saline phase is programmed, 7 ml contrast medium is added to the total volume to allow enough fluid for the air purge. If there is no saline phase, 5 ml contrast medium is added. • Sum the total volume of saline to be used in the programmed protocol. If a contrast phase is programmed, 7 ml saline is added to the total volume to allow enough fluid for the air purge. If there is no contrast phase, 5 ml saline is added. • Add 25 ml saline if the SA DOOR/FILL option is enabled. If no saline phase is programmed and the SA DOOR/FILL option is enabled, the total saline volume will be 25 ml
Dual Fill	Dual Fill mode enables you to enter the fill volume for both syringes by entering values on a keypad. Enter the contrast medium volume, press **Continue**, enter the saline volume, and then press **Begin** to start filling the syringes.
Fill	Fill mode allows you to fill a single syringe. Press **Fill** in either the contrast or saline area, enter the fill volume on the keypad, and then press **Begin** to start filling the syringe.
Manual	For manual filling, use the fast and slow reverse arrow keys to retract the Injector ram.

Injector Features (continued)

Arrow Keys	Description
▼	Slow Reverse: Injector ram retracts to fill the syringe at 0.5 ml/s
▼▼	Fast Reverse: Injector ram retracts to fill the syringe at 10 ml/s
▲	Slow Forward: Injector ram advances (to purge air) at 1 ml/s
▲▲	Fast Forward: Injector ram advances (to purge air) at 10 ml/s

Purge Options

The Injector Controller offers the following options to advance the Injector ram and purge all air from the syringe and tubing. For specific instructions, see "Purge Air from the Syringes and Tubing" on page 39.

Purge Option	Description
▲	Slow Forward
▲▲	Fast Forward
Auto Purge	If enabled at installation, the Injector Controller can also use the Auto Purge function. When Auto Purge has been enabled, the Injector automatically retracts to 15 ml, then advances to 0 ml, and then retracts to the programmed volume, drawing fluid into the syringe.
Hand Knobs	Hand knobs associated with each syringe are located on the bottom of the Injector Head and can be used to manually advance the syringe plunger forward to purge air from the syringes and tubing.
Purge Line	This option is available on the Injector if the PURGE TO LINE option is enabled in the Setup screen on the Remote Control. • If both syringes are filled, the Injector will purge 5 ml from the contrast syringe first, followed by 5 ml from the saline syringe. • If only one syringe is filled, the Injector will purge 5 ml from that syringe.

Injector Features (continued)

SALINE ADVANCE, ARM, RUN, PAUSE and STOP Options

When the injection protocol has been programmed, the syringes are filled, the syringes and tubing are purged of all air, and the Injector Head is tilted down to the Run position, the ARM option becomes available on the Injector Controller and at the Remote Control.

If the SA DOOR/FILL option is enabled in the Setup screen at the Remote Control, or if a saline phase is programmed at the Remote Control, the Saline Advance option is also available at the Injector Controller. The Saline Advance option is used to inject saline before arming the Injector and running the injection protocol.

When the ARM option is selected (at either the Injector Controller or at the Remote Control), the Injector Controller presents two more options: RUN and STOP.

If ARM is selected when the Test Injection feature is enabled in the Setup screen and a test injection is programmed at the Remote Control, the Injector Controller will display the TEST INJECT and STOP buttons. Following the test injection, the RUN and STOP options are available.

When RUN is selected, the Injector Controller presents a PAUSE option. The injection can also be paused at the Remote Control by touching the screen anywhere except the Flow Rate controller window, which is displayed in the upper right corner of the Main screen while the injection is running, or by pressing the red pendant button. Selecting PAUSE causes the RUN and STOP options to appear again.

For more information about how to use the Test Injection feature, see page 47.

For more information about how to use the Saline Advance feature, see page 47.

For more information about how to use the ARM, RUN, and STOP functions, see page 48.

Flow Rate Options

During an injection, the flow rate can be adjusted by pressing the + and – buttons on the Injector Controller touchscreen. You can also adjust the flow rate by pressing the up and down arrows on the Flow Rate box in the upper right corner of the Remote Control touchscreen.

Injector Features (continued)

Replace Syringe Options

When the injection has stopped, the patient is disconnected from the Injector and the Injector Head is in the Load (upright) position, the Injector Controller will display the Replace Syringe option. When you select the Replace Syringe option, the Injector Controller displays two options to prepare syringes for removal, as described in the table below. Press and hold **Dual** or **Single** until the Injector responds.

Replace Syringe Option	Description
Dual	Remove and replace both the contrast and saline syringes simultaneously.
Single	Remove the selected syringe only.

For more information about replacing a syringe, refer to page 53.

Prepare the Patient

To prepare the patient, do the following:

1. Verify that the patient has an intravenous catheter inserted properly.

WARNING

To minimize the possibility of an extravasation use the following guidelines:

- *Connections to the patient are to be made from commercially available catheters that are indicated for diagnostic imaging. For information on pressure settings and limits, refer to instructions provided by the catheter manufacturers.*
- *Minimize the effects of patient movement by taping the catheter firmly to the patient's skin. If planning on using the EDA extravasation device, do not put tape proximal to the insertion point on the skin of the patient.*
- *The antecubital vein in the left arm is the preferred injection site for IV contrast. The right arm as well as the veins in the hands or wrists can be used when there is no other access. These locations will cause more pain to the patient and, because they are more distal, will offer higher resistance to the flow of contrast medium, increasing the risk of extravasation. This position permits the arms to be placed over the head during body scans without the danger of kinking either the catheter or tubing. Use of a 60 inch (1.5 m), coiled, low-pressure tube also reduces the motion effects associated with table movement.*
- *Do not use catheters that are kinked or that have been kinked. Telling the patient to put their hands over their heads after connecting the Injector to the IV will usually result in their bending their arms, risking kinking of the catheter. If possible, have the patient hold their arms straight out, either above them so their hands are resting on the gantry or, if over their head, guide them to keep their arms straight out when possible.*
- *If a patient presents with one or more indwelling intravenous lines, do not assume that the intravenous set is acceptable for use with the EmpowerCTA®+ Injector System. If possible, place a new intravenous line. Any resistance to your flushing that catheter may be reason to suspect occlusion in the catheter or the patient's vein. Do not inject in IVs that offer resistance to saline flush.*
- *Central venous lines and heparin locks are not recommended.*
- *To augment clinical monitoring during contrast injection and to help detect potentially serious extravasations, Bracco Injeneering S.A. recommends use of the Extravasation Detection Accessory (EDA) in conjunction with the EmpowerCTA®+ Injector System.*

2. If you have the Extravasation Detection Accessory (EDA), refer to Section 7 for proper use of the EDA.

Load and Fill the Syringes with Contrast and Saline

Required Consumable Kits

If you intend to inject both contrast and saline, you will need kits in one of the following configurations:

- If using FastLoad™ CTA Dual Syringe Packs:
  - One FastLoad™ CTA Dual Syringe Pack, which contains two 200 ml FastLoad™ syringes, one low-pressure connecting Y-tube, and one fill tube (J-tube).

FastLoad™ CTA Dual Syringe Pack with J-tube

  - One FastLoad™ CTA Dual Syringe Pack with Spikes, which contains two 200 ml FastLoad™ syringes, one low-pressure connecting Y-tube, and two spikes.

FastLoad™ CTA Dual Syringe Pack with Spikes

Load and Fill the Syringes with Contrast and Saline (continued)

- If using FastLoad™ CT Syringe Packs:
  - Two FastLoad™ CT Syringe Packs, each containing one 200 ml FastLoad™ Syringe, one low-pressure coiled tube, and one fill tube (J-tube).

FastLoad™ CT Syringe Pack with J-tube

  - Two FastLoad™ CT Syringe Packs with Spikes, each containing one 200 ml FastLoad™ syringe, one low-pressure coiled tube, and a small spike.

FastLoad™ CT Syringe Pack with Spike

Load and Fill the Syringes with Contrast and Saline (continued)

If injecting contrast only, you will need kits in one of the following configurations:

- One FastLoad™ CT Syringe Pack (described above). One Transfer Set (described below) required when filling a syringe from a spiked fluid source.
- One FastLoad™ CT Syringe Pack with Spikes (described above).
- One FastLoad™ CTA Syringe Pack, with or without spikes (described above). Also required: one Coiled Connector Tube (available separately) for each syringe. When using kits without spikes, one Transfer Set is also required (described below and available separately) to fill each syringe from a spiked fluid source.

Additional Consumable Components

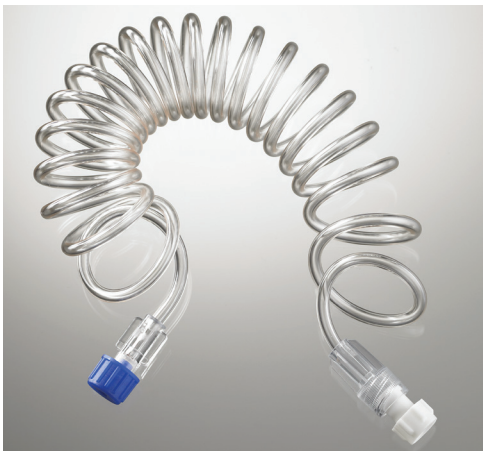
Depending on the kit you are using, you may require one of the following additional components:

- Transfer Set with female swabable valve and short, vented spike to 20 inches (0.5 m) of tubing. Required when filling a syringe from a spiked fluid source.

- EmpowerCTA® Connecting Tube

Load and Fill the Syringes with Contrast and Saline (continued)

- Coiled Connector Tube



WARNING

When operating the EmpowerCTA®+ Injector System, you must put only contrast medium in the contrast syringe and saline in the saline syringe. Failure to do so may lead to inadequate diagnostic results and potential injury to the patient.

WARNING

The EmpowerCTA®+ Injector System must be used properly to prevent the risk of an air embolism. Always fill the syringe with the Injector pointing fully upward.

WARNING

The EmpowerCTA®+ Injector System works properly with Bracco Injeneering S.A. supplies. To prevent the risk of incompatibilities and equipment failures during procedures, use only syringes and connecting tubes supplied directly by Bracco Injeneering S.A. or its authorized distributors.

WARNING

After the FastLoad™ syringe has been filled with contrast medium, it should be used within the maximum time recommended by the contrast medium manufacturer. Always follow the contrast medium and saline manufacturers' labeling for handling, loading, use, storage and disposal of the product.

WARNING

To prevent transmission of infection, observe aseptic techniques when handling contrast medium, saline, or any equipment or materials that contain or conduct the contrast medium or saline, including syringes, fill tubes, and intravenous administration sets. Never reuse any of these single-use items. Discard these disposable items using proper procedures for biohazardous waste.

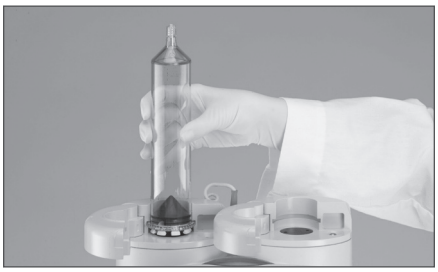
Load and Fill the Syringes with Contrast and Saline (continued)

WARNING

To assure sterility, as well as to prevent spills or damage to the equipment, always inspect the packaging of the connecting tube and the syringe itself to verify that there are no broken seals or other signs of damage. If such conditions exist, do not use the syringe.

Preparation Needed

- If a syringe is still loaded from a prior procedure, disconnect the patient catheter from the Injector (see page 53) and then unload the old syringe or syringes (see page 53) from the Injector Head using the appropriate Replace Syringe option. Close the syringe doors after removing syringes.
- Ensure that the Injector Head is in the Load (upright) position, as shown:



- Warm the contrast medium before starting the Load and Fill procedures.
- Have available the contrast medium, saline, and the required consumable kits.

Load and Fill the Syringes with Contrast and Saline (continued)

How to Load Syringes

Note

In all cases, if three or more contrast phases are programmed at the Remote Control, saline functions will be disabled and the saline syringe cannot be initialized using any of these options.

If Using…	Then…
One or two syringes and auto initialize **(Auto ON)**	1. Select **Auto ON** at the Injector Controller. The Injector Controller will then display the Auto OFF option. 2. Make sure that at least one contrast phase is programmed at the Remote Control or the SA DOOR/FILL option is set to Enabled in the Setup screen. 3. Open the contrast and/or saline syringe door(s). 4. Using aseptic technique, insert the syringe(s) in the chamber(s) and close the syringe door(s). 5. The Injector will automatically initialize both syringes.
Two syringes and the **Dual Initialize** option	1. Open the contrast and saline syringe doors. 2. Using aseptic technique, insert the syringes and close the syringe doors. 3. Press and hold **Dual Initialize** on the Injector Controller until it begins initializing the syringes. 4. The Injector will initialize the syringes simultaneously.
One or two syringes and the **Single Initialize** option	1. To load a contrast syringe, open the contrast syringe door. 2. Using aseptic technique, insert the syringe and close the syringe door. 3. To initialize the contrast syringe, press and hold **Initialize** in the contrast area on the Injector Controller until it begins initializing. 4. To load a saline syringe, open the saline syringe door. 5. Using aseptic technique, insert the syringe and close the syringe door. 6. In the saline area, press and hold **Initialize** until the Injector begins initializing the saline syringe.

In addition to the automated options described in the table above, you can also initialize the syringes manually, by selecting the Manual button on the Injector Controller and then using the arrow keys described on page 22.

Load and Fill the Syringes with Contrast and Saline (continued)

How to Fill Syringes

Preparing Fluid Dispensing Sources

There are multiple ways to load fluid into the syringe. Three methods of preparing fluid sources are described below, and facilities can utilize their own techniques as well. Refer to the Instructions for Use for the specific kit you are using. Always utilize aseptic technique when loading the syringe.

- If using a fill tube: Remove the protective cap from the top of the syringe. Attach the short end of the supplied fill tube to the tip of the syringe. Insert the other end into the fluid source.

Tip: When holding the contrast medium bottle, maintain its orientation such that the end of the fill tube does not create a vacuum with the bottom surface of the bottle. Creating a vacuum will produce unwanted cavitation bubbles in the contrast medium that will be difficult to purge. Additionally, relieving the vacuum after filling could cause unwanted contrast medium spillage.

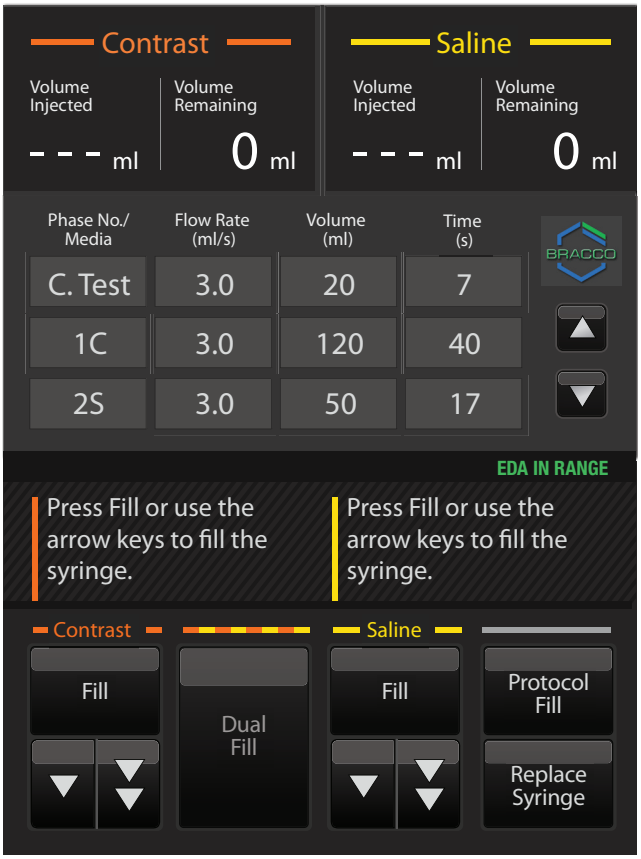
- If using a transfer set: Remove the protective cap from the top of the syringe. To the tip of the syringe, attach a sterile fluid dispensing device such as a transfer set with a vented spike to 20 inches (0.5 m) of tubing to a female Luer lock swabable valve. Attach the bag or bottle of fluid to the spike. When using a bag, you may need to squeeze the bag to help load fluid into the syringe.
- If using a FastLoad™ CT Syringe Kit with Spikes or a FastLoad™ CTA Syringe Kit with Spikes: Remove the protective cap from the syringe, attach the female Luer fitting of the spike to the tip of the syringe, remove the protective cap from the spike tip, and puncture the fluid supply container with the spike tip.

CAUTION

When connecting the syringe with a spike, do not over tighten the spike on the syringe luer lock in order to prevent from damage and occlusion of the fluid path. Failure to properly vent the syringe when retracting the syringe plunger can cause the plunger to recoil forward when the Injector ram reaches the Replace Syringe position. If needed, contact your local Bracco Injeneering representative.

Load and Fill the Syringes with Contrast and Saline (continued)

The Injector Controller displays options to fill the syringes. The fill options that are available depend on the initialize mode.



Load and Fill the Syringes with Contrast and Saline (continued)

In addition to the automated fill options described in the following table, you can also fill the syringes manually by using the arrow keys described on page 23.

If You Are Filling...	Then...
One or two syringes simultaneously, and the protocol is already set up in the Remote Control	1. Prepare your fluid dispensing sources. If filling two syringes, be sure to connect both fluid sources to the syringes. 2. Press and hold **Protocol Fill** until the Injector begins the fill process. Based on the protocol defined at the Remote Control, the system will automatically calculate the amount of fluid to add to each syringe, plus an additional 7 ml. If you are using only a contrast syringe, the system will add 5 ml to the calculated contrast medium volume. If the SA-DOOR/FILL option is set to Enabled, the system will automatically add an additional 25 ml of saline to the saline syringe. This enables you to use the Saline Advance feature, provided at least one contrast phase is programmed on the Remote Control. The fill process starts immediately after you select **Protocol Fill**. If the Auto Purge option was enabled during installation, the system will also perform an Auto Purge operation for each syringe during the fill process. 3. Detach the fluid dispensing devices from the syringes and from the containers of contrast and saline. 4. Visually inspect both syringes to ensure that they are properly filled and purged of air. Do not proceed if air is present. 5. Clip the warmer to the contrast syringe.

Load and Fill the Syringes with Contrast and Saline (continued)

If You Are Filling...	Then...
Two syringes simultaneously without a protocol entered in the Remote Control	1. Prepare your fluid dispensing sources for the syringes. If you are filling two syringes, be sure to have both fluid sources connected to the syringes. 2. Select **Dual Fill.** 3. Enter the amount of fluid you wish to use when you fill the contrast syringe. Include several milliliters to be expelled when purging air from the system prior to making the patient connection. 4. Select **Continue**, then repeat step 3 for the saline syringe. 5. Select **Begin** to start filling the syringes. If the Auto Purge option was enabled during installation, the system will also perform an Auto Purge operation for each syringe during the fill process. 6. Visually inspect both syringes to ensure that they are properly filled and purged of air. If air is present, select **Purge Line**. The system will expel 5 ml of contrast and then 5 ml of saline from the syringes. You may also manually purge air by pressing the Slow Forward or Fast Forward arrow keys under each syringe. 7. Detach the fluid dispensing devices from the syringes and from the containers of contrast medium and saline. 8. Clip the warmer to the contrast syringe.

Load and Fill the Syringes with Contrast and Saline (continued)

If You Are Filling...	Then...
One syringe at a time	1. Prepare your fluid dispensing source. 2. Select **Fill** on the Injector Controller under either contrast or saline. 3. Enter the amount of fluid you wish to use when you fill the syringe. Include several milliliters to expel when purging air from the system prior to making the patient connection. 4. Select **Begin** to start filling the syringe. If the Auto Purge option was enabled during installation, the system will also perform an Auto Purge operation for each syringe during the fill process. 5. Visually inspect the syringe to ensure that it is properly filled and purged of air. If air is present, select **Purge Line**. The system will expel 5 ml of solution from the syringe. You may also manually purge air by pressing the Slow Forward or Fast Forward arrow keys under the syringe. 6. Repeat steps 1 through 5 to fill a second syringe. 7. Detach the fluid dispensing devices from the syringes and from the containers of contrast medium and saline. 8. Clip the warmer to the contrast syringe.

Purging and Connections

Attach the Tubing

Note

Insert the Luer connector and then turn the syringe to secure the connection between the tubing and the Luer connector.

CAUTION

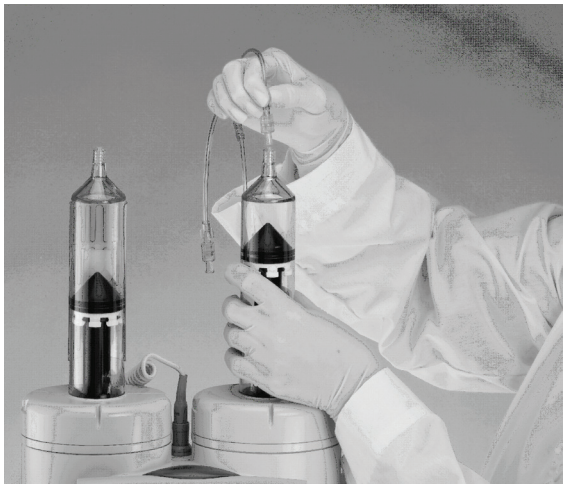
Ensure all consumable kits are installed properly. Ensure all kit connections are secure to prevent leaks, disconnections, air introduction, or component damage.

CAUTION

Do not over-tighten connections or use tools to assist in the installation or removal of consumable kits.

If You Are Using...	Then...
A contrast and a saline syringe (2 syringes)	There are two options for connecting the tubing to the syringes: • When using the FastLoad™ CTA Dual Syringe Pack, use the low-pressure connecting Y-tube supplied with the syringe pack. Connect the longer Y extension (with the blue line) of the connecting tube to the saline syringe, and connect the shorter Y extension (no blue line) to the contrast syringe. The connecting Y-tube includes the coiled tubing. or • When using two FastLoad™ CT Syringe Packs, use a connecting tube and one low pressure coiled tube (one coiled tube is supplied with each CT Syringe pack). Connect the longer Y extension (with the blue line) of the connecting tube to the saline syringe, and connect the shorter Y extension (no blue line) to the contrast syringe. Then connect the Luer connector at the single tubing end of the connecting tube to the corresponding Luer connector on the low-pressure coiled tube.
A contrast syringe (1 syringe)	Attach the low pressure coiled tube (supplied with each CT Syringe Pack) directly to the contrast syringe.

Purging and Connections (continued)



Purge Air from the Syringes and Tubing

WARNING

Failure to carefully follow these instructions in this task may result in serious injury and/or death. If you do not completely understand these instructions, do not proceed.

1. If the PURGE TO LINE feature is enabled in the Setup screen and the syringes are loaded and filled, you can select **Purge Line** on the Injector Controller to automatically purge 5 ml of contrast medium and 5 ml of saline, in that order. If only one syringe is loaded and filled, the Injector will automatically purge 5 ml from the filled syringe.

   Verify that all air has been removed from both syringes, from the connecting tube and from the coiled tubing. If all air has been removed, proceed to step 5.

2. Use the slow and fast forward arrow keys for the contrast syringe to advance the Injector ram and purge all air from the syringe and the connecting tube (for two syringes), bringing the contrast medium into the beginning of the coiled tubing. Alternatively, the hand knob on the bottom of the Injector Head can be used to move the syringe plunger forward manually. Do not attempt to move the syringe plunger backward manually because the check valves on the connecting tube will not allow this action.

   If bubbles adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles. If saline is not being used, proceed to step 4.

   Remember that if you want to test the IV with saline before starting the injection, you must remove the contrast medium from the tubing. Purge the air from the contrast side (just past the "Y" connector), then run saline all the way out the tubing, with some additional saline to purge the contrast medium from the tubing. If you do not plan to test with saline first, then purge saline first and then run contrast medium all the way out the tubing so you will be ready to start injecting contrast medium as soon as the injection begins.

Purging and Connections (continued)

3. Use the slow and fast forward arrow keys to advance the Injector ram and purge all air from the saline syringe, from the connecting tube and from the full length of the coiled tubing.

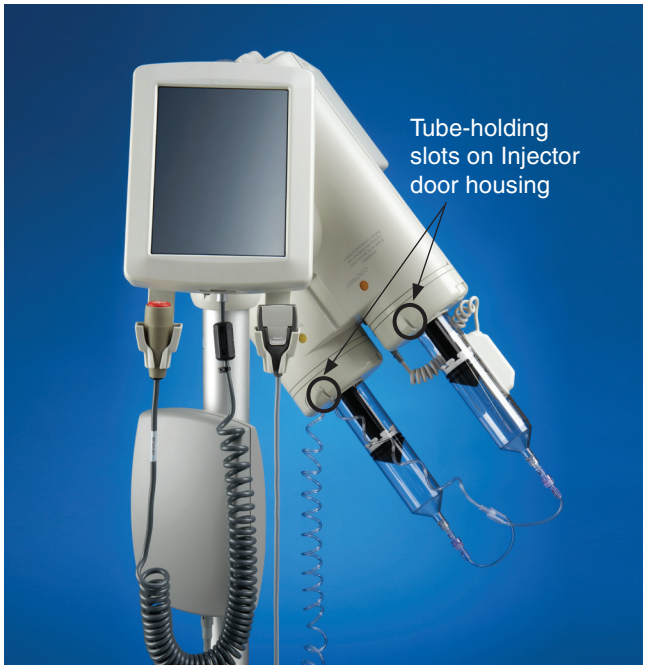
   If bubbles adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles.

4. Verify that ALL air has been removed from both syringes, from the connecting tube and from the coiled tubing. If you have any doubts about the presence of air, do not proceed. Use either the slow forward button or the hand knob on the Injector Head to expel more contrast or saline until all air is gone.

5. Once the contrast medium or saline has completely filled the connecting tube/coiled tubing and a small meniscus is present at the patient end of the tube, recap the syringe and use the slots on the Injector Head door housing (shown in step 6) to hold the tubing as required.

6. Attach the free end of the coiled tubing to the patient's catheter.

   Tilt the Injector Head fully downward toward whichever side is most convenient as shown below. Both the Injector Controller and the Remote Control will show the Injector Head as tilted down in the Run position.



7. If using extravasation detection, refer to Section 7 for proper instructions to load and apply the patch.

8. The Injector System is now ready for an injection.

If the injection protocol is already set up in the Remote Control, then you may begin to perform the injection, as described on page 48. Otherwise, programming the Remote Control is described in the following pages.

Program the Remote Control

Reading a Program

An injection program is a series of injection phases, which is defined and displayed on the Remote Control as a numbered list of flow rates, volumes, and time durations. For example, using the information shown below, the Injector System would inject 50 ml of contrast medium at 3.0 ml/s for 17 seconds, then conclude with 50 ml of saline at 3.0 ml/s for 17 seconds.

The Remote Control uses a touch screen display. When the Remote Control has recognized the selection of a button, it will beep.

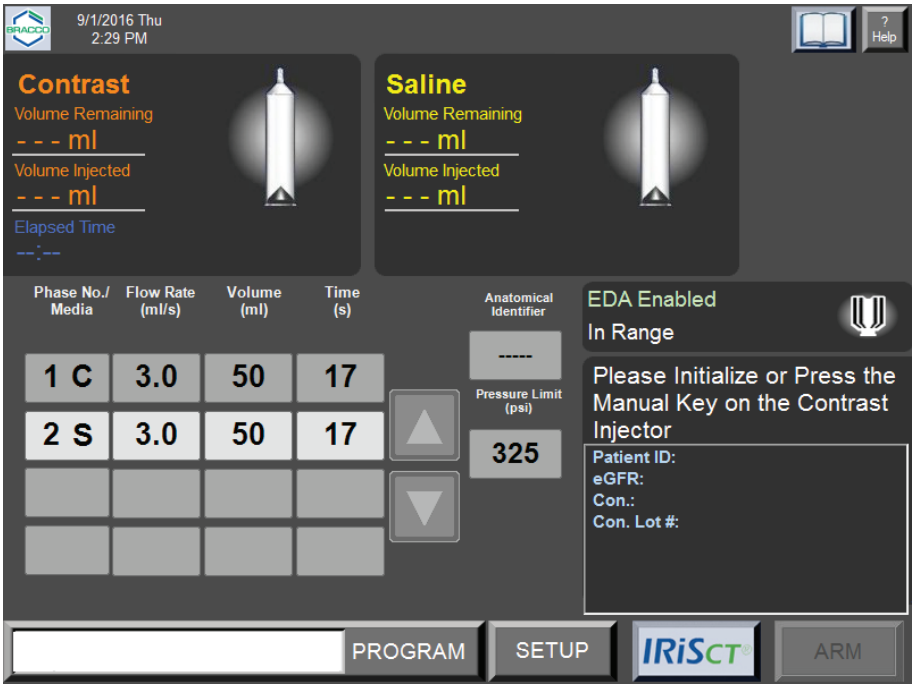
The entire injection is the "program." Each of the individual steps within the program is an "injection phase." When the injection program is run, the Injector System will execute each phase, sequentially, and then will stop automatically.

This section describes the basic procedures for reading and creating programs. For information about advanced programming features, see Chapter 4.

When the injector is networked to the hospital information system through Nexo® system, the main screen is slightly different and the programing procedure is simplified. Refer to section 5 on page 71 for the procedure using Nexo®.

This program indicates that for Phase 1, the Injector will inject 50 ml of contrast medium at 3.0 ml/s for a total of 17 seconds

In Phase 2, the Injector will inject 50 ml of saline at 3.0 ml/s for a total of 17 seconds



Program the Remote Control (continued)

Removing an Existing Program from the Main Screen

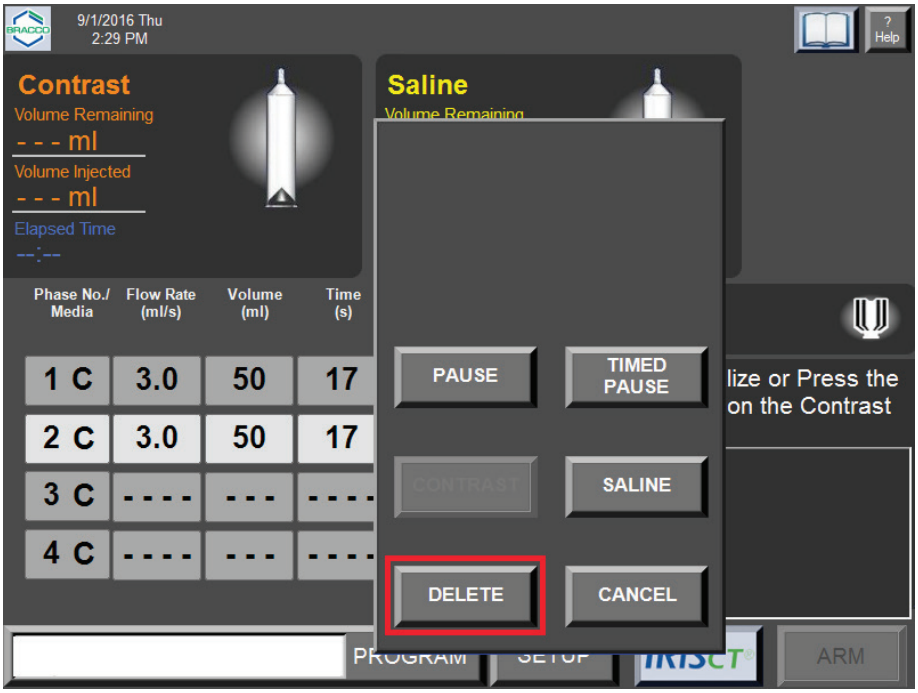
To remove an existing program from the Main screen:

1. If the phase table on the Remote Control defines a saline phase, select the saline (S) phase in the table's Phase Number column, otherwise select the first contrast phase.

   After selecting a cell in the Phase No./Media column, a pop-up window displays the DELETE and CANCEL buttons, as shown below.

2. Select the **DELETE** button. This phase of the existing program will be deleted, and the remaining phases will move up one row in the table and will be renumbered.

3. Repeat steps 1 and 2 until the table is completely blank except for the phase numbers.



Note

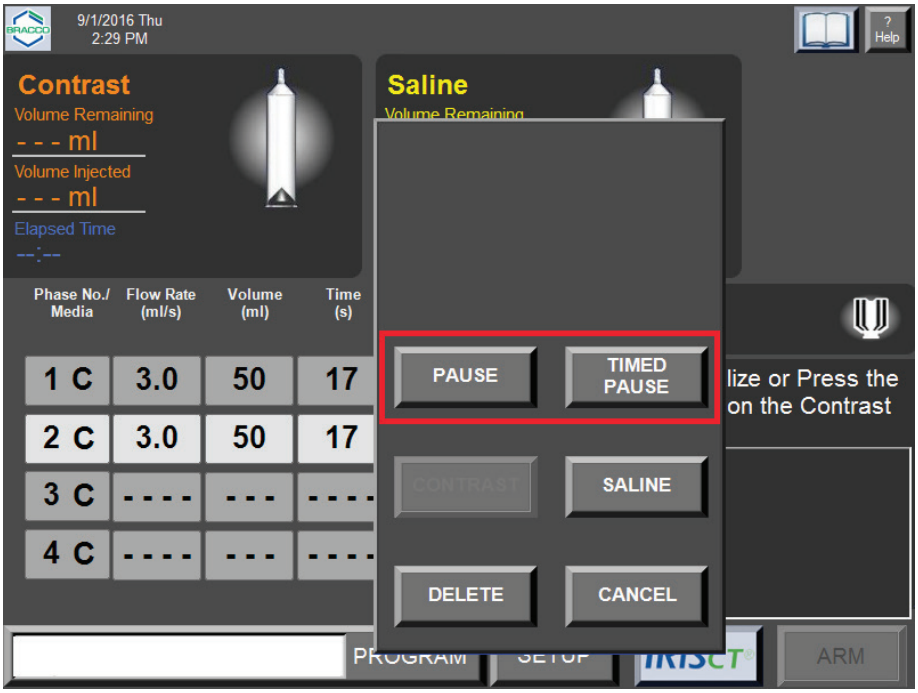
If at any time you have difficulty using or understanding this or any screen on the Remote Control, select the Help button at the top right corner of the screen to access the Remote Control's built-in Help feature.

Program the Remote Control (continued)

Entering a New Program

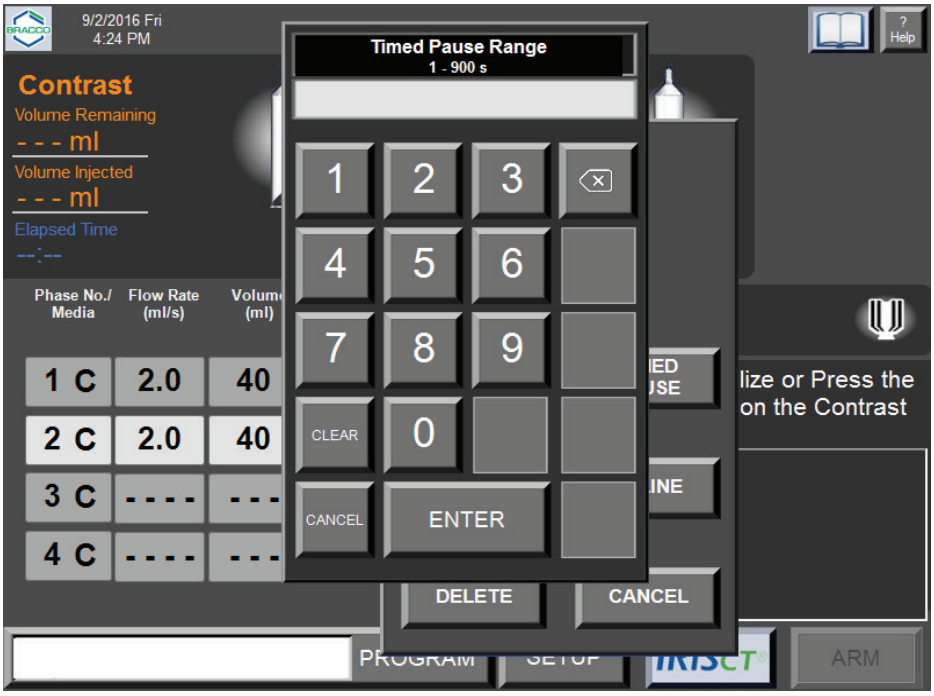
A program must be created phase-by-phase, beginning with phase 1 in the first row of the table. For each phase, a flow rate must be specified first. Thereafter, either Volume or Time can be specified; the Remote Control will then calculate the variable that was not specified (Volume or Time) to complete that phase. For contrast-only programs, a maximum of eight phases can be entered. If using both contrast medium and saline, a maximum of three phases can be entered. Phase 1 must be contrast (C). Phases 2 or 3 can be specified as either contrast (C) or saline (S). By default, all phases are selected as a contrast phase.

When the program has contrast phases only, you can program a pause between phases by defining a phase as either an indefinite Pause or a Timed Pause. To define a phase as a PAUSE or a TIMED PAUSE, select the phase number, then select either **PAUSE** or **TIMED PAUSE** in the pop-up window. The first and last phases cannot be either a pause or a timed pause.

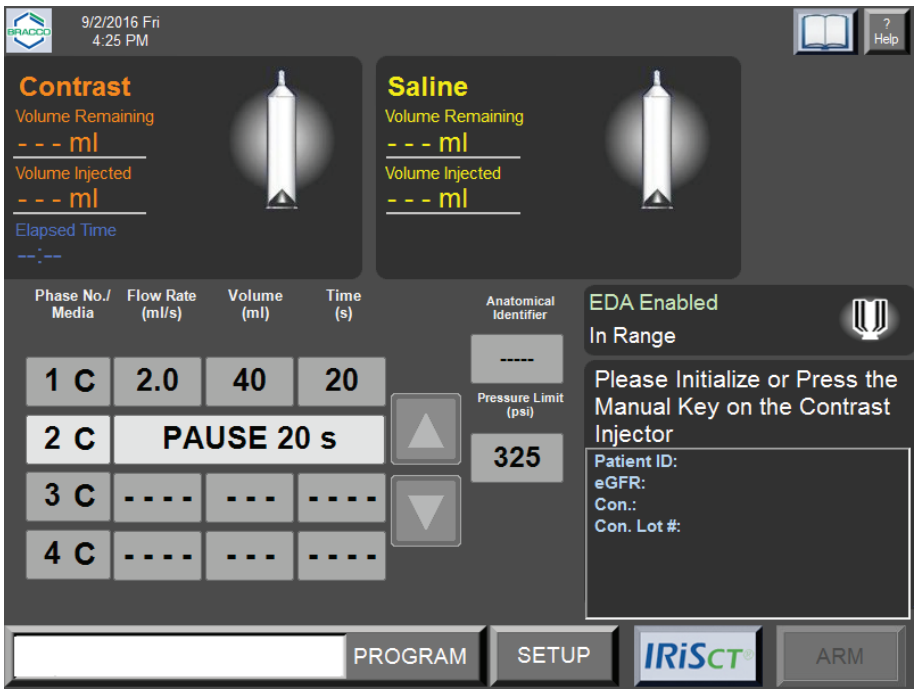


Program the Remote Control (continued)

Selecting **TIMED PAUSE** will open an additional keypad window (shown below) to set the duration of the timed pause.



The timed pause range is 1-900 seconds (up to 15 minutes). Enter the value in seconds and select the **ENTER** button. The selected phase will show the timed pause entry, as shown in the example below:



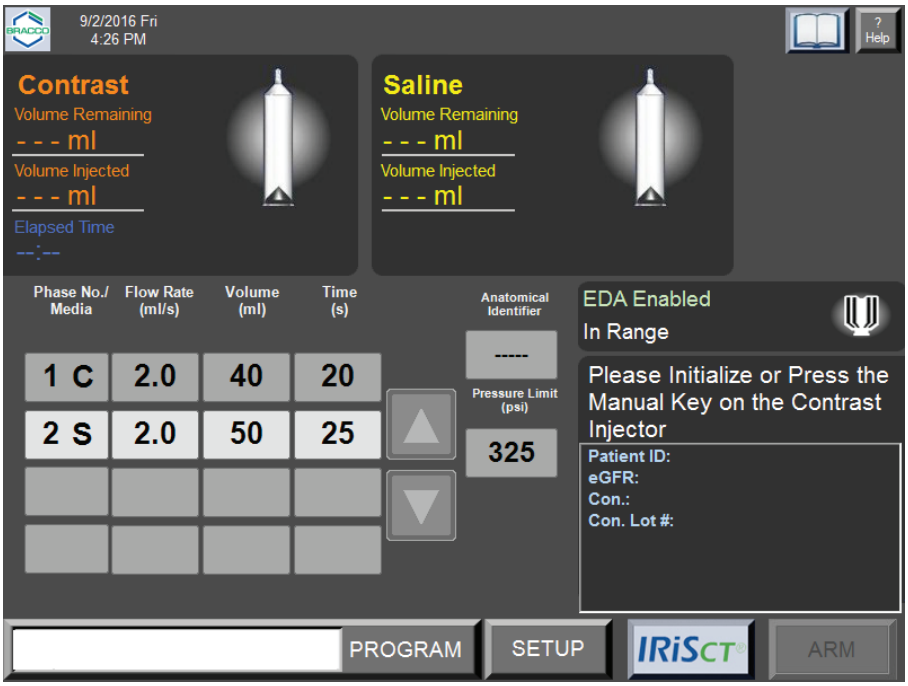
Program the Remote Control (continued)

A Saline Chase program can only be programmed in the following two combinations:

- The first phase can be a contrast phase followed by a second phase of saline.
- The first and second phases are contrast phases followed by a third phase of saline.

If a Saline Chase phase is selected, the following restrictions apply:

- No indefinite Pause or Timed Pause phases can be programmed.
- If phase 2 or 3 is selected as a Saline Chase phase, all subsequent phases will be removed as shown below:



The first phase cannot be a saline phase. Also, if you enter a third contrast phase, a system message will indicate that the saline flush is disabled. You must acknowledge the message prior to entering information into the third phase. If the third phase is deleted or reestablished as a saline phase, the Saline Chase will be re-enabled.

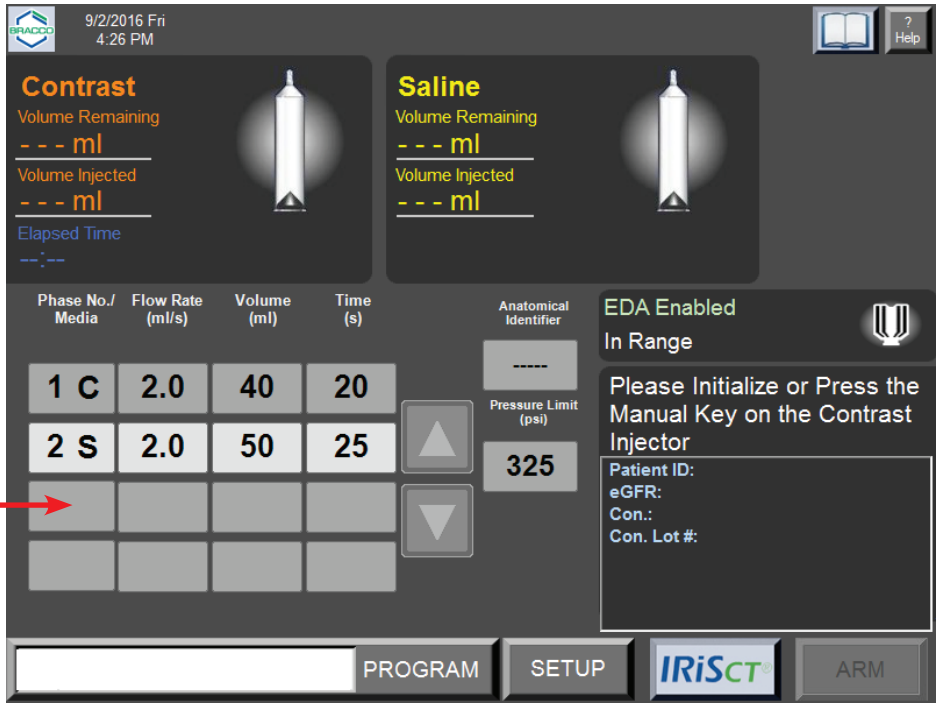
To program a Saline Chase Injection:

1. Starting with the first phase, select the **Flow Rate** field. A Flow Rate pop-up window will appear to enter the flow rate. The allowable range is 0.1-10.0 ml/s in 0.1 ml/s increments. Enter the desired flow rate in ml/s. Enter only the digits. For the Flow Rate only, the Remote Control will automatically add one decimal place to whatever is entered (e.g., if you enter "100", the Remote Control will enter this as "10.0"). To correct any entry mistakes, select the ⌫ ("backspace") button to erase one character at a time.

Program the Remote Control (continued)

2. When the desired flow rate has been specified in the Flow Rate Range window, select **ENTER**. The window will disappear. The Main screen will return, with the specified flow rate entered into the phase table.
3. Next, you have the choice to enter a value in either the Volume field or the Time field (the other field will be calculated and entered automatically). Select the **Volume** or the **Time** field. A Volume Range or Time Range pop-up window will appear, similar to the Flow Rate Range window.
4. To enter the desired volume in ml (the allowable range is 1–200 ml in 1 ml increments) or enter the desired time in seconds (the allowable range is based on the flow rate entered and the maximum volume limit of the 200 ml syringe). When finished, select **ENTER**. The entry window will disappear, and the Main screen will return with the user-entered Volume value and the calculated Time value entered in the table.
5. To program the second or third phase as a saline phase, select the appropriate **Phase No./Media** button. Select **SALINE** in the pop-up window, and an 'S" will appear after that phase number in the table. All phases after the saline phase will be removed from the table. To select a phase as saline, all phases that follow it must be empty, as shown below:

All phases after the saline phase are removed from the table.



Program the Remote Control (continued)

Using the Test Injection Feature

If the Test Injection feature has been enabled in the Setup screen, you can pre-program a contrast test injection to take place prior to the first programmed phase. The volume and flow rate for the contrast test injection are set up in the phase table, in the line above the first phase. The volume range for the test injection is 1-200 ml and the flow rate range is 0.1–10 ml/s.

If the Test Injection feature is enabled, a test injection is programmed, and the EmpowerCTA®+ Injector System is in the ARM mode, the Remote Control and Injector Controller screens will display the TEST INJECT button.

If ready to proceed, select the **TEST INJECT** button. The EmpowerCTA®+ Injector System will perform the contrast-only test injection only. When this test injection is paused or is allowed to conclude, the EmpowerCTA®+ Injector System remains in ARM mode.

After the test injection is completed, the RUN button will be available to start the programmed injection, and the TEST INJECT button will no longer be available.

Using the Saline Advance Feature

The Saline Advance feature can be used to test for vein patency before performing the injection.

The SALINE ADVANCE option will be available on the Injector Controller prior to arming the system when there is at least one valid contrast phase programmed at the Remote Control and the saline syringe contains at least some fluid. In addition, the SALINE ADVANCE option requires the following:

- The SA DOOR/FILL option is set to Enabled in the Remote Control's Setup screen (see page 89 for more information),

  OR

- A saline phase is programmed at the Remote Control (in this case, the SALINE ADVANCE option will be available even if the SA DOOR/FILL option is set to Disabled).

Note

If the programmed injection at the Remote Control defines three or more contrast phases, saline functions will be disabled and the SALINE ADVANCE option will not be available at the Injector Controller even if the SA DOOR/FILL option is set to Enabled.

Program the Remote Control (continued)

To use the Saline Advance feature:

1. Make sure that the SA DOOR/FILL option is set to Enabled in the Remote Control's Setup screen or that a saline phase is programmed at the Remote Control.
2. Make sure that the saline syringe contains enough saline for both the Saline Advance (maximum 25 ml per Saline Advance) and for the programmed injection. Refill the saline syringe if necessary. When using the Protocol Fill option to fill syringes while the SA DOOR/FILL option is enabled, an extra 25 ml of saline will be added to the saline syringe in addition to the volume of saline required for the programmed injection.
3. Make sure that the Injector Head is tilted down (in either direction) to the Run position.
4. Review the flow rate. The flow rate for the Saline Advance is the flow rate specified for the first contrast phase in the programmed injection.
5. To start the Saline Advance either press and hold the red button on the pendant, or press and hold the **Saline Advance** button on the Injector Controller.
6. To stop the Saline Advance, release the red button on the pendant or release the **Saline Advance** button on the Injector Controller. The Saline Advance will also stop when the 25 ml limit is reached.
7. You can restart the Saline Advance, provided that the saline syringe contains enough saline, and the same 25 ml limit will apply.

Perform the Injection

When the patient, EmpowerCTA®+ Injector System, and program have all been prepared, follow the instructions on the following page AFTER reading these warnings:

WARNING

To pause the injection, do any of the following:

- *Touch the Remote Control screen anywhere except in the Flow Rate box at the upper right, or*
- *Select PAUSE on the Injector Controller, or*
- *Press the red button on the pendant.*

The system will also pause automatically if:

- *The EDA detects a possible extravasation condition, or*
- *The system detects an overpressure condition, or*
- *If the system detects that the Injector Head is not tilted down in the Run position.*

To resume the injection after a pause, select the RUN button on the Injector Controller or on the Remote Control, or press the red button on the pendant.

Perform the Injection (continued)

WARNING

Pressure limiting and over-pressure messages may occur due to simultaneous selection of a high flow rate and a low pressure limit value, or because of a blockage in the fluid path. If either of these messages is displayed, check the fluid path. If there are no blockages, you may need to adjust the flow rate or pressure limit in accordance with physician's orders.

WARNING

If pressure limiting during an injection causes the contrast medium or saline delivery to remain at a sustained flow rate less than the programmed flow rate, the user is notified by an acknowledgment tone and a message that displays on the Remote Control. Unless there is some intervention by the clinician, such a pressure-limited injection will generally continue until completion. The decision to continue or stop the injection for this or any reason rests with the clinician.

WARNING

In the event of a system malfunction, immediately turn off the EmpowerCTA®+ Injector System and quickly disconnect the patient from the unit. Confirm that the system malfunction has been repaired before reconnecting the patient. Turn the system on, arm the Injector and perform a test injection. If the system shows no further malfunction, reconnect the patient. If a fault message still exists and cannot be corrected and/or the Injector is still malfunctioning, DISCONTINUE USE of the EmpowerCTA®+ Injector System until the problem is properly identified and solved. Contact local Bracco Injeneering S.A. technical support for further assistance.

WARNING

Failure to carefully follow these instructions in this task may result in serious injury and/or death. If you do not completely understand these instructions, do not proceed.

To perform an injection, follow these steps:

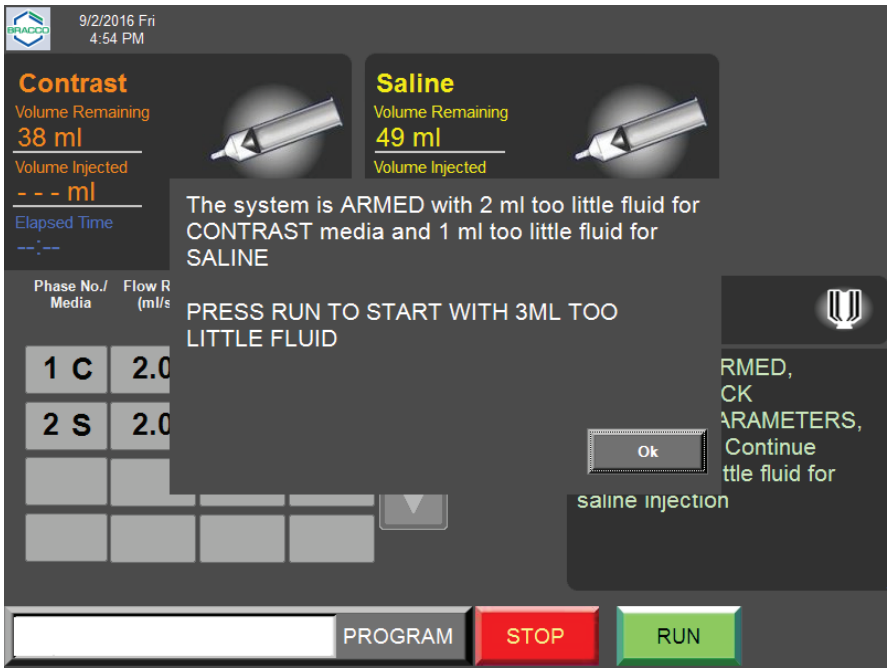
1. If the EDA message area on the Injector Controller and at the Remote Control display "EDA Enabled Out of Range", the EDA is indicating that the extravasation detection patch and/or the EDA cable are not set up properly. Check the connections carefully and see "How to Load and Apply the EDA Patch" on page 116.
2. If the SA DOOR/FILL option is enabled in the Setup screen, you can use the **Saline Advance** option on the Injector Controller to inject saline before arming the system for the injection.
3. When you are ready to start the programmed injection, select the **ARM** button at the lower right of the Remote Control's screen, which will now be green instead of gray. The ARM option will also be displayed on the Injector Controller if there are four or fewer phases programmed on the Remote Control.
4. In the ARM mode, the EmpowerCTA®+ Injector System lets you review the programmed parameters one more time.

Perform the Injection (continued)

If the system was displaying the "EDA Enabled Out of Range" message prior to arming the system, the EDA status will now be "EDA User Disabled." If the Test Injection feature is enabled and a Test Injection phase is programmed, the system will display the TEST INJECT button on both the Remote Control and the Injector Controller screens. The test injection must be performed before proceeding to the actual injection.

When you are ready to proceed, select **RUN** at either the Injector Controller or the Remote Control, or press the pendant switch. Alternatively, to return to the Main screen on the Remote Control, pause the injection, then select **STOP**. Selecting **RUN** begins the injection. The Remote Control will display the progress of the injection as it runs.

Note: After the ARM option is selected, the following message is displayed on the right side of the screen: "System is armed. Please check injection parameters." If the volume of contrast in the syringe is less than the total volume required for the programmed protocol by 1 ml or more, there is an additional message, "Press RUN to continue with X ml too little fluid for contrast injection," where X is the difference in volume between the available contrast and the amount requested by the protocol. The following message will also be displayed: "The system is ARMED with X ml too little CONTRAST. PRESS RUN TO START WITH X Ml TOO LITTLE FLUID". You must acknowledge this message before you can run the injection.

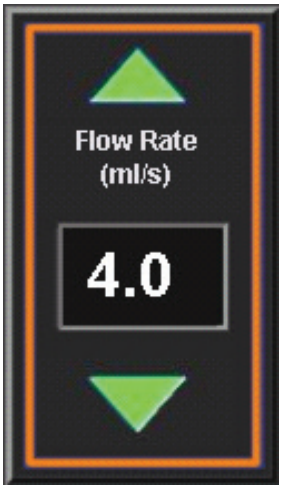


This information is designed to assist you in determining if the contrast volume is sufficient to obtain the desired image, particularly in time critical situations. To continue, you must choose one of the following options:

Perform the Injection (continued)

- To proceed with the contrast volume shown, select RUN.
- To delay the case in order to refill the syringe, select STOP

You can adjust the flow rate of the current phase while it is in progress by pressing and holding down the up or down (i.e., increase or decrease, respectively) green arrow above or below the Flow Rate box in the upper right corner of the Remote Control screen, or by selecting the + and – buttons at the Injector Controller. Use caution when manually adjusting the flow rate during an injection. The flow rate controller on the Remote Control is shown below:



5. When a programmed injection includes a Saline phase, the Remote Control displays a "Saline Jump" button during the last contrast phase of the injection program:

Selecting the Saline Jump button while the injection is in the last contrast injection phase causes the system to immediately stop injecting contrast medium and to jump to the programmed saline injection phase.

The Injector will display the syringe pressure, which is continuously updated throughout the injection. The syringe pressure is also displayed at the Remote Control.

The Saline Jump feature is useful when the scanner has stopped and the Injector is still injecting contrast medium during the last contrast phase of the injection. This option lets you stop the contrast phase and immediately 'jump' to the saline phase to minimize the amount of contrast medium injected into the patient.

6. The Elapsed Time displays the time in minutes and seconds since the start of the injection. It continues throughout the injection and is reset when the system is armed again. Selecting the icon next to the elapsed time when the injection is completed or stopped will stop the timer (but will not reset it) and will remove the icon.

Perform the Injection (continued)

7. The injection will end automatically when it completes all phases of the program, or when it completes the saline phase if the Saline Jump button is selected during the final contrast phase of the injection. Respond to the 'Is the procedure complete?' prompt if it appears. The Main screen is displayed.
8. Optionally, if the label printer is connected and the PRINT option is enabled in the Setup screen, you can select the label printer icon to print a label. The printed label has the following information: Patient ID, date, time of injection, contrast medium brand, contrast medium lot number, eGFR value, serum creatinine (SCr) value, amount of contrast medium injected, and the program values (phase number and medium, flow rate per phase, volume per phase, and time for each phase).

Label Printer Icon →

Disconnect from the Patient and Remove the Syringe(s)

When an injection has stopped, the Main screen will be redisplayed. At that time the system will need to be re-loaded and re-armed to continue with another procedure. In these concluding steps, the patient must be disconnected from the EmpowerCTA®+ Injector System and the connecting tube must be removed from the syringes before the syringe is unloaded.

Disconnect the Patient from the Injector System

WARNING

In the event of a system malfunction, immediately turn off the EmpowerCTA®+ Injector System and quickly disconnect the patient from the unit. Confirm that the system malfunction has been repaired before reconnecting the patient. Turn the system on, arm the Injector and perform a test injection. If the system shows no further malfunction, reconnect the patient. If a fault message still exists and cannot be corrected and/or the Injector is still malfunctioning, DISCONTINUE USE of the EmpowerCTA®+ Injector System until the problem is properly identified and solved. Contact local Bracco Injeneering S.A. technical support for further assistance.

1. Disconnect the coiled tubing from the patient catheter.
2. Close off the catheter or remove it in accordance with site practice.
3. If an extravasation detection patch was used, carefully peel it off of the patient and discard it using the instructions on page 121. Extravasation detection patches should never be reused.

Remove the Syringes

CAUTION

When retracting the syringe plunger with the EmpowerCTA®+ Injector System during contrast medium or saline filling or after the end of an injection, do not let a vacuum build in the syringe by leaving the EmpowerCTA®+ Connecting Tube attached to the end of the syringe. In addition, do not allow the tubing pathway to occlude the J-Tube (fill tube) or patient coiled tubing to the syringe. When connecting the syringe with a spike, do not over tighten the spike onto the syringe luer lock in order to prevent from damage and occlusion to the fluid path. Failure to let the syringe properly vent when retracting the syringe plunger can cause the plunger to recoil forward when the Injector ram reaches the Replace Syringe position. If needed, contact the local Bracco representative.

CAUTION

Dried contrast medium may make removal of the Luer fittings difficult. Do not let contrast medium dry. Make sure that the Luer connection is not over tightened.

1. With the patient disconnected from the Injector System, remove and discard the connecting tube set (which includes the check valves) from the ends of the syringes, using institutional procedures for the disposal of biohazardous waste. If you are using one syringe only, there is no need to remove the coiled tubing from the syringe.

Disconnect from the Patient and Remove the Syringe(s) (continued)

2. Tilt the Injector Head up into the upright (Load) position (as shown below).

3. Select the **Replace Syringe** button on the Injector Controller.

   To replace a single syringe, press and hold the **Single** button under the appropriate heading (Contrast or Saline) until the Injector responds. (This step is not necessary when using DUAL to replace both syringes.)

   To replace both syringes, press and hold **Dual** until the Injector responds.

   Wait for the syringe plunger(s) to retract completely. The Injector Controller then displays the initialize options.

4. Open the syringe door(s).
5. Remove and discard the syringe(s) using institutional procedures for the disposal of biohazardous waste.
6. If two syringes were in use but the **Dual** replace syringe option was not used in step 4, select the **Replace Syringe** button to replace the desired syringe. Press and hold the **Single** button until the Injector responds. Wait for the syringe plunger to retract completely, then repeat steps 5 and 6 to remove and discard the second syringe.

Cleanup and Storage

After the last procedure of the day, or in the event of any accidental spill on the equipment, clean the EmpowerCTA®+ Injector System using the following procedure.

WARNING

Failure to follow these instructions may damage the equipment or create the possibility of an electrical shock to the technologist or patient.

1. Shut down the Remote Control as described on page 111 and turn off power to the Injector System using the rocker switch located on the underside of the Injector Controller touch screen.
2. Dampen a paper towel with mild hospital-grade disinfectant cleaner, and carefully wipe off any dirt or spilled fluids. Do not use strong disinfectants or cleansers; do not allow any liquid cleaner to get inside the EmpowerCTA®+ Injector System. Never submerge either unit in water.
3. Clean the Remote Control with a soft towel and mild detergent. Clean the touch screen with a soft towel and a computer monitor cleaning agent.

When not in use, the Remote Control and the Injector System should be stored in a safe place, away from dust, from extreme or quickly changing temperatures, and from the possibility of spills or other accidental damage.

Injector Controller Touch Screen Calibration

The Injector Controller touch screen requires calibration in the following situations:

- Calibration drift (selecting a field on the Injector Controller touch screen does not produce a response, or seems slow to respond).
- Fault 230 Touch Screen Calibration Failure occurs.
- The Injector Controller touch screen is replaced.
- The single board computer/controller board is replaced.

Note

Injector Controller touch screen calibration is not available when syringes are installed in the Injector Head.

To calibrate the Injector Controller touch screen:

1. If the Injector is powered on, turn it off by flipping the rocker switch on the right underside of the touch screen.
2. If any syringes are installed, remove them. See page 53 for instructions on removing the syringes.
3. Tilt the Injector Head so that it is parallel to the floor, half way between the Load position and the Run position.
4. Power on the Injector by flipping the rocker switch on the right underside of the touch screen.
5. When the blue calibration screen appears, touch anywhere on the Injector Controller screen within 5 seconds.
6. Press and briefly hold the calibration target in the center of the screen to begin the calibration.
7. Continue to press and briefly hold the target as it moves around the screen. A confirmation window opens when calibration is complete.
8. Tap the confirmation screen within 30 seconds to register the new settings, or wait to keep the current settings. If you wait, the blue calibration screen will appear again.

System Preventive Maintenance

The EmpowerCTA®+ Injector System is intended to be serviced on an annual basis to maintain the basic safety and essential performance. A specific service date is programmed through the Service function on the Setup screen. This option is accessible to local, authorized, and qualified Bracco Injeneering S.A. representatives only, and is password protected.

The EmpowerCTA®+ Remote Control notifies the user of necessary maintenance upon start up.

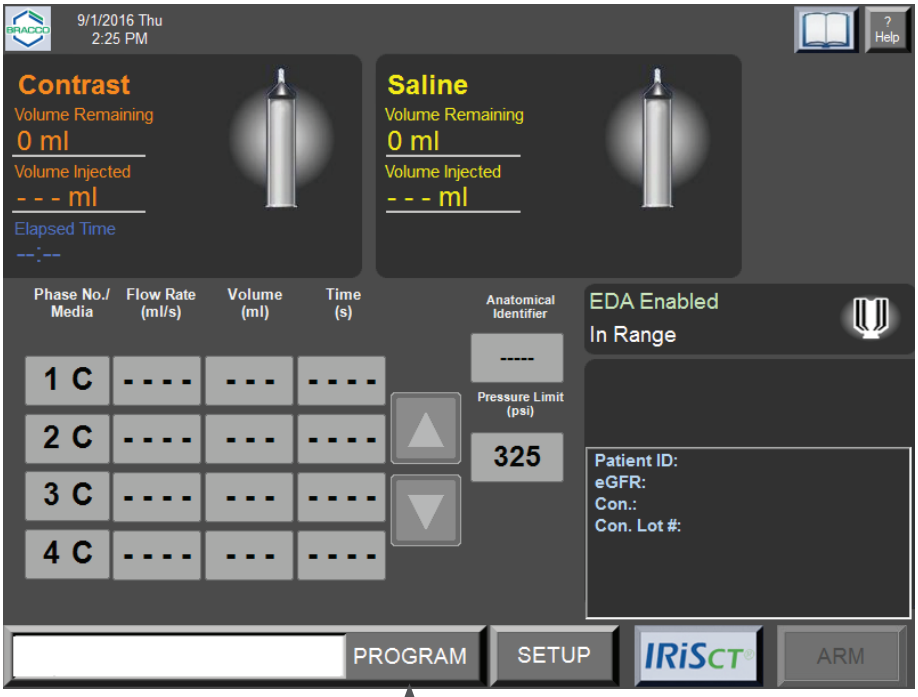
Service must be performed by a local, authorized, and qualified Bracco Injeneering S.A. representative using the appropriate EmpowerCTA®+ Injector System Service Manual.

4 Advanced Programming Procedures

Remote Control Main Screen

The EmpowerCTA®+ Remote Control has a wide variety of injection programming features, a few of which were described briefly in the preceding section. Most of these features are accessible from the Program screen.

To view the Program screen, begin at the Remote Control's Main screen, as shown below, and select the **PROGRAM** button.

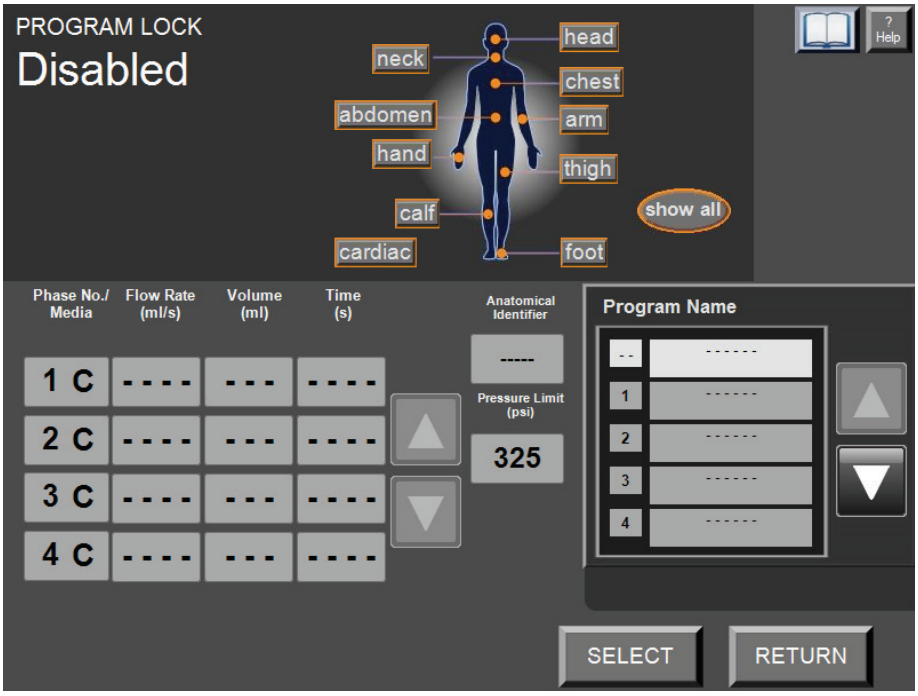


PROGRAM button

If the Main screen is not displayed, but the Remote Control is active, select the **RETURN** button at the lower right corner of the screen until the Main screen is displayed.

Remote Control Program Screen

Selecting the PROGRAM button displays the Program screen, as shown below.

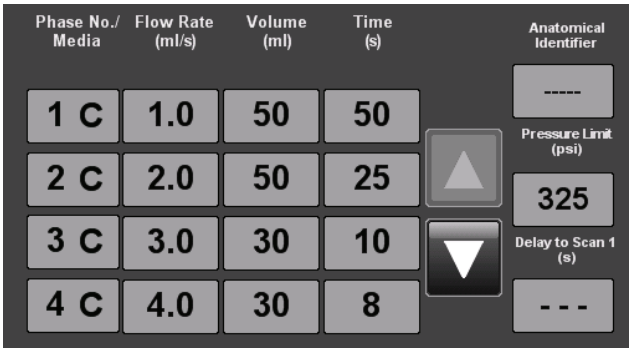


Among other things, this screen allows you to examine and select an existing program. If the Program Lock option in the Setup screen is set to Disabled, you can also create programs, save new programs, and delete old programs that are no longer needed. All of these features are described in the following sections.

Reading and Creating Programs

Phase Table

The basics of reading and creating programs are described in the preceding section, beginning on page 41. Everything related to these activities works the same in the Program screen as it does in the Main screen. To review briefly: a program is a series of phases containing flow rates and volumes. These phases are listed sequentially in the phase table as shown below:

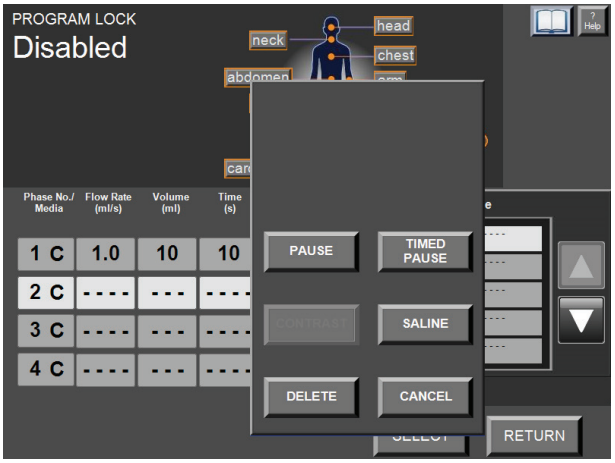


If the program is more than four phases long, all of the phases cannot be displayed on the screen simultaneously. Use the up and down arrow keys next to the phase table to scroll up and down.

Pressing on a flow rate or volume can alter the information in the phase table. The duration (Time) will be updated automatically.

Following a selection of flow rate or volume, a corresponding pop-up Range window will be displayed. Using the buttons in either of these windows, enter the desired value and then select **ENTER** to add it to the phase table. If you make a mistake, select ⌫ to erase it one character at a time, select **CLEAR** to erase the value completely, or select **CANCEL** to leave the entry window without specifying a new value.

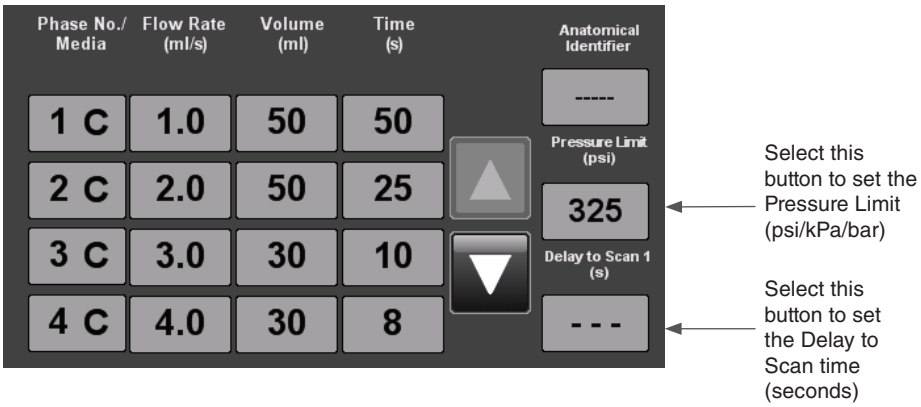
To enter an indefinite PAUSE (which will suspend the program's execution until you resume it) or a TIMED PAUSE, or to delete an unwanted phase, select the phase number. In the pop-up window, select **PAUSE** to define an indefinite pause, or select **TIMED PAUSE** followed by **ENTER** to complete the duration entry, or select **DELETE** to delete the phase, or select **CANCEL** to exit without changing the phase.



Reading and Creating Programs (continued)

Pressure Limit and Delay To Scan

In addition to the above features, a pressure limit or a delay to scan can be specified for an entire program, in either the Main screen or in the Program screen. These values are entered just to the right of the phase table.



The Pressure Limit parameter specifies the maximum allowable syringe pressure for a programmed injection procedure. If the pressure of the contrast medium or saline being injected reaches this value, the Injector System will slow down to maintain the pressure limit value. If the injection flow rate falls to 0 ml/s, the injection will pause with an "Overpressure" message on the Remote Control and on the Injector. You can then correct any problems with the patient, the coiled tubing, the connecting tube or the catheter before electing to resume the procedure.

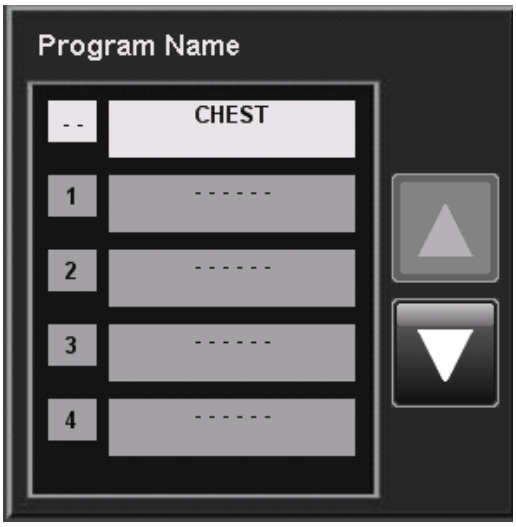
The Delay to Scan parameter specifies, in seconds, how long the Remote Control should wait after an injection begins, before announcing a "start the scanner" voice prompt or tone. If the screen does not include a place to enter a Delay to Scan value, but one is desired, see the discussion about enabling scanner messages beginning on page 95.

To change either of these parameters, select the value to be changed, and a corresponding pop-up window will be displayed, similar to the window for flow rates and volumes.

Specify the desired value, and then select **ENTER**.

Examining and Selecting Existing Programs

The lower right portion of the Program screen displays a list of program names as shown below.



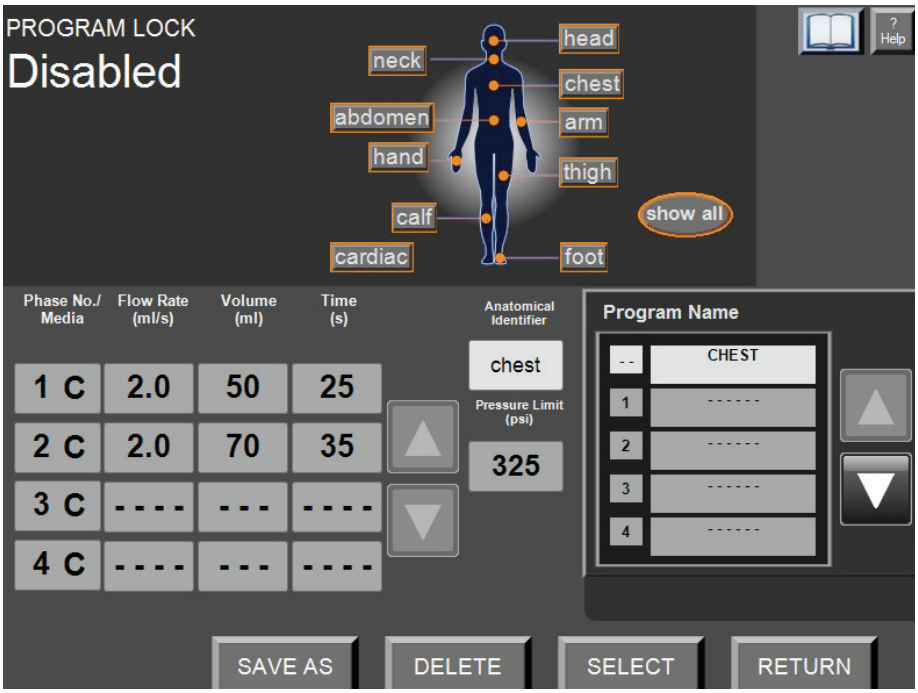
Scroll up and down through this list of up to 100 program names by pressing on the arrows located just to the right of it. These arrows will cause the list to scroll down by one program each time the appropriate arrow is pressed and released, or will scroll continually if an arrow is held down.

You can also sort the program list to only those programs intended for use when scanning a particular part of the body, by selecting any anatomical identifier contained on the human body diagram at the top of the screen. To return to the full list of programs after viewing an anatomically limited list, select a program name then select the **show all** button.

To examine the contents of a stored program, select its name. The program will be displayed in the phase table, with the corresponding anatomical identifier, pressure limit, and delay to scan.

Examining and Selecting Existing Programs (continued)

Use the **SELECT** button to choose the current program to use in the Main screen, and the Main screen will display this program name in the lower left corner of the screen. To return to the Main screen without selecting a program, select **RETURN** in the lower right corner of the Program screen.



Modifying Existing Programs

To modify existing programs, the PROGRAM LOCK option in the Setup screen must be set to Disabled.

To change the name of a program after it is displayed, select its name again. An alphanumeric pop-up window will be displayed as shown below.

Modifying Existing Programs (continued)

This window works like all the Range and other numeric-only windows seen elsewhere, except that this window also allows entry of letters, spaces, special characters, and the ENTER button will not appear until a name at least one character long has been specified. To save a new program name, select **ENTER**.

To make any other adjustment to a program (i.e., change its phase information, anatomical identifier, pressure limit, or delay to scan) use the same techniques as would have been used to set that criterion originally.

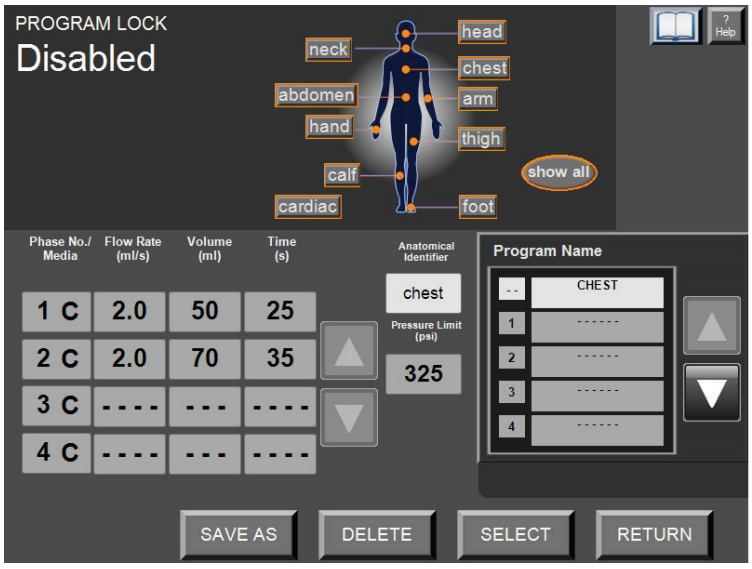
Saving and Deleting Programs

To save and delete programs, the PROGRAM LOCK option in the Setup screen must be set to Disabled.

When adding programs, you can either modify an existing program, duplicate a program to create a new one, or create a program as previously detailed. To save changes to an existing program with the same program name, select **SAVE** near the lower left of the screen. You will be asked to confirm that you want to permanently replace the previous information for that particular program. Select **Yes** to confirm or **No** to not save the program information.

To save changes to an existing program as a new program, or to save a new program that has just been created, select **SAVE AS**. The program will be saved in the next available program number. There are up to a maximum of 100 programs. If an attempt is made to use SAVE AS to save a program that is identical to an existing program, a message will state which other program is the same as the current one, and ask if you wish to proceed anyway. Select **Yes** to confirm or select **No**.

Once a program has been saved, it will be stored in the Remote Control's memory, until someone changes it or deletes it. To delete a program, select its name in the program name list, then select **DELETE** at the bottom of the screen.



Saving and Deleting Programs (continued)

Anatomical Identifiers

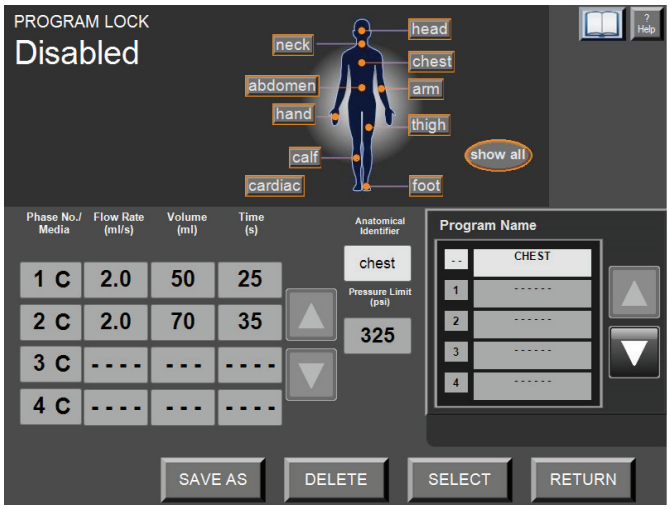
The anatomical identifier enables you to associate an injection protocol to a specific part of the human anatomy. It serves as a way to group all programmed protocols to a specific body part. This identifier can be used to specify the primary part of the body that will be scanned to an associated injection protocol.

For example, if you have multiple injection protocols for scanning the abdomen, by associating the abdomen anatomical identifier to them as part of the stored program, they can be retrieved by anatomical location along with its specific naming convention.

To associate an anatomical identifier for the program currently displayed in the Program screen, select the anatomical identifier area adjacent to the program phases. The area will be given a white background, as shown:

Then, using the human body diagram at the top of the screen (example shown below), select the name of the part of the body associated with the program. The anatomical identifier value will change to the body part pressed.

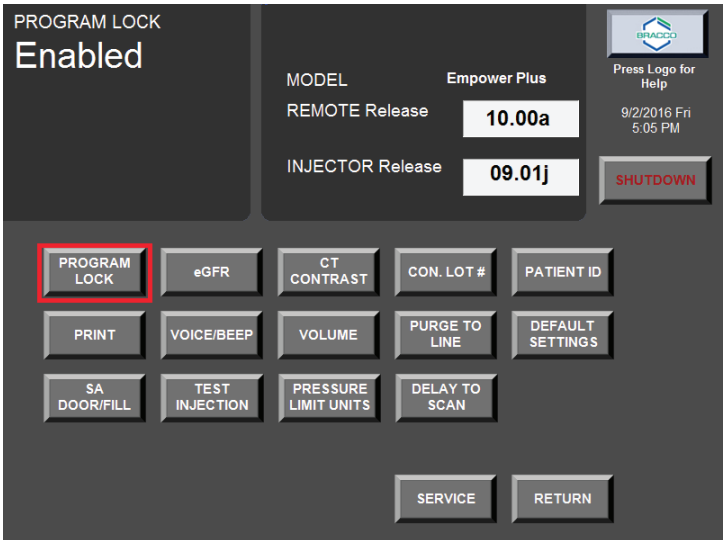
Saving and Deleting Programs (continued)



In addition, you can sort through the various programs associated with an anatomical identifier by selecting a particular human body identifier. Only programs associated with that anatomical identifier will be displayed. If you want to look at the programs, select **show all** and the program names will be redisplayed in numerical order.

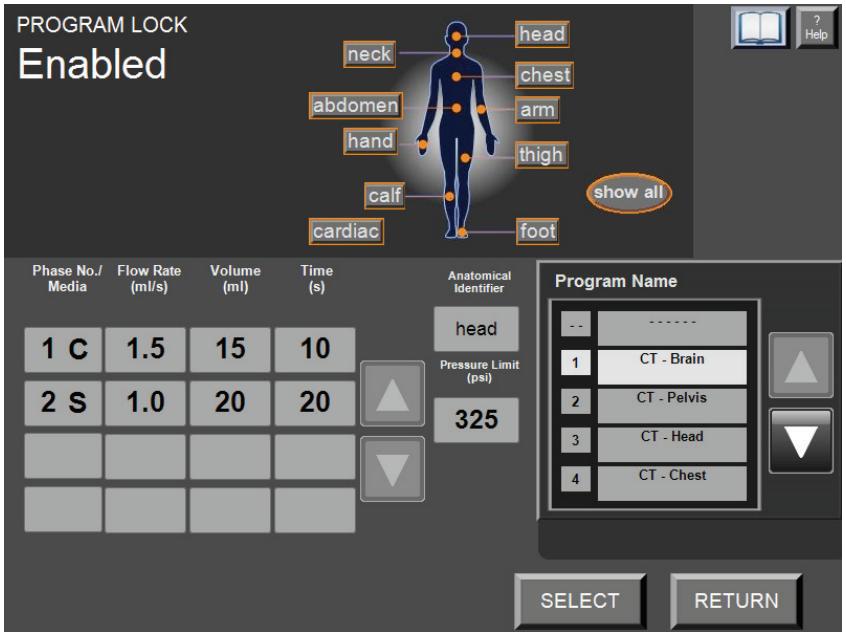
The Program Lock Feature

The programs can be locked such that once they have been entered by the site, they cannot be modified. To activate the Program Lock feature when this feature is disabled, select **SETUP** in the Main screen and then select the **PROGRAM LOCK** button twice to display the feature as Enabled as shown below:



Saving and Deleting Programs (continued)

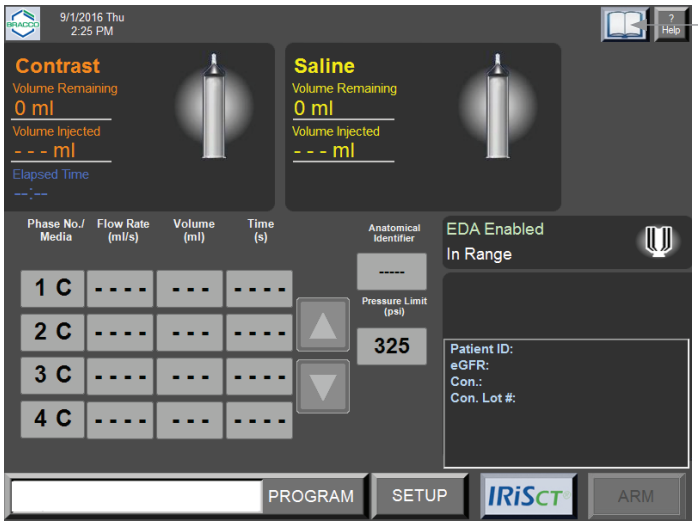
Select **RETURN** to go back to the Main screen. On the Program screen, the SAVE, SAVE AS, and DELETE buttons will no longer be available. You can only select a program, as shown below:



Using the Bracco Protocol Reference Guide

If your site uses Bracco contrast media (Isovue® 370 or Iomeron® 400), you may have access to the Bracco Protocols. Contact your local Bracco Injeneering S.A. representative to activate this feature.

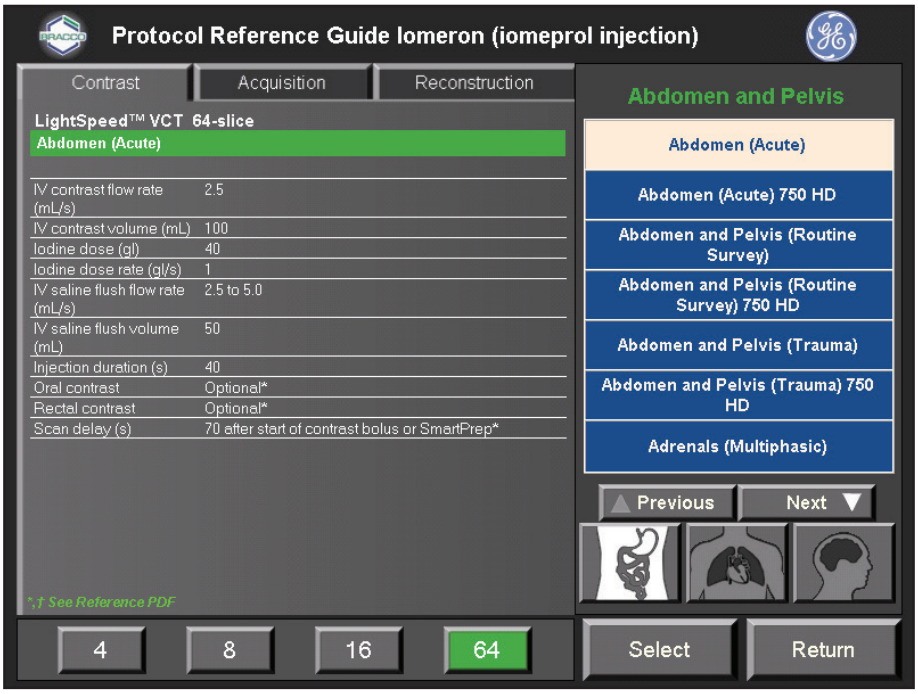
To access the Bracco Protocol Reference Guide, select the book logo in the upper right corner of the Remote Control Main screen, as shown:



Select this icon to access the Bracco Protocols.

Using the Bracco Protocol Reference Guide (continued)

The following example shows the Bracco Protocol Reference Guide for an Abdomen (Acute) indication using Isovue and a 64-slice GE scanner:



The Bracco-provided MDCT protocols are specific to Philips, GE, Siemens, and Toshiba scanners, and serve as only as a guide when working with the EmpowerCTA®+ Injector System.

During system configuration, the Remote Control is configured to the particular CT contrast and CT scanner that is used in the suite associated with the EmpowerCTA®+ Injector System.

The protocols are grouped based on the following indications:

- Abdomen and Pelvis
- Brain, Head, and Neck
- Chest and Cardiovascular

Using the Bracco Protocol Reference Guide (continued)

To access and use the Bracco Protocol Reference Guide:

1. Select the book icon from the Remote Control Main screen. For first-time use, read the legal notice and disclaimer and indicate acceptance before proceeding.
2. Select a body area indication (abdomen and pelvis; brain, head and neck; or chest and cardiovascular).
3. Select a specific protocol from the provided list. Use the **Next** and **Previous** buttons to view all options.
4. Some protocols have specified ranges. When prompted, adjust the protocol to the desired flow rate and volume within the range.
5. Adjust the protocol for the corresponding number of scanner slices.
6. Review the information provided on the Contrast tab, the Acquisition tab, and the Reconstruction tab. Select the **Accept** button to continue (or select the **Return** button to exit the Bracco Protocol Reference Guide).
7. If, in step 6 you selected the Accept button, the protocol will display in the Phase area and the Program Name area of the Remote Control Main screen. Optionally, enter IRiSCT® information, or select the **Return** button.
8. (Optional) Select **PROGRAM** and **SAVE AS** to save the program, which can then be re-selected from the Program Names list.

5 Using EmpowerCTA®+ with Nexo®

Understanding Nexo® Connectivity

Note

For US only, please contact your local distributor to have the availability of this feature in your country.

This section concerns the EmpowerCTA®+ Injector System connected to a Nexo® server.

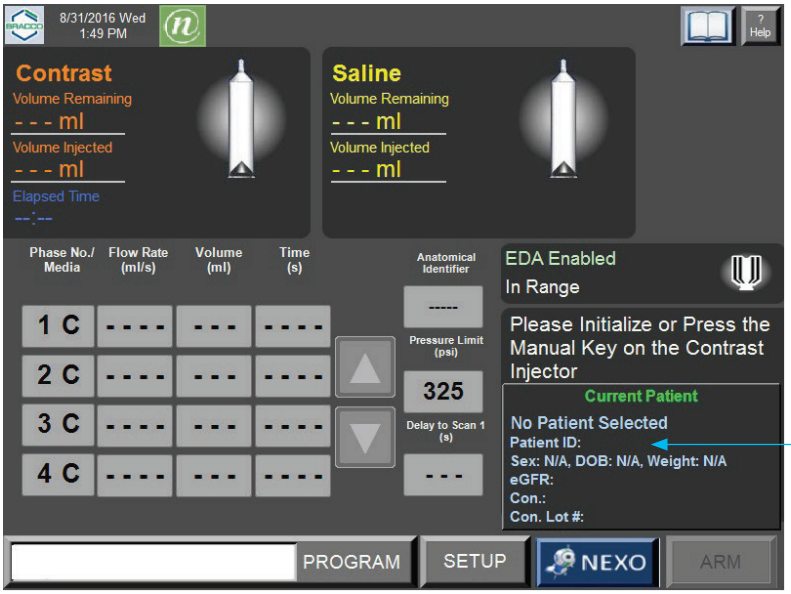
Nexo® is a self-contained software package distributed by Bracco Injeneering, aimed to network Bracco Injectors and add connectivity to RIS/PACS (Radiology Information System/Picture Archiving and Communication System) to them. Nexo® can be enabled on Bracco Injectors as an additional software option. The EmpowerCTA®+ Injector System is compatible with Nexo®. For more information on Nexo® and its availability in your Country, please contact your local representative.

To verify the connectivity status of the injector, check the Nexo® Connectivity Icon on the top left of the main screen. According to the connectivity status:

icon	Meaning
	Nexo® Connection Icon in green - The connection to Nexo®, PACS and RIS is working properly
	Nexo® Connection Icon in red - The connection to Nexo®, PACS and RIS exists but there are synchronization issues between Nexo® and the injector. The data shown on EmpowerCTA®+ Injector may not be up-to-date. The connection to Nexo®, PACS and RIS is not working properly.

Using the Current Patient Tab

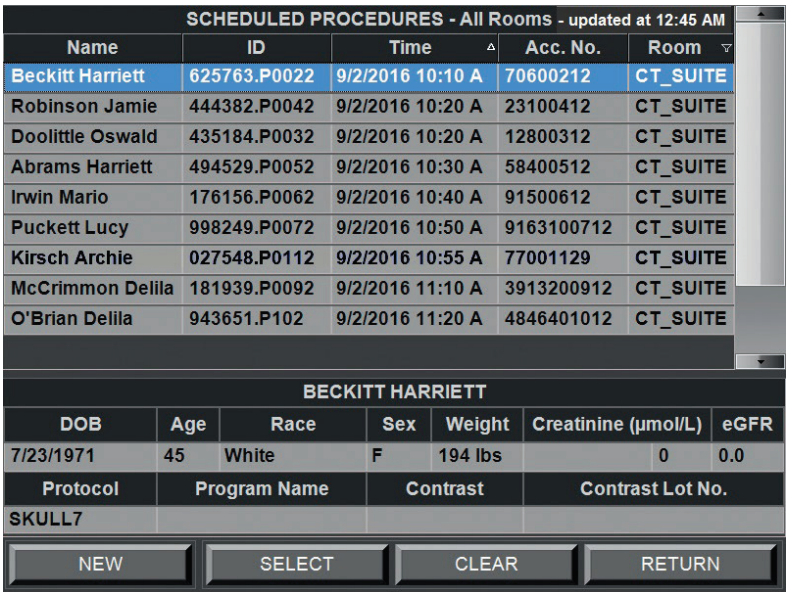
The Current Patient tab displays information about the patient who will undergo the injection procedure in the lower right corner of the Remote Control's main screen, as shown below:



Click on the Current Patient button to choose a patient from the worklist

Scheduled Procedures Screen

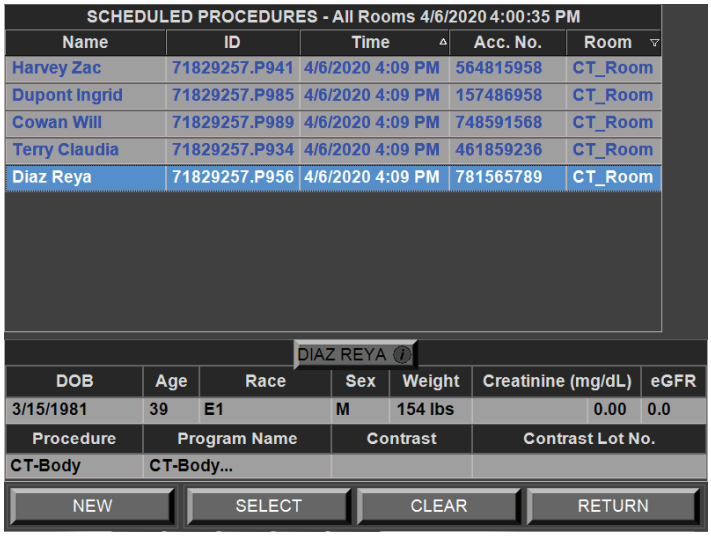
If the connection to the RIS is operational (green Nexo® Connection icon: ") and if the hospital's work list has scheduled patient procedures, then when you select the **Current Patient** tab, the system will display the **SCHEDULED PROCEDURES - All Rooms** work list (<hh:mm> of last data update), and it will highlight the patient that best matches the current time, as shown below:



Note that depending on Nexo® configuration, the list may display only the patients scheduled for that injector, or also the patients scheduled in other rooms.

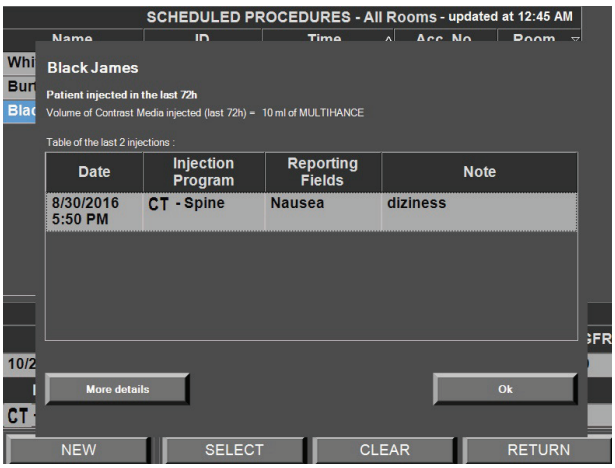
Scheduled Procedures Screen (continued)

The information regarding the Date of Birth (DOB), Race, Sex and Weight may come from RIS. If not, they can be inserted manually.
The Age is calculated by the injector by using the Date of Birth.
The information regarding the Creatinine, contrast and Contrast Lot Number must be inserted manually.
eGFR can be manually inserted or calculated through the eGFR calculator (refer to Creatinine and eGFR Setup on page 100).
Protocol information comes from RIS. The value displayed depends on Nexo® configuration.
If you change the weight of the patient, the new value will also be visible in Nexo® and in procedure reports stored in PACS. When patients have already at least one procedure completed in the past stored in Nexo®, then they are considered as returning patients. All procedures for this type of patients are displayed in blue backround (and all procedures for non-returning patients are displayed in black font). When a returning patient is selected, the patient name in the lower part of the screen becomes a clickable information button as shown below:



When the information button is clicked, a window appears informing whether the patient has been already injected in the last 72 hours and the total volume of contrast media injected in the last 72 hours (expressed in grams of Iodine). Also, a table shows the last two injections performed on the patient as shown below. When Nexo® Simplified Access screen is available, the button "More Details" redirects to this screen (see section "Scheduled Procedures Screen") and highlights the past procedures performed on the selected returning patient.

Scheduled Procedures Work List Options



Use the options available on the bottom of the Scheduled Procedures work list as follows:

Select	To..
NEW	Access the New Patient and Procedure screen.
SELECT	Causes the currently-selected patient data to appear in the Current Patient tab on the main screen.
CLEAR	Causes the currently-selected patient data not to appear in the Current Patient tab on the main screen.
RETURN	Causes the Current Patient tab on the main screen to remain unchanged.

Sorting Data on the Scheduled Procedures Work List

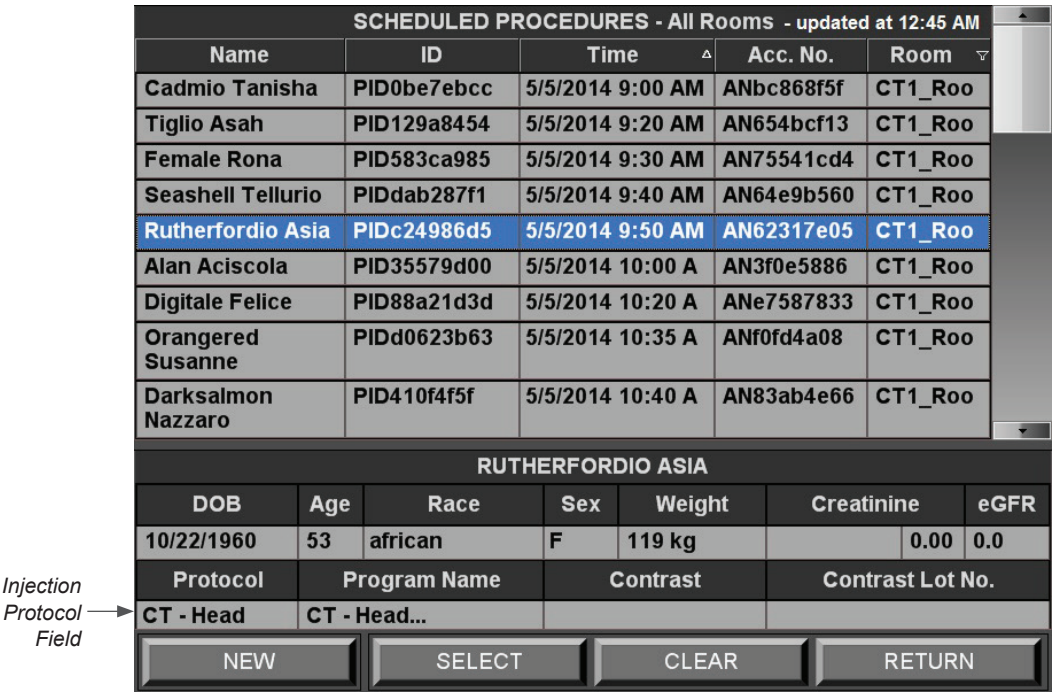
Data sorting options available on the Scheduled Procedures work list are as follows:

If you select	Then...
	The selected column will sort in *ascending* order.
	The selected column will sort in *descending* order.
Name	You may sort the list in alphabetical order, ascending or descending.
ID	You may sort the list in order of patient ID numbers, ascending or descending.
Time	You may sort the list by time of day, ascending or descending.
Acc. No.	You may sort the list by accession number, ascending or descending.
Room	You may sort the list by CT Suite room number, in alphabetical order, ascending or descending.
	You may select, from a pop-up menu, to view all scheduled procedures for a specific room, or no rooms, or all rooms, This symbol is referred to as the *filter* symbol.

Most users sort the workflow list by time, showing the order of the scheduled procedures for the day.

Protocol to Program Matching

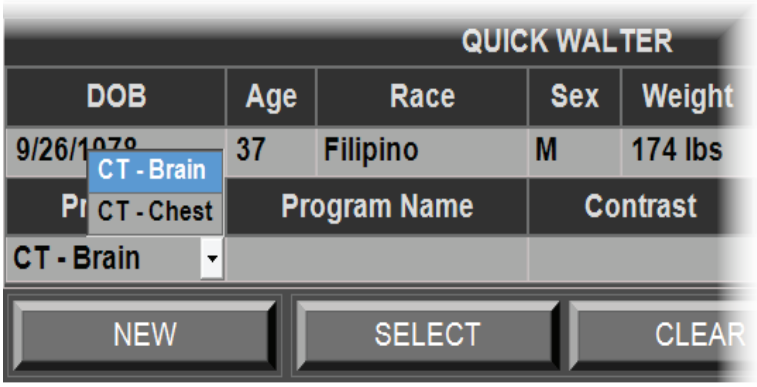
A patient's data on the SCHEDULED PROCEDURES work list includes an injection Protocol field.



Injection Protocol Field

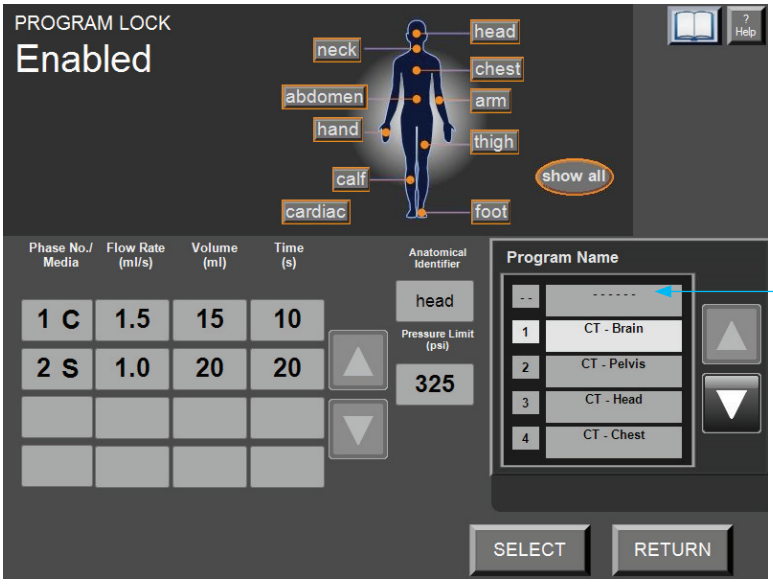
The protocol named in the Protocol field must correlate to an injection Program Name set up Nexo® and also visible on the PROGRAM screen of the EmpowerCTA®+ Injector.

A patient listed on the SCHEDULED PROCEDURES work list may have more than one injection procedure scheduled. When this is the case, you may select a protocol by clicking on the dropdown list at the bottom left of the screen, as shown below:

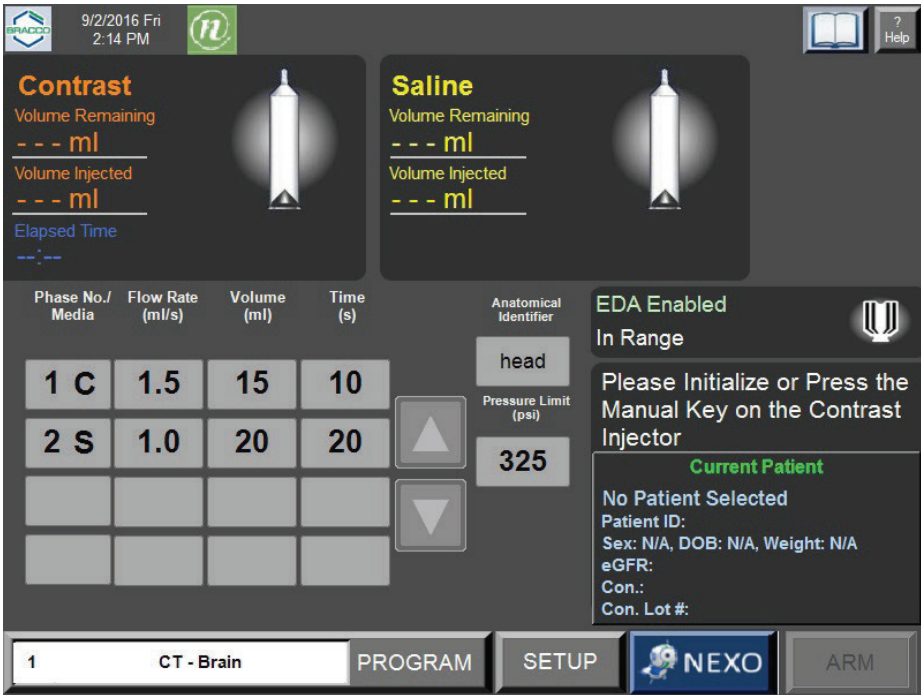


Protocol to Program Matching (continued)

When you select the patient and protocol from the SCHEDULED PROCEDURES work list, the associated program name is displayed, as shown in the example below:



When you choose the SELECT button, the protocol is displayed in the main screen. For example:



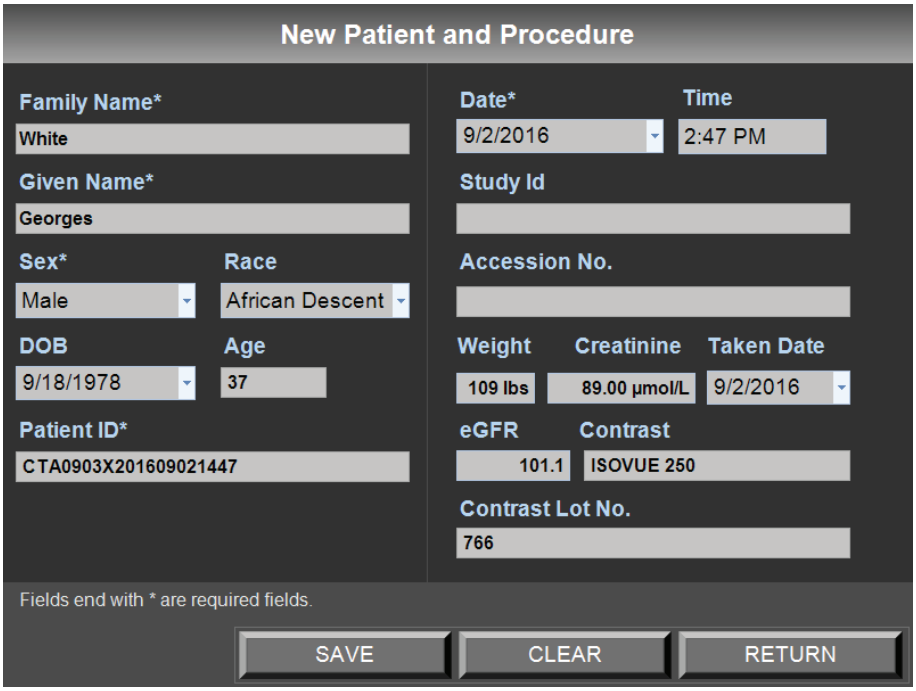
Using the Multi-programs Tab

A patient listed on the SCHEDULED PROCEDURES work list may have more than one injection procedure scheduled. If the patient selected had more than one procedure scheduled, a **Multi-Programs** tab will be displayed after the first injection program has been executed. You may select from two or more injection protocol names listed on the Multi-programs tab, as shown below:

Refer to paragraph "Reporting the Injection Procedure to the PACS" on page 80 which describes the procedure to complete at the end of each injection program execution.

Using the New Patient and Procedure Screen

When you select the **NEW** option from the SCHEDULED PROCEDURES - All Rooms list, or when you select from the **Current Patient** tab and there are no patient procedures scheduled in the hospital's work list or there is no connection with RIS, the **New Patient and Procedure** screen is automatically displayed, as shown in the example below. The default value for the **Family Name** parameter is the name of the local Remote Control. The default value for the **Given Name** parameter is the current date in the format *yyyymmddhhmm*. The default value for the **Patient Id** is the current date appended to the name of the local Remote Computer.



To enter patient data, select a desired field. The keyboard will appear:

Provide patient information for each field that has an asterisk (*) next to the field name and then select the SAVE button. The patient data you enter appears in the Current Patient area of the Remote Control main screen. Every subsequent time you open the New Patient and Procedure window, default data values will appear in the fields until you change them.

Using the New Patient and Procedure Screen (continued)

A description of each field on the New Patient and Procedure screen is as follows:

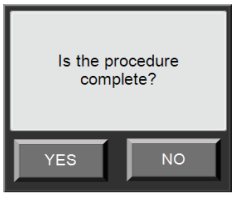
Field	Description
Family Name*	Patient's last name. This is a required field.
Given Name*	Patient's first name. This is a required field.
Sex*	A drop-down list enables you to select Male, Other, Female, or None. This is a required field.
Race	A drop-down list enables you to select Other, African Descent., or None.
DOB	Date of Birth. You may use the on-screen keyboard (or the pop-up calendar) to enter the patient's birth date in the following format: *mm/dd/yyyy* or *dd/mm/yyyy* depending on your language settings.
Age	Age of the patient. If the date of birth is specified, then the age is automatically calculated and displayed in this field. If the date of birth is not entered, then this field will remain blank.
Patient ID*	Patient's identification number. May be alphanumeric up to 64 characters. This is a required field.
Date*	Date of the injection procedure. You may select the date from a pop-up calendar (or use the on-screen keyboard). The default value is the current date. This is a required field.
Time	You may use the on-screen keyboard to change the time using the format, *hh:mm*, where *hh* is the hour and *mm* is the minute.
Study ID	You may use the on-screen keyboard to enter the patient's Study Identification number. May be alphanumeric up to 16 characters.
Accession No.	You may use the on-screen keyboard to enter the patient's Accession Number. May be alphanumeric up to 16 characters.
Weight	You may use the pop-up keypad to enter the patient's weight. The range is 50 to 600 pounds or 23 to 273 kgs.
Creatinine	You may use the pop-up keypad to enter the patient's creatinine value. The range is 0.3 to 7.0 mg/dL or 26 to 618 µmol/L
Taken Date	You may use the pop-up calendar or the on-screen keyboard to enter the date the patient's creatinine was measured using the format: *mm/dd/yyyy* or *dd/mm/yyyy* depending on your language settings.

Once you have entered the required information on the New Patient and Procedure screen, you may choose one of the three options:

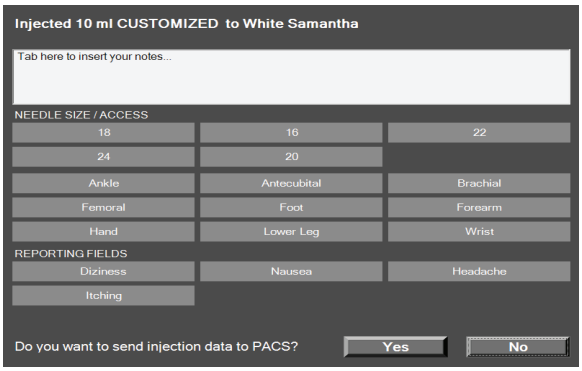
Select...	To...
SAVE	View the new patient information in the Current Patient tab on the main screen.
CLEAR	Clear/delete any data entered and reset the data to system defaults.
RETURN	Discard the changes and return to the SCHEDULED PROCEDURES-All Rooms list.

Reporting the Injection Procedure to the PACS

At the end of an injection, the following window will automatically appear:



Select YES when the procedure has been completed successfully and you want to report it to the PACS. You can select NO if you don't wish to report this procedure, or if there are other procedures still scheduled for this patient (example: Multi-Programs). If you click YES, you will be prompted as follows:



Selecting the gray placeholder for notes, will make the keyboard appear:

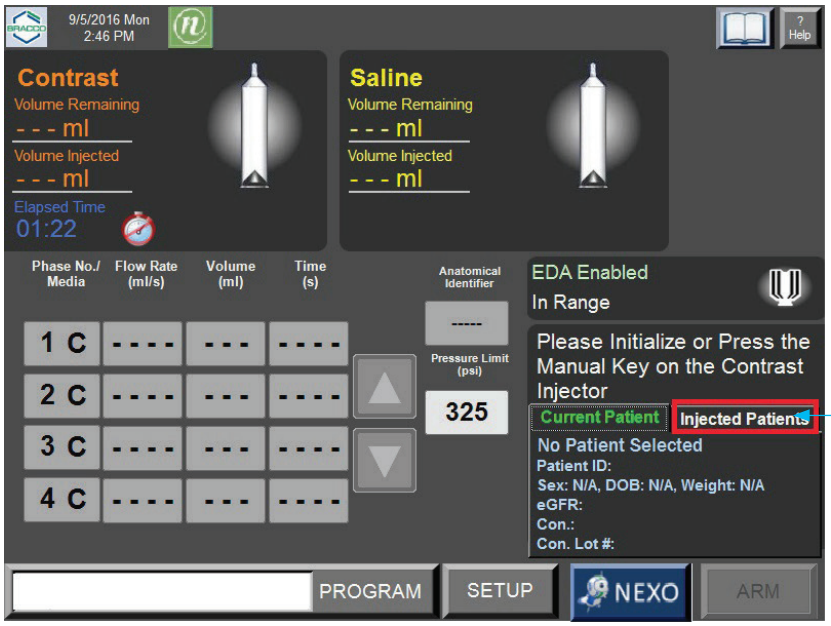
You can then enter free text that will be transmitted along with the report to the PACS.

More information on the performed injection can be transmitted by completing additional fields such as needle size, vascular access point on patient body ,etc. The list of available fields is predefined by the hospital through Nexo® and allows you to record specific observations regarding the patient's injection. You can activate or deactivate the field of interest by pressing the associated button.

Click YES to proceed sending the report, or NO to cancel.

Using the Injected Patients Tab

The Injected Patients tab may appear on the main screen if injections have been performed using the new patient feature and the injector is connected to the hospital's PACS network OR if the user decided not to send the injection report to PACS right after the injection procedure was completed.

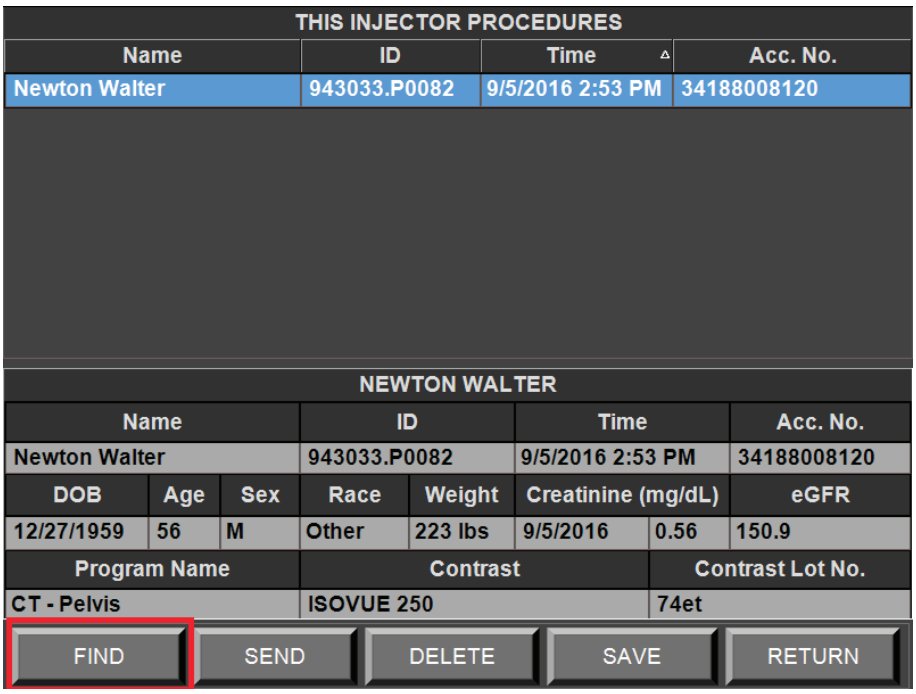


Use the Injected Patients tab to correlate the patient data stored in the EmpowerCTA®+ system with the patient data shown on the work list.

When you select the Injected Patients tab, the system displays the Manage Patients button and a message displays if there are one or more completed patient injection procedures not stored in the hospital's PACS. For example:

Using the Injected Patients Tab (continued)

When you select the **Manage Patients** button, the THIS INJECTOR PROCEDURES screen shows the procedures that have been performed by the EmpowerCTA®+ injector and not yet stored in the hospital's PACS system, as shown in the example below:



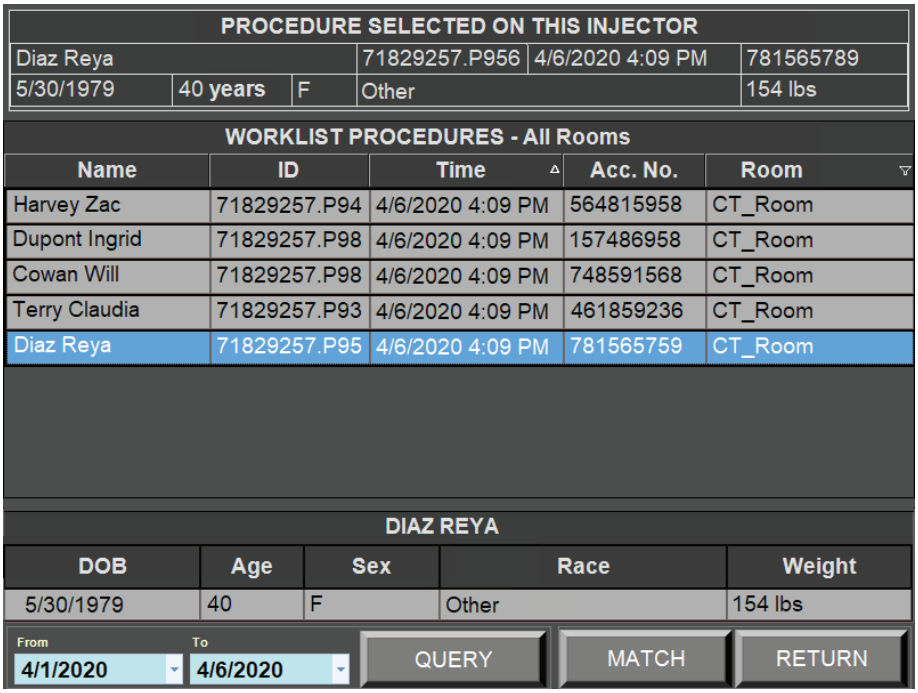
For each patient listed on the THIS INJECTOR PROCEDURES screen, you may:

- merge the data with the data in the hospital work list by selecting the **FIND** button;
- store the data in the hospital's PACS system by selecting the **SEND** button;
- delete the data by selecting the **DELETE** button;
- edit the data in the fields displayed in the lower half of the THIS INJECTOR PROCEDURES screen and then select the **SAVE** button to save the edited changes to the EmpowerCTA®+ system; or
- return to the main screen by selecting the **RETURN** button.

Using the Find Option

When you select the FIND button, the system displays a screen that shows the procedure selected on the injector, and the work list procedures for all rooms.

For example:



PROCEDURE SELECTED ON THIS INJECTOR					
Diaz Reya			71829257.P956	4/6/2020 4:09 PM	781565789
5/30/1979	40 years	F	Other		154 lbs

WORKLIST PROCEDURES - All Rooms

Name	ID	Time	Acc. No.	Room
Harvey Zac	71829257.P94	4/6/2020 4:09 PM	564815958	CT_Room
Dupont Ingrid	71829257.P98	4/6/2020 4:09 PM	157486958	CT_Room
Cowan Will	71829257.P98	4/6/2020 4:09 PM	748591568	CT_Room
Terry Claudia	71829257.P93	4/6/2020 4:09 PM	461859236	CT_Room
Diaz Reya	71829257.P95	4/6/2020 4:09 PM	781565759	CT_Room

DIAZ REYA

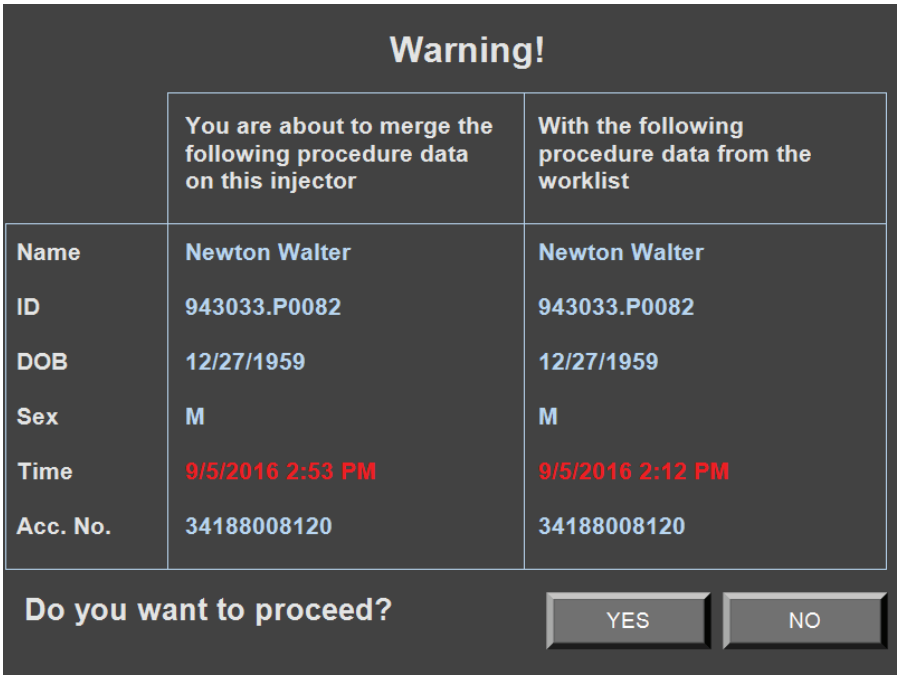
DOB	Age	Sex	Race	Weight
5/30/1979	40	F	Other	154 lbs

From 4/1/2020 To 4/6/2020 QUERY MATCH RETURN

You can specify a range of dates to locate the desired patient name in the work list using the QUERY button. Once you have selected the patient on the work list that correlates to the patient in the PROCEDURE SELECTED ON THIS INJECTOR section of the screen, you may select the MATCH button to combine patient data. On-screen prompts enable you to proceed or not. To do nothing, select the RETURN button.

Using the Find/ Match Option

When you select the MATCH button, the system provides an opportunity to review the procedure data, as shown below:

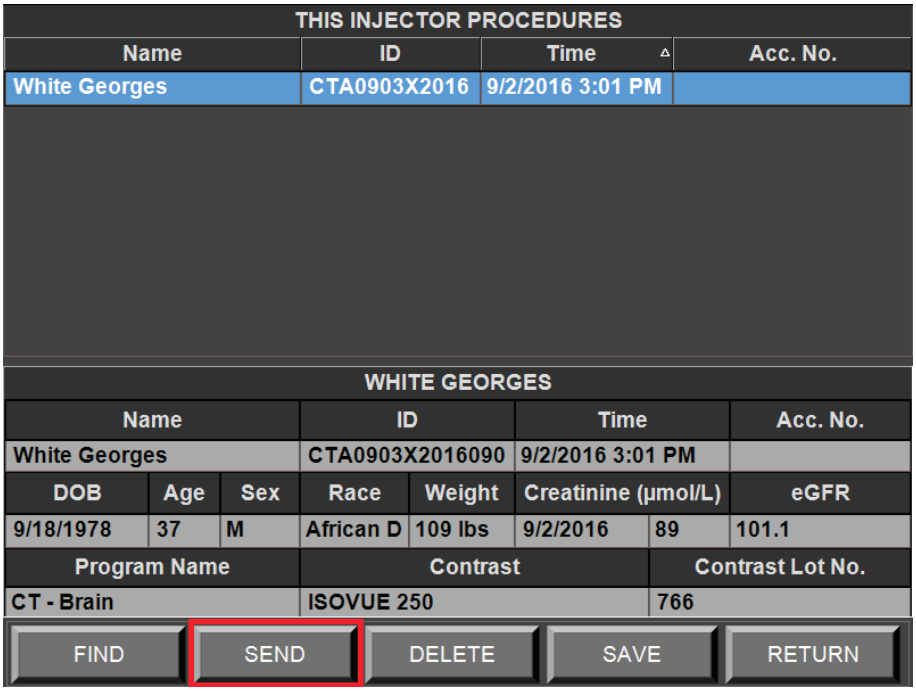


Note that the text that appears in red indicates that the procedure data in the injector does not match the data on the work list. If you select NO, the previous screen is displayed again. If you select YES, then the procedure data on the injector is merged with data coming from RIS and stored on the hospital's PACS system. The THIS INJECTOR PROCEDURES screen will no longer display the matched patient name.

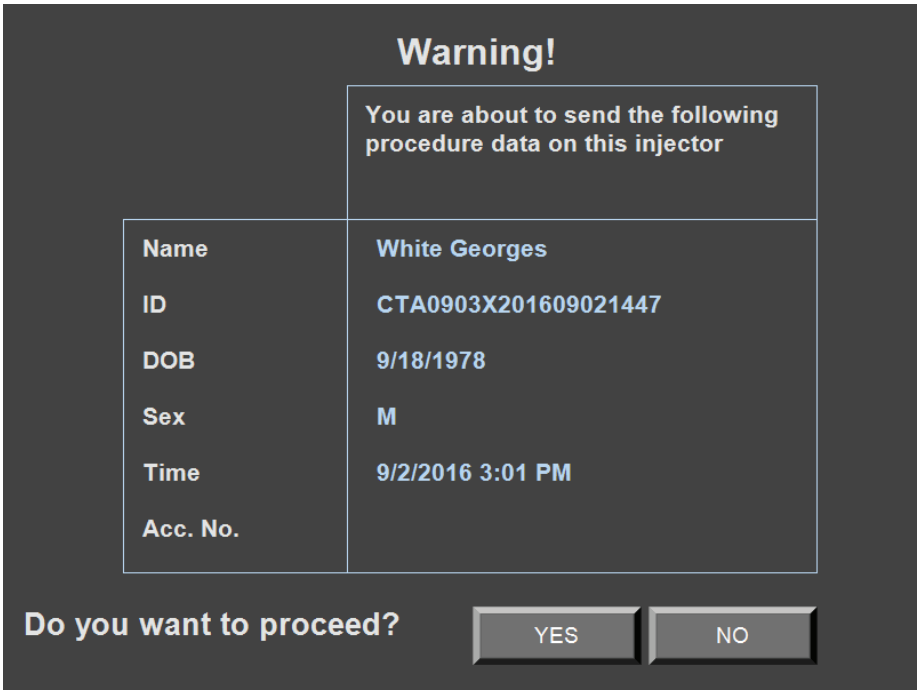
You must select the RETURN button to return to the main screen:

Using the Send Option

To store the procedure data on the hospital's PACS network, select the SEND button from the THIS INJECTOR PROCEDURES screen (shown below):



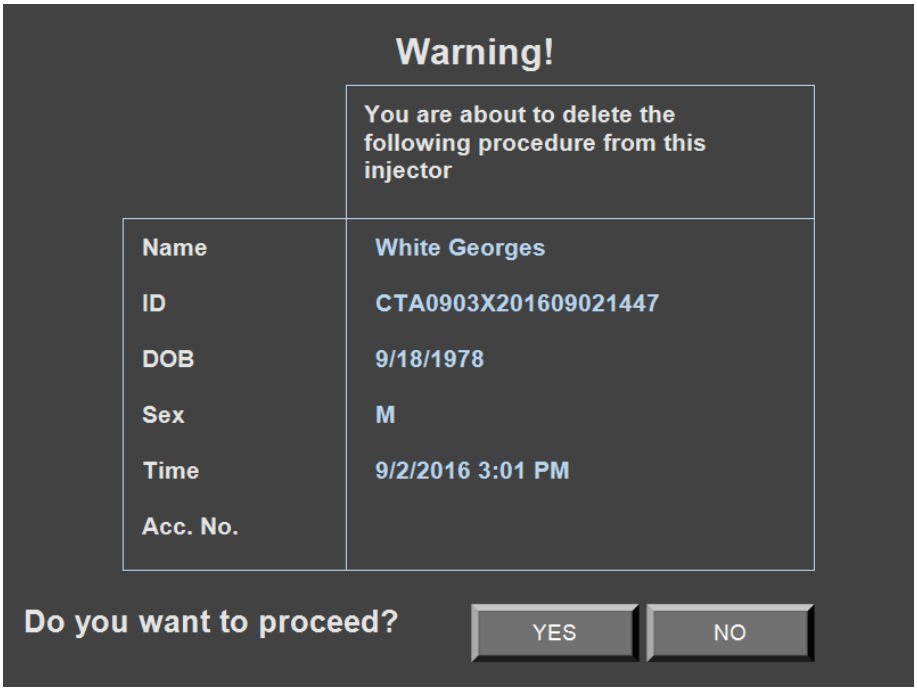
When you select the SEND button, the following type of screen displays:



If you select YES, the system will store the procedure data and remove the patient from the list. If you select NO, the procedure data will not be stored on the PACS and the THIS INJECTOR PROCEDURES screen is displayed.

Using the Delete Option

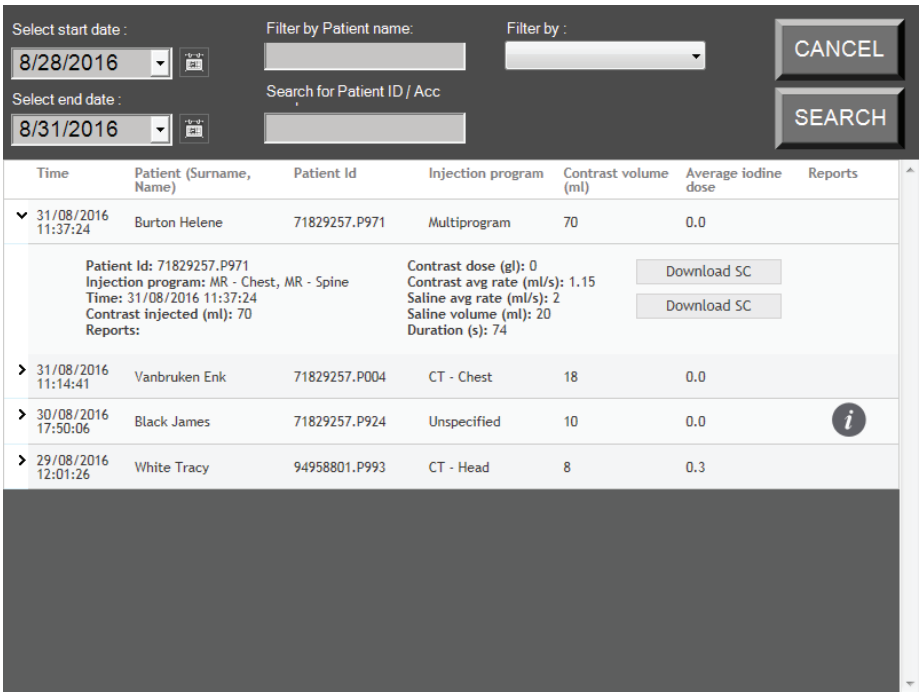
To delete procedure data stored on the injector, select the DELETE button from the THIS INJECTOR PROCEDURES screen. The system prompts you to confirm or decline, as shown below:



If you select YES, the procedure data will be deleted from the THIS INJECTOR PROCEDURES screen. If you select NO, the THIS INJECTOR PROCEDURES screen remains unchanged. Select the RETURN button to return to the main screen.

Using the Simplified Nexo® Access

The Nexo® blue button in the lower right corner of the Remote Control's main screen displays the Simplified Nexo Access as shown below:



If the connection with Nexo is operational (green Nexo® Connection icon:) the system will display the list of procedures completed and sent to PACS in the last 3 days. Clicking on the arrow to the left of each procedure will expand the view, showing more details about the injected patient and injection parameters. The Secondary Capture of the procedure stored in PACS can be viewed by pressing the **Download SC** button. When patient went through more than one injection procedure (multi-program), a **Download SC** button will be shown for each one as shown on the figure above.

The list of executed procedures can be filtered by date, patient name, patient ID, patient accessory number and/or by reporting fields that were specified in Nexo®. Refer to paragraph "Reporting the Injection Procedure to the PACS" on page 80 which describes the procedure to complete at the end of each injection program execution and the reporting fields that were specified in Nexo®. The button **SEARCH** must be pressed in order for the filters to apply.

6 System Configuration

The Setup Screen

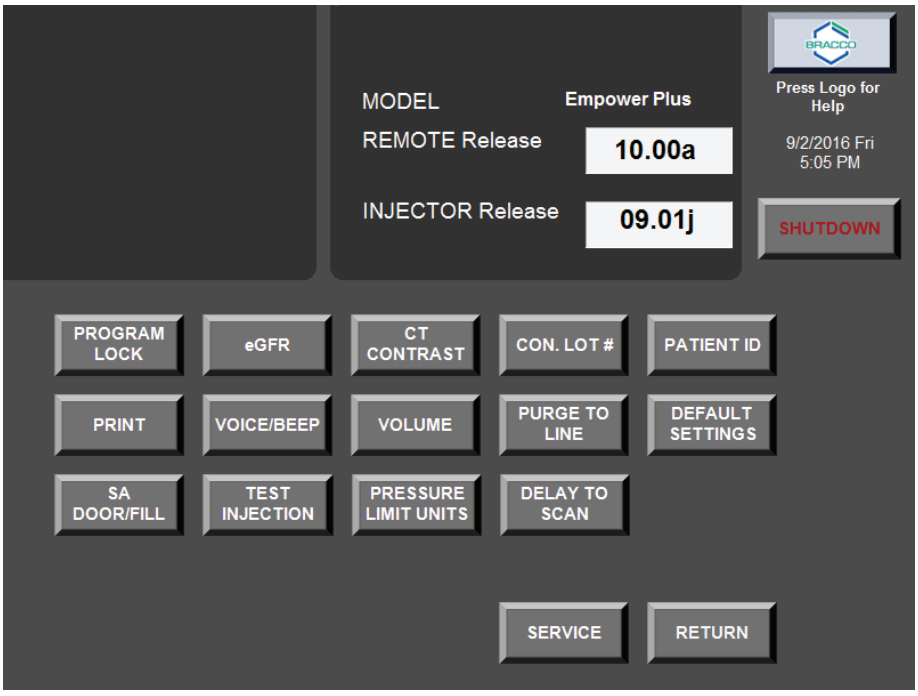
To view the Setup screen, select the **SETUP** button on the Main screen on the Remote Control.

EmpowerCTA®+ Remote Control has a software module called IRiSCT® (Injector Reporting Information System CT). This software records contrast medium, injections and EDA utilization, plus the patient ID, program name, creatinine and eGFR values, CT contrast medium brand and concentration, and the CT contrast medium lot code. IRiSCT® is configured through the Setup screen.

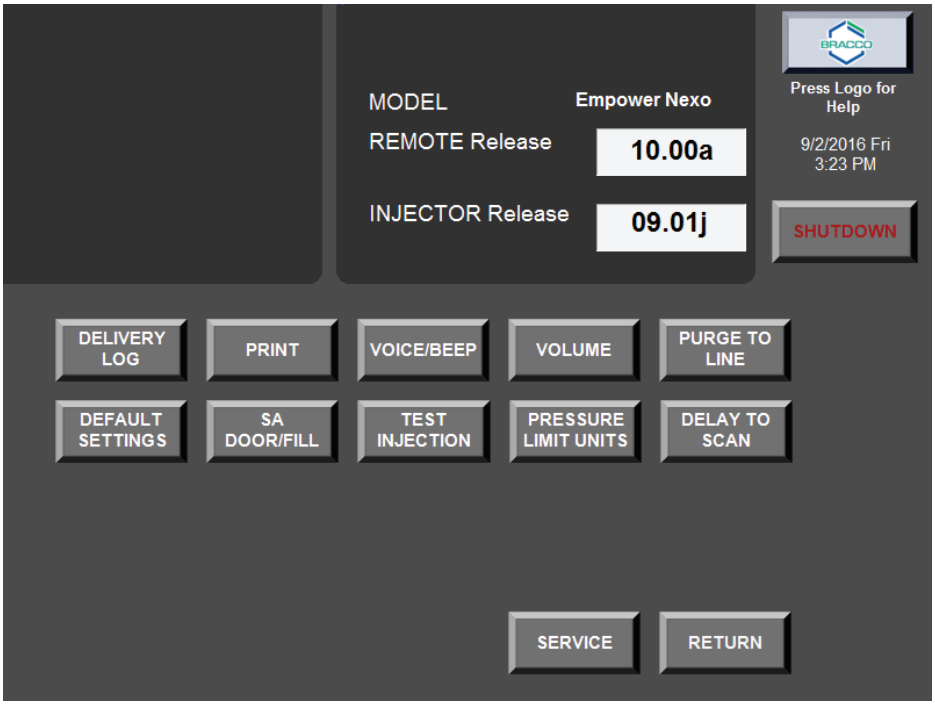
The Setup screen can also be used to set other user-configurable system options and to shut down the Remote Control. The Setup screen also provides local authorized and qualified Bracco Injeneering S.A. representatives with access to service functions.

The Setup Screen (continued)

The Setup screen appears as shown below:



Nexo® system provides all the functionalities of IRiSCT® with additional features and integration to the hospital information system. This is why IRiSCT® is disabled when Nexo® is used. As a consequence, all its configuration buttons are hidden in the Setup screen, which appears as shown below:



The Setup Screen (continued)

Setup Screen Options

The following table describes the functions of the buttons in the Setup screen.

Setup Screen Option (Button)	Instruction
CON. LOT #	Enables or disables the option to enter the contrast medium lot code when using the CT CONTRAST button on the IRiSCT® panel to specify the type of contrast medium. The default setting is Enabled. When CT CONTRAST is set to Off and the CON LOT # option is set to Enabled, the CT CONTRAST option is automatically set to Basic. For more information about entering the contrast medium lot code when the CON LOT# option is enabled, see page 97.
CT CONTRAST	Sets the method that the system uses to remember the CT Contrast entry. Select the CT CONTRAST button until the desired setting appears. The default setting is Expert. • In Expert mode, use the CT CONTRAST button in the IRiSCT® panel to specify the type of CT contrast medium (brand, concentration, optional lot code). The system will remember the last entry for every procedure, until you select another type of contrast medium or shut down the Remote Control. • In Basic mode, you can also specify the type of CT contrast medium, but the system will remember it for one procedure only. The entry will be reset when you confirm the end of the procedure or when the syringe ram reaches the Replace Syringe position. • In Off mode, the IRiSCT® panel does not include the CT CONTRAST button, and the CON LOT # option is automatically set to Disabled. For more information about using the CT CONTRAST button on the IRiSCT® panel, see page 97.
DEFAULT SETTINGS	Restores settings to their factory default values. The system will ask for confirmation. If you have questions about changing settings to their factory defaults, contact your local Bracco Injeneering S.A. technical support representative before doing so.

The Setup Screen (continued)

Setup Screen Option (Button)	Instruction
DELAY TO SCAN	Enables or disables the ability to program a time-delayed “start the scanner” voice message. This button will not be available if the EmpowerSync® option has been activated. More details are provided on page 95. The default setting is Disabled.
eGFR	Allows you to specify whether the user has access to the eGFR calculator or the ability to enter Creatinine. Options are Expert, Basic or Off. Select the eGFR button until the desired option is displayed. For further setup details, see page 100. The default setting is Expert.
PATIENT ID	Enables or disables the user’s ability to enter the patient ID for the IRiSCT® system. For more details, see page 108. The default setting is Enabled.
PRESSURE LIMIT UNITS	Sets the units for the pressure limit setting to psi or kPa or bar. Press this button to display the next option. The default setting is psi.
PRINT	Enables or disables the optional label printer. The default setting is Disabled.
PROGRAM LOCK	Enables or disables the ability to modify the programs stored in the Remote Control. See page 67 for more information. The default setting is Disabled.
PURGE TO LINE	Enables or disables your ability to use the Purge Line feature on the Injector. The default setting is Disabled. For more information about the Purge Line function, see page 39.
RETURN	Returns to the Main screen.
SA DOOR/FILL	This option can be set to Enabled or Disabled. When the SA DOOR/FILL option is set to Enabled, the Injector will add 25 ml to the saline syringe during a Protocol Fill operation, the saline syringe will be initialized using the Auto Initialize feature even if a saline phase is not programmed at the Remote Control, and the Saline Advance feature will be available on the Injector even if a saline phase is not programmed on the Remote Control. The default setting is Disabled. For more information about using the Saline Advance option, see page 47.

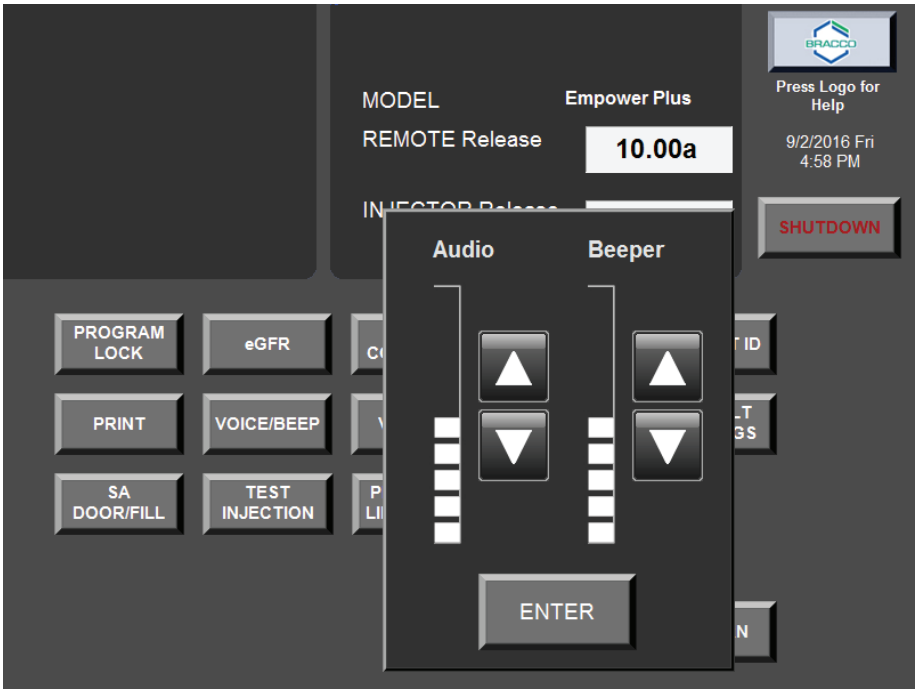
The Setup Screen (continued)

Setup Screen Option (Button)	Instruction
SERVICE	Proceeds to either the supervisor or service menu area. This option is for local Bracco Injeneering S.A-authorized representatives and is password protected.
SHUTDOWN	Closes the Remote Control software and then turns off power to the Remote Control. The system will ask for confirmation before proceeding. For more information, see page 111.
TEST INJECTION	Enables or disables the Test Injection feature. For more information, see page 47. The default setting is Disabled.
VOICE/BEEP	Enables or disables voice messages, except for “Check for Possible Extravasation,” which cannot be disabled. The default setting is Voice Message Enabled.
VOLUME	Allows you to change the audio volume of the voice messages and beeps emitted by the system. For more information, see page 94.

The Setup Screen (continued)

Changing the Audio Volume

To change the volume of the audio voice messages or the beeper tone, select the **VOLUME** button in the Setup screen. A pop-up window displays two volume bars as shown below:



The bar on the left represents the volume of the voice messages and the message beeps. The bar on the right represents the volume of the tone that sounds when the user touches the Remote Control touch screen.

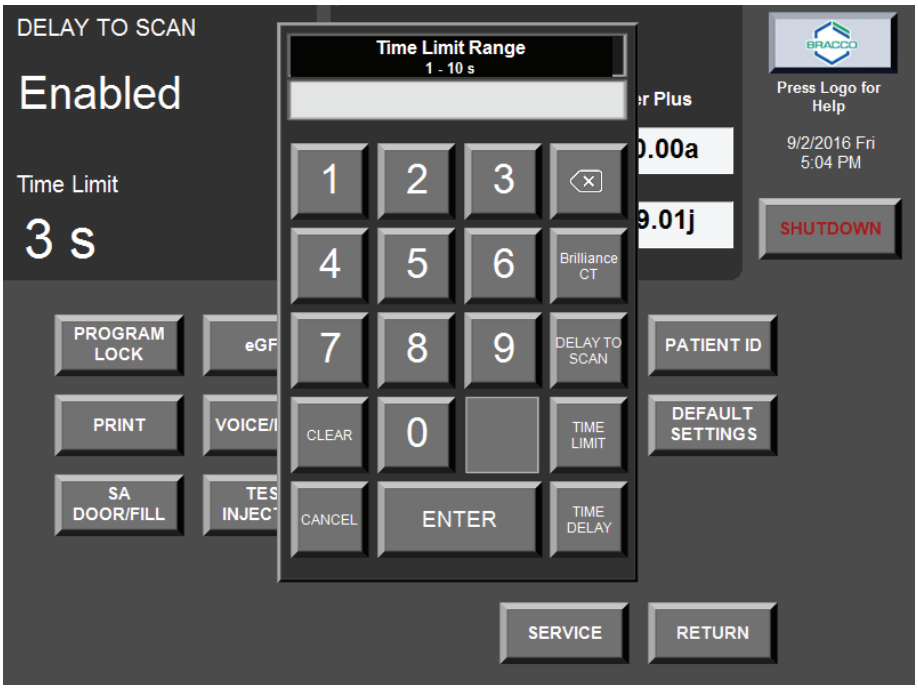
To adjust either of the displayed volume bars, and the corresponding volume, select the up or down arrow buttons immediately to the right of the bar to be adjusted. The Remote Control will play an example of the new volume to let you confirm the new volume level.

When you are satisfied with the volume settings, select **ENTER**.

The Setup Screen (continued)

Enabling or Disabling the Delay to Scan Feature

Selecting the **DELAY TO SCAN** button in the Setup screen displays the Time Limit Range keypad window, as shown below:



The DELAY TO SCAN button on the keypad enables the single or dual Delay to Scan feature or disables it entirely. Select the **DELAY TO SCAN** button in the pop-up keypad window until the desired state (Disabled, Enabled or Dual Enabled) is shown in the upper left corner of the screen, then select **ENTER**. If Delay to Scan is set to Dual Enabled, two separate Delay to Scan fields will be displayed on the Main screen.

Enabling the Delay to Scan as either Single or Dual will display the TIME LIMIT and TIME DELAY buttons on the keypad. Disabling the Delay to Scan will hide the TIME LIMIT and TIME DELAY buttons.

Time Delay: After the Delay to Scan time has elapsed, this is the delay time before the CT trigger signal is sent to the scanner.

Time Limit: This is the time limit that the scanner can remain on after the CT trigger signal is sent to the scanner.

A local authorized Bracco Injeneering S.A. representative can invoke the Philips Brilliance CT scanner synchronization option. Consult with a local authorized Bracco Injeneering S.A. representative for supported hardware compatibility and interoperability. Once the Philips Brilliance CT is activated, the Delay to Scan feature will be removed from the Main screen, and the Time Limit and Time Delay parameters will not be used.

The Setup Screen (continued)

This feature allows the scanner to know if the Injector status is in RUN Mode. A signal will be sent to the Philips Brilliance CT scanner whenever the Injector enters the RUN mode from either the ARM or the PAUSE mode. The signal will be turned off whenever the Injector enters PAUSE or STOP mode.

This feature requires an interconnect cable that connects the EmpowerCTA®+ Injector System to the target scanner or device. If not properly connected and the feature is activated, the message "Check Scanner Cable" displays on the Remote Control.

WARNING

If you select a scanner option, make sure that the interconnect cable is installed. The unit will not arm unless the cable has been installed and properly tested.

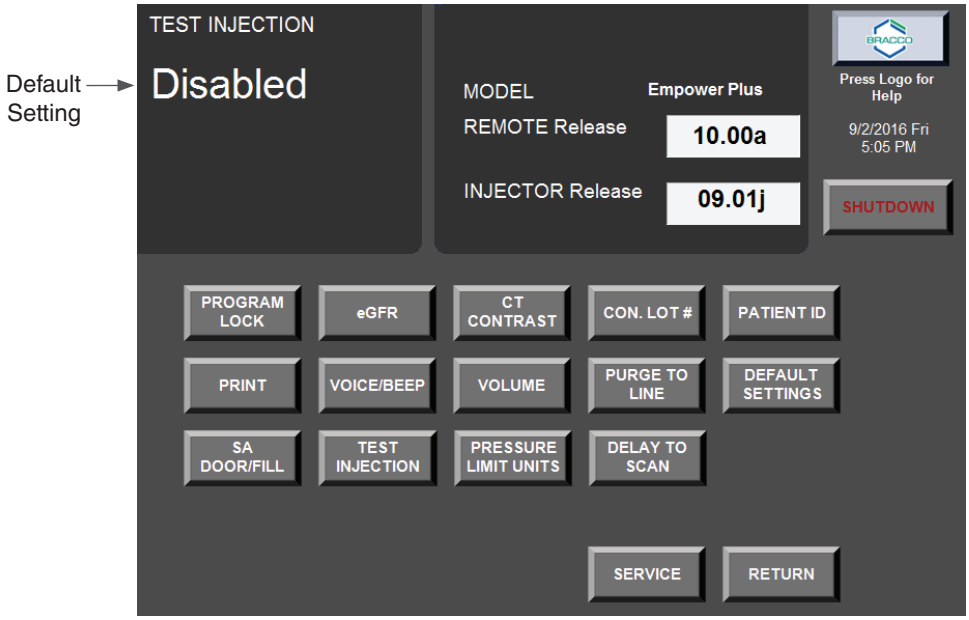
To leave this window without making any changes, select **CANCEL**.

Enabling or Disabling the Test Injection Feature

When the TEST INJECTION button is selected in the Setup screen, the current TEST INJECTION setting (Enabled or Disabled) will be displayed in the upper left hand corner.

The default setting is Disabled, as shown below. Select the **TEST INJECTION** button to toggle the feature from Disabled to Enabled.

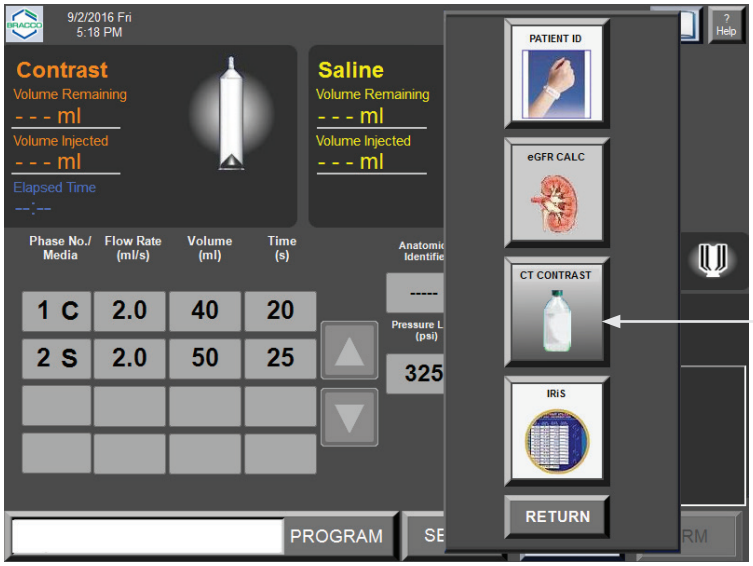
When the Test Injection feature is enabled, a test injection can be programmed in the phase table on the Main screen to take place prior to the first injection phase. For more information, see "Using the Test Injection Feature" on page 47.



The Setup Screen (continued)

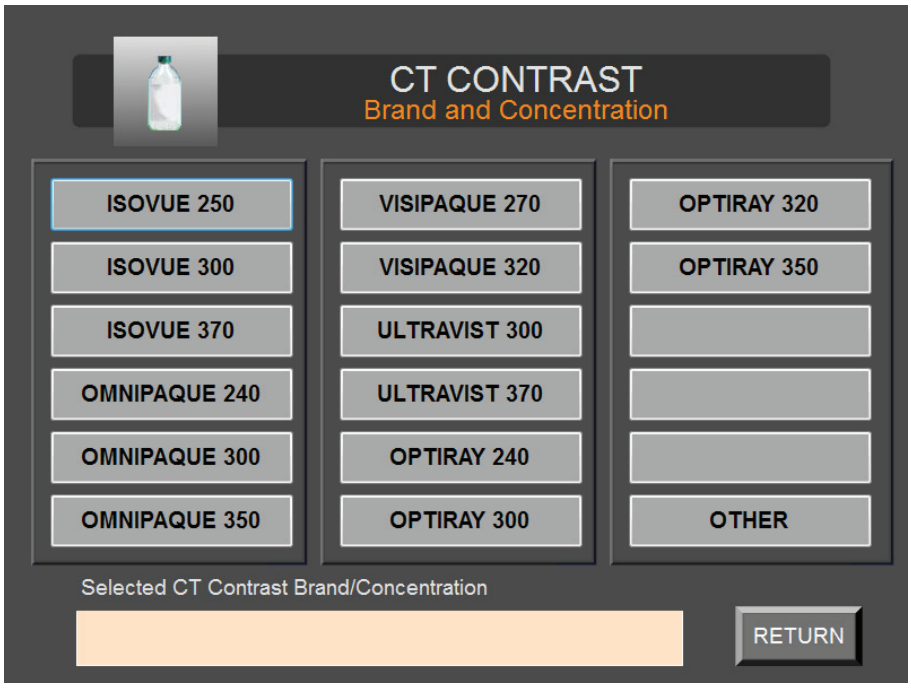
CT Contrast and Lot Code Entry

If the CT CONTRAST option is set to Basic or Expert in the Setup screen, the IRiSCT® panel includes the CT CONTRAST button. On the Main screen, select the **IRiSCT** button, then select **CT CONTRAST** in the IRiSCT® panel, as shown below.



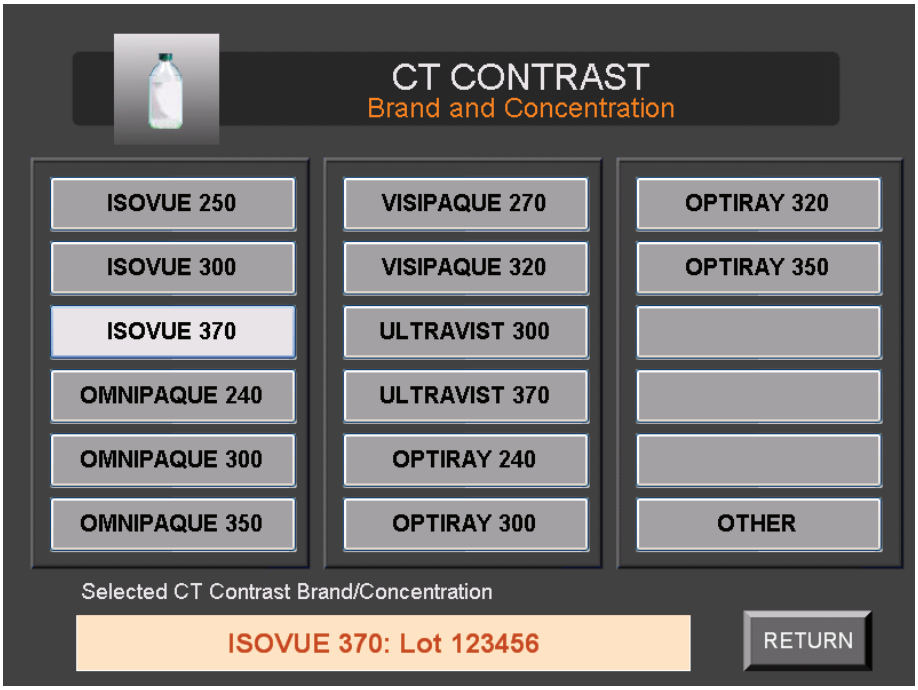
Next, a list of CT contrast media brands and concentrations is displayed for selection.

Select the brand and concentration of CT contrast medium to be used for the upcoming injection from the list. If the CON LOT # option is set to Enabled, the system will also prompt you to enter the contrast medium lot code.



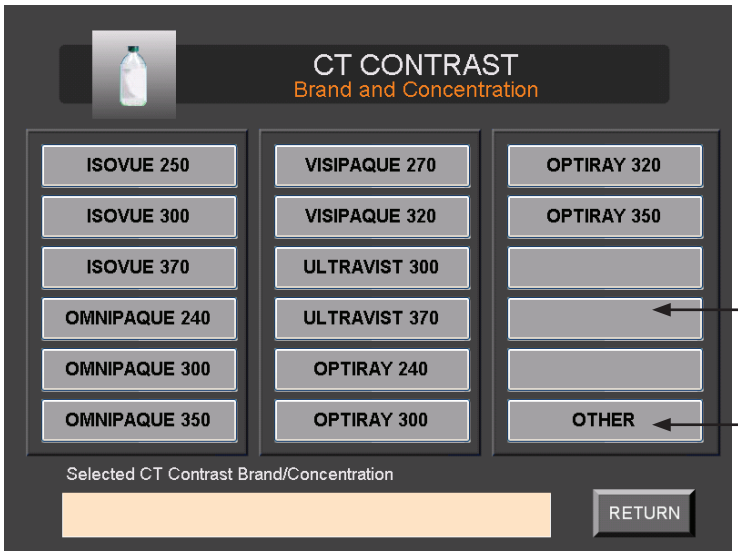
The Setup Screen (continued)

The selected brand, concentration, and lot code (if entered) is displayed at the bottom of the screen, as shown in the example below:



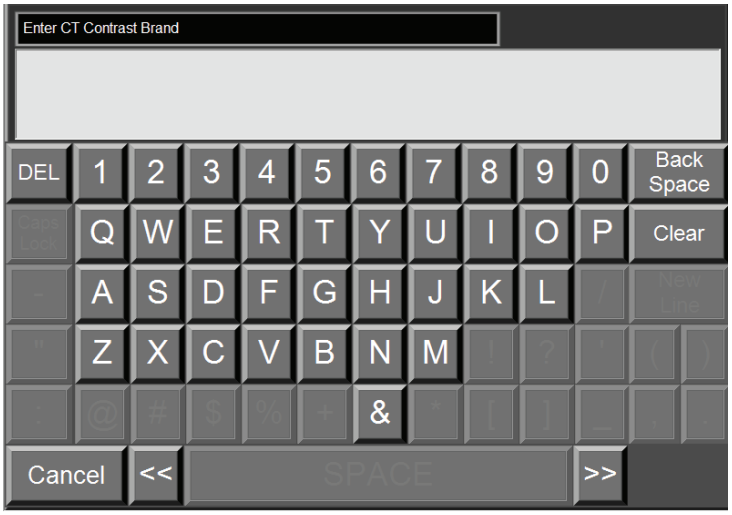
Verify that the selected CT contrast medium brand and concentration are correct, then select **RETURN**.

In addition, CT contrast media brands and concentrations that are not displayed in the window can be manually entered by selecting **OTHER** in the Brand and Concentration list. The system can record up to three user entries; starting with the fourth entry the oldest user entry will be overwritten when another entry is added.



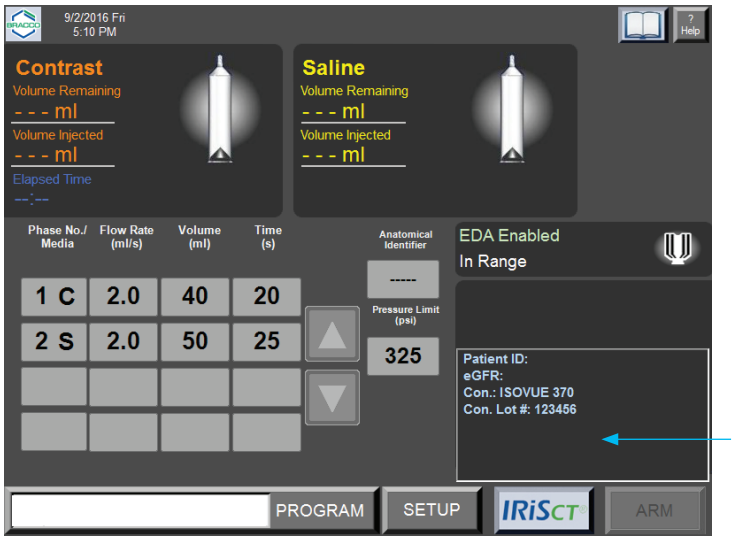
The Setup Screen (continued)

In the pop-up keypad, manually enter the brand name of another type of contrast medium (up to 12 characters). Following the brand entry, another pop-up keypad window will prompt you to enter the contrast medium concentration (maximum 4 characters). The entry will then appear in one of the three available user-specified contrast medium entries, in the lower right corner of the CT CONTRAST screen.



Verify that the selected CT contrast medium type and lot code (if entered) match the contrast medium type for the upcoming procedure and then select **RETURN**.

The Main screen will then display the contrast medium brand and concentration plus the lot code (if it was entered), as shown below:



Contrast Medium Brand, Concentration, and Lot Number

WARNING

Prior to each injection, the CT Contrast Brand and Concentration should be reviewed for accuracy. It is the sole responsibility of the facility to assure that the value selected is accurate.

The Setup Screen (continued)

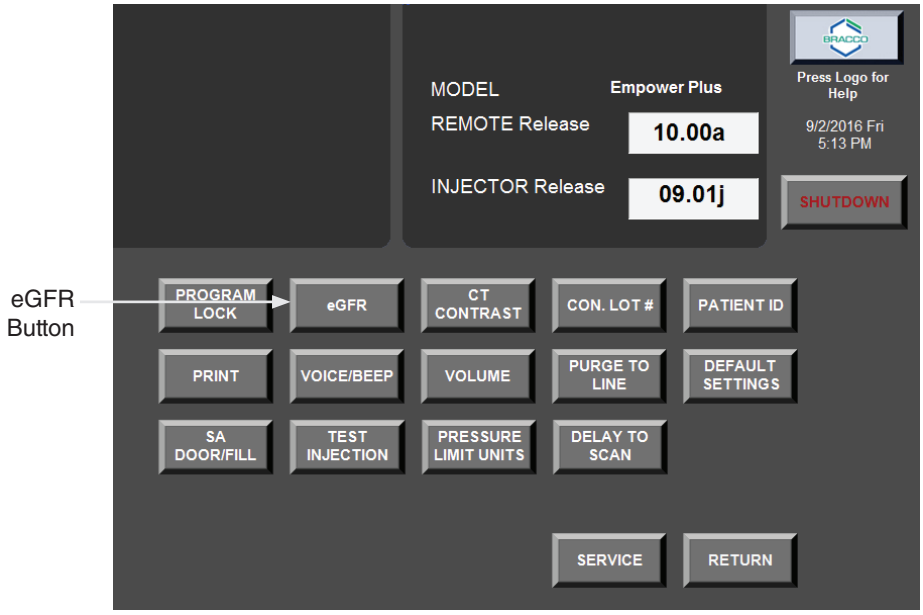
Reminder: if the CT CONTRAST option in the Setup screen is set to Basic, the CT Contrast and CT Contrast Lot Code will be removed the next time the contrast syringe moves into the Replace Syringe position. If CT CONTRAST is set to Expert mode, the CT Contrast and CT Contrast Lot Code will be changed only if you select another contrast medium brand and concentration, or if the Remote Control is shut down and restarted.

Creatinine and eGFR Setup

IRiSCT® will store the values of the creatinine and eGFR (estimated Glomerular Filtration Rate) for each patient. The eGFR 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, sex and race. The eGFR, in conjunction with creatinine level, can be used as tools for the facility for use with CT contrast injections. The eGFR and creatinine values are additional screening tools for use by the facility to determine the use of CT contrast as part of CT scan. It is the facility's ultimate responsibility to review these values and determine the best course of action for the patient.

This eGFR Calculator is intended to assist the facility in determining whether a patient's renal function allows for the administration of IV contrast. It is not intended to act as a substitute for a physician's diagnosis of conditions, which may preclude the administration of IV contrast or the patient's ability to accept the procedure.



The Setup Screen (continued)

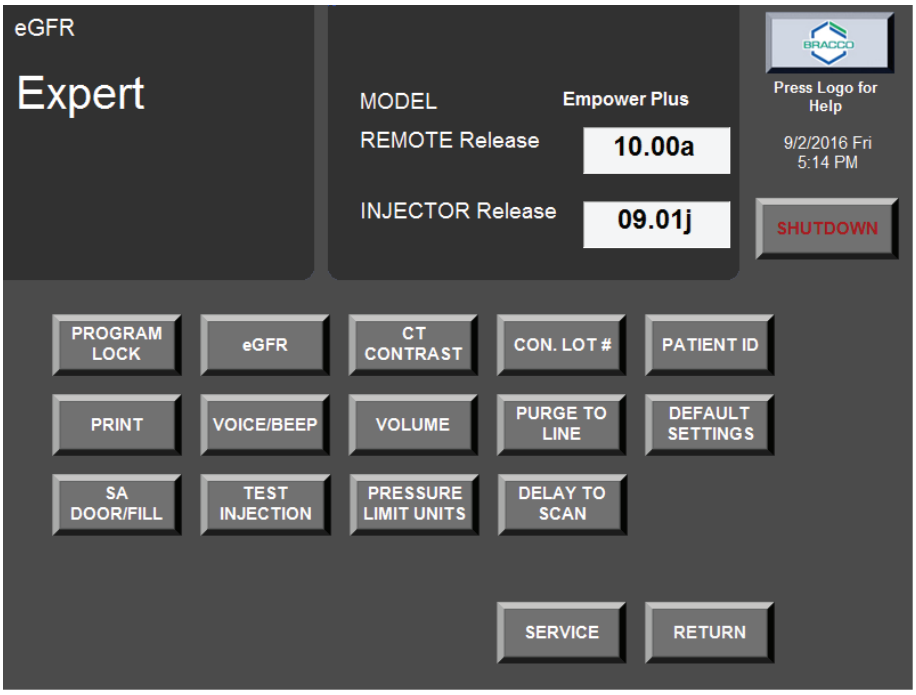
When using the eGFR Calculator, you should not assume that the patient does not have chronic kidney disease (CKD) until a physician confirms it. eGFR estimates may not be reliable in certain individuals as there are other factors besides CKD that can yield erroneous eGFR values. It is important that you talk to the physician if you have any concerns about a patient's kidney function or the results from using this calculator. This eGFR Calculator is to be used for adults 18 years and older.

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.

Select the **eGFR** button on the Setup screen to toggle the eGFR setting to one of the following values:

eGFR Setting	Description
Off	In Off mode, the IRiSCT® panel will not display the option to use the eGFR Calculator or store the Creatinine value.
Basic	In Basic mode, the IRiSCT® panel will display the option to store the Creatinine value. The Creatinine value entered will be displayed for one procedure only.
Expert	In Expert mode, IRiSCT® panel will include the eGFR calculator. The eGFR value entered will be displayed until you change it or until the Remote Control is shut down and turned on again.

The current eGFR setting is displayed in the upper left corner of the Setup screen, as shown below.



The Setup Screen (continued)

eGFR Calculation Setup

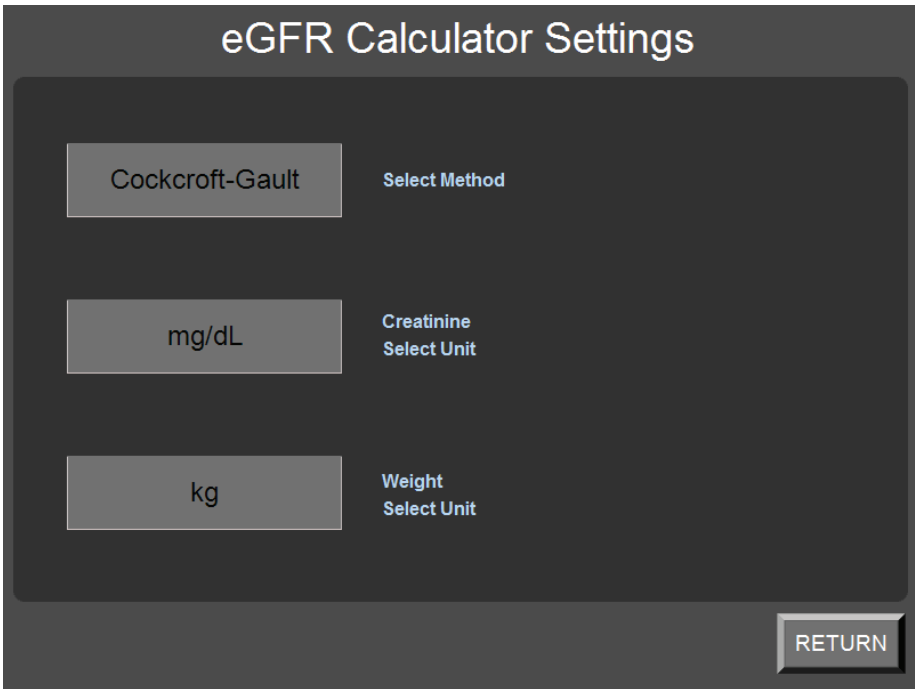
If the Expert mode was selected for the eGFR option, the next step is to set up the eGFR calculation, as follows.

1. Display the Setup screen, if it is not already displayed, by selecting **SETUP** in the Main screen.
2. In the Setup screen, select **SERVICE**. Your local Bracco Injeneering S.A. technical support representative will provide the authorized password to access the protected service area.
3. In the Supervisor screen, select **eGFR CALC SETTINGS** to view the eGFR Calculator Settings screen.
4. Select the desired eGFR calculation parameters.

   The eGFR Calculator Settings screen will display the configurable parameters. These include the types of equations that can be selected: Cockcroft-Gault or MDRD or CKD-EPI. The default equation is MDRD.

   The creatinine of the patient can be expressed either in µmol/L or in mg/dL The default unit is mg/dL, as shown on the following example screen.

   The weight of the patient can be set either as kilograms or pounds. The default value is kilograms, as shown on the following example screen.



5. After all the settings have been entered, select **RETURN** twice. It is the facility's responsibility to state, monitor and review the required methods and units to be used for the eGFR calculation.

The Setup Screen (continued)

Setting the eGFR and the Creatinine Thresholds

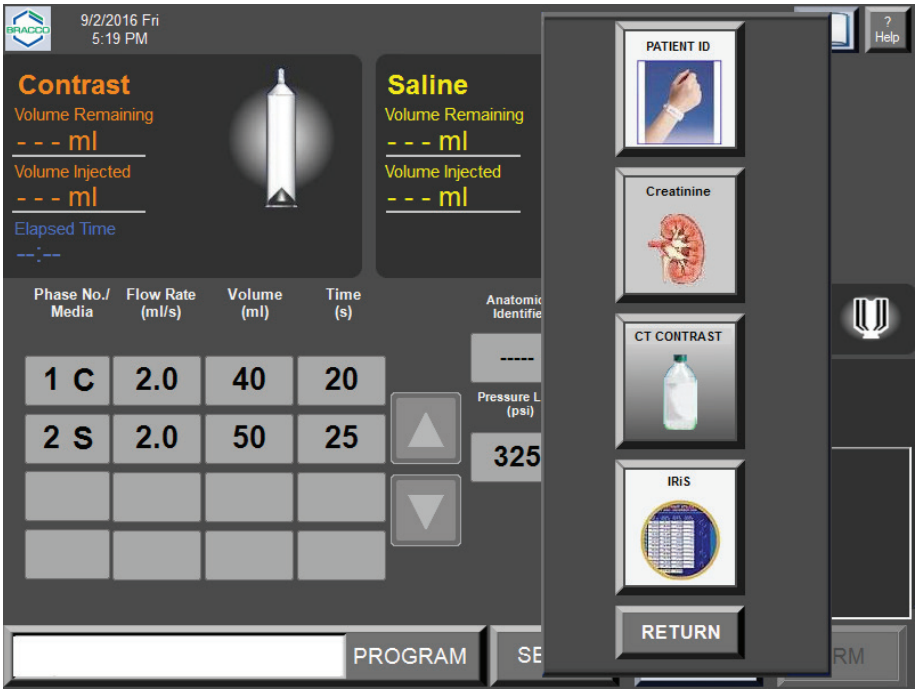
If the Expert mode was selected for the eGFR option, you can also set the eGFR threshold, as follows:

1. Display the Setup screen, if it is not already displayed, by selecting **SETUP** in the Main screen.
2. In the Setup screen, select **SERVICE**. Your local Bracco Injeneering S.A. technical support representative will provide the authorized password to access the protected service area.
3. In the Supervisor screen, select **eGFR Threshold** to open a pop-up keypad window.
   - To enter the eGFR threshold, select **eGFR** in the keypad and enter the eGFR threshold value. The default value is 60.
   - To enter the Creatinine threshold, select **Creatinine** in the keypad and enter the threshold value. The default value is 1.6 if the selected unit is mg/dL and 141 if the selected unit is µmol/L.
4. After all the settings have been entered, select **RETURN** twice. It is the facility's responsibility to state, monitor and review the eGFR and creatinine threshold values.

The Setup Screen (continued)

Creatinine Entry

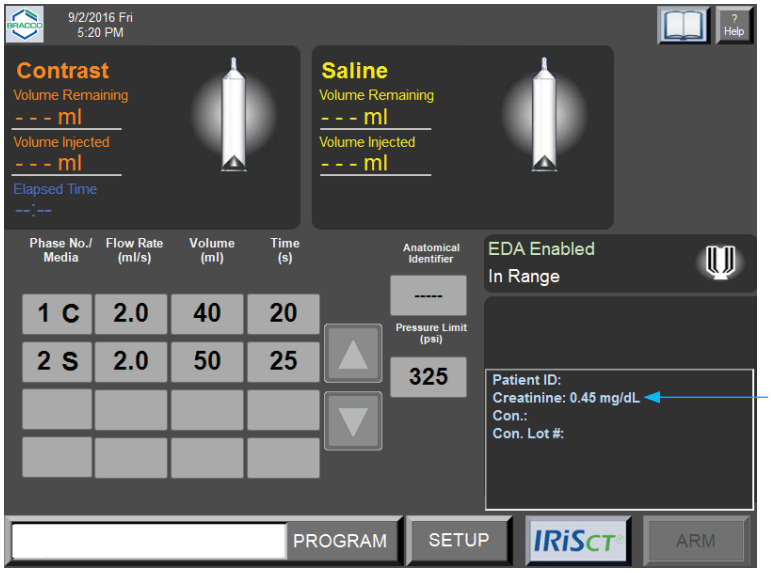
If the eGFR option in the Setup screen has been set to Basic, only the Creatinine value will be stored in IRiSCT®. To store the value, select the **IRiSCT** button followed by the **Creatinine** button, as shown below:



Next, enter the Creatinine value and select **ENTER**:

The Setup Screen (continued)

If the value entered is below the user-defined threshold (for instructions on setting this threshold, see page 103), the value will be stored and displayed in the Patient Information area of the Main screen as shown below:



Creatinine Value

If the entered value is above the user-defined threshold, there will be a message prompt alerting that the value is above the threshold. Select **OK** to continue. Once accepted, the value will be displayed on the Main screen. Text in the patient information area will be displayed in yellow and a cautionary symbol will also be displayed near the value. This value WILL NOT inhibit the use of the EmpowerCTA®+ Injector System. It is the facility's ultimate responsibility to review this value and determine the best course of action for the patient.

WARNING

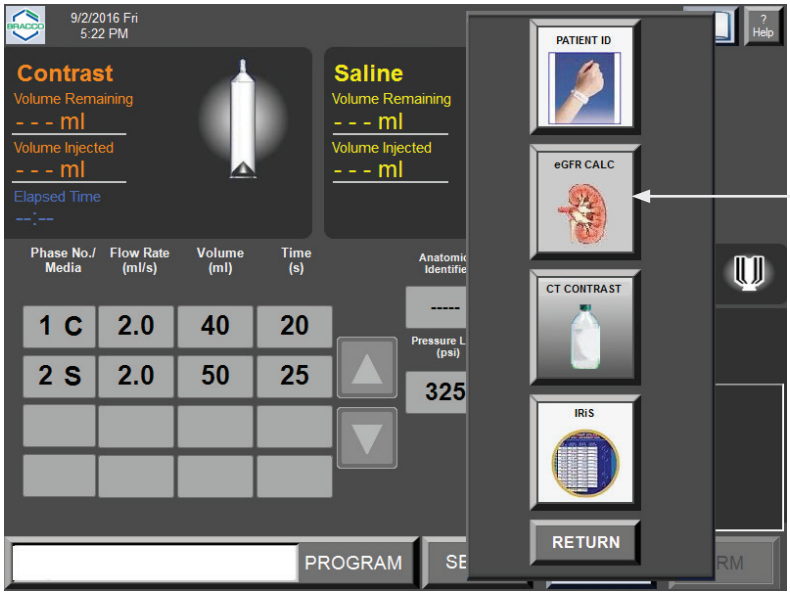
Prior to each injection, the creatinine value displayed should be reviewed for accuracy. It is the sole responsibility of the facility to assure that the value entered is accurate.

The creatinine value will continue to be displayed until you confirm the end of the procedure (if prompted) or until the syringe ram is in the Replace Syringe position. Prior to the next injection, the value will have to be entered for this patient.

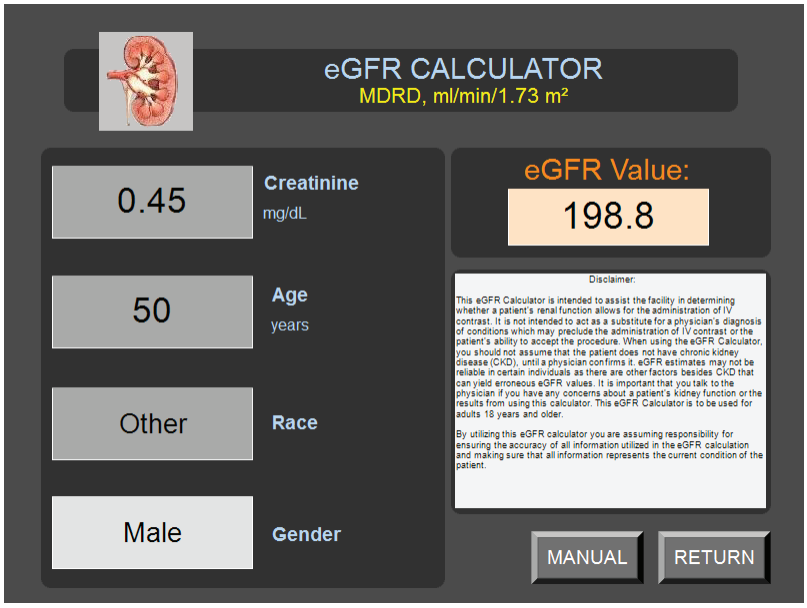
The Setup Screen (continued)

eGFR Entry

If the eGFR setting is Expert, the eGFR value can be calculated and stored in IRiSCT®. The eGFR CALC option will be available in the IRiSCT® panel, as shown below:



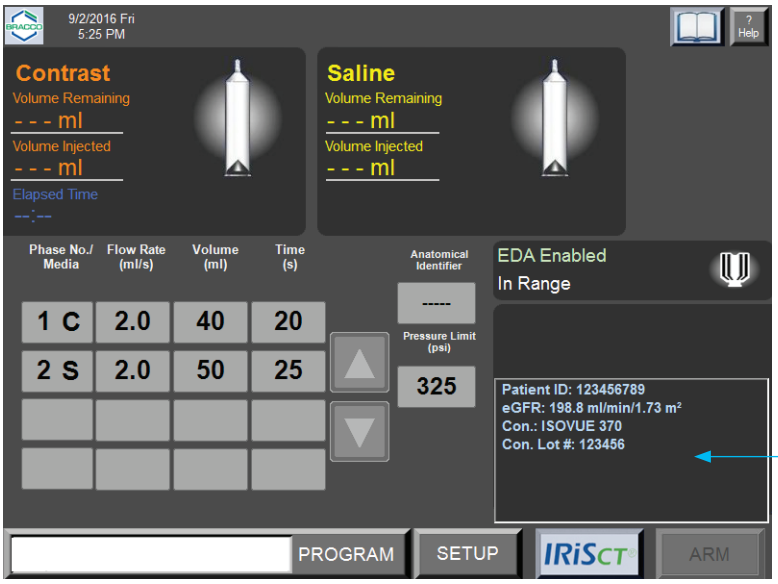
To calculate and store the eGFR value, select the **IRiSCT** button and then select the **eGFR CALC** button. The system displays the eGFR Calculator. In the following example, the eGFR Calculator uses the MDRD equation and the mg/dL unit of creatinine for reference purposes only.



The equation and units used in the calculation are pre-set using the eGFR Calculator Settings screen (accessible through the Service function on the Setup screen as described on page 102).

The Setup Screen (continued)

Review the units and equation prior to any entry into the eGFR Calculator screen. Once the value has been calculated, review the value displayed on the screen and confirm by selecting the **RETURN** button. If the calculated eGFR value is greater than the user-defined threshold, it will be stored and displayed in the Main screen, as shown below.



If the calculated eGFR value is equal to or below the user-defined threshold, a message prompt will appear to alert you that the value is below the threshold. (For instructions on how to set this threshold, see page 103). Enter a new value or select **OK** to continue. Once accepted, the value will be displayed in the Main screen. Text in the patient information area will be displayed in yellow, and a cautionary symbol will also be displayed near the value.

It is the facility's ultimate responsibility to review these values and determine the best course of action for the patient. In addition, the value of the eGFR can be manually entered by selecting the **MANUAL** button in the calculator window. A pop-up keypad will appear. The value can be manually entered and it will be stored and displayed in the Patient Information area of the Main screen on the Remote Control.

WARNING

Prior to each injection, the eGFR value displayed should be reviewed for accuracy. It is the sole responsibility of the facility to assure that the value entered is accurate.

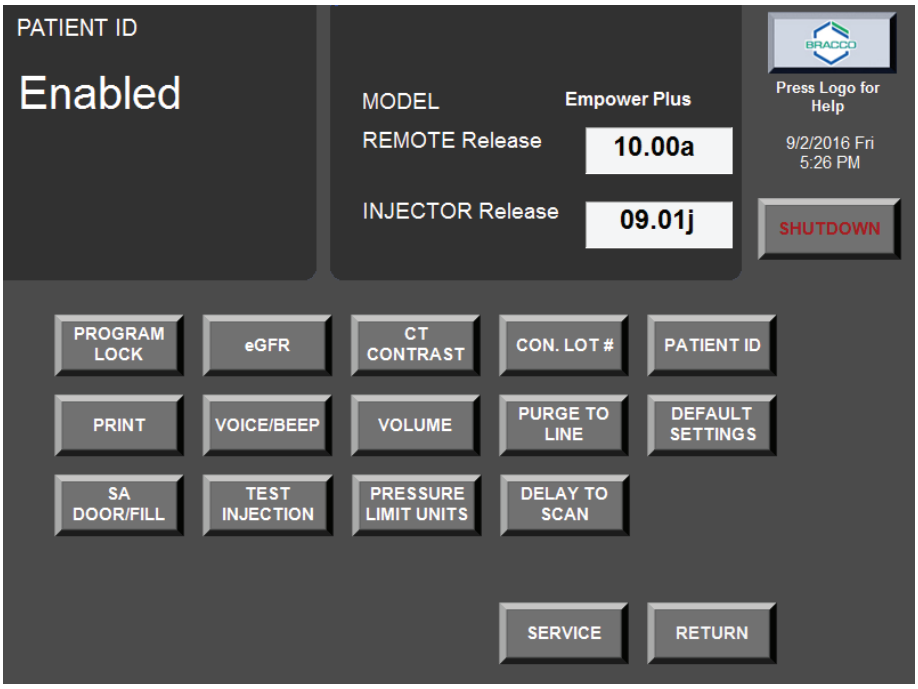
The eGFR value will continue to be displayed on the Main screen until the user confirms that the procedure is ended (if prompted), or until the syringe ram is in the Replace Syringe position. Prior to the next injection, the value will have to be entered for this patient.

The Setup Screen (continued)

Patient ID Setup

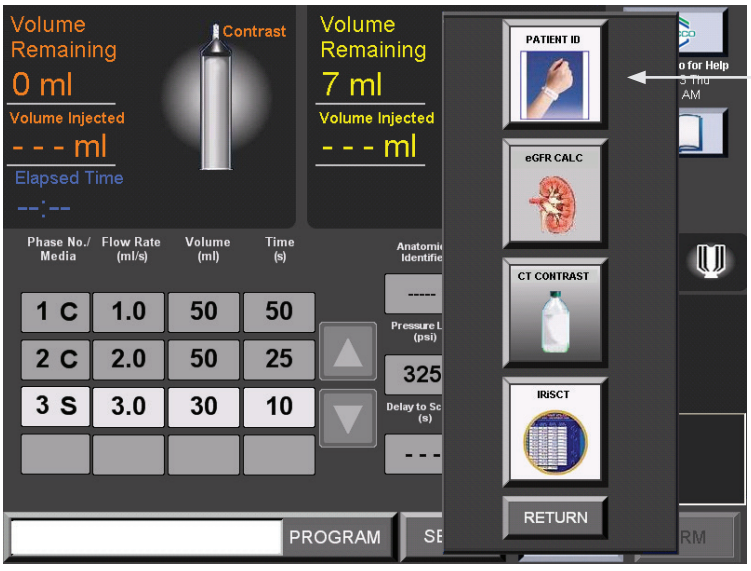
The PATIENT ID option will appear on the IRiSCT® panel when the Patient ID option is set to Enabled in the Setup screen. Select the **PATIENT ID** button in the Setup screen to toggle this option between Enabled and Disabled, and the current selection is displayed in the upper left corner of the Setup screen. Select **RETURN** to go back to the Main screen.

By default, the PATIENT ID option is set to Enabled, as shown below:



Patient ID Entry

If the PATIENT ID option is set to Enabled in the Setup screen, the IRiSCT® panel will display the PATIENT ID button, as shown below:



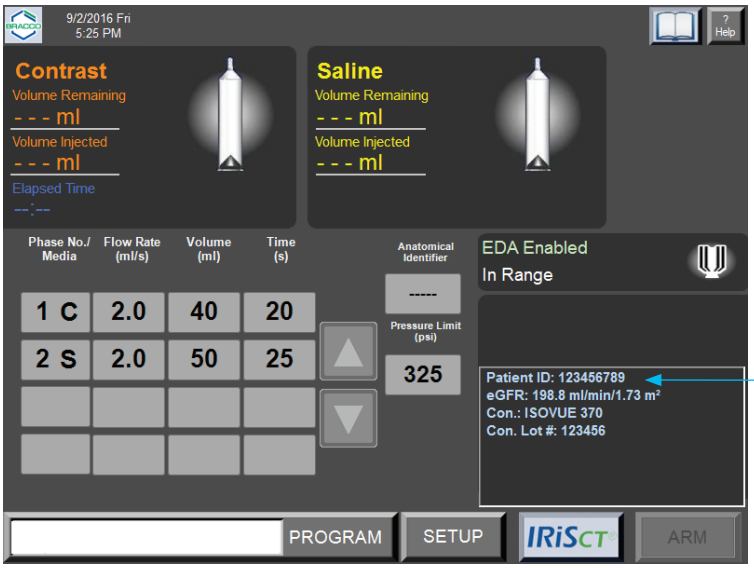
PATIENT ID button

The Setup Screen (continued)

To enter the patient ID, select the **IRiSCT** button, then select the **PATIENT ID** button. A pop-up keyboard window is displayed as shown below:

Enter the alphanumeric value of the Patient ID (maximum 12 characters) and select **ENTER**.

The user-entered Patient ID is then displayed in the patient information area of the Main screen, as shown below:



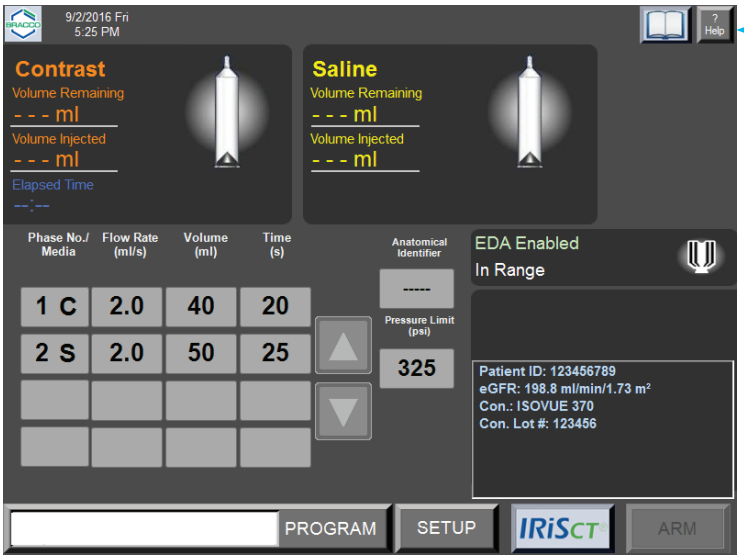
WARNING

Prior to each injection, the displayed Patient ID should be reviewed for accuracy. It is the sole responsibility of the facility to assure that the value that was entered is accurate.

The patient ID will continue to be displayed on the Main screen until the user confirms that the procedure is ended (if prompted) or until the syringe ram is in the Replace Syringe position. Prior to the next injection, the value will have to be entered for this patient.

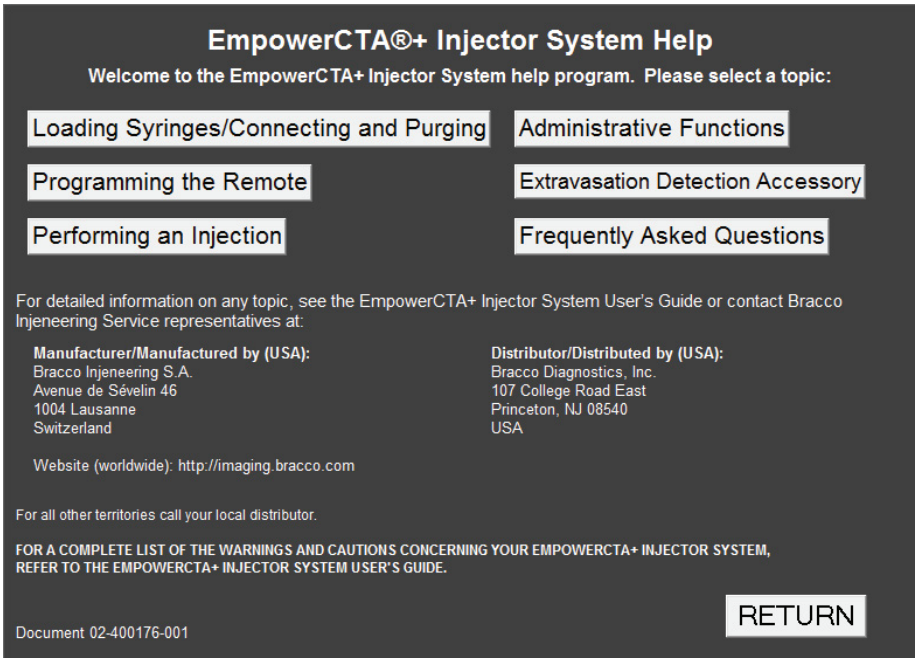
Help Feature

The EmpowerCTA®+ Remote Control has a feature to aid you in the use of the EmpowerCTA®+ Injector System. This feature is called the Help feature. It is activated by selecting the Help button on the Main screen as shown below. The Help feature can also be activated on the Program and Setup screens.



Select the Help button to activate the Help feature

Once the Help button is selected, the Main Help screen will be displayed as shown below:



Each key topic will display a set of instructions. In each topic, the RETURN button is used to return to the previous Main Help screen. To exit the Help system, select the **RETURN** button on the Main Help screen.

System Shutdown

Remote Control Shutdown

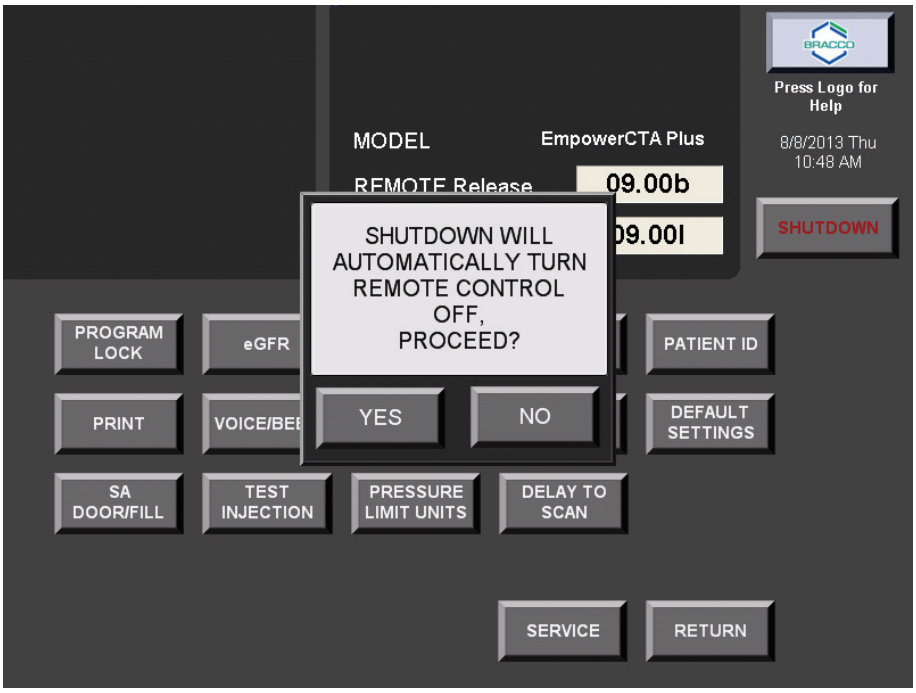
The SHUTDOWN function on the Remote Control closes the Remote Control software and then turns off power to the Remote Control unit.

CAUTION

The Remote Control must be shut down with the proper procedure to avoid loss of data and/or function.

For routine shutdown, do not turn off power to the Remote Control by pressing the power button on the Remote Control; instead, always shut down the Remote Control using the following procedure:

1. If the Main screen is not displayed, select **RETURN** to return to the Main screen.
2. Select **SETUP**.
3. In the Setup screen, select **SHUTDOWN**. Select **YES** in the confirmation message. The software application will close, and power to the Remote Control will be automatically turned off.



Turning Off Power to the Injector System

To shut down the Injector System, follow the normal process of concluding an injection and unloading the syringe, then turn off power to the Injector System using the rocker switch behind the right side of the Injector Controller touch screen.

7 Understanding Extravasation Detection

Suggested Techniques for Minimizing Extravasations

Clinical personnel monitoring the patient can detect extravasation of contrast medium. It is recommended that EmpowerCTA®+ Injector users follow best clinical practices and standards of care established by their respective institution when monitoring the patient for extravasation during contrast medium injection.

WARNING

To minimize the possibility of an extravasation use the following guidelines:

- *Connections to the patient are to be made from commercially available catheters that are indicated for diagnostic imaging. For information on pressure settings and limits, refer to instructions provided by the catheter manufacturers.*
- *Minimize the effects of patient movement by taping the catheter firmly to the patient's skin. If planning on using the EDA extravasation device, do not put tape proximal to the insertion point on the skin of the patient.*
- *The antecubital vein in the left arm is the preferred injection site for IV contrast. The right arm as well as the veins in the hands or wrists can be used when there is no other access. These locations will cause more pain to the patient and because they are more distal, will offer higher resistance to the flow of contrast medium, increasing the risk of extravasation. This position permits the arms to be placed over the head during body scans without the danger of kinking either the catheter or tubing. Use of a 60 inch (1.5 m), coiled, low-pressure tube also reduces the motion effects associated with table movement.*
- *Do not use catheters that are kinked or that have been kinked. Telling the patient to put their hands over their head after connecting the Injector to the IV will usually result in their bending their arms risking kinking of the catheter. If possible, have the patient hold their arms straight out, either above them so their hands are resting on the gantry, or if over their head, guide them to keep their arms straight out when possible.*
- *If a patient presents with one or more indwelling intravenous lines, do not assume that the intravenous set is acceptable for use with the EmpowerCTA®+ Injector System. If possible, place a new intravenous line. Any resistance to your flushing in that catheter may be reason to suspect occlusion in the catheter or the patient's vein. Do not inject in IVs that offer resistance to saline flush.*

Suggested Techniques for Minimizing Extravasations (continued)

- *Central venous lines and heparin locks are not recommended.*
- *To augment clinical monitoring during Contrast injection and to help detect potentially serious extravasations, Bracco Injeneering S.A. recommends use of the Extravasation Detection Accessory (EDA) in conjunction with the EmpowerCTA®+ Injector System.*

Overview of the Extravasation Detection Accessory (EDA)

If your Injector System does not include an EDA and you would like to obtain one, contact your local Bracco Injeneering S.A. representative.

WARNING

It is important for the owner/operator of the "Extravasation Detection Accessory" (EDA) to understand that this device is to be used only by trained, qualified and authorized personnel. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the patient. The EDA is provided as an auxiliary device feature, which assists users in the detection of a possible extravasation. As with all equipment that monitors a patient's physiological response, it is not intended as a substitute for observation and intervention by a trained healthcare professional. Diligence on the part of the owner/operator is an essential requirement of overall patient safety.

Throughout this user's guide, reference is made to the EmpowerCTA®+ Extravasation Detection Accessory or EDA. The EDA is a device mounted on either the floor stand or ceiling suspension system. Its function is monitoring for, and assisting in detecting Contrast extravasation only during an injection. This device does not aid in the detection of saline extravasations.

The detection capability of the EDA is seamlessly integrated with the functionality of the Injector System. If an extravasation is detected the EDA will pause the EmpowerCTA®+ Injector System automatically. If use of this accessory is not desired for a procedure, the EDA can be disabled for any injection protocol.

The EDA uses the principle of bioimpedance to locally monitor the patient's tissue over the outlet of the venous access catheter. If for some reason, contrast medium should start to extravasate local to the outlet of the catheter, the tissue bioimpedance underneath the EDA patch changes. The EDA system monitors this change over a period of time. Based on the injection flow rate, it establishes a permissible bioimpedance change indicative of 20 ml maximum contrast medium extravasation. Once this threshold is reached, the EDA communicates this information to the Injector System. At that time the contrast injection is paused and the user is informed of the occurrence of a possible extravasation.

Overview of the Extravasation Detection Accessory (EDA) (continued)

Extravasation Detection Patch with Access Slot

The sensitivity and hence effectiveness of the EDA patch is greatest for contrast medium extravasations that accumulate in the tissue directly underneath the patch. Extravasations of this type most commonly exhibit a local wheal underneath the patch.

In cases where extravasated contrast medium migrates into subcutaneous tissue or septal planes, the sensitivity and effectiveness of the EDA patch is lower than those where it directly accumulates underneath the patch. These types of extravasations typically do not reveal any localized whealing or swelling. Additionally, for extravasations that initiate downstream or distal to the end of the catheter beyond the area of coverage of the EDA patch, the EDA is not designed to detect bioimpedance changes associated with this extravasation condition.

Overview of the Extravasation Detection Accessory (EDA) (continued)

Based on this, the EDA augments and enhances a user's best clinical practice in their ability to provide the highest standard of care. As designed, the EDA continues to monitor the patient during the latter part of the contrast injection just prior to or during the scanning sequence when the patient is typically left alone in the scanner room when the x-ray equipment is in use. To realize maximum effectiveness with the EDA, it must be used in conjunction with close monitoring by a trained clinician.

For systems configured with the EDA, this accessory device is designed to augment clinical monitoring for contrast extravasation. The EDA is not designed to be a full or partial substitute for the normal diligence associated with best clinical practices when monitoring for extravasation.

Note

Use only the Extravasation Detection Patch with Access Slot.

How to Load and Apply the EDA Patch

Read this First

The ability of the EDA to successfully detect an extravasation is dependent on proper placement of the Extravasation Detection Patch. It is important for all users of the EmpowerCTA®+ Injector System with EDA to read and understand the contents of this section. Also, the Help feature, accessed via the Help button on the Remote Control's Main screen, includes a training video for your reference. (This video is available in English only.)

Loading and placing the patch should only be performed after starting up the equipment, loading and filling the syringe with contrast medium, properly preparing the patient, connecting the coiled tubing to the syringe and catheter and programming the Remote Control.

Notes

- *The EDA patch must be loaded and placed on the patient before arming the EmpowerCTA®+ Injector System.*
- *After each startup, the Injector Controller and Remote Control will display the EDA ENABLED OUT OF RANGE message until the EDA patch is properly connected to the patch connector and to the Injector System and the EDA patch is properly placed on the patient.*

Load the Patch into the EDA Connector

Be sure to read and understand information in the "Read This First" section before proceeding. Refer also to Instructions for Use for the Extravasation Detection Patch with Access Slot.

Note

Patients with an excessive amount of body hair may need to be locally shaved prior to placement of the catheter and the EDA patch.

How to Load and Apply the EDA Patch (continued)

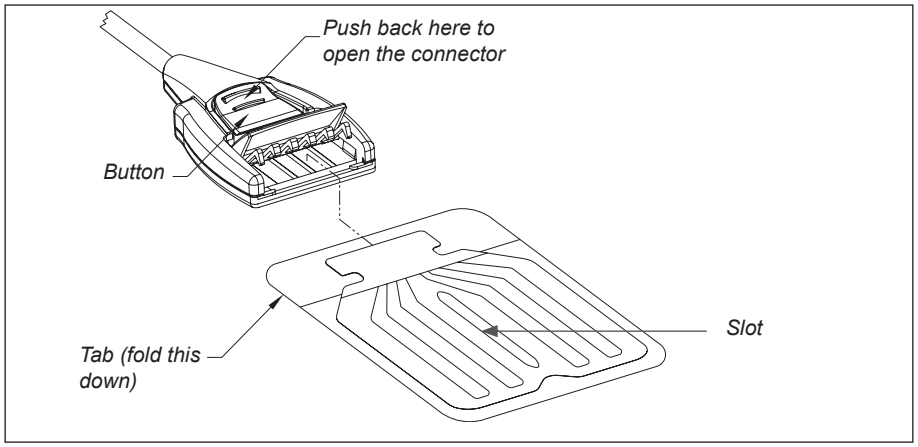
To load the EDA patch into the EDA patch connector, follow these steps:

1. Route the patient end of the EDA cable parallel to the coiled extension set and bring the EDA patch connector near the patient's catheter site.
2. Remove the EDA patch from the foil package.

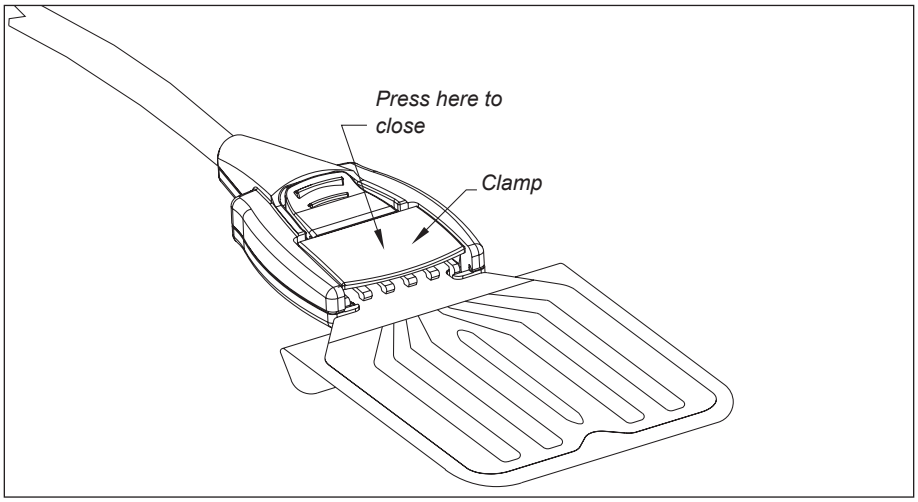
Note

The slot in the center of the EDA patch provides direct access to the patient's skin before the protective backing is removed from the patch.

3. Fold down the clear backing tab at the connection end of the EDA patch. Do not remove the backing from the EDA patch at this time.
4. Open the connector by pushing back on the button (as shown) while supporting the patch connector from underneath.
5. With the tab of the protective backing folded down, insert the EDA patch into the EDA patch connector as shown below.



6. Close and latch the connector by pressing on the top of the clamp until you hear a click and the clamp is securely closed and latched.



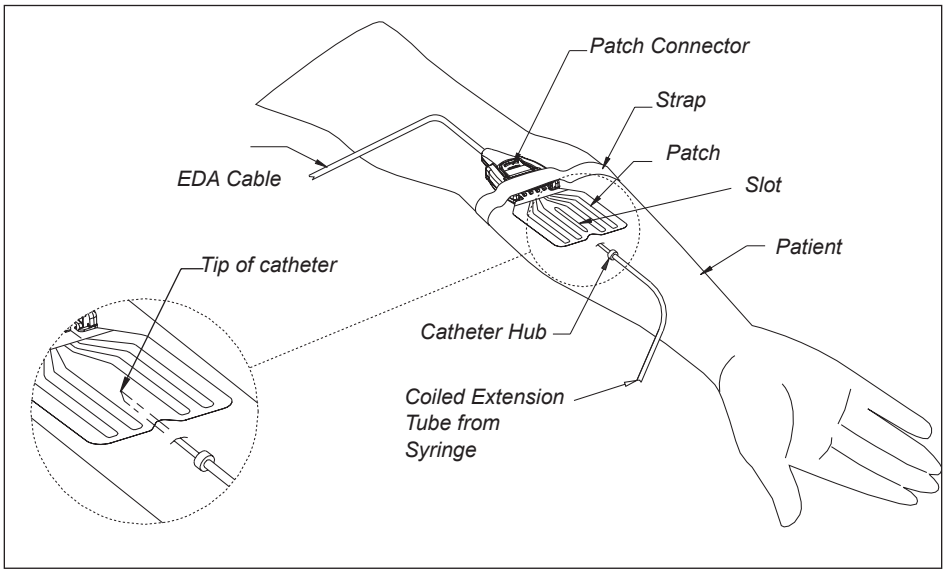
How to Load and Apply the EDA Patch (continued)

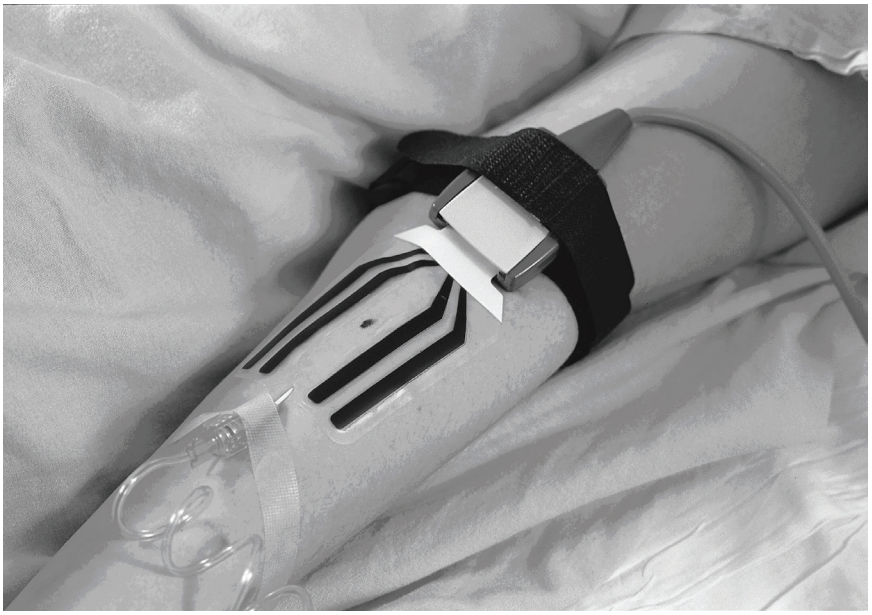
Place the Extravasation Patch on the Patient

When you are ready to apply the EDA patch to the patient, do the following:

1. Route the patient end of the EDA cable parallel to the coiled extension set and bring the EDA patch connector near the patient's catheter site.
2. Pull off the folded-down tab to peel off the protective backing and to expose the adhesive surface.
3. Place the patch on the patient's skin so that the patch runs in the same direction as the catheter, as shown in the inset in the illustration on the next page. The center of the EDA patch should be over the tip of the needle/catheter, which is below the skin.
    - DO NOT COVER THE NEEDLE/CATHETER ENTRY POINT WITH THE PATCH.
    - Do not place the patch over adhesive tape, bandages, or other topical dressings.
4. When the EDA patch is in the proper position, gently press the patch over the patient's skin wherever necessary to eliminate all air gaps.
5. Use the black arm strap to secure the patch connector to the patient as shown in the photo on the next page.
6. Carefully check the catheter and the EDA patch placement prior to operating the EmpowerCTA®+ Injector System.

How to Load and Apply the EDA Patch (continued)





How to Load and Apply the EDA Patch (continued)

7. When the patch is placed on the patient, the Injector Controller and the Remote Control will briefly display "EDA ENABLED NO BASELINE", followed by "EDA ENABLED IN RANGE". This message indicates that the EDA connector and EDA patch are properly connected to the Injector System and that the EDA patch has been properly placed on the patient. The injection is ready to begin. For instructions on how to perform an injection, see page 48.

Note

If the "EDA ENABLED NO BASELINE" or the "EDA ENABLED OUT OF RANGE" message is displayed at any time after the EDA connections have been completed, it indicates that the EDA connector and/or the EDA patch are not properly connected or that the EDA patch is not properly placed on the patient. Make sure that the EDA connector is properly connected to the Injector, that the EDA patch is properly inserted in the connector, and that the EDA patch is correctly placed on the patient.

8. To remove the EDA patch, see "Completing the Injection" on page 121.

Detecting an Extravasation During an Injection

If a possible extravasation is detected during the RUN mode, the following will occur:

- The system will halt the injection sequence.
- The system will go into the PAUSE mode.
- The Injector Controller will display CHECK FOR EXTRAVASATION.
- The Remote Control will activate a verbal message CHECK FOR POSSIBLE EXTRAVASATION three times.
- The Remote Control will display CHECK FOR POSSIBLE EXTRAVASATION.

After checking the patient for possible extravasation and an extravasation is found, a qualified healthcare professional must determine the appropriate corrective action to be taken.

The injection procedure can be continued by selecting the **RUN** button on the Remote Control, or by pressing the pendant switch.

If it is determined that the procedure must be stopped, select the **STOP** button on the Remote Control.

Detecting an Extravasation During an Injection (continued)

The injection procedure can also be continued with EDA disabled by the user by following this procedure:

1. While in the PAUSE mode, select the EDA button on the Remote Control. The Injector Controller and Remote Control will display "EDA USER DISABLED" in the EDA message area.
2. Select the RUN button on the Remote Control, or press the pendant switch.

During the injection, you can manually pause the system by pressing the pendant switch, by touching the Remote Control touch screen or by selecting PAUSE on the Injector Controller.

Completing the Injection

When the injection procedure is complete, do the following:

1. For patients with fragile skin or medical conditions that may predispose the skin to mechanical trauma, gently grasp the edge of the patch, stabilize the skin with a finger from your other hand, and remove the patch by pulling slowly. Continue to stabilize the newly exposed skin with your finger until the patch is completely removed.

   For all other patients, gently grasp the edge of the patch and remove the patch by pulling with a continuous motion at moderate speed in the direction of hair growth.

   The Injector Controller and the Remote Control will display the "EDA ENABLED OUT OF RANGE" message when the EDA patch is removed from the patient.
2. Open the connector by pushing back on the button while supporting the patch connector from underneath. Remove the EDA patch from the connector.
3. Discard the EDA patch in accordance with institutional policy.

WARNING

Do not reuse the Extravasation Detection Patch.

4. Refer to page 53 for instructions on how to disconnect the patient catheter from the EmpowerCTA®+ Injector.
5. Place the EDA patch connector back into its holder on the Injector.

8 Using the IRiSCT® Utility

Introduction

The IRiSCT® (Injector Reporting Information System CT) application captures all injection-related information produced by your EmpowerCTA®+ Injector Systems. The information is useful for reports, presentations, research, quality assurance, or to aid in analyzing your CT injections to improve workflow and increase productivity.

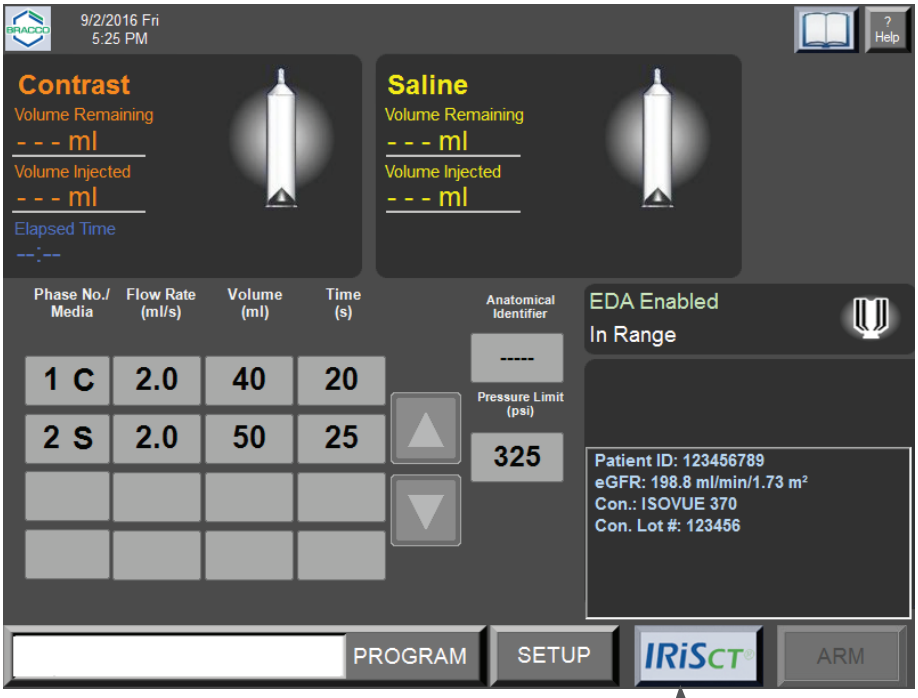
The IRiSCT® Viewer application resides on the Remote Control and will display information relative to that individual Injector System.

Note the following:

- No features of IRiSCT® affect the specified performance of the EmpowerCTA®+ Injector System.
- Capturing extravasation data requires installation and use of the Extravasation Detection Accessory (EDA).
- Nexo® system provides all the functionalities of IRiSCT® with additional features and integration to the hospital information system. This is why IRiSCT® is disabled when Nexo® is used.

IRiSCT® Remote Viewer Navigation

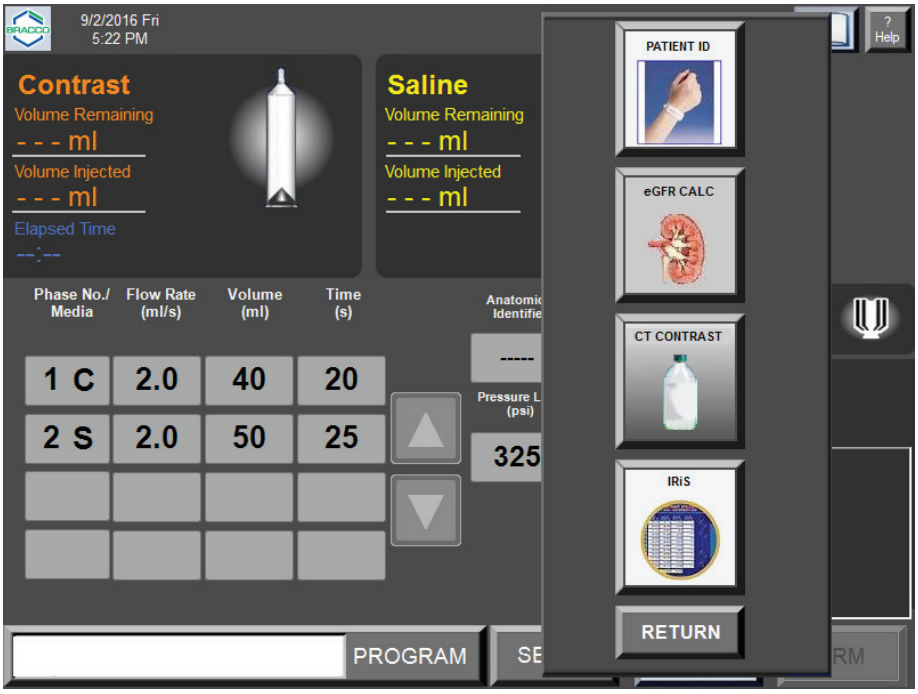
To open the IRiSCT® Viewer application select the **IRiSCT** button located at the bottom of the Remote Control Main screen, as shown below. (This button is only available on the Main screen.)



IRiSCT Button

IRiSCT® Remote Viewer Navigation (continued)

Selecting the IRiSCT button displays the IRiSCT® options panel, which is shown below. The available options in the IRiSCT® panel depend on the configuration defined in the Setup screen.



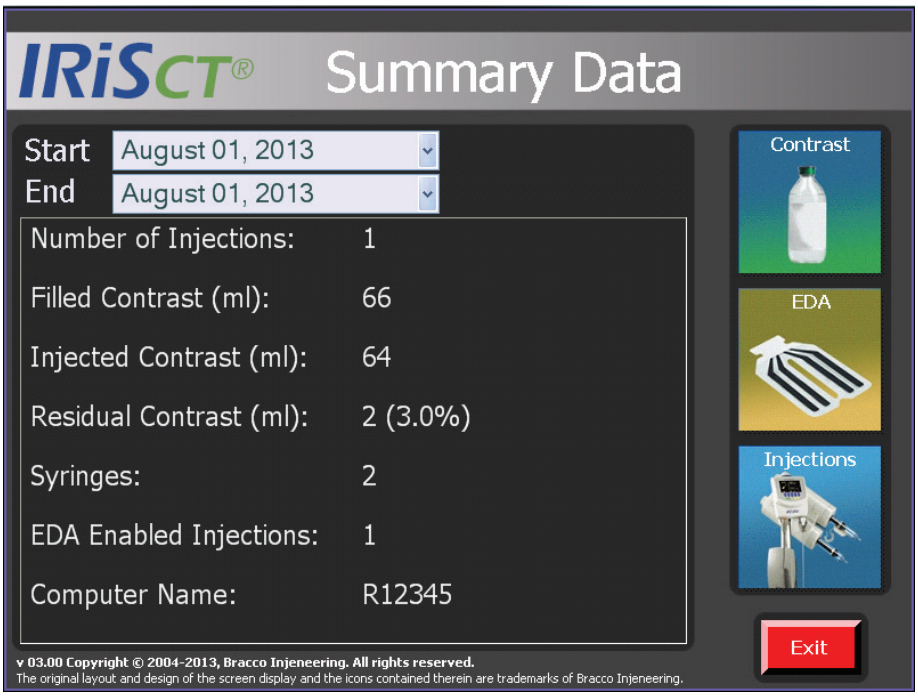
Note

While the IRiSCT® application is active on the Remote Control, you will be unable to arm or run an injection, however, you can still load, fill and unload syringes as required.

Select the **IRiSCT** button, to display the IRiSCT® Summary Data screen.

IRiSCT® Remote Viewer Navigation (continued)

An example of the IRiSCT® Summary Data screen is shown below:



IRiSCT® has three main display areas:

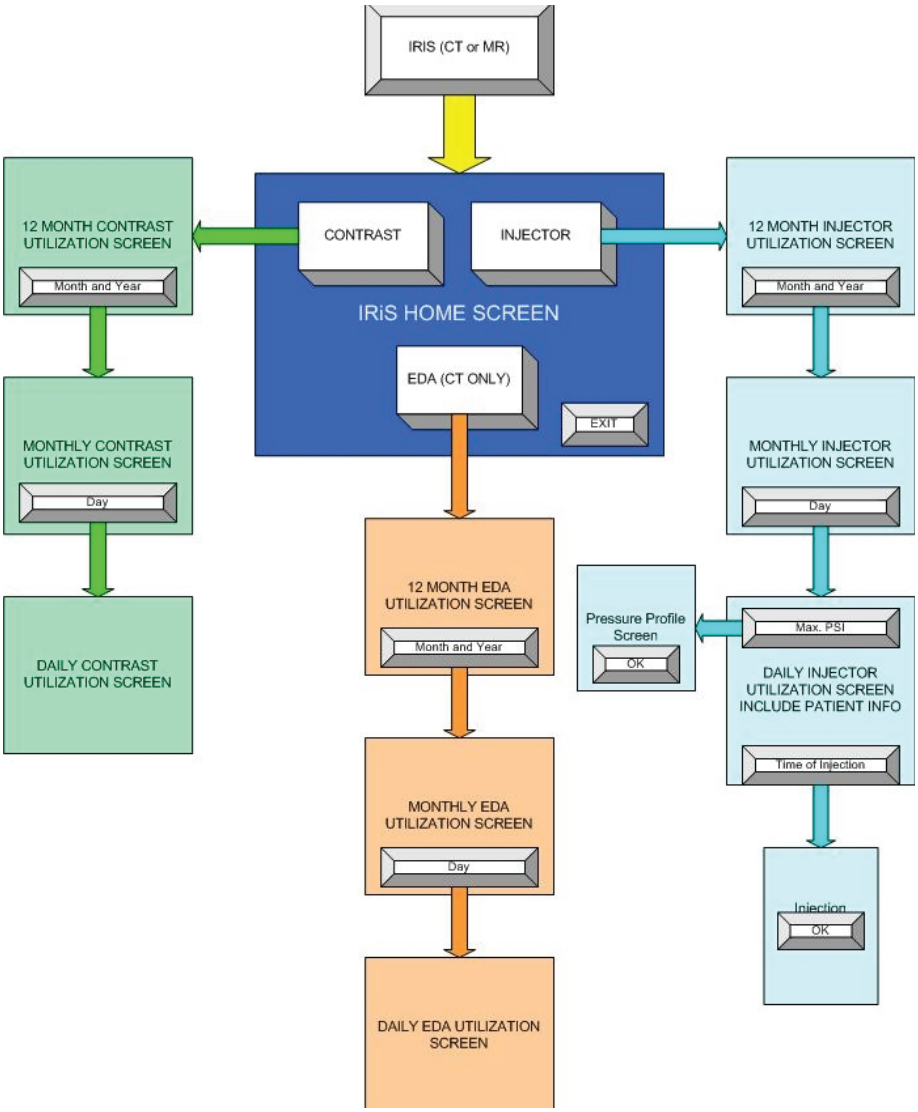
- Contrast Utilization,
- Extravasation Data, and
- Injector Information.

Navigation to one of the three screens is performed by selecting the specific labeled button in the right panel of the screen.

The EXIT button will close the IRiSCT® application and display the Remote Control Main screen.

IRiSCT® Remote Viewer Navigation (continued)

Upon selecting one of three main buttons on the right panel, IRiSCT® will display a 12 month summary of the selected display area with the current month as the last displayed month. The following chart describes the flow and navigation of the various screens.



Each of the three key areas (Contrast, EDA and Injections) has a 12 month summary followed by a one-month summary followed by a daily summary.

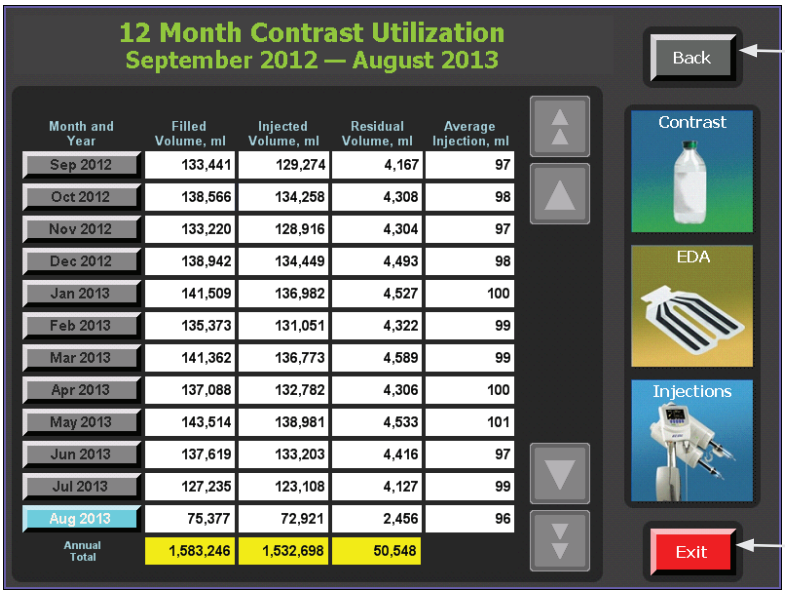
Each area begins by displaying a 12 month view of the most current data. Access to the month summary is done by selecting one of the 12 highlighted displayed months.

By selecting the field for that day of the month, you can display every injection performed for that day. Totals are provided on each screen for the data of that particular screen.

IRiSCT® Remote Viewer Navigation (continued)

In addition, each screen has a BACK button, which allows you to return to the previous screen. The EXIT button closes the IRiSCT® application and your system will be returned to the Remote Control Main screen.

On all of the screens, there are four sets of arrows: single up, single down, double up and double down. These arrows are used to navigate to data not currently displayed. If the arrows are active, further data is available.
For example, the chart below shows the arrow and its function on the various screens.



The chart below shows the arrow and its function on the various screens.

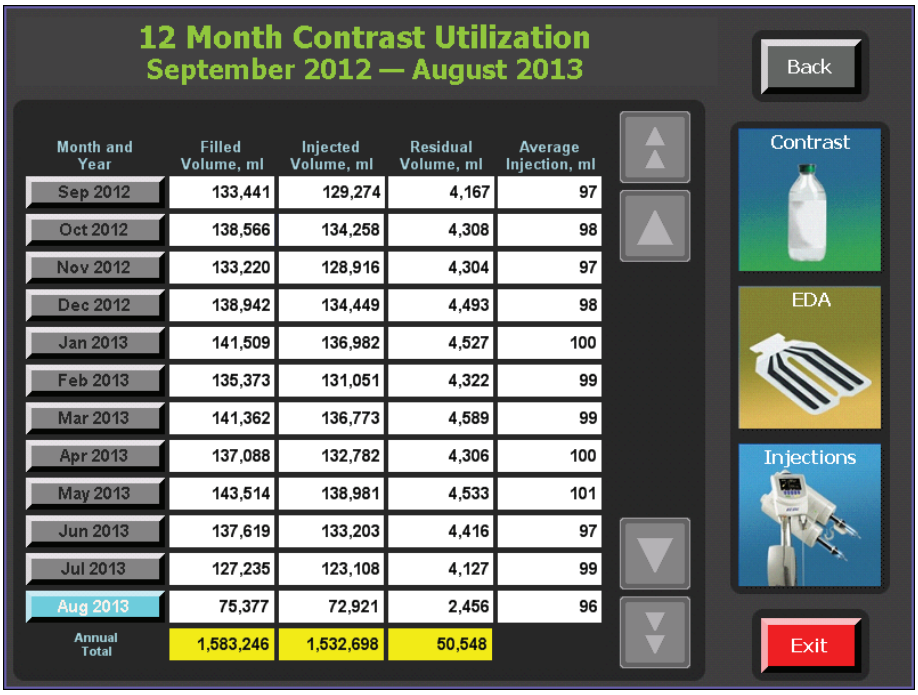
	Type of Arrow	12 Month Screen	Month Screen	Daily Screen
	Double up arrow	12 months up	1 month up	1 day up
	Single up arrow	1 month up	12 days up	12 injections up
	Single down arrow	1 month down	12 days down	12 injections down
	Double down arrow	12 months down	1 month down	1 day down

Reviewing Contrast Utilization

12 Month Contrast Utilization

Select the **Contrast** button to view the 12 Month Contrast Utilization window, which displays a 12 month view of contrast medium utilization. Selecting either the double or single arrow scrolls through the months displaying any 12 month view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



Month and Year	Filled Volume, ml	Injected Volume, ml	Residual Volume, ml	Average Injection, ml
Sep 2012	133,441	129,274	4,167	97
Oct 2012	138,566	134,258	4,308	98
Nov 2012	133,220	128,916	4,304	97
Dec 2012	138,942	134,449	4,493	98
Jan 2013	141,509	136,982	4,527	100
Feb 2013	135,373	131,051	4,322	99
Mar 2013	141,362	136,773	4,589	99
Apr 2013	137,088	132,782	4,306	100
May 2013	143,514	138,981	4,533	101
Jun 2013	137,619	133,203	4,416	97
Jul 2013	127,235	123,108	4,127	99
Aug 2013	75,377	72,921	2,456	96
Annual Total	1,583,246	1,532,698	50,548	

The definitions of the titles of the data columns for contrast medium utilization screens are as follows:

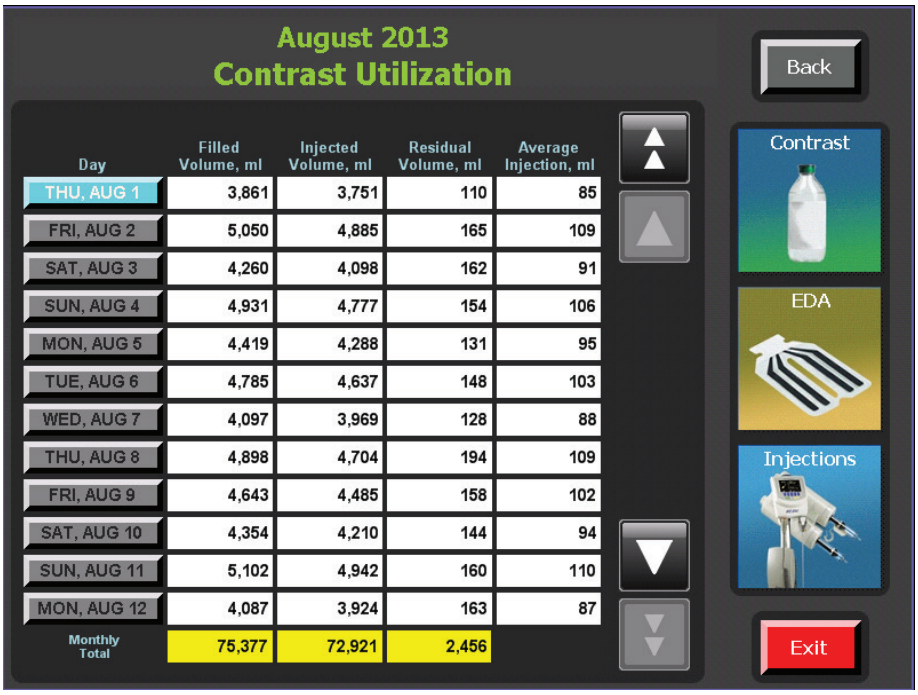
Title	Definition
Filled Volume, ml	The loaded contrast medium volume in the syringe when the system is at armed.
Injected Volume, ml	The total contrast medium volume injected into the patient.
Residual Volume, ml	The difference between the filled contrast medium volume and the injected contrast medium volume.
Average Injection, ml	The average injected contrast medium volume for the displayed period of time.

Reviewing Contrast Utilization (continued)

Monthly Contrast Utilization

Select one of the months to drill down to the monthly Contrast Utilization window, which displays the contrast medium utilization per day of the selected month. Selecting either the double or single arrow scrolls through the days displaying any 12-day view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



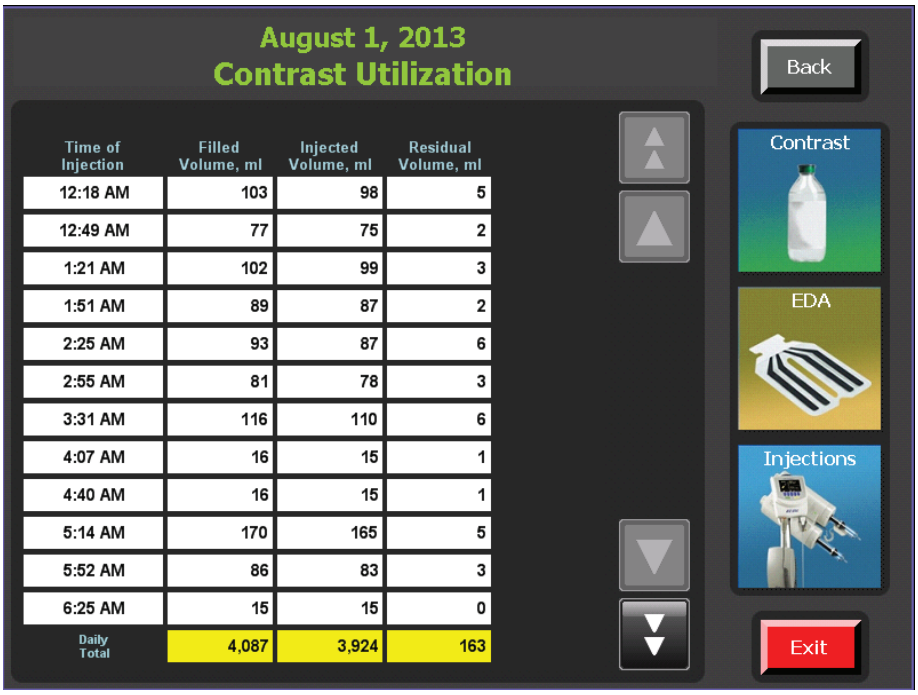
Day	Filled Volume, ml	Injected Volume, ml	Residual Volume, ml	Average Injection, ml
THU, AUG 1	3,861	3,751	110	85
FRI, AUG 2	5,050	4,885	165	109
SAT, AUG 3	4,260	4,098	162	91
SUN, AUG 4	4,931	4,777	154	106
MON, AUG 5	4,419	4,288	131	95
TUE, AUG 6	4,785	4,637	148	103
WED, AUG 7	4,097	3,969	128	88
THU, AUG 8	4,898	4,704	194	109
FRI, AUG 9	4,643	4,485	158	102
SAT, AUG 10	4,354	4,210	144	94
SUN, AUG 11	5,102	4,942	160	110
MON, AUG 12	4,087	3,924	163	87
Monthly Total	75,377	72,921	2,456	

Reviewing Contrast Utilization (continued)

Daily Contrast Utilization

Select one of the days to drill down to the daily Contrast Utilization window, which displays contrast medium usage per injection for that selected day. Selecting either the double or single arrow scrolls through the injections displaying any 12-injection view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



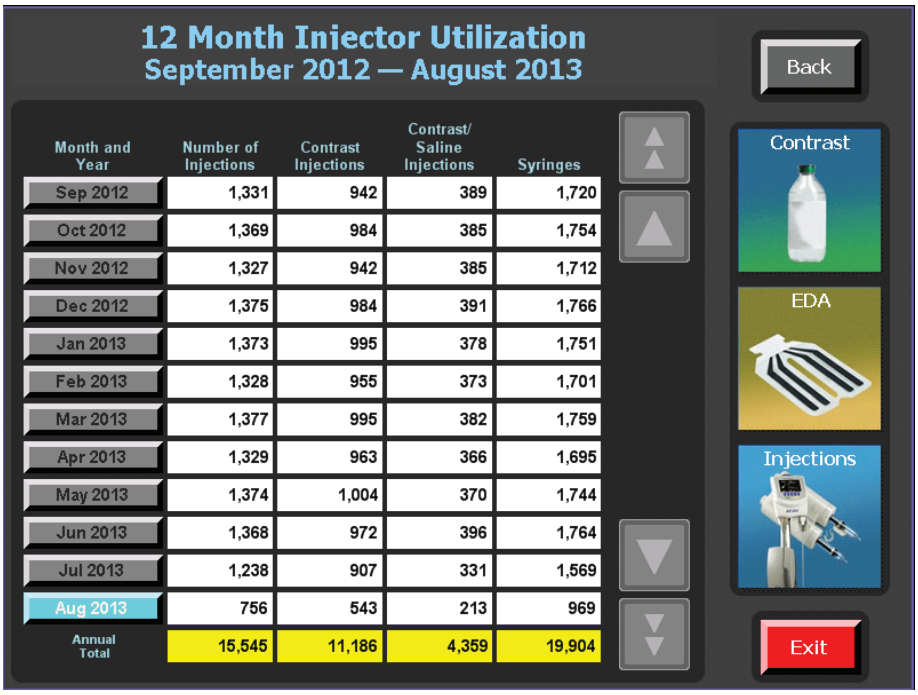
Time of Injection	Filled Volume, ml	Injected Volume, ml	Residual Volume, ml
12:18 AM	103	98	5
12:49 AM	77	75	2
1:21 AM	102	99	3
1:51 AM	89	87	2
2:25 AM	93	87	6
2:55 AM	81	78	3
3:31 AM	116	110	6
4:07 AM	16	15	1
4:40 AM	16	15	1
5:14 AM	170	165	5
5:52 AM	86	83	3
6:25 AM	15	15	0
Daily Total	4,087	3,924	163

Reviewing Injector Utilization

12 Month Injector Utilization

Select the **Injections** button to view the 12 Month Injector Utilization window, which displays a 12 month view of Injector utilization. Selecting either the double or single arrow scrolls through the months displaying any 12 month view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



Month and Year	Number of Injections	Contrast Injections	Contrast/ Saline Injections	Syringes
Sep 2012	1,331	942	389	1,720
Oct 2012	1,369	984	385	1,754
Nov 2012	1,327	942	385	1,712
Dec 2012	1,375	984	391	1,766
Jan 2013	1,373	995	378	1,751
Feb 2013	1,328	955	373	1,701
Mar 2013	1,377	995	382	1,759
Apr 2013	1,329	963	366	1,695
May 2013	1,374	1,004	370	1,744
Jun 2013	1,368	972	396	1,764
Jul 2013	1,238	907	331	1,569
Aug 2013	756	543	213	969
Annual Total	15,545	11,186	4,359	19,904

The definitions of the titles of the data columns for Injector Utilization screens are as follows:

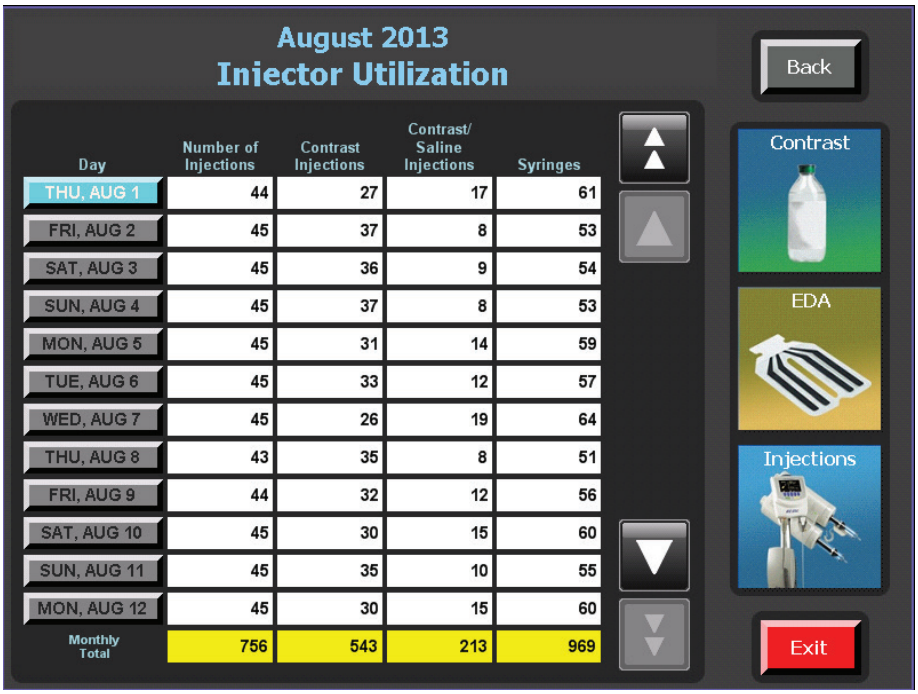
Title	Definition
Number of Injections	The total number of injections for that period of time.
Contrast Injections	The total number of contrast-only injections.
Contrast/Saline Injections	The total number of contrast medium and saline injections.
Syringes	The total number of syringes utilized in that particular Injector.

Reviewing Injector Utilization (continued)

Monthly Injector Utilization

Select one of the months to drill down to the monthly Injector Utilization window, which displays the number of injections per day of the selected month. Selecting either the double or single arrow scrolls through the days displaying any 12-day view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



Day	Number of Injections	Contrast Injections	Contrast/ Saline Injections	Syringes
THU, AUG 1	44	27	17	61
FRI, AUG 2	45	37	8	53
SAT, AUG 3	45	36	9	54
SUN, AUG 4	45	37	8	53
MON, AUG 5	45	31	14	59
TUE, AUG 6	45	33	12	57
WED, AUG 7	45	26	19	64
THU, AUG 8	43	35	8	51
FRI, AUG 9	44	32	12	56
SAT, AUG 10	45	30	15	60
SUN, AUG 11	45	35	10	55
MON, AUG 12	45	30	15	60
Monthly Total	756	543	213	969

Reviewing Injector Utilization (continued)

Daily Injector Utilization

Select one of the days to drill down to the daily Injector Utilization window, which displays Injector usage per injection for that selected day. Selecting either the double or single arrow scrolls through the injections displaying any 12-injection view while updating the totals located on the bottom of the columns in yellow boxes.

For example:

Time of Injection	Avg. Contr. Rate	Contr. Vol.	Saline Rate	Saline Vol.	Avg. PSI	Max. PSI	EDA Enab.	Poss. Extrav.
9:38 AM	4.4	98		0	285	290	N	N
	6.0	75		0	280	285	N	N
	3.3	99		0	229	234	N	N
	4.1	87		0	205	211	Y	N
	3.1	87		0	180	185	Y	N
	6.0	78		0	155	161	N	N
	4.0	110	4.0	30	162	166	Y	N
	6.0	15	6.0	30	168	172	N	N
	5.0	15	5.0	30	266	270	N	N
	5.0	165		0	232	236	N	N
	2.1	83		0	197	202	N	N
	6.0	15	6.0	30	240	244	Y	N
Daily Total		3,924		470			20	1

Reviewing Injector Utilization (continued)

The definitions of the titles of the data columns for Injector Utilization screens are as follows:

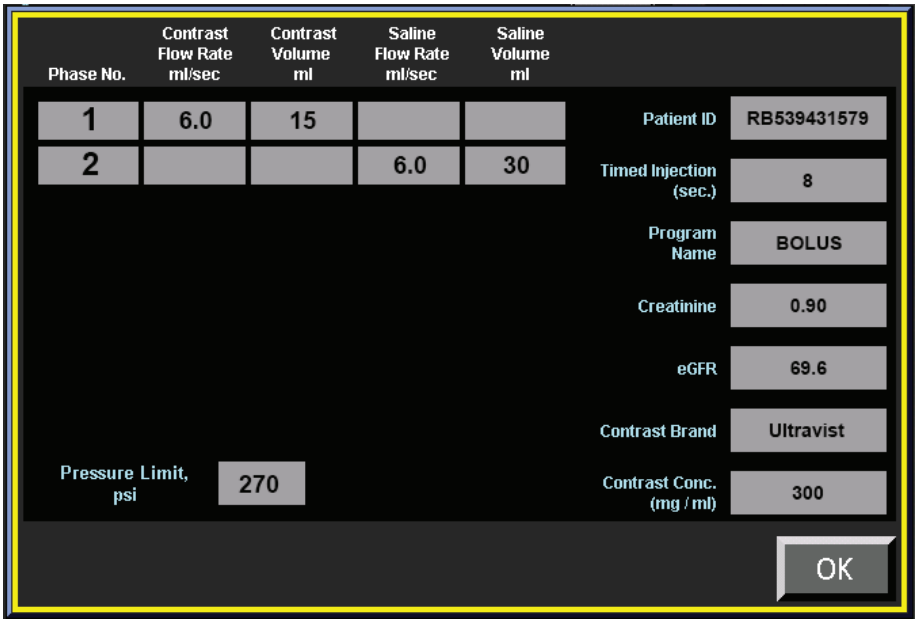
Title	Definition
Time of Injection	The time in 12-hour format that the injection took place.
Avg. Contr. Rate	The average of all the contrast medium flow rates weighted with the contrast medium volumes (ml/s).
Contr. Vol.	The summation of all the contrast medium phase volumes (maximum displayed value of 200 ml).
Saline Rate	The saline flow rate (ml/s).
Saline. Vol.	The summation of all the saline phase volumes (maximum displayed value of 200 ml).
Avg. PSI	The average pressure throughout the contrast medium injection in units of psi.
Max. PSI	The maximum pressure throughout the contrast medium injection in units of psi. If this value is selected, it will display a graph of the entire contrast medium injection (refer to “Pressure Profile” on page 138).
EDA Enab.	If the EDA was Enabled, there will be a Y (Yes). Otherwise, there will be an N (No).
Poss. Extrav	If the EDA was Enabled and declared a possible extravasation, there will be a Y (Yes). Otherwise, there will be an N (No).

Reviewing Injector Utilization (continued)

Injection and Patient Parameters

To display the injection parameters for a particular injection, select the Time of Injection field on the Daily Injector Utilization screen. There will be a pop-up displaying the programmed parameters for that particular injection. Select OK to close the pop-up window.

For example:



Reviewing Injector Utilization (continued)

The definitions of the titles of the data columns for the injection and patient parameters are as follows:

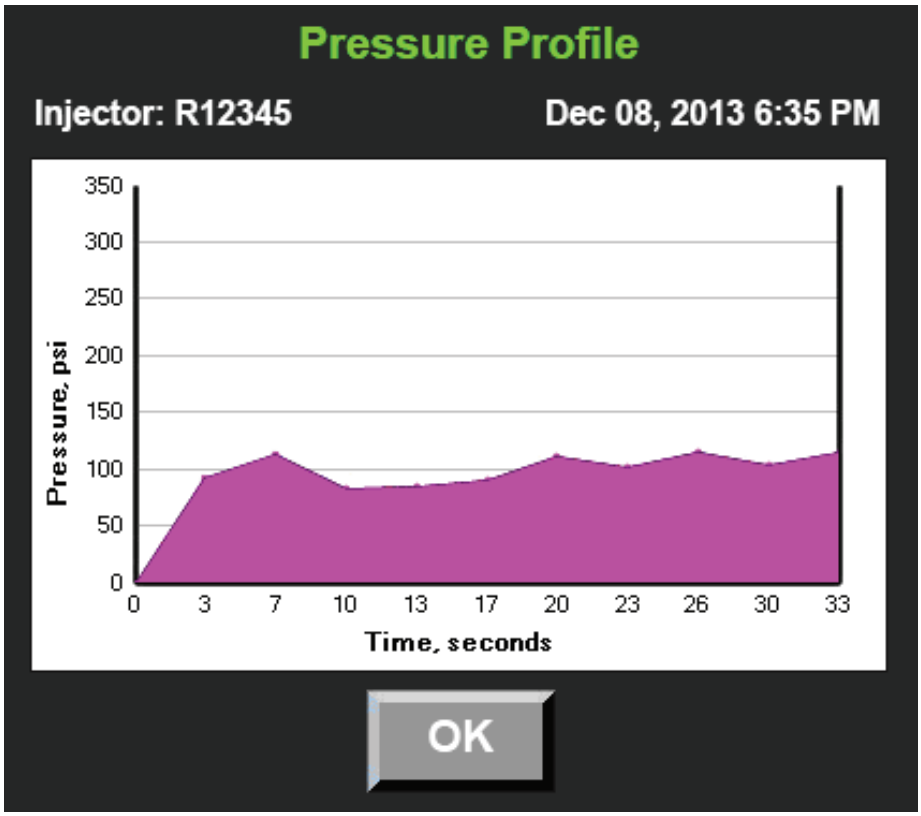
Title	Definition
Phase No.	The phase number.
Contrast Flow Rate	The programmed contrast medium flow rate for that phase in ml/s.
Contrast Volume	The programmed contrast medium volume for that phase in ml.
Saline Flow Rate	The programmed saline flow rate for that phase in ml/s.
Saline Volume	The programmed saline volume for that phase in ml.
Patient ID	The patient identification number.
Timed Injection	The total time of the injection excluding pause phases in seconds.
Program Name	The selected program name used for the injection.
Creatinine	The inputted value of the serum creatinine in mg/dL or µmol/L.
eGFR	The calculated value of the glomerular filtration rate.
Contrast Brand	The selected CT contrast medium brand name.
Contrast Conc	The selected CT contrast medium concentration in mg/ml.
Pressure Limit psi	The pressure limit for the specific injection.

Reviewing Injector Utilization (continued)

Pressure Profile

To display the pressure profile for a particular injection, select the Max. PSI field on the Daily Injector Utilization window. A pop-up graph will be displayed that shows the profile for the entire length of the contrast medium injection. The x-axis is 10 equally distributed time points in seconds representing the total contrast medium injection. The y-axis units are in psi and ranges from 0 to 350 psi (0 to 2413 kPa/0 to 24.1 bar). Select OK to close the graph. If the Max. PSI field is red, this indicates the system was pressure limiting during the contrast medium injection.

For example:

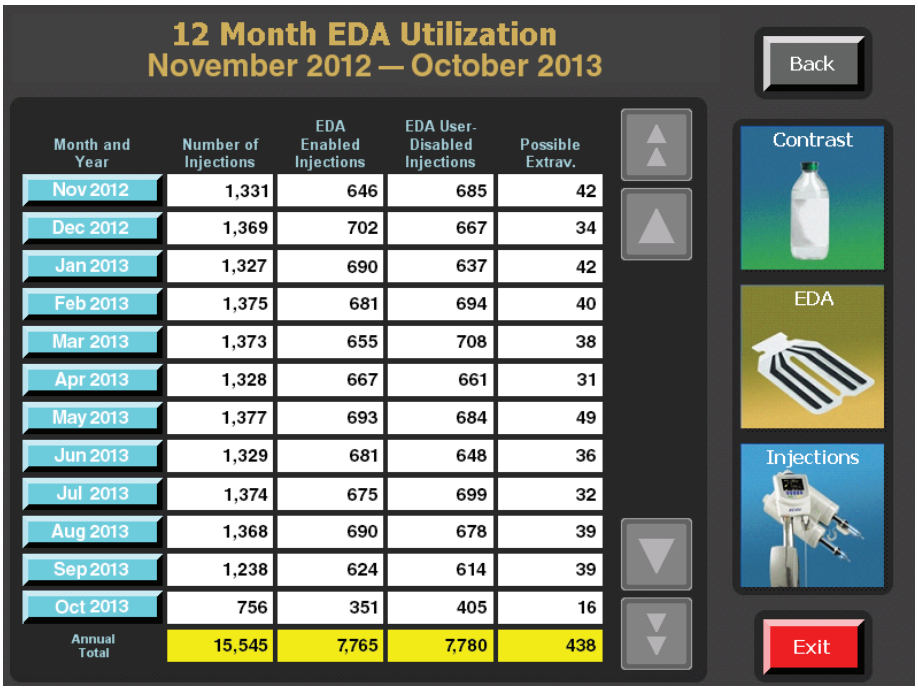


Reviewing EDA Utilization

12 Month EDA Utilization

Select the **EDA** button to view the 12 Month EDA Utilization window, which displays a 12 month view of EDA utilization. Selecting either the double or single arrow scrolls through the months displaying any 12 month view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



Month and Year	Number of Injections	EDA Enabled Injections	EDA User-Disabled Injections	Possible Extrav.
Nov 2012	1,331	646	685	42
Dec 2012	1,369	702	667	34
Jan 2013	1,327	690	637	42
Feb 2013	1,375	681	694	40
Mar 2013	1,373	655	708	38
Apr 2013	1,328	667	661	31
May 2013	1,377	693	684	49
Jun 2013	1,329	681	648	36
Jul 2013	1,374	675	699	32
Aug 2013	1,368	690	678	39
Sep 2013	1,238	624	614	39
Oct 2013	756	351	405	16
Annual Total	15,545	7,765	7,780	438

The definitions of the titles of the data columns for the EDA Utilization screens are as follows:

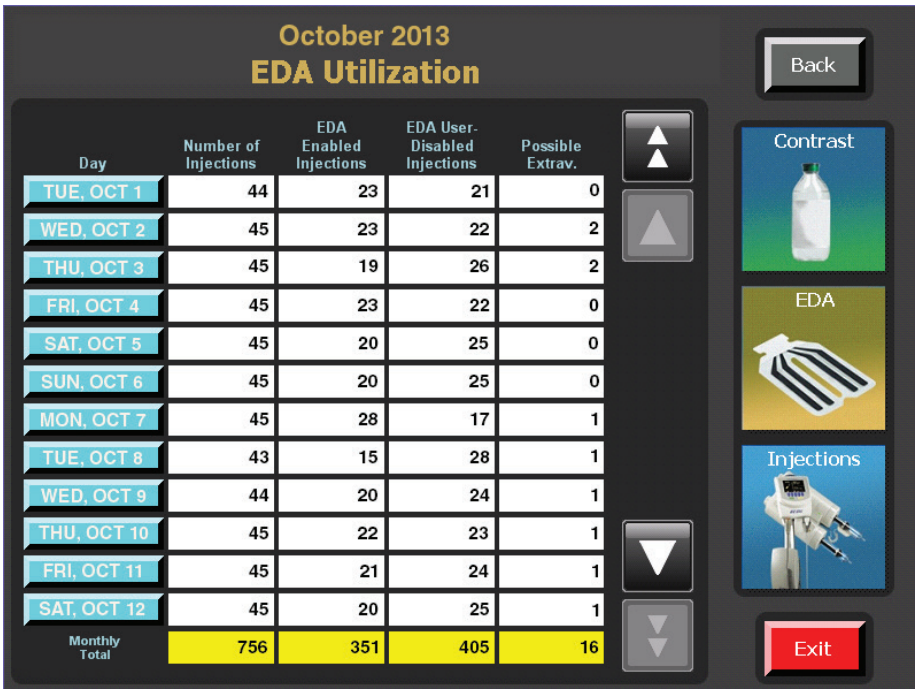
Title	Definition
Number of Injections	The total number of injections for that period of time.
EDA Enabled Injections	The total number of EDA Enabled injections or an indicator if the EDA was utilized for a particular injection.
EDA User Disabled Injections	The total number of EDA User-Disabled injections or an indicator if the EDA was not utilized for a particular injection.
Possible Extrav.	The total number of times that the EDA was Enabled, and the system declared a possible extravasation.

Reviewing EDA Utilization (continued)

Monthly EDA Utilization

Select one of the months to drill down to the Monthly EDA Utilization window, which displays the number of EDA utilizations per day of the selected month. Selecting either the double or single arrow scrolls through the days displaying any 12-day view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



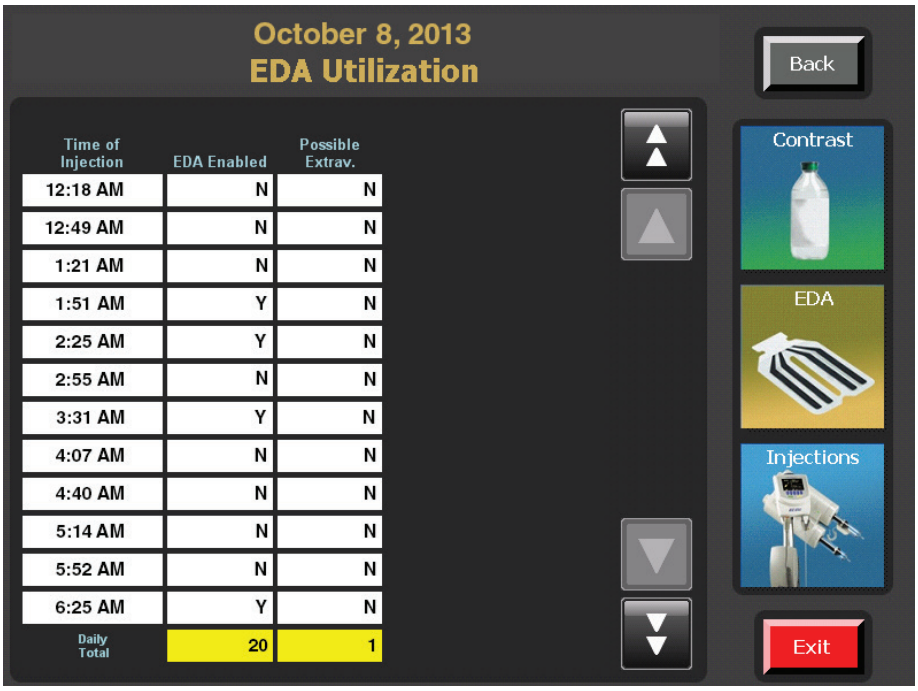
Day	Number of Injections	EDA Enabled Injections	EDA User-Disabled Injections	Possible Extrav.
TUE, OCT 1	44	23	21	0
WED, OCT 2	45	23	22	2
THU, OCT 3	45	19	26	2
FRI, OCT 4	45	23	22	0
SAT, OCT 5	45	20	25	0
SUN, OCT 6	45	20	25	0
MON, OCT 7	45	28	17	1
TUE, OCT 8	43	15	28	1
WED, OCT 9	44	20	24	1
THU, OCT 10	45	22	23	1
FRI, OCT 11	45	21	24	1
SAT, OCT 12	45	20	25	1
Monthly Total	756	351	405	16

Reviewing EDA Utilization (continued)

Daily EDA Utilization

Select one of the days to drill down to the Daily EDA Utilization window, which displays EDA usage per injection for that selected day. Selecting either the double or single arrow scrolls through the injections displaying any 12-injection view while updating the totals located on the bottom of the columns in yellow boxes.

For example:



9 CT Scanner Interconnect

Background

The EmpowerCTA®+ Injector System already contains EmpowerSync®, a CT scanner communications protocol designed to allow communication between the EmpowerCTA®+ Injector System and a CT scanner. EmpowerSync® allows signals to be transmitted and coordinated between the CT scanner and the Injector System. The communications between the two systems allows for the improved workflow and timing between the two systems. In addition under certain conditions, the Injector System can be started and stopped by the CT scanner.

Overview of Operation

A local authorized Bracco Injeneering S.A. representative can activate the EmpowerSync® CT scanner synchronization option. Contact your local Bracco Injeneering S.A. representative for hardware compatibility and interoperability. If the required cable that connects the EmpowerCTA®+ Injector System to the CT scanner is not properly connected and the feature is activated, the scanner interconnect software will display a message that it is not connected. Once the feature has been activated and communication established, a scanner interconnect message displays on the screen to denote which connection mode is active. There are three types of modes:

- Monitor
- Tracking
- Control

In Monitor mode, the two systems act independently of each other. The systems share the data but a loss of communications does not impede the use of either system.

In Tracking mode, the system can be armed locally at the Injector System, however, the injection cannot be started until the CT scanner sends a ready signal to the Injector System.

Overview of Operation (continued)

In Control mode, the CT scanner has full control to arm, run, pause and stop the Injector System. In all modes, the Injector System has the ability to be paused either at the Injector Controller, Remote Control or via the pendant switch.

When EmpowerCTA®+ is in coupled mode with any CT scanner it is not possible to start the injection using the RUN button on the injector head in the scan room. To initiate an injection the injector head needs to be tilted down in the Run Position, armed on the injector head, and the injection must then be started from either the remote screen in the CT Control Room or via the scanner control screen.

This is a feature of the EmpowerCTA®+ injector to ensure the user is not exposed to radiation by inadvertently commencing a synchronized scan and injection whilst in the scan room.

CAUTION

In the event of a loss of communications between the two systems, the Injector System will go to Monitor mode. An acknowledgement message will be displayed to denote the fault occurrence.

Note

EmpowerSync® is not compatible with all CT scanning systems. Contact a local Bracco Injeneering S.A. representative for more information on activation and compatibility.

10 Limited Warranty

EmpowerCTA®+ Injector System Limited Warranty

Bracco Injeneering S.A. warrants that the Bracco Injeneering S.A. EmpowerCTA®+ Injector System will be free of defects in material and workmanship for a period of one (1) year following installation. This warranty is available and extended only to the original end-user purchaser of the Bracco Injeneering S.A. product. The foregoing is Bracco Injeneering S.A.'s sole warranty.

Any part or component of the EmpowerCTA®+ Injector System that is judged to be covered under this warranty by Bracco Injeneering S.A. during the warranty period will be repaired or replaced by Bracco Injeneering S.A. at its option and its expense. Remedies available to the purchaser under this warranty are limited to repair or replacement of malfunctioning parts or system replacement with the specific remedy subject to determination by Bracco Injeneering S.A. in its sole and reasonable judgment. Application for warranty coverage and remedy must be made to Bracco Injeneering S.A. within ten (10) days of the apparent malfunction.

This warranty is void if the product has been: (a) repaired by someone other than Bracco Injeneering S.A. or its authorized agent; (b) modified or altered in any way as to, in the judgment of Bracco Injeneering S.A., affect its function: (c) misused (which includes, but is not limited to, the use of non-Bracco Injeneering S.A. syringes and/or tubing with the EmpowerCTA®+ Injector System); or (d) damaged by negligence, accident, or intent including damage caused by contrast media or other substances.

This warranty does not cover routine wear and tear on the product.

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BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. DUE TO BIOLOGICAL DIFFERENCES IN HUMAN PATIENTS AND BECAUSE BRACCO INJENEERING S.A. HAS NO CONTROL OVER THE CONDITIONS UNDER WHICH PRODUCTS ARE USED, DIAGNOSIS OF THE PATIENT, THE METHOD OR ADMINISTRATION OF THE PRODUCT OR THE HANDLING OF THE PRODUCT AFTER IT LEAVES BRACCO INJENEERING S.A.'S POSSESSION, BRACCO INJENEERING S.A. DOES NOT WARRANT EITHER A GOOD EFFECT OR AGAINST ILL EFFECT FOLLOWING THE USE OF THE BRACCO INJENEERING S.A. PRODUCT AND BRACCO INJENEERING S.A. MAKES NO WARRANTY AS TO WHETHER OR NOT ANY PARTICULAR OR DESIRED RESULT IS OBTAINABLE BY APPLICATION OR USE OF THE BRACCO INJENEERING S.A. PRODUCT.

BRACCO INJENEERING S.A. SHALL UNDER NO CIRCUMSTANCES BE LIABLE TO THE PURCHASER OR ANY THIRD PARTY FOR SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR EXEMPLARY DAMAGES OF ANY NATURE, WHATSOEVER, INCLUDING, BUT NOT LIMITED TO, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR REVENUE, REAL OR PERCEIVED LOSS OF USE, LOSS ARISING FROM A DEFECT IN DESIGN, MATERIAL AND/OR MANUFACTURE OR WORKMANSHIP AND/OR THE FAILURE OF THE PRODUCT(S) TO PERFORM AS SPECIFIED, EVEN IF BRACCO INJENEERING S.A. SHALL HAVE BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

THE BRACCO INJENEERING S.A. PRODUCT 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 PROCEDURE. BRACCO INJENEERING S.A. DISCLAIMS LIABILITY FOR ALL INJURIES, DEATHS, OR PROPERTY DAMAGE ARISING FROM THE USE OF THE PRODUCT BY ANYONE, OTHER THAN QUALIFIED PERSONNEL DESCRIBED ABOVE, OR THE IMPROPER, NEGLIGENT OR RECKLESS USE OF THE PRODUCT, OR THE USE OF THE PRODUCT FOR ANY UNAPPROVED INDICATION OR FOR ANY USE NOT SPECIFICALLY INDICATED IN THE OWNER'S MANUAL OR OTHER PRODUCT INSTRUCTIONS.

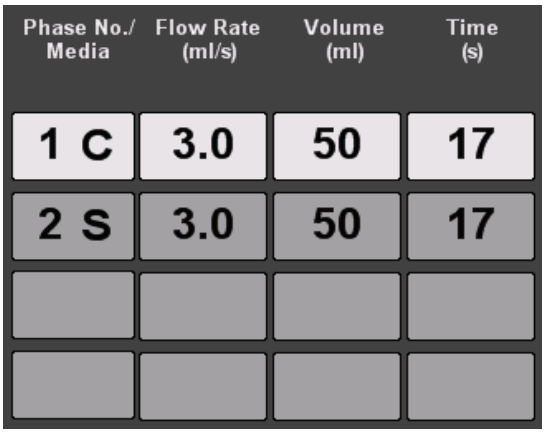
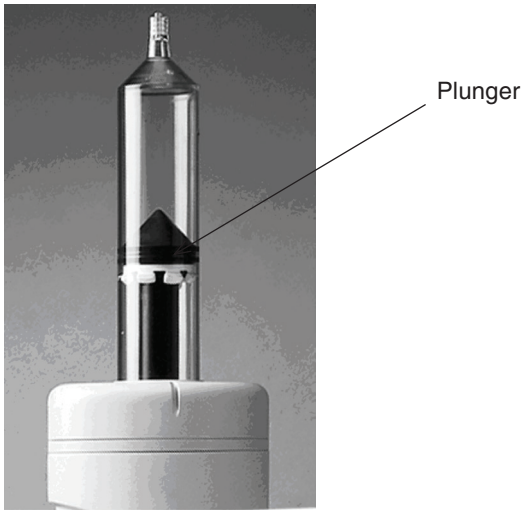
A charge will be applied for all repair service not covered under this limited warranty.

Appendix A – Glossary

Glossary

Glossary Term	Definition
Arming	Arming is the procedure just prior to running the Injector that verifies and loads the injection protocols. The EmpowerCTA®+ Injector System must be armed before an injection can proceed.
Coiled Tubing	The tubing that connects the EmpowerCTA®+ Injector System syringe to the patient's indwelling intravenous catheter.
Contrast Medium (Media)	Injectable ionic or non-ionic iodinated contrast agent used for CT image enhancement.
Connecting Tube	A bifurcated tube with one male Luer lock to two female Luer locks (with two one-way check valves), used to connect the contrast and saline syringes to the coiled tubing.
EDA	Extravasation Detection Accessory. An optional device that may be attached to an EmpowerCTA®+ Injector System to augment monitoring for contrast medium extravasation.
Extravasation	The condition that results when contrast medium is injected primarily into the surrounding tissue resulting from a defect in the vein or misplaced catheter.
Flow Rate	The number of milliliters of contrast medium or saline injected, per second.
Fill Tube (J-Tube)	A curved tube that is used for transferring contrast medium from its original bottle into the syringe. Because the fill tube has a shape like the letter J, it is also referred to as a J-tube.
Injector	The part of the EmpowerCTA®+ Injector System that injects the contrast medium or saline that will allow the user to arm and run the injection.

Glossary (continued)

Glossary Term	Definition
Out of Range	A condition of the EDA, shown on the Remote Control's Main screen, to indicate that the EDA is not properly connected to a patient.
Overpressure	Condition caused by an occlusion in the administration set that essentially prevents any contrast medium or saline from being delivered to the patient's catheter.
Phase	One of the steps of an injection, consisting of a specified flow rate and volume.
Phase Table	A table in the lower left of the Main screen or Program screen, used to describe the exact series of steps that will comprise an injection: 
Plunger	The rubber jacket inside the syringe, which is actuated by the Injector ram: 

Glossary (continued)

Glossary Term	Definition
Program (Injection Protocol)	A series of steps that the Injector System will perform, displayed on the Remote Control touch screen as a numbered list of flow rates, volumes, and durations.
Remote Control	One of the components of the EmpowerCTA®+ Injector System. The Remote Control, usually located in the CT control room, allows you to program and select the injection protocol, and to arm and run the injection from a remote location.
Saline Chase (Saline Flush)	Chasing is to use a saline medium to “push” the contrast along to create a tight bolus to achieve improved uniform opacification and exam outcome. It may also be referred to as a Saline Flush.
Syringe	The vessel in which the EmpowerCTA®+ Injector System holds its contrast medium or saline until instructed to inject it.
Volume	The number of milliliters of fluid to be injected during a particular phase of an injection program. In conjunction with the phase flow rate, this also determines how long the phase will last; when the desired amount is completed, the phase will be considered over and the next phase will begin.
Warmer	A device that attaches to the contrast syringe to maintain the pre-warmed contrast at a steady temperature state of approximately 98°F (37°C).

Appendix B – Troubleshooting

Frequently Asked Questions

This appendix contains frequently asked questions and their answers:

No.	Question	Answer
1	The Remote Control is powered on, but the screen is completely black except for a randomly blinking Bracco Injeneering logo. Why?	The black screen with the flashing logo is the Remote Control screen saver, a feature that activates automatically after 30 minutes of inactivity to protect the touch screen on the Remote Control from being damaged by displaying one static image for too long. To leave the screen saver and return to the Remote Control normal operations, press once anywhere on the Remote Control touch screen.
2	Someone knocked out the power cord. What should we do?	Turn off the component that was accidentally unplugged, plug it back in, and turn it on. The system should recover smoothly, unless damage occurred to the power cord or the unit. It will not be possible to resume the current injection if power was lost in the middle of it. NOTE: Ensure the patient is disconnected prior to re-powering any part of the system.
3	The injection stops for a possible extravasation condition, but no such condition exists. How can I continue the injection?	In this case, it is likely caused by a poor or marginal patient connection, excessive digital palpation over the patch or excessive patient movement. In any of these cases, when the possible extravasation message is displayed, at your discretion select the EDA button near the lower right corner of the Remote Control touch screen to disable the EDA and continue the injection. However, be aware that disabling the EDA in this way will also prevent it from detecting an extravasation condition for the remainder of this injection.

Frequently Asked Questions (continued)

No.	Question	Answer
4	Why is the system refusing to arm?	When the system refuses to arm, it means that something is not ready for the injection. The most common causes of this situation are: • The last listed phase in the current program does not contain both a flow rate and a volume. All phases that will be used in the phase table must be complete before the system will arm. • The Injector Head is not tilted fully downward. Look for the downward-tilted graphic on the Remote Control or Injector Controller to confirm that the Injector Head is in the proper position. If it is not, tilt it down further to the Run position. • The syringe contains 0 ml of contrast medium or is at the Replace Syringe position. • A saline injection has been selected and the saline syringe contains 0 ml of saline or is at the Replace syringe position. • The Remote Control and Injector have lost communication with each other. Check the cables that run from each component to the power supply. If the cables are tight, try powering both components off, then back on. • A system fault is displayed on the Injector Controller and Remote Control. In this case, follow the instructions as listed on the Injector Controller and Remote Control. In addition, the following conditions must be met to arm the Injector: • The Remote Control has one to eight valid phases programmed (the ARM option appears only at the Remote Control) or one to four valid phases programmed (the ARM option appears at both the Injector Controller and the Remote Control). • The Remote Control is displaying the Main screen. • There has been no Remote Control activity for two or more seconds. If the situation persists, contact a local Bracco Injeneering S.A. representative.

Frequently Asked Questions (continued)

No.	Question	Answer
5	Is it possible to remove or reinsert a loaded syringe?	Yes, as long as the syringe is not currently attached to the patient. ***WARNING*** *Attempting to remove a syringe from the Injector while it is attached to the patient coiled tubing is likely to cause injury to the patient.* If the syringe is not connected to anything, you can remove it from the Injector while it is still loaded with contrast medium. To do this, tilt the Injector Head fully upright, then press and hold down the REPLACE SYRINGE button. Make sure that the connecting tube set (with check valves) has been removed, then select the appropriate REPLACE SYRINGE option. Allow the plunger to retract. When the Injector ram and syringe plunger have stopped moving, open the syringe door and remove the syringe. Ordinarily, a syringe removed in this way should be discarded. Once contrast medium has been exposed to the air, there is a very limited amount of time before it will begin to lose its sterility in a normal environment. However, if you follow your institution's guidelines for maintaining a sterile field around the syringe, and if you label the syringe with its contents and the time and date it was filled, you could reinsert the loaded syringe back into the Injector, close the syringe door, then force all the air out of it using the normal procedure described on page 39. This is not recommended by Bracco Injeneering S.A. If you choose to do this, it is the responsibility of your institution to establish safety guidelines for this practice.
6	The Injector Controller is beeping continually and displaying a message about a fault. What should I do?	A fault is an error in the Injector System. Make note of the fault number. Power off and on the Injector only. Verify that the fault message is no longer displayed. If the fault appears again, contact a local Bracco Injeneering S.A. representative.

Frequently Asked Questions (continued)

No.	Question	Answer
7	The Scanner is not able to communicate with the Injector System (EmpowerSync® Option Only), What should I do?	Perform the following start-up procedure: 1. Shut down the EmpowerCTA®+ Remote Control and Injector. • The EmpowerCTA®+ Power Supply can remain powered on. • For a first attempt the Scanner can remain on and the next step skipped. If this procedure fails to restore communication it should be repeated with the next step included. 2. Re-boot the Scanner and wait for the system to boot up completely. 3. Power on the Injector. 4. Power on the Remote Control.
8	The label printer icon appears on the Main screen, but it is red. What does this mean?	The PRINT option is set to Enabled in the Setup screen, but there is a problem with the printer. 1. Make sure that the label printer is properly connected to a USB port on the Remote Control. 2. Make sure that the label printer has enough paper, and that the paper is not jammed. 3. If the print label icon is now blue, press the icon to try printing again.
9	The Remote Control software seems “frozen” and will not respond to any inputs.	Press and hold the power button on the Remote Control for 5 seconds to turn off power. Then press the power button again to restart the Remote Control.

System Messages

The following table lists alert messages displayed by the EmpowerCTA®+ Injector System.

Message	Recommendation
SHUTDOWN WILL AUTOMATICALLY TURN REMOTE CONTROL OFF, PROCEED?	The user selected the SHUTDOWN button on the Setup screen and the system is requesting confirmation before proceeding with the shutdown. To shut down the Remote Control to a power off condition, select YES. To cancel the shutdown and continue using the Remote Control, select NO.
SALINE FLUSH WILL BE DISABLED, REMOVE SALINE SYRINGE, Press OK to Continue Injection Protocol without Saline Flush	Saline functions are disabled whenever three or more contrast phases are programmed at the Remote Control. To continue with three or more contrast phases but no saline, select OK. To continue with saline, select OK and program the injection with no more than two contrast phases.
SAVE WILL OVERWRITE CURRENT MEMORY. PROCEED?	At least one parameter in a previously saved program has been changed, and the user is attempting to save the modified program. This message asks for confirmation before overwriting the previously saved program.
PROGRAM EXISTS IN MEMORY AS PROGRAM NUMBER XX. PROCEED?	The SAVE AS function specifies a program name that already exists, and the system is asking for confirmation before it overwrites the program saved in the specified program number.
DELETE WILL REMOVE THE CURRENT PROGRAM FROM MEMORY. PROCEED?	The user selected the DELETE function, and the system is asking for confirmation before it deletes the specified program.
HIGHLIGHTED PROGRAM HAS CHANGED, AUTO SAVE, PROCEED?	At least one parameter in the currently selected program has been changed, and the user has selected another program without saving. The system is asking whether you want to automatically save the changes made to the previous program before opening another program.
A PAUSE as last parameter is not allowed and can not be saved.	A saved program was modified so that the last program phase is a PAUSE or a TIMED PAUSE. Before you can save the program, the last PAUSE or TIMED PAUSE phase must be deleted.

System Messages (continued)

Message	Recommendation
All Program Locations are Full	EmpowerCTA®+ can store a maximum of 100 programs on the Remote Control. This Remote Control already has 100 programs saved, and it is not possible to save this program unless another program is deleted first.
Program can not be selected. Contact Bracco Injeneering S.A. for support.	Contact a local Bracco Injeneering S.A. representative for assistance.
Phase 1 can not be deleted because Phase 2 is Saline.	If phase 2 is defined as saline, phase 1 cannot be deleted because the first phase would then be saline, which is not allowed.
A PAUSE parameter in Phase 2 is not allowed with the third phase set for Saline.	Whenever the third phase is defined as saline, a PAUSE or a TIMED PAUSE cannot be defined as the second phase.
Initialization of EmpowerSync® hardware is not successful. Press OK button to continue.	Although initialization was attempted, there is no communication between the EmpowerCTA®+ Remote Control and the EmpowerSync® power supply. Select the **OK** button to attempt to restart EmpowerSync® communication.
Restarting EmpowerSync® Control in Progress. PLEASE WAIT.	EmpowerSync® initialization has failed, or EmpowerSync® communication between the Remote Control and the EmpowerSync® power supply has been lost.
Unsuccessful Restart of EmpowerSync® Control. Press OK button to close this screen.	EmpowerSync® communication has been lost, and an attempt to restart communication was not successful. Contact a local Bracco Injeneering S.A. representative for assistance.
LOSS OF EmpowerSync® COMMUNICATION (1), Press OK button to continue.	EmpowerSync® communication between the Remote Control and the scanner has been lost. The number in the message is intended to help authorized Bracco Injeneering S.A. representatives identify the problem. Select **OK** to restart EmpowerSync® communication.

System Messages (continued)

Message	Recommendation
LOSS OF EmpowerSync® COMMUNICATION (5), Press OK button to restart.	EmpowerSync® communication between the Remote Control and the scanner has been lost. The number in the message is intended to help authorized Bracco Injeneering S.A. representatives identify the problem. Select **OK** to restart EmpowerSync® communication.
AN INJECTOR HARDWARE FAULT WAS DETECTED.	Contact a local Bracco Injeneering S.A. representative for assistance.
Re-power injector or Call for Service	Turn off power to the Injector and then turn it back on again (do not shut down the Remote Control). If this does not solve the problem, contact a local Bracco Injeneering S.A. representative for assistance.
SYSTEM FAULT No. 212 INTERNAL FAULT RE-POWER INJECTOR OR CALL FOR SERVICE	Check syringe position. If the syringe is not in the Replace Position, power off the Injector, manually move the syringe to the Replace Position, and power on the Injector. If the error persists, contact a Bracco Injeneering S.A. representative.

Appendix C – Technical Specifications and EMC Tables

Component Specifications

Injector

Voltage Rating	100-240 V~, 150 VA, 50/60 Hz, with external switching power supply that auto-seeks to applied voltage.
Wattage	150 watts, maximum
Weight	18 lbs (8.16 kg)
Dimensions	Height (including floor stand): 39.75 in (100.97 cm) Width (including floor stand): 26.5 in (67.31 cm)
Touch Screen	8 in (20.3 cm), measured diagonally Resolution 600 x 800

Remote Control Computer

Voltage Rating	100-240 V~, 150 VA, 50/60 Hz, with external switching power supply that auto-seeks to applied voltage.
Wattage	61 watts, maximum
Weight	12.3 lb (5.6 kg)
Dimensions	Height: 13.31 in (33.80 cm) Height with mount 17.31 in (43.97 cm) Width: 15.12 in (38.39 cm) Depth: 2.72 in (6.90 cm) Depth with mount 4.72 in (11.99 cm)
Touch Screen	17 in (33.80 cm), measured diagonally Resolution:1280 x 1024
Device Ports	Keyboard and mouse
I/O Ports	USB, Serial, Ethernet, Video Out, Audio
Media	Internal HDD

Extravasation Detection Accessory

Patient Current Leakage	Less than 10 microamperes, type CF.
Extravasation Detection	Less than 20 milliliters.

Overall System Accuracies and Ranges

Volume

Range	1 to 200 ml in user-specified increments of 1 ml.
Accuracy	± 2% of programmed volume + 1 ml.

Pressure

Range	40 to 325 psi in user-specified increments of 1 psi 276 to 2241 kPa in user-specified increments of 1 kPa 2.8 to 22.4 bar in user-specified increments of 0.1 bar
Accuracy	± 10% of programmed pressure limit + 10 psi (69 kPa, 0.69 bar), under conditions of stable pressure-limiting control. ± 10% of programmed pressure limit + 75 psi (517.1 kPa, 5.17 bar) for no more than 3 seconds, for transient pressure deviations resulting from hard occlusions or abrupt phase transitions.

Flow Rate

Range	0.1 to 10.0 ml/s in user-specified increments of 0.1 ml/s. When accelerating between two flow rates that differ by ≥ 2.5 ml/s, the flow rate will uniformly change under program control to the new rate within three seconds.
Accuracy	± 5% of programmed rate + 0.1 ml/s under conditions of stable flow rate control for at least 3 seconds. +5% of programmed rate + 0.1 ml/s maximum instantaneous flow rate.

Label Printer

Voltage	Input voltage: 100 – 240 VAC, 50/60 Hz, 1.6 Amps Output voltage: 24 VDC, 2.5 Amps

Regulatory Requirements

Requirement	Description
Anesthetic Warning	This equipment not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXED WITH AIR or OXYGEN or NITROUS OXIDE.
Electrical Safety	With respect to electric shock, fire, mechanical and other specified hazards, only in accordance with EN/IEC 60601-1.
Hazard Rating	EmpowerCTA®+ is Classified to the following hazards: Shock, Fire, Casualty per EN/IEC 60601-1. Software is not relied upon for meeting safety requirements related to mechanical, fire and shock.
Biological Contamination	Biological contamination can result from failure to follow instructions for use.
Environmental Requirements	Meets requirements set forth in EN/IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety.
Electromagnetic Compatibility (EMC)	Meets requirements set forth in EN/IEC 60601-1-2, Medical Electrical Equipment Part 1: Collateral Standard, Electromagnetic Compatibility.
Protection against ingress of fluids	Ordinary.
Mode of Operation	Continuous operation .
Fuse Rating	F6.3 A, 250V
Preferred Cleaning Method	Use mild hospital grade disinfectant cleaner.
Mains Disconnect	The line cord is used as the primary mains disconnect.
Disposal of Equipment and Accessories	This product should be recycled and not disposed of as general waste (subject to WEEE annex IV resp. EN 50419). In accordance with European Union WEEE Directive 2002/96/EC, Bracco Injeneering S.A. will be fully responsible for the coordination, logistics, and costs of the WEEE process.
Parts for Use in Patient Environment	The EmpowerCTA®+ Injector System, Power Supply, EDA Module, Power and Communication Cables, EDA Patient Cable, Pendant Switch and Contrast Syringe Warmer.
Safety Certification	The EmpowerCTA®+ Injector System and EDA Accessories have been tested to EN/IEC 60601-1 harmonized national standard. The system has been investigated per EN/IEC 60601-1 in accordance with situation 3b. However, should additional computing equipment be connected, use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Regulatory Requirements (continued)

Note

Bracco Injeneering S.A. shall make available only to qualified representatives upon request certain circuit diagrams, components parts lists, descriptions, and calibration instructions or other information for those parts of the EmpowerCTA®+ Injector System which are designated by the manufacturer as field repairable.

Environmental Requirements

Requirement	Standard
Operating Conditions	Meets requirements set forth in EN/IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety. Operation: • Temperature 10°C to 40°C (50°F to 104°F) • Humidity 5% to 95% • Altitude –200 m to 2000 m (656 ft to 6561.7 ft)
Storage Conditions	Storage and Transportation: • Temperature –29°C to +60°C (–20.2 °F to 140°F) • Humidity 0% to 85% • Altitude –200 m to 4267 m (656 ft to 13999.3 ft)
Shock and Vibration	ASTM 4169

Software

Requirement	Description
Remote Control software version	10 and approved modifications (and higher versions) thereof.
Compatibility	Injector System 9.01k (and higher versions).
Operating system	Windows 7 embedded standard SPI

Accessories, Disposables, and Consumables

Catalog Number	Description
017344	FastLoad™ CT Syringe Pack J-Tube
017345	FastLoad™ CT Syringe Pack with Spike
017346	FastLoad™ CTA Dual Syringe Pack J-Tube
017347	FastLoad™ CTA Dual Syringe Pack with Spikes
017352	EDA Patch
017354	FastLoad™ CTA Dual Syringe Pack (DCV)
017355	FastLoad™ CTA Dual Syringe Pack with Spikes (DCV)

EMC Requirements

WARNING

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 EmpowerCTA®+ should be observed to verify that they are operating normally.

The use of accessories, transducers and cables other than those specified, with the exception of those transducers and cables specified or provided by Bracco Injeneering, may result in increased electromagnetic emissions or decreased electromagnetic immunity of the EmpowerCTA®+ Injector system 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 EmpowerCTA®+, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The operating environment in which the EmpowerCTA®+ Systems is used is a CT Suite. The EmpowerCTA®+ System shall be used only when it will be connected to a proper electrical source.
The EmpowerCTA®+ is a medical equipment with essential performance and the operator can expect to have the phenomena and operation listed below due to electromagnetic disturbances.

Declaration

The following are the performances of the EmpowerCTA®+ Injector system that were determined to be essential performance, the absence or degradation of them would result in an unacceptable risk.
Max pressure shall not exceed set pressure limit (within specified tolerances). Flow rate shall not exceed programmed flow rate (within specified tolerances). Total Volume delivered shall not exceed programmed volume (within specified tolerances). Display shall accurately reflect current status of the system and the current protocol. The Extravasation Detection Assembly (EDA) shall detect an extravasation within the detection limits.

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

Cables :

Cables Identification	Cable type	Length	Terminations
Remote Control Power cable	specifically manufactured by Bracco Injeneering	79 in (2 m)	Depend on country
Power supply Power cable	specifically manufactured by Bracco Injeneering	79 in (2 m)	Depend on country
USB communication cable	Braid, multiconductor	116.2 in (2.95 m)	USB
Injector power/ communication cable	foil & braid, multiconductor	60 ft (18.25 m)	10 pin circular

EMC Requirements (Continued)

Other accessories :

Identification	Connectors type	Length	Terminations
Pendant switch	fiber optic, multiconductor	118 in (3 m)	8 pin circular
EDA accessory and patient cable	foil & braid, multiconductor	79 in (2 m)	6 pin circular
EmpowerSync Siemens Scanner cable	CAN 425 multiconductor	95.1 in (29 m)	DB15
Nexo® Ethernet	multiconductor, category 5U/UTP	118 in (3 m)	RJ-45
Heater	braid, multicolor	29.5 in (0.75 m)	4 pin circular
Injector power / communication cable 75’	foil & braid, multiconductor	75 ft (23 m)	10 pin circular
Injector power / communication plenum cable 60’	Plenum foil & braid, multiconductor	60 ft (18.25 m)	10 pin circular
Injector power / communication plenum cable 50’	Plenum foil & braid, multiconductor	50 ft (15.25 m)	10 pin circular
Injector power / communication riser 15’ plenum cable	Plenum foil & braid, multiconductor	15 ft (4.5 m)	10 pin circular
Injector power / communication riser 12’ plenum cable	Plenum foil & braid, multiconductor	12 ft (3.5 m)	10 pin circular

Table 2: Accessories

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, §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
Remote Control Power cable	EmpowerCTA®+
Power supply Power cable	EmpowerCTA®+
USB communication cable	EmpowerCTA®+
Injector power/communication cable	EmpowerCTA®+
EDA cable and EDA accessory	EmpowerCTA®+
Nexo® Ethernet	Nexo® Manufactured by Bracco Injeneering
Pendant switch	EmpowerCTA®+
Heater	EmpowerCTA®+
Empower Sync	specifically manufactured by Bracco Injeneering S.A

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

EMC Tables

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2007 - edition 3 / 1721 & 1731).

The EmpowerCTA®+ Injector System is intended for use in the electromagnetic environment specified below. The user of the EmpowerCTA®+ I njector System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The EmpowerCTA®+ Injector System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The EmpowerCTA®+ is suitable for use in all establishments other than domestic establishment 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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2014 - edition 4 / 1731).

The EmpowerCTA®+ is intended for use in the electromagnetic environment specified below. The user of the EmpowerCTA®+ should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The EmpowerCTA®+ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The EmpowerCTA®+ is suitable for use in all establishments, including domestic establishments 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	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: Electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2007 - edition 3 / 1721 & 1731).

The EmpowerCTA®+ Injector System is intended for use in the electromagnetic environment specified below. The user of the EmpowerCTA®+ Injector System should assure 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%.
Electrical fast 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 IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EmpowerCTA®+ Injector System requires continued operation during power mains interruptions, it is recommended that the EmpowerCTA®+ Injector System be powered from an uninterruptible power supply or 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.
Note: Ut is the AC mains voltage prior to application of the test level.			

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2014 - edition 4 /1731).

The EmpowerCTA®+ is intended for use in the electromagnetic environment specified below. The customer or the user of the EmpowerCTA®+ should assure 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, ± 4, ± 8, ± 15 kV air	± 8 kV contact ± 2, ± 4, ± 8, ± 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%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV, 100kHz for power supply lines* ± 1 kV, 100 kHz for input/output lines*	±2 kV, 100kHz for power supply lines* ±1 kV, 100 kHz for input/output lines*	Mains power quality should be that of typical commercial or hospital environment. *Not applicable for DC and I/O if cable < 3 m
Surge IEC 61000-4-5	±0.5, ±1 kV line(s) to line(s)* ±0.5, ±1, ± 2 kV line(s) to earth*	±0.5, ±1 kV line(s) to line(s)* ±0.5, ±1, ± 2 kV line(s) to earth*	Mains power quality should be that of 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 IEC 61000-4-11	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 typical commercial or hospital environment. *Not applicable for DC and I/O if cable < 3 m. If the user of the EmpowerMR® requires continued operation during power mains interruptions, it is recommended that the EmpowerCTA®+ be powered from an uninterruptible power supply or battery. UT is the a.c. mains voltage (110-240) prior to application of the test level.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	Deviation see Note[1].	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note[1]: Not tested, because no magnetic susceptibility components inside EmpowerCTA®+.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: Electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2007 - edition 3 / 1721 & 1731).

The EmpowerCTA®+ Injector System is intended for use in the electromagnetic environment specified below. The user of the EmpowerCTA®+ Injector System should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the EmpowerCTA®+ Injector System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 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 survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a. 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 EmpowerCTA®+ Injector System is used exceeds the applicable RF compliance level above, the EmpowerCTA®+ Injector System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the EmpowerCTA®+ Injector System.

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

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: Electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2014 - edition 4 /1731)

Portable and mobile RF communications equipment should be used no closer to any part of the EmpowerCTA®+, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. 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.

Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band * 6 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band *	3 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band * 6 Vrms 150 kHz to 80 MHz outside ISM bands and radio amateur band *	If the measured field strength in the location in which the EmpowerCTA®+ is used exceeds the applicable RF compliance level, the EmpowerCTA®+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EmpowerCTA®+. Minimum separation distance shall be calculated by following equation: $d = \frac{6}{E} * \sqrt{P}$ *E* is the immunity test level in [V/m] *d* is the minimum separation in [m] *P* is the maximum power in [W] **RF wireles equipement 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	
Proximity field from RF wireless communication equipment IEC 61000-4-3	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	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	

*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.

If the measured field strength in the location in which the EmpowerCTA®+ is used exceeds the applicable RF compliance level above, the EmpowerCTA®+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EmpowerCTA®+.

Recommended Separation Distances Between Portable and Mobile RF Communication Equipment and the EmpowerCTA®+ Injector System

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: Electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2007 - edition 3 / 1721 & 1731).

The EmpowerCTA®+ Injector System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the EmpowerCTA®+ Injector System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EmpowerCTA®+ Injector System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power 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

For transmitters rated at a maximum 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.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Medical Electrical Equipment - Part 1-2: General Requirements for basic safety and Essential Performances - collateral Standards: electromagnetic Disturbances - Requirement and Tests (IEC 60601-1-2: 2014 - edition 4 / 1731)

The EmpowerCTA®+ is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EmpowerCTA®+ can help prevent electro-magnetic.

The EmpowerCTA®+ is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EmpowerCTA®+ can help prevent electromagnetic interference by maintaining a miminum distance between portable and mobile RF communications equipment (transmitters) and the EmpowerCTA®+ as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power 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 *** $d = 2.0\sqrt{P}$	**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.

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INJENEERING
Innovative Injection Technology

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CE
2797

Bracco Injeneering S.A.
Avenue de Sévelin 46
CH-1004 Lausanne
Switzerland
http://imaging.bracco.com