EmpowerMR®

Contrast Injection System

EmpowerMR® Injector System

User's Guide • software version 10

Bracco Group

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Proprietary Information Notice

Main Contact Information

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Contents

1 Introduction

EmpowerMR® Injector System

The EmpowerMR® Injector System is a low-pressure, venous-side injector that is used to inject MR contrast media followed by a saline flushing solution into the human vascular system in conjunction with magnetic imaging resonance (MRI) procedures. It is not intended for any other use.

Rx Only

CAUTION

Federal law (USA) restricts this device to sale by or on the order of a physician.

Note

The EmpowerMR® Injector System is to be used only by medical professionals with adequate training and experience in the operation of the EmpowerMR® Injector System and MRI procedures and techniques. Additionally, individuals using this device must be alert and attentive to the operation of the system while it is connected to the patient. Diligence on the part of the user is an essential requirement of overall device safety.

About this Guide

This User's Guide provides instructions for setting up and operating the EmpowerMR® Injector System. For instructions on using your particular MRI system, please consult the manuals provided by the manufacturer. This user's guide includes the following sections:

Section	Purpose
Section 1: Introduction	Identifies the purpose and structure of this guide.
Section 2: Warnings, Cautions, and Symbol Definitions	Users must read and understand this section thoroughly before using the MR Injector.
Section 3: System Description	Describes the system components and functions.

About this Guide (continued)

Section	Purpose
Section 4: Injection Procedure	Provides instructions for preparing, programming, and administering an injection.
Section 5: Remote Control Operation and Programming	Describes the menu and mode screens and provides procedures for storing and retrieving programs.
Section 6: Using EmpowerMR® with Nexo®	Provides instructions for managing programs, patients and injections when the EmpowerMR® Injector System is connected to Nexo® system.
Section 7: Minimizing Extravasations	Provides suggested techniques for minimizing extravasations.
Section 8: Using the IRiSMR® Utility	Provides instructions for using the IRiSMR® Viewer Application.
Section 9: Limited Warranty	Provides the EmpowerMR® Injector System Limited Warranty.
Appendix A: Glossary	Provides definitions of terms.
Appendix B: Troubleshooting	Provides answers to frequently-asked questions, as well as a list of system messages.
Appendix C: Technical Specifications	Provides technical specifications for the Injector Head, Remote Control, and Hydraulic Controller.
Appendix D: EMC Tables	Provides EMC compliance tables.

Related Documentation

For installation and service information, consult the following manuals:

Purpose	Document Part Number	Document Title
Installation Instructions	901194	EmpowerMR® Installation Manual
Service Information	901195	EmpowerMR® Service Manual

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 EmpowerMR® Injector System, please 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 EmpowerMR® Injector System or other equipment. If you have any questions after reading this section, please contact Bracco Injeneering S.A. local technical support.

Warnings

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

- The sole purpose of the EmpowerMR® Injector System is to intravenously inject MRI contrast media and saline flushing solution into the human vascular system in conjunction with magnetic resonance imaging (MRI) procedures. It is not intended for any other use. DO NOT use this equipment for any application other than its expressed purpose.
- The Injector Head is MR-Conditional and is the only part of the EmpowerMR® Injector System that should be placed in the MRI scanner room. The Remote Control and Hydraulic Controller are MR-Unsafe and should never be placed in the MRI scanner room. Failure to comply may lead to serious injury and/or death.
- Non-clinical testing has demonstrated that the EmpowerMR® Injector Head is MR-Conditional in MR environments with MRI scanners having a static magnetic field strength up to and including 7.0 tesla and a spatial gradient field up to and including 8.0 tesla/m. The specific absorption rate (SAR) is not applicable since the EmpowerMR® Injector Head is deployed inside the scanner bore and there are no patient connections that are conductive from the injector.
- When operating with EmpowerMR® Injector System, you must put only contrast media in the Contrast syringe and Saline solution in the Saline syringe. Failure to do so may lead to inadequate diagnostic results and potential injury to the patient.

Warnings (continued)

- MR prescribing clinicians must read and follow all contrast manufacturers' labeling when used in conjunction with EmpowerMR®. Failure to adhere to contrast manufacturers' prescribing information, dosing regimen, warnings, cautions, indications and contraindications could result in renal toxicity or other adverse reactions leading to serious harm or permanent injury.
- This equipment is not for use in chemotherapy, drug infusion, or any other application for which it is not indicated.
- The EmpowerMR® 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 with 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 the slow reverse (Contrast Reverse key/Saline Reverse key), fast forward (Contrast Forward to Limit key/Saline Forward to Limit key) or fast reverse (Contrast Reverse to Limit key/Saline Reverse to Limit key) keys on the EmpowerMR® Injector System while it is connected to the patient.
- In the event of a system malfunction, immediately turn off the EmpowerMR® 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 EmpowerMR® Injector System until the problem is properly identified and solved. Contact Bracco Injeneering S.A. local technical support for further assistance.
- Exercise extreme caution when setting the flow rate on the Remote Control 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.
- A risk of explosion exists if the EmpowerMR® 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 EmpowerMR® Injector System has been proven to work 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.

Warnings (continued)

- After the FASTLOAD™ MR syringe has been filled with contrast or saline, it should be used in accordance with the contrast and saline manufacturer's labeling for handling, loading, use, storage, and disposal of their product.
- To prevent transmission of infection, observe aseptic techniques when handling contrast, saline or any equipment or materials that contain or conduct the contrast or saline, including syringes, fill spikes, and intravenous administration sets. Never reuse any of these single-use items. Discard these disposable items using proper procedures for bio-hazardous waste.
- To assure sterility, as well as to prevent spills or damage to the equipment, always inspect the packaging of the connecting tube and each syringe. Also inspect the syringe itself to verify that there are no broken seals or other signs of damage. If any conditions exist, do not use the syringe.
- Spilled fluid can result in the possibility of electrical shock. Do not allow contrast, saline, or other fluids to spill over the EmpowerMR® Injector System. Do not immerse any parts of the EmpowerMR® Injector System when cleaning. This could create a conductive path between metallic parts of the EmpowerMR® Injector System and the patient.
- Use the EmpowerMR® System only when connected to a proper electrical source. Plug the Hydraulic Controller and the Remote Control directly into grounded, hospital-grade electrical outlets. Do not use extension cords. Do not use adapters to plug units into two-pronged, non-grounded outlets. Use the appropriate cord set and plug for the country of sale to be provided by the customer or distributor, if not provided by manufacturer. Replace any worn or frayed wires immediately.
- The EmpowerMR® 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.
- Attempting to open any component of the EmpowerMR® 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 authorized Bracco Injeneering S.A. local service personnel should perform servicing of the injector system.
- Administering intravenous contrast 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 EmpowerMR® Injector System can be found in "Minimizing Extravasations" on page 125.

Warnings (continued)

- Always instruct the patient to immediately notify the MRI personnel of any pain or change in feeling that is experienced during the procedure.
- Due to the pressure in the system, do not disconnect the hydraulic fittings while the Hydraulic Controller is powered on. Power down the Hydraulic Controller, wait 30 seconds for the pressure to dissipate, and then disconnect.
- To avoid injury when moving or carrying the Hydraulic Controller, hold the handle with two hands as the weight of the unit is significant

Cautions

The following cautions refer to hazards that could result in injury or damage to the MR Injector system or other equipment. Read this section carefully.

- Connect the EmpowerMR® Injector System only to an electrical source of the proper voltage and frequency as specified in "Appendix C – Technical Specifications" on page 153. If an incorrect voltage is used, the Injector System may be damaged when it is turned on.
- When retracting the Injector's syringe plunger during contrast or saline filling or after the end of an injection, do not allow a vacuum to build in the syringe by leaving the Connecting Tube attached to the end of the syringe. Also, do not allow the patient connecting tubing to occlude. 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.
- 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.
- The Hydraulic Controller must be operated in the upright position on a flat, level surface so as not to leak hydraulic oil.
- Never connect any devices other than the Hydraulic Controller to the Remote Control without the consent of Bracco Injeneering S.A.

Symbol Definitions

The following symbols are used on the EmpowerMR® System components and throughout this manual:

Symbol	Definition
	Patient Applied Part, Injector Head, Degree of protection against electric shock, Type BF
	Alternating current
	Potential equalization
	Protective earth ground
	Attention! Read the user's guide before using.
	Refer to instruction manual/booklet to mitigate safety hazards
	Do not reuse
	Do not resterilize
	On (power connection to line power)
	Off (power disconnection to line power)
	Manufacturer
	Date of manufacture
	Serial number
	Catalog number
	Lot number
	CAUTION: Federal (USA) law restricts this device to sale, distribution, and use by, or on the order of, a physician
	Dangerous voltage

Symbol Definitions (continued)

Symbol	Definition
	Explosion hazard
	Do not tip
	Contact for service
	Sterilized using ethylene oxide
	Use by date
	Do not use if packaging is damaged
	Temperature limitation
	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 electric shock, fire, mechanical and other specified hazards, only in accordance with EN/IEC 60601-1.
	Compliance with European Directive 93/42/EC, Medical Device Directive
	MR Conditional symbol identifies an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use.

Symbol Definitions (continued)

Symbol	Definition
	MR Unsafe symbol identifies an item that is known to pose hazards in all MR environments.
	Contains DEHP.
IP21	Environmental enclosure rating, protected against objects greater than 12 mm and protected against dripping water, injector head
	Do not tilt out of the upright position.
	Medical Device
	Importer.
	Authorized representative in the European Community.
	Consult instructions for use or consult electronic instructions for use.
	Packaging unit.

3 System Description

System Overview

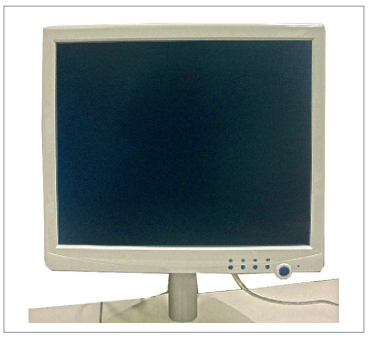
The EmpowerMR® Injector System is considered a non-sterile, reusable active medical device that supplies a gadolinium based contrast media and flushing media at a user-determined flow rate and volume.

The EmpowerMR® Injector System is comprised of three main components:

- Injector Head
- Remote Control
- Hydraulic Controller

Although they are each located in separate areas, they are connected with power and communication cables and hydraulic tubing.

Injector Head



Remote Control

Hydraulic Controller

Throughout this user's guide, the terms Injector Head and Injector are used interchangeably, and the terms Remote Control and Remote are used

System Overview (continued)

interchangeably. The term flushing media is referred to as saline throughout this manual because saline is considered the primary flushing media.

Injector Head

The Injector Head is located in the MR suite near the MR scanner gantry and connected to the patient during an MRI procedure.

The EmpowerMR® Injector Head can be positioned on either the right or left side of the MR scanner, on either side of the patient gantry. The controls on the Injector Head should be outward facing to the clinician to assure that the patient can be observed concurrently with the injector controls.

There is no minimum distance requirement within these locations to the exterior of the MR scanner within these prescribed locations for field strengths up to 7.0 tesla.

It can be tilted in the run position to the left,

Run (Rotated to Left)

or to the right depending upon where it is positioned relative to the patient.

Run (Rotated to Right)

The Injector Head can also be rotated to the vertical position to perform the loading and unloading procedures.

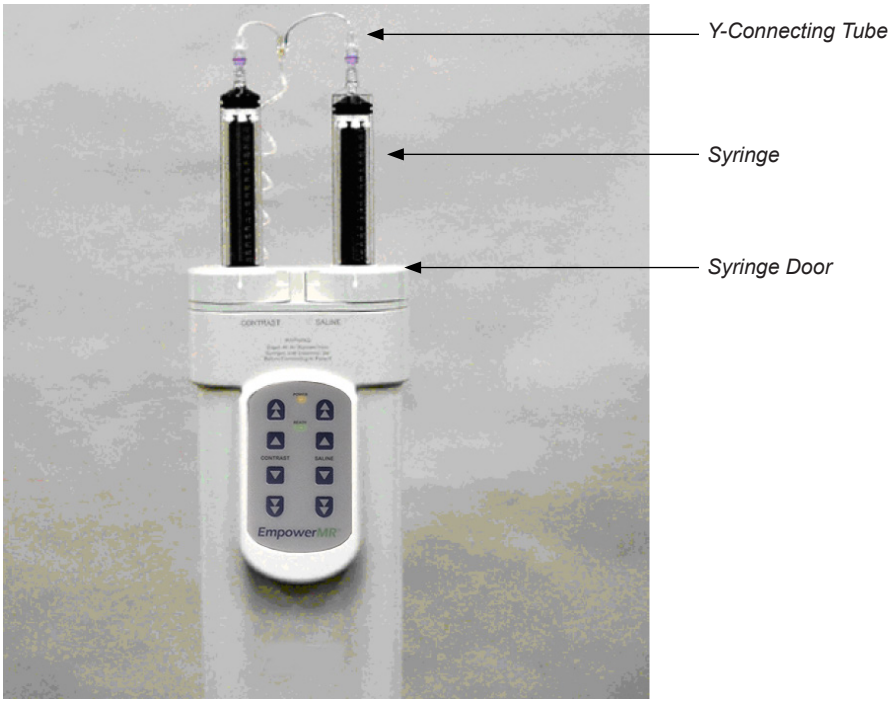
Vertical (Load/Unload)

Injector Head (continued)

Once the Injector Head is properly positioned, lock the locking casters on the injector stand base to prevent any unintended movement of the injector system by staff or the patient during use.

The Injector Head uses two FASTLOAD™ MR Syringes and operator controls for loading and filling syringes and administering contrast media and saline solutions. The flow of contrast and saline are controlled by the movement of an internal ram in each syringe that forces fluid from the syringe at a steady, adjustable rate.

Prior to starting an injection, the FASTLOAD™ MR Syringes are loaded into the Injector Head:



They are then filled with contrast media and saline flushing solutions, and connected to a Y connecting tube. After the Remote Control has been programmed, the opposite end of the Y connecting tube is connected to the patient's intravenous administration set (inserted during patient prep). At this point, the technologist can arm the system and then commence the injection.

All of the controls that are used during loading and filling syringes and for initiating injections are accessible on the Injector Head's user interface as described below. Injections can also be initiated, monitored, and stopped at the Remote Control.

Injector Head User Interface

The Injector Head's user interface contains eight membrane keys on the front of the Injector for loading and filling injectors (four keys for contrast and four corresponding keys for saline). In addition, two redundant sets of color coded membrane keys (four keys in each set) are located at the bottom of the Injector on either side of the handle for performing an injection. The user interface also includes two LEDs and the Injector Head handle that illuminates and indicates ram movement.

The corresponding colored membrane keys in the redundant sets perform the same functions. The purpose of the redundant sets is to make the controls easily accessible to the technologist when the Injector is in the RUN mode position, regardless of whether the Injector Head is rotated to the left or to the right.

Injector Head Front Membrane Keys

The saline and contrast membrane keys are located on the front of the Injector Head.

Saline Forward key (▲) (momentary switch) – while depressed, it advances the saline injection ram at a fixed rate of 1.0 mL/sec.

Saline Reverse key (▲) (momentary switch) – while depressed, it retracts the saline injection ram at a fixed rate of 3.0 mL/sec.

Saline Forward to Limit key (▲▲) (latching switch) – upon pressing and holding for one second, the switch will automatically latch and advance the saline injector ram at an achieved rate of 5 mL/sec. When the switch is latched, the ram will advance to its furthest extent and automatically stop. This is the 0 mL position. The syringe is ready for filling.

Saline Reverse to Limit key (▼▼) (latching switch) – upon pressing and holding for one second, the switch will latch and will automatically retract the saline injector ram at an achieved rate of 5 mL/sec. The ram will fully retract to the REPLACE SYRINGE position. The FASTLOAD™ Syringe can be loaded or removed from the Injector in this position.

Contrast Forward key (▲) (momentary switch) – while depressed, it advances the contrast injection ram at a fixed rate of 1.0 mL/sec.

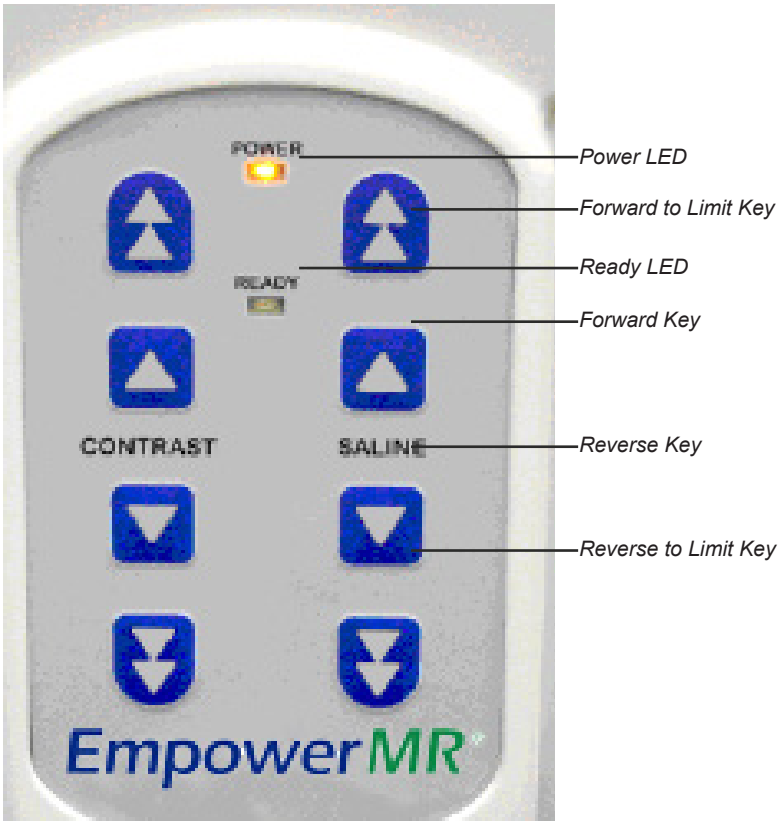
Contrast Reverse key (▼) (momentary switch) – while depressed, it retracts the contrast injection ram at a fixed rate of 3.0 mL/sec.

Contrast Forward to Limit key (▲▲) (latching switch) – upon pressing and holding for one second, the switch will latch and will automatically advance the contrast injector ram at an achieved rate of 5 mL/sec. When the switch is latched, the ram will advance to its furthest extent and automatically stop. This is the 0 mL position. The syringe is ready for filling.

Contrast Reverse to Limit key (▼▼) (latching switch) – upon pressing and holding for one second, the switch will latch and will automatically retract the contrast injector ram at an achieved rate of 5 mL/sec. When the switch is

Injector Head Front Membrane Keys (continued)

latched, the ram will fully retract to the REPLACE SYRINGE position. The FASTLOAD™ Syringe can be loaded or removed from the Injector in this position.



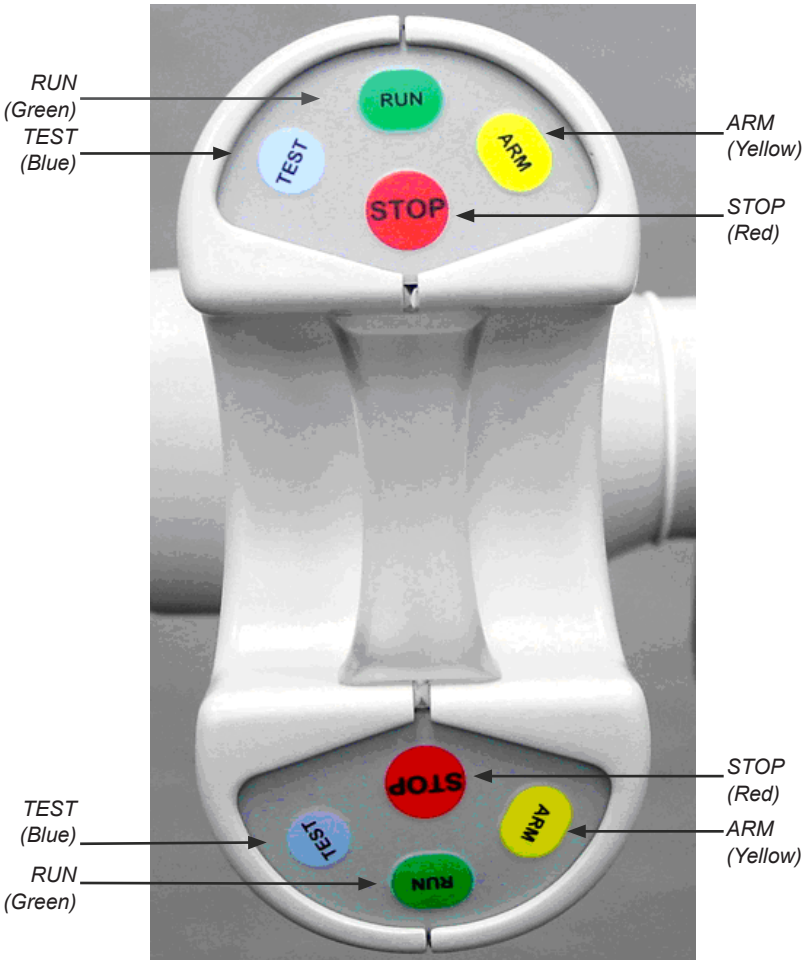
POWER and READY LEDs

The Injector Head has two LEDs:

- POWER LED (yellow) – located on the front of the Injector towards the top and between the contrast and saline membrane keys. Illuminates when the Injector Head is powered up.
- READY LED (green) – located on the front of the Injector below the yellow POWER LED. Illuminates when the Injector is in the STOP mode and when the conditions to arm are met. This includes the Injector Head tilted to the RUN position, both syringe housing doors are closed, volume in each syringe is greater than 0 mL, communication to Hydraulic Controller is present, and the Remote Control is powered on.

Color-Coded Membrane Keys on the Injector Head

The color coded membrane keys on either side of the Injector's handle enable the technologist to test, arm, run, and stop the injector. The technologist may use whichever side is more accessible.



Key	Color Code	Description
System ARM	Yellow	A single action switch. When pressed, will bring the system to the ARM mode.
System STOP	Red	A single action switch. When pressed, will bring the system to the STOP mode.
System RUN	Green	A single action switch. When pressed, will bring the system to the RUN mode.
Test Inject	Blue	Functions as a latching switch, which must be pressed and held for one second. When latched, and the system is in the ARM mode, the injector administers a predefined bolus of contrast media followed by a predefined bolus of saline.

Indicator Lights on the Injector Head Handle

The Injector Head handle, shown below, illuminates in orange and blue and flashes while an Injector ram is in motion.

STOP mode (both Injector rams are stationary) – handle is not illuminated.

ARM/PAUSE modes (both Injector rams are stationary) – handle is illuminated in solid blue and solid orange.

Contrast Injector Ram – handle will flash orange while the Contrast Injector ram is moving in either direction regardless of current mode and regardless if it is moving automatically or under manual control. The orange flash rate is proportional to the speed of the contrast injection ram, therefore as the contrast flow rate increases; the orange flash rate proportionally increases.

Saline Injector Ram – handle will flash blue while the Saline Injector ram is moving in either direction regardless of current mode and regardless if it is moving automatically or under manual control. The blue flash rate is proportional to the speed of the saline injection ram, therefore as the saline flow rate increases; the blue flash rate proportionally increases.

Remote Control

The Remote Control is located in the MR control room and is used by the technologist to program the contrast and saline injection protocol parameters, arm and run the injection procedure, and monitor the procedure status.

The Remote features a color LCD display panel with a select screen and speakers. It displays visual prompts, icons, and softkeys that guide and provide the technologist with controls during the injection procedure.

The MR Remote Control is not to be connected to any hardware or communication lines other than intended. The Remote Control may be connected to a local or hospital Local Area Network (LAN) provided that it is secured and protected by a firewall. No other connections are permitted except by qualified Bracco Injeneering S.A. local technicians. The MR System is to be connected to the provided power supply only. Connection of other power sources or components/peripherals can cause serious harm to the user and/or patient.

Detailed discussions on Remote Control programming and operation are provided on page 47 and page 67.

Hydraulic Controller

The Hydraulic Controller is typically located in the MR equipment room and contains the control electronics and hydraulic components that remotely actuate the hydraulic cylinders in the Injector Head. The only user control provided is the power rocker switch. All other Injector controls are provided on the Injector Head and the Remote Control.

The Power and Status LEDs are located side-by-side in the upper left corner of the Hydraulic Controller's front panel. Each LED is bicolor (green/red), but will appear orange when both colors are present.

The Power LED is...	When...
Solid Orange	The unit is powered and in Self Test mode or an Operational mode.
Solid Green	The unit is in Standby mode.
Solid Red	The unit has a hardware error.
Off	The unit is not powered.

Hydraulic Controller (continued)

The Status LED is...	When...
Solid Orange	The unit is in the ARM mode, RUN mode, PAUSE mode, or the cylinders are moving (Test Injected, KVO, manual membrane keys).
Flashing Orange	Communication between the Remote and Injector Head has been lost.
Solid Green	The unit is in STOP mode.
Flashing Red	The unit is in Error mode.
Off	The unit is in Standby mode.

Description of Operation

The EmpowerMR Injector System has four modes of operation when powered up:

- STOP
- ARM
- RUN
- PAUSE

STOP Mode

Following a successful power up and self diagnostic procedure, the system enters the STOP mode, and the Remote displays the Main Screen.

While in this mode, the Injector Head handle is not illuminated provided both Injector rams are stationary. Within this mode, the technologist can set up and verify functions for each component of the system prior to initiating injection.

The following can be performed while in the STOP mode:

- Injector Head
  - Load/Unload and fill syringe(s)
  - Establish patient connection
  - Arm the system
- Remote Control
  - Program, store, or recall injection protocol data
  - Change system setup
  - Access Help
  - Keep Vein Open (KVO) function
  - Arm the system

Description of Operation (continued)

ARM Mode

The ARM mode is an intermediate mode between STOP and RUN, and the Injector Head handle is illuminated in solid orange and blue provided both Injector rams are stationary. This mode performs two primary functions:

- Creates an additional step prior to start RUN to ensure that the technologist does not start the injection unintentionally, and
- Allows system software to perform a series of diagnostic checks examining the various states of the Injector and Remote.

If one or more components fail the diagnostic check, the system is automatically returned to the STOP mode and an appropriate message is displayed on the Remote. If all components pass, the system remains in the ARM mode, and the technologist is provided with a final advisory to check the integrity of the patient and delivery protocol before beginning the injection.

While in the ARM mode, the system continues to monitor itself, and, in the event of a problem, will return itself to the STOP mode and display an appropriate message on the Remote. The KVO function can also be enabled while in ARM mode.

Note

While in the ARM mode, the technologist is prevented from making changes to the system setup. The system must be returned to the STOP mode to make changes.

RUN Mode

RUN mode starts the injection procedure delivering contrast and flushing media to the patient in accordance with the programmed protocol. While in the RUN mode, the following occurs:

- Injection(s) is being administered.
- The Remote displays updates to provide the technologist with feedback on injection status and progress.
- The system will automatically return to the STOP mode upon successful completion of the injection protocol.
- While in RUN, the technologist can suspend the procedure by entering PAUSE mode.
- System continues to perform status checks. If a recoverable fault occurs, the procedure is suspended in PAUSE mode and the appropriate message is displayed on the Remote.

While in the RUN mode, the Injector Head handle will illuminate in solid orange and blue provided both Injector rams are stationary. The handle will flash orange while the Contrast Injector ram moves, and it will flash blue while the Saline Injector ram moves. The flash rate is proportional to the flow rate.

Description of Operation (continued)

PAUSE Mode

The system will enter the PAUSE mode under any of the following conditions (the Injector Head handle illuminates solid orange and blue provided both Injector rams are stationary):

- The system is executing a phase where a Pause or a Timed Pause has been programmed.
- Pressing any key on the Injector Head or selecting any part of the screen on the Remote Control during RUN.
- A recoverable fault occurs during RUN mode. These faults include:
- Tilt Out of RUN Position
- Contrast Syringe Door Open
- Saline Syringe Door Open
- Overpressure

During PAUSE, the status of the current injection protocol is maintained. The technologist can choose to return to RUN mode and resume the protocol from the point that it was suspended, or return to STOP mode where the protocol can be changed or restarted. If the system is in a TIMED PAUSE, it will execute the next phase in the protocol after the Pause has timed out.

Power Up/Down the Injector System

When the entire Injector system is powered up, the yellow LED on the Injector Head is illuminated and a screen is displayed on the Remote Control.

During normal operation, it is recommended to power down the Remote Control at the end of the day. This will help prolong the life of its hard drive. It is not necessary, however, to power down the Hydraulic Controller. It will go into "sleep" mode after being idle for a period of time. It will come out of its "sleep" mode and be reactivated when the Injector Head or the Remote Control is selected (after it has been powered up).

Routine Power Up

This procedure assumes that the Hydraulic Controller is in its "sleep" mode.

Step	Instruction
1	Power up the Remote Control by pressing the rocker switch on the right underside of the Remote.
2	If necessary, simply select the Remote Control or the Injector Head to power up the Hydraulic Controller. This, in turn, will power up the Injector Head.

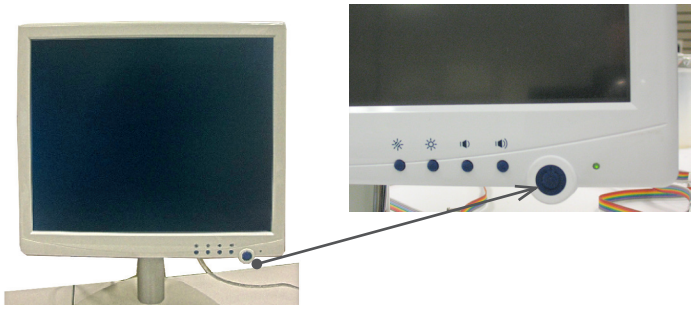
Note

Moving the Injector Head, or pressing any of its control keys, even when the Remote Control is off; will power up the Hydraulic Controller and the Injector Head.

Power Up/Down the Injector System (continued)

Power Up Entire Injector System

This procedure assumes that the Remote Control and the Hydraulic Controller are powered down. This can occur at initial installation or when the entire system has been powered down for maintenance, cleaning or storage purposes:

Step	Instruction
1	Begin in the MR equipment room and power up the Hydraulic Controller by pressing the rocker switch. The switch is located at the rear of the Hydraulic Controller's enclosure:  *Rocker Switch* ***Note*** *Powering up the Hydraulic Controller will also cause the Injector Head to power up. The yellow LED on the front of the Injector Head, between the contrast and saline membrane keys, will illuminate.*
2	Go to the MR control room and power up the Remote Control by pressing the power button on the front of the Remote, as shown below: 

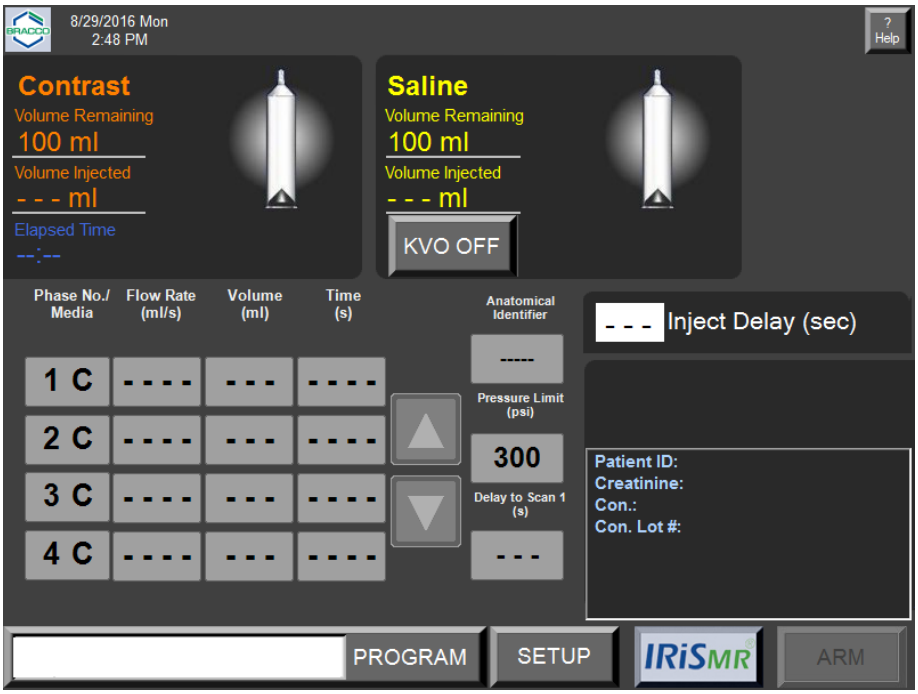
Power Up/Down the Injector System (continued)

Upon powering up, the Remote will perform internal diagnostics and will initially display the Power-Up Screen, which contains the following:

- The BRACCO logo
- An image of the MR Injector
- The Software Release Identifier
- The message, PERFORMING DIAGNOSTICS, PLEASE WAIT.
- The BRACCO customer service numbers and return addresses.
- If the periodic service date has been reached, the Remote will also display, Preventive Maintenance Due, Please Contact BRACCO Customer Service. Refer to "System Preventive Maintenance" on page 28.

The Power-Up Screen will be displayed for the duration of the internal diagnostics or five seconds, whichever is longer.

When the system has completed the internal diagnostic routines, the Remote will display the Main Screen, as shown below:



During diagnostics, the Remote Control will attempt to establish communications with the Injector Head and the Hydraulic Controller. If communications are not established, it will display the message, Injector Not Found. This message will disappear when communications are established.

Routine Power Down

At the conclusion of a day's procedure load, you may power down the Remote, as described in the following procedure:

Note

It is highly recommended that this procedure be used to shutdown the Remote. The Remote contains a hard drive and this will ensure that all files are properly closed and maintained.

Step	Instruction
1	Select **RETURN** at the bottom right of the Remote's select screen to display the Main Screen.
2	Select **SETUP** to display the Setup Screen.
3	Select **SHUTDOWN** and then select **YES** when asked as to whether you wish to proceed.
4	Unload syringes from the Injector Head.

Note

The Hydraulic Controller will go into "sleep" mode after it has been idle for a period of time, but the yellow LED on the Injector Head will blink.

Power Down Entire Injector System

Under some circumstances, such as maintenance, cleaning, or storing the equipment, it may become necessary to power down the entire Injector system, as described in the following procedure:

Step	Instruction
1	Perform Steps 1 through 4 in *Routine Power Down*.
2	Power down the Hydraulic Controller in the MR equipment room by pressing the rocker switch located at the rear of the unit's enclosure as shown below. This will also remove power from the Injector Head, and the yellow LED will go off.  *Rocker Switch*

System Preventive Maintenance

The MR Injector System is intended to be serviced on an annual basis. Service is to be performed by a Bracco Injeneering S.A. local authorized and qualified technician only. The MR System is programmed to notify the user of necessary maintenance after 12 months have passed from the date of last service.

Preventive maintenance includes, but is not limited to, a visual inspection of the overall system, an inspection of the injector head, an inspection of the hydraulic controller, an inspection of the remote control, and a testing and calibration routine. Personnel performing preventive maintenance procedures on an MR system shall follow the EmpowerMR® System Preventive Maintenance Checklist.

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
- Serum creatinine (SCr) value
- 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 EmpowerMR® remote control panel.

4 Injection Procedure

Overview of the Injection Procedure

For operation, only the Hydraulic Controller and the Remote Control must be plugged into grounded, hospital-grade electrical outlets. All of the other connections are made at the time of installation.

Performing an injection procedure consists of the following activities:

1. Ensuring that the EmpowerMR® Injector System is powered up.
2. Preparing the patient.
3. Loading two MR FASTLOAD™ Syringes and filling them with contrast or saline.
4. Programming the Remote Control.
5. Performing the injection.
6. Disconnecting patient at end of procedure and unloading the syringes.

Ensuring System is Powered Up

When powered up, the yellow LED on the Injector Head will be illuminated and the main screen will display on the Remote Control. If necessary, power up the system as described on page 23.

Preparing the Patient

WARNING

Follow all facility MR-Safety procedures. Remove all metal objects from the patient. Patients with pacemakers and certain metal implants should not be scanned. Failure to comply may lead to serious injury and/or death.

Verify that the patient has an intravenous catheter properly inserted.

The following is recommended to minimize the possibility of an extravasation. Follow your instructions and guidelines to prevent extravasation. Always monitor patient and look for extravasation.

WARNING

Extravasation can result in serious personal injury to the patient.

- Use a catheter that is 20 gauge or greater in the largest vein possible. Bracco Injeneering S.A. recommends an Angiocath®, Angio-Set®, or equivalent. (Angiocath® and Angio-Set® are registered trademarks of Becton, Dickinson and Company.)
- Minimize the effects of patient movement by taping the catheter firmLy to the patient's skin. Use of an Angiocath-type butterfly, Saf-T-Intima Ref #383335, permits easy insertion and secure taping.
- The forearm is the preferred location for venipuncture. 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 96-inch/2.4-meter, 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.
- If a patient presents with one or more indwelling intravenous lines, do not assume that the intravenous set is acceptable for use with the EmpowerMR® Injector System. If possible, place a new intravenous line.
- Central venous lines and heparin-locks are not recommended.

Loading and Filling Syringes with Contrast/Saline

Preparing the Injector Head for an injection procedure involves the following activities:

1. Loading (installing) the FASTLOAD™ MR Syringe(s) into the Injector Head.
2. Filling the syringes with contrast and saline.
3. Attaching the Connecting Tube.
4. Removing all air from the Syringes and Tubing.

Note that all keys referenced in the following procedures refer to the membrane keys on the Injector Head.

WARNING

Use proper procedures to avoid an Air Embolism. Failure to do so may result in serious injury or death to patient.

WARNING

Failure to observe the following when preparing and administering an injection may result in serious injury or death to patient.

- *Rx Only. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.*
- *Only use Bracco Injeneering S.A. FASTLOAD™ MR Syringes.*
- *Do not use syringe pack if package is open or damaged. Always inspect syringes visually prior to use.*
- *Syringes and all components are sterile and for single use only.*
- *Ensure all consumable kits are installed properly. Ensure all kit connections are tightly secured 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.*
- *Maximum operating pressure is 300 psi (2068 kPa, 20.7 bar).*
- *Always refer to the EmpowerMR® User's Guide for complete instructions on the proper use of your Bracco Injeneering S.A. EmpowerMR® Injector System.*

Loading Syringes and Filling with Contrast/Saline (continued)

Loading the FASTLOAD™ MR Syringe into the Injector Head

The following provides instructions for loading (installing) the syringes into the Injector Head.

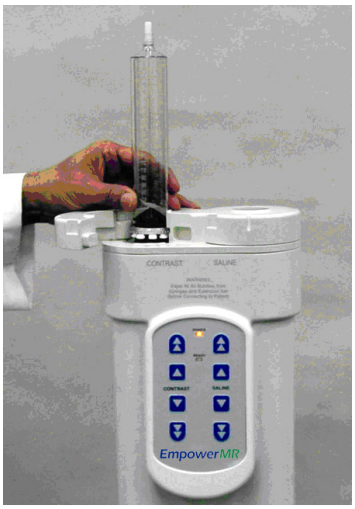
These instructions are for use of the FASTLOAD™ MR Syringe Pack (Ref 017348). The FASTLOAD™ MR Syringe Pack is a sterile, single use, disposable syringe kit for the EmpowerMR® Injector System.

Note

Do not use the Bracco Injeneering S.A. REF# 017344, 017345, 017346, or 017347 syringes with EmpowerMR® Injector Systems.

Step	Instruction
1	Rotate the Injector Head to a vertical position with the syringe doors facing up, as shown: 

Loading Syringes and Filling with Contrast/Saline (continued)

Step	Instruction
2	Ensure that both Injector rams are fully retracted. If necessary, press and hold the Contrast Reverse to Limit key (▼▼) on the front of the Injector Head for one second and release, as shown below.  The ram will retract and stop at the REPLACE SYRINGE position. Repeat for the saline injector by pressing the Saline Reverse to Limit key (▼▼) for one second.
3	Open the contrast syringe door (labels on the Injector Head identify the contrast and saline sides).
4	Using aseptic technique, remove the first FASTLOAD™ MR Syringe from its package. Do not touch the plunger portion of the syringe, and do not remove the protective cap.
5	Insert the syringe lip into the groove of the syringe housing and close the syringe door firmLy, as shown below: 

Loading Syringes and Filling with Contrast/Saline (continued)

Step	Instruction
6	Press and hold the Contrast Forward to Limit key (▲▲) for one second and release. The syringe plunger will automatically advance to the front end at the “0 mL” position and stop, as shown: 
7	If loading a saline syringe, open the saline syringe door and repeat steps 5 and 6. Use the Saline Forward to Limit key (▲▲). This can be started while the contrast syringe plunger is still advancing.

Note

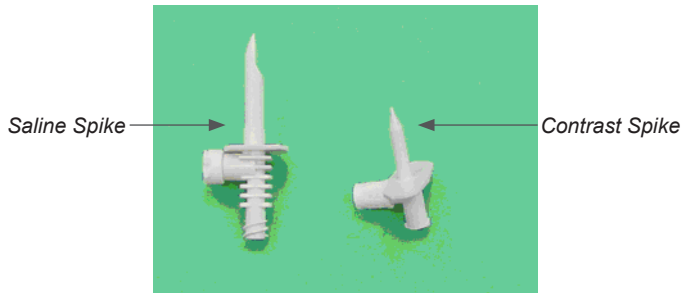
The Injector Head handle will flash orange as the Contrast Injector ram moves in either direction. It will flash blue as the Saline Injector ram moves. The flash rate is proportional to the ram speed.

Filling Syringes

There are two alternate filling procedures described below depending on whether the syringe is being filled from a bottle, using a bottle spike, or from a pre-filled syringe, using a female-to-female adapter.

Filling Syringes with Bottle Spikes

This procedure may be used for filling Bracco Injeneering S.A. FASTLOAD™ MR syringes with contrast medium and/or saline from a bag or bottle. (Note that syringes may be filled simultaneously.) The two spikes used in this procedure are shown below. The saline spike is the larger spike.

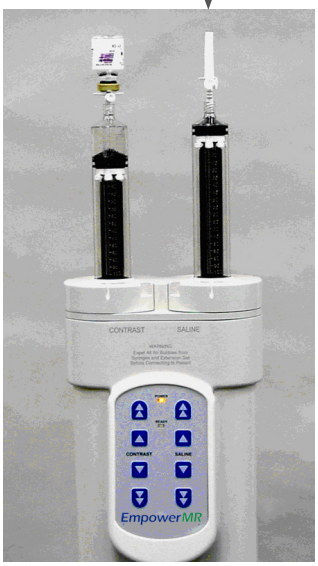


Step	Instruction
1	Using aseptic technique, open a bottle of contrast medium.
2	Remove the protective cap from the syringe.
3	Remove the contrast bottle spike from the syringe package (smaller spike).
4	Attach the female Luer fitting of the contrast bottle spike to the contrast syringe tip, as shown below: 
5	Remove the protective cap from the contrast bottle spike tip.

Filling the Syringes (continued)

Step	Instruction
6	Invert the bottle of contrast medium and place it over the spike tip. Push down to penetrate the bottle membrane with the spike tip, as shown: *Place the contrast bottle over the spike tip* 
7	Press and hold the CONTRAST REVERSE key (▼) on the Injector membrane panel to fill the syringe, as shown below. The Injector Head handle will flash orange.  *Press and hold the Contrast Reverse key*
8	Lightly tap the syringe to dislodge any air bubbles that may be in the syringe.
9	When filling is complete, release the CONTRAST REVERSE key (▼).
10	Remove the spike from the syringe.

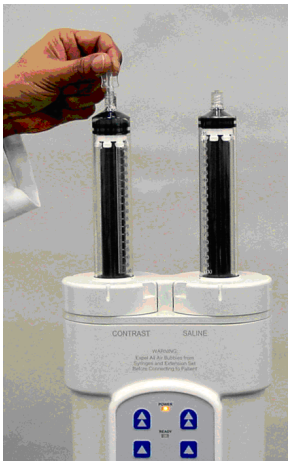
Filling the Syringes (continued)

Step	Instruction
11	If filling a second syringe for saline, follow steps 1–11 for the saline side using the larger spike with a bag of saline, as shown below. Use the SALINE REVERSE key (▼). The Injector Head handle will flash blue. *Place the saline spike on the saline syringe*  *Place the saline bag over the spike tip* 

Filling the Syringes (continued)

Filling Syringes with Female-to-Female Adapter

This procedure may be used for filling Bracco Injeneering S.A. FASTLOAD™ MR Syringe with contrast medium from a pre-filled syringe.

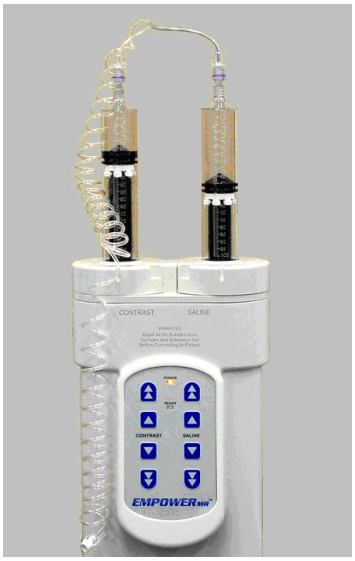
Step	Instruction
1	Using an aseptic technique, remove the female-to-female adapter (sold separately) from its package.
2	Remove the protective cap from the syringe.
3	Attach the female-to-female adapter to the syringe tip, as shown below: 
4	Using an aseptic technique, remove the pre-filled contrast syringe from its package.
5	Attach the pre-filled contrast syringe to the female-to-female adapter, as shown below: 

Filling the Syringes (continued)

Step	Instruction
6	Press and hold the CONTRAST REVERSE key (▼) to fill the syringe, as shown below:  The Injector Head handle will flash orange.
7	Lightly tap the syringe to dislodge any air bubbles that may be in the syringe.
8	When filling is complete, release the CONTRAST REVERSE key (▼).
9	Remove the female-to-female adapter with the pre-filled syringe from the syringe.

Filling the Syringes (continued)

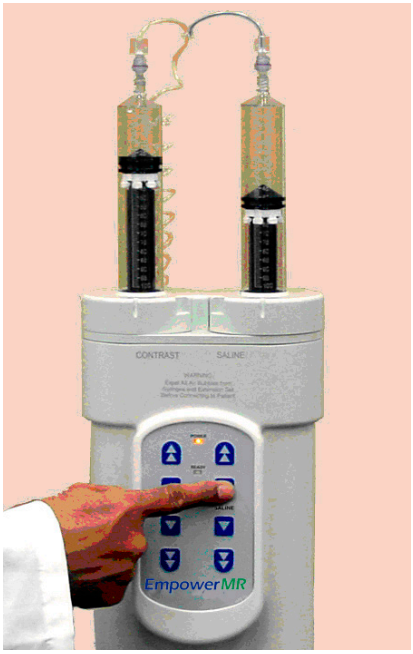
Attaching the Connecting Tube

Step	Instruction
1	Remove the connecting tube from the syringe package.
2	Attach the female Luer fitting with the blue-striped tubing to the saline syringe tip.
3	Attach the other female Luer fitting to the contrast syringe tip, as shown below: 

Filling the Syringes (continued)

Removing All Air from the Syringes and Tubing – KVO Not Used

Use this procedure when KVO will not be used and the first injection will be contrast.

Step	Instruction
1	Temporarily remove the end cap from the patient end of the connecting tubing.
2	Press and hold the SALINE FORWARD key (▲) to advance the saline through the connecting tube up to and including the y-fitting, as shown below. Make sure to remove all air bubbles from the syringe and the connecting tubing. The Injector Head handle will flash blue.  Should air bubbles adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles.

Filling the Syringes (continued)

Step	Instruction
3	Press and hold the CONTRAST FORWARD key (▲) to advance the contrast media through the entire length of the connecting tube, as shown below:  Make sure to remove all air bubbles from the syringe and the entire connecting tube. The Injector Head handle will flash orange. If bubbles should 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 and the connecting tube. If you have any doubts about the presence of air, do not proceed. Use the SALINE FORWARD key (▲) or CONTRAST FORWARD key (▲) to expel more contrast or saline until the air is gone.

WARNING

Use proper procedures to avoid an Air Embolism. Failure to do so may result in serious injury or death to patient.

Filling the Syringes (continued)

Step	Instruction
5	Once the contrast or saline has completely filled the connecting tube and a small meniscus is present at the patient end of the tube, recap and use tube-holding slots (located on Injector syringe door housing) as required.
6	Attach the free end of the connecting tube to the patient's catheter.
7	Tilt the Injector Head fully downward toward whichever side is most convenient in preparation for injection, as shown below:  The syringes will be displayed as tilted down on the Remote Control.
8	The Injector Head is prepared for the injection.

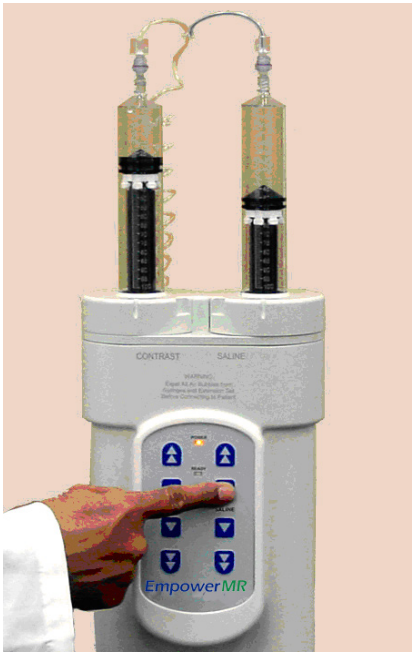
Filling the Syringes (continued)

Removing All Air from the Syringes and Tubing – KVO Used

Use this procedure when KVO will be used or if the first injection will be saline.

Step	Instruction
1	Temporarily remove the end cap from the patient end of the connecting tubing.
2	Press and hold the CONTRAST FORWARD key (▲) to advance the contrast medium through the connecting tube up to and including the y-fitting. Make sure to remove all air bubbles from the syringe and the connecting tubing. The Injector Head handle will flash orange.  Should air bubbles adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles.

Filling the Syringes (continued)

Step	Instruction
3	Press and hold the SALINE FORWARD key (▲) to advance the saline solution through the entire length of the connecting tube, as shown below:  Make sure to remove all air bubbles from the syringe and the entire connecting tube. The Injector Head handle will flash blue. If bubbles should adhere to any part of the syringe or tubing, gently tap your fingers on that area to dislodge the bubbles.

WARNING

Use proper procedures to avoid an Air Embolism. Failure to do so may result in serious injury or death to patient.

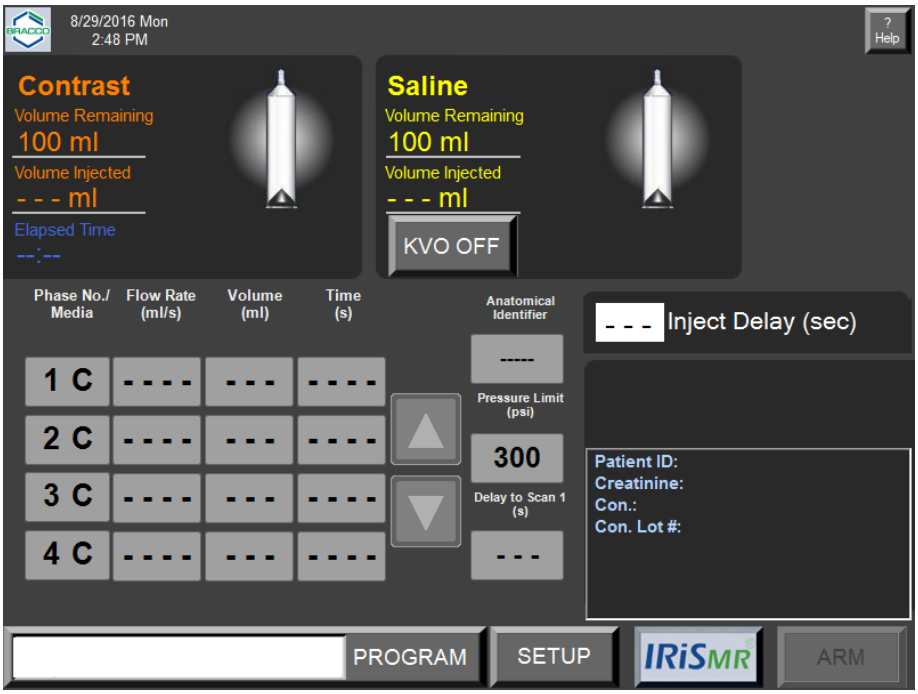
Filling the Syringes (continued)

Step	Instruction
4	Verify that all air has been removed from BOTH syringes and the connecting tube. If you have any doubts about the presence of air, do not proceed. Use the SALINE FORWARD key (▲) or CONTRAST FORWARD key (▲) to expel more contrast or saline until the air is gone.
5	Once the contrast or saline has completely filled the connecting tube and a small meniscus is present at the patient end of the tube, recap and use tube-holding slots (located on Injector syringe door housing) as required.
6	Attach the free end of the connecting tube to the patient's catheter.
7	Tilt the Injector Head fully downward toward whichever side is most convenient in preparation for injection, as shown below:  The syringes will be displayed as tilted down on the Remote Control.
8	The Injector Head is prepared for the injection.

Programming the Remote Control

The following subsections describe how to read, program, and modify programs in the Remote Control's Main Menu Screen. Upon powering up, the Remote starts in the Power-Up Screen and performs self-diagnostics.

Following successful diagnostics, it displays the Main Menu Screen. If the Remote is displaying any other screen, select RETURN as often as necessary until the Main Menu Screen is displayed, as shown:



For a detailed discussion of the Remote Control screens and additional programming features, see "Remote Control Operation and Programming" on page 67.

Reading a Program

The terms 'program' and 'protocol' are used interchangeably in this user's guide and refer to the parameters entered into the Remote Control that make up the injection procedure. For each protocol, the following three parameters govern delivery performance for contrast and saline:

- Flow Rate
- Volume
- Delivery Pressure Limit

Note

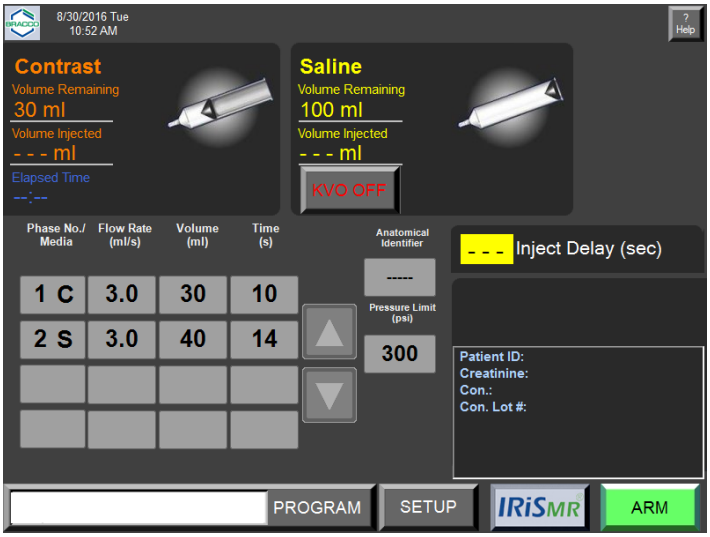
If the technologist chooses not to enter a Delivery Pressure Limit, the system uses 300 psi (2068 kPa, 20.7 bar) as the default value.

Programming the Remote Control (continued)

The technologist also has the option of programming Pause or Timed Pause (for injections that include contrast only) and Delay to Scan, a user-programmed delay between start of injection and starting scan.

An injection program can be viewed or programmed in the Remote's Main Menu Screen. The program consists of numbered phases with each phase containing programmed values for flow rate and volume. Each phase also contains a time interval that is automatically calculated and displayed. When the injection is initiated by entering the RUN mode, the Injector will execute the phases sequentially and stop when it reaches a PAUSE (for non-saline injections) or when the final phase has been completed.

In the following example, the Injector System would inject 30 mL of contrast at 3.0 mL/sec for 10 seconds then conclude by injecting 40 mL of saline at 3.0 mL/sec for 14 seconds. The delivery Pressure Limit in this example is 300 psi (2068 kPa, 20.7 bar).



The Remote Control allows the technologist to access controls by simply selecting softkeys on the screen. The Remote will emit a sound (beep) whenever a softkey is selected and the system will respond accordingly.

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 6 on page 107 for the procedure using Nexo®.

Entering a New Program

The technologist has the option of creating a new injection protocol in the Main Menu Screen, or retrieving an existing protocol in the Program Screen. The following provides instructions for creating a new protocol in the Main Menu Screen. For a discussion on saving and retrieving protocols, refer to Advanced Programming Features on page 83.

A program must be created phase-by-phase, beginning with Phase 1 in the first row of the table. By default, the phase number will always be followed

Programming the Remote Control (continued)

by a C for contrast. When a phase number key is pressed, a pop-up window is displayed allowing selection of Pause, Delete, Saline, Timed Pause, and Cancel. If saline is selected, an S will replace the C in the key (except for Phase 1). The following requirements apply to all types of injections:

For each phase, a flow rate and a volume must be specified. The Remote Control will then calculate the time to complete the phase and display the Time column. Alternatively, a flow rate and a time can be specified. The Remote Control will then calculate the volume to complete the phase and display the Volume column.

You must complete a phase before proceeding to the next one. Also, you must proceed through each phase in sequential order. The system will not permit you to skip a phase and leave it blank. As you complete a phase, the system will allow you to add the next phase, as needed.

Any order may be used to make changes to an existing program. Scroll to the desired phase using the adjacent arrows.

Requirements for Programming Contrast Only

Up to eight phases can be programmed for injection procedures that use contrast only.

Requirements for Programming Contrast and Saline

There can be no more than three phases when including saline in an injection procedure, and only two combinations are permitted:

Combination A: The first phase is contrast, and the second phase is saline.

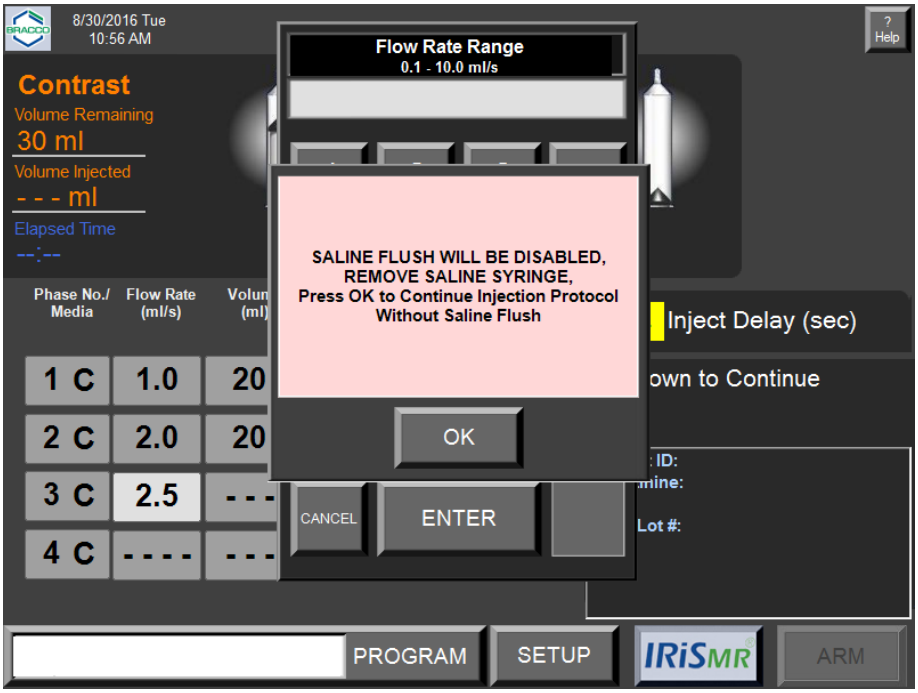
Combination B: The first and second phases are contrast, and the third phase is saline.

The following is a summary of requirements when using saline in an injection procedure:

- A maximum of three phases can be programmed when including saline.
- A phase must be completed before proceeding with the next one.
- Phase 1 is for contrast only.
- There can be only one saline phase in a protocol.
- A saline phase must be preceded by a contrast phase with finite values for flow rate and volume.
- No additional phases can be added following a saline phase.

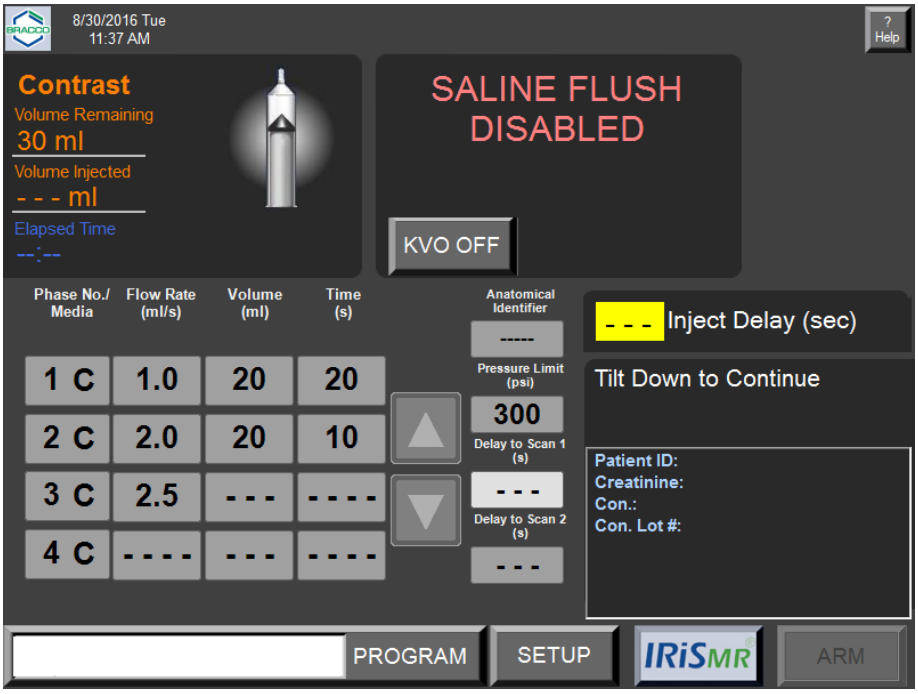
Programming the Remote Control (continued)

- If Phase 2 is programmed for contrast and an attempt is made to program contrast for Phase 3, all information relating to saline will be automatically disabled. The Remote Control will display "SALINE FLUSH INJECTION WILL BE DISABLED, REMOVE SALINE SYRINGE, Press OK to Continue Injections Protocol Without Saline Flush," as shown:



Programming the Remote Control (continued)

– When the technologist acknowledges the instruction to remove the saline syringe, the Remote Control will display SALINE FLUSH DISABLED, as shown:



– If the third contrast phase is deleted, saline programming will be re-enabled.

- Programs that include a saline injection cannot have a programmed Pause.

Programming a Contrast and Saline Injection

The following provides a procedure for programming contrast for Phase 1 followed by saline for Phase 2. Alternatively, you can program contrast for Phases 1 and 2 followed by saline for Phase 3. No additional phases can be programmed following saline.

Programming the Remote Control (continued)

<table>
<tr><th>Step</th><th>Instruction</th></tr>
<tr><td>1</td><td>Starting with Phase 1, program contrast as follows:
<table>
<tr><th>Step</th><th>Instruction</th></tr>
<tr><td>a</td><td>Select the Flow Rate key for Phase 1. A Flow Rate range data input pop-up window is displayed.</td></tr>
<tr><td>b</td><td>Enter the desired flow rate in mL/sec and select ENTER. The Remote Control will automatically enter one decimal place and display the value in the Flow Rate column (for example, if you enter 100, the Remote Control will show this as 10.0). To make corrections in the pop-up window, press  to erase one character at a time.
The allowable flow rate range is 0.1 to 10.0 mL/sec in 0.1 mL/sec increments.</td></tr>
<tr><td>c</td><td>Select either the Volume or Time key for Phase 1. A Volume or Time range data input pop-up window is displayed.</td></tr>
<tr><td>d</td><td>Enter the desired volume in mL or time in seconds and press ENTER. The value will be displayed in the Volume or Time field. The Remote will also calculate and display the time interval in the Time column or the Volume interval in the volume column.
The allowable volume range is 1 to 100 mL in 1 mL increments. The allowable time range is dependent on the flow rate entered.</td></tr>
</table></td></tr>
<tr><td>2</td><td>Program saline in Phase 2 as follows:
<table>
<tr><th>Step</th><th>Instruction</th></tr>
<tr><td>a</td><td>Select the Phase 2 key in the Phase column and select SALINE in the pop-up window. An S will replace C in the Phase 2 key.</td></tr>
<tr><td>b</td><td>Repeat steps 1a through 1d to program flow rate and volume for the saline.</td></tr>
</table></td></tr>
</table>

Programming the Remote Control (continued)

Programming the Pressure Limit

The delivery Pressure Limit value applies to all phases. If the technologist chooses not to program a value, the system will automatically default to 300 psi (2068 kPa, 20.7 bar). To enter a different value, do the following:

Step	Instruction
1	Select the Pressure Limit softkey displaying the current value. A pop-up keypad is displayed.
2	Enter a new value using the keypad. Up to three characters may be entered. The allowable range is 40 to 300 psi (276 to 2068 kPa, 2.8 to 20.7 bar) 1 psi increments.
3	Select ENTER on the keypad. The new value is entered and the keypad disappears.

The pop-up keypad also contains the following keys:

CLEAR – clears the entered value in the keypads preview pane.

 – erases previously entered digit.

CANCEL – removes keypad without making any changes to current value.

Requirements for Programming Pause and Timed Pause

Programming a Pause or Timed Pause is optional. During RUN mode, an injection procedure will stop when it executes a phase where either type of pause has been programmed.

To resume the injection procedure, press RUN on the Remote Control or press one of the System RUN (green) membrane keys on either side of the Injector Head handle. For Timed Pause, if the technologist does neither, the system will advance to the next phase in the protocol after the Pause has timed out.

The requirements for programming Pause or Timed Pause are the same and include:

- Pause or Timed Pause may not be programmed for Phase 1.
- Pause or Timed Pause may not be programmed in a protocol that includes a saline injection.
- Two consecutive phases may not be programmed for Pause or Timed Pause or any variation of these pauses.

Programming the Remote Control (continued)

Programming a Pause

To program a pause, do the following:

Step	Instruction
1	Select a Phase number (except Phase 1) where the pause is to occur. A pop-up window is displayed.
2	Select **PAUSE** in the pop-up window.

Programming a Timed Pause

To program a timed pause, do the following:

Step	Instruction
1	Select a Phase number (except Phase 1) where the pause is to occur. A pop-up window is displayed.
2	Select **TIMED PAUSE** in the pop-up window. A pop-up keypad is displayed.
3	Enter the number of seconds to pause and select **ENTER**. The keypad will disappear and the programmed time will be displayed in the selected phase key. Up to 3 digits may be entered allowing a range of 1 to 900 seconds in 1 second increments.

Programming Delay to Scan

The technologist can choose to program a delay between starting RUN and starting the MRI scan procedure. The EmpowerMR® Injector System provides two Delay to Scan features: Delay to Scan (1) can be programmed from 1 to 300 seconds in 1 second increments. Delay to Scan (2) can be programmed from 1 to 900 seconds in 1 second increments. To make these features available on the Main Menu Screen or Program Screen, the technologist must enable them in the Setup Screen (see "Setup Screen" on page 81).

Programming the Remote Control (continued)

To program a Delay to Scan, do the following:

Step	Instruction
1	From within the Setup screen, select the **DELAY TO SCAN** softkey. A pop-up keypad is displayed, as shown:  *The pop-up keypad contains the following keys:* *CLEAR – clears the entered value in the keypads preview pane.* *– erases previously entered digit.* *CANCEL – removes keypad without making any changes to current value.* *RESET – sets the value to "---".*
2	Enter a new value using the keypad. Up to three digits may be entered. Do not exceed the allowable ranges.
3	Select **ENTER** on the keypad. The new value is entered and the keypad disappears.
4	Repeat, if applicable, for the other Delay to Scan function.

Note

Invalid values will not be allowed and the technologist will be alerted with a displayed message.

Programming the Remote Control (continued)

Programming Inject Delay

The EmpowerMR® Injector System provides an Inject Delay feature. The technologist can choose to program a delay to occur at any time after selecting the inject delay key up until starting the injection.

To program an Inject Delay, do the following:

Step	Instruction
1	From the Main Screen, select the Inject Delay softkey. A pop-up keypad is displayed , as shown:  *The pop-up keypad contains the following keys:* *CLEAR – clears the entered value in the keypads preview pane.* *– erases previously entered digit.* *CANCEL – removes keypad without making any changes to current value.* *RESET – sets the value to "---".*
2	Enter a new value using the keypad. Up to three digits may be entered. Do not exceed the allowable ranges.
3	Select **ENTER** on the keypad. The new value is entered and the keypad disappears.

Note

Invalid values will not be allowed and the technologist will be alerted with a displayed message.

Programming the Remote Control (continued)

Removing an Existing Program

To remove an existing program, do the following:

Step	Instruction
1	Select the Phase 1 softkey. A pop-up window is displayed.
2	Select the **DELETE** key in the pop-up window. The first phase is deleted and the remaining phases will move up and be renumbered.
3	Repeat steps 1 and 2 until the phases are cleared. Note that the phase keys will remain numbered.

Note

To delete an individual phase, just select the phase softkey showing the desired phase number and select **DELETE** *in the pop-up window.*

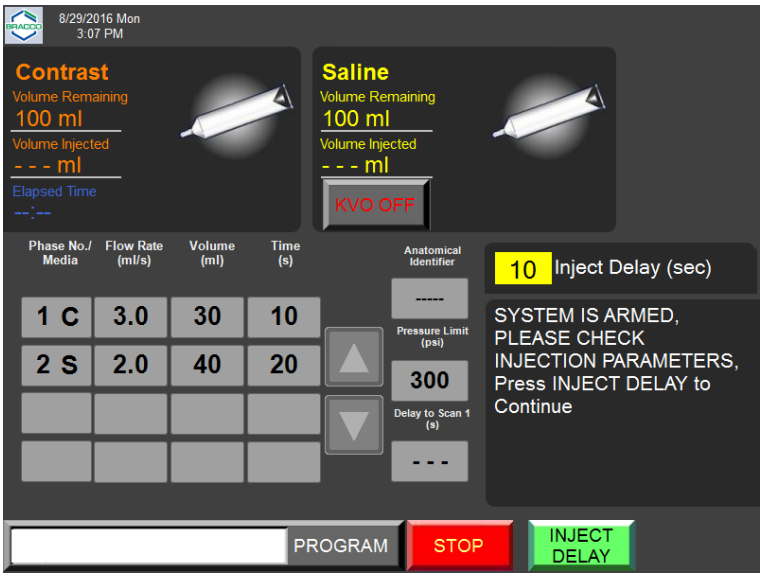
Performing the Injection

Perform the injection when the patient, EmpowerMR® Injector System, and program have all been properly prepared.

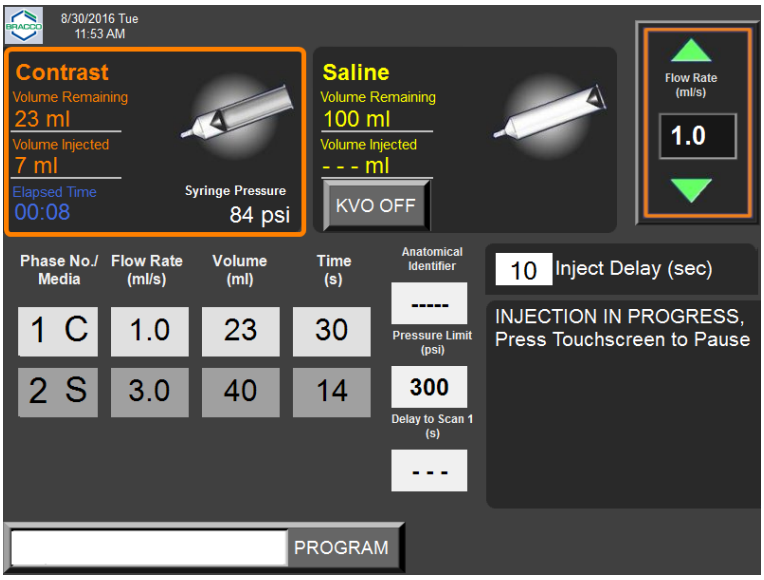
Initiate the injection as follows:

Note

The ARM softkey will be enabled on the Remote only if (1) the Injector Head is tilted down, (2) volume is greater than 1 mL, (3) valid injection parameters have been entered, and (4) both syringe doors are closed.

Step	Instruction
1	Select the ARM softkey at the lower right of the Remote Control's screen, which is now colored green. The Remote displays the ARM Mode Screen, which displays a message such as SYSTEM IS ARMED, PLEASE CHECK INJECTION PARAMETERS, PRESS INJECT DELAY TO CONTINUE, as shown below:  In addition, a voice message saying the system is armed is announced. Alternatively, press either yellow System ARM membrane key on the Injector Head.

Performing the Injection (continued)

Step	Instruction
2	In the ARM mode, the EmpowerMR® Injector System offers the opportunity to review the programmed parameters one more time. If ready to proceed, select **RUN** on the Remote (or the green System RUN membrane key on the Injector Head) or if the Inject Delay has been set, select the **INJECT DELAY** key on the Remote. The Inject Delay function will display the countdown, in seconds, before the injection starts. The Remote displays the RUN Mode Screen, as shown below:  The injection begins and will stop and return to the Main Screen after all of the phases have been sequentially executed, manually stopped, or stopped by the system due to a detected problem. ***Note*** *If an inject delay time is programmed and ARM mode is entered, the Inject Delay key will take the place of the Run key. If the Inject Delay key is selected, the timer will countdown from the set time down to zero and then the injection will automatically start.* During the procedure, the Remote Control will display the progress of the injection as it runs. This includes the volume remaining and volume injected for contrast and saline and the elapsed time. In addition, the Remote Control will display the syringe pressure, which is continuously updated throughout the injection. The Injector Head handle will flash orange while contrast is being injected and will flash blue while saline is being injected. The flash rate is proportional to the flow rate.

Performing the Injection (continued)

Additional Notes:

- During RUN mode, the technologist can adjust the flow rate of the current phase while it is in progress by selecting and holding the Up Arrow key (increase) or Down Arrow key (decrease). They are located above and below the flow rate box in the upper right corner of the Remote's Run Mode Screen. Use caution when manually adjusting the flow rate during an injection.
- During RUN mode, the technologist can pause the injection procedure at any time by: (1) selecting any part of the Remote's select screen (except at the flow rate box at the upper right in the Run Mode Screen), or (2) selecting any membrane key on the Injector Head. To resume the injection after a pause, select RUN on the Remote or the green RUN membrane key on the Injector Head.
- The Injector will deliver contrast and saline at the programmed flow rates. If syringe pressure reaches the Delivery Pressure Limit, the flow rate will automatically be reduced in order to maintain the pressure limit. If the flow rate drops below 25% of its programmed value, the Remote will sound a one second tone every ten seconds and display Pressure Limiting Occurring. If the pressure limited flow rate falls below 0.1 mL/s for 5 seconds, the system will enter PAUSE mode and indicate an overpressure condition. In addition, the system will enter PAUSE mode and indicate an overpressure condition if there is an immediate extreme spike in pressure indicating a possible full occlusion.
- Pressure limiting and over-pressure messages may occur due to simultaneous selection of a high flow rate and a low pressure limit, or because of an occlusion in the fluid path. If either of these messages is displayed, check the fluid path. If there is blockage; stop injection and seek medical advice. If there are no blockages, adjustments may need to be made to the flow rate or pressure limit in accordance with physician's orders.
- The Elapsed Time starts at the onset of the injection and continues throughout the injection. It will reset when the system is armed again. If the user selects the icon next to the Elapsed Time, it will stop the timer and the icon will be removed. The elapsed time feature gives you the time in minutes and seconds since the start of the injection.

WARNING

In the event of a system malfunction or a patient complication during injection, pause the injection by selecting any part of the Remote's select screen (except the flow rate box at the upper right) or pressing any membrane key on the Injector Head immediately.

Performing the Injection (continued)

- 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).

Unloading Syringes from the Injector Head

Disconnect the Patient

After completing an injection, the Main Screen will be re-displayed. At that time the system will need to be re-loaded and re-armed to continue with another procedure. In the concluding step, the patient must be disconnected from the EmpowerMR® Injector System according to the procedure below:

Step	Instruction
1	Disconnect the Injector's connecting tube from the patient.
2	Close off the catheter or remove in accordance with site practice.

Remove the Connecting Tube

Before removing the syringe, follow this procedure:

WARNING

The connecting tube must be removed prior to replacing the syringe. If it is not removed, this will cause a vacuum to develop in the syringe, which will result in the syringe plunger recoiling when the Injector Ram reaches the REPLACE SYRINGE position. This could result in contrast or saline spillage and syringe breakage.

Step	Instruction
1	Remove the connecting tube from the syringes.
2	Discard the connecting tube using institutional procedures for disposal of bio-hazardous waste.

Unloading Syringes from the Injector Head (continued)

Remove the Syringe

Use the following procedure to remove the syringe from the Injector Head:

Step	Instruction
1	Ensure the connecting tube is removed from the syringes.
2	Tilt the Injector Head back into the upright position. Fully retract the syringe plunger by pressing the CONTRAST REVERSE TO LIMIT (▼▼) key for one second and release (as shown below): 
3	After the syringe plunger has fully retracted, open the syringe door and grasp the barrel of the syringe and remove, as shown below:  Discard the syringe using institutional procedures for the disposal of bio-hazardous waste.
4	If a saline syringe has been used, follow steps 2-3 for the saline side using the SALINE REVERSE TO LIMIT key (▼▼). The Injector Head handle will flash blue. This can be started while the contrast syringe plunger is still retracting.

WARNING

The connecting tube must be removed prior to replacing the syringe. If it is not removed, this will cause a vacuum to develop in the syringe, which will result in the syringe plunger recoiling when the Injector Ram reaches the REPLACE SYRINGE position. This could result in contrast or saline spillage and syringe breakage.

Performing Test Injections

The volume and flow rate for contrast and saline test injections are set up in the Setup Menu as described in the procedure below.

A test injection can be initiated while in the ARM mode by pressing the blue Test Inject key located on either side of the Injector Head handle. At the Remote, a single beep will sound at the start of the test injection, and TEST INJECTION IN PROGRESS, PLEASE WAIT will be displayed until the injection is completed. A predefined test bolus of contrast media followed by a predefined test bolus of saline is administered.

The Injector Head handle will flash orange while contrast is being injected and will flash blue while saline is being injected. The flash rates are proportional to the flow rate.

Programming a Test Injection

Starting in the Remote's Main Screen, program the volume and flow rate parameters for a test injection as follows:

Step	Instruction
1	Select the **SETUP** key. The Setup Screen is displayed.
2	Select the **TEST INJECTION** key. A pop-up keypad is displayed, as shown, which includes a preview pane, a numerical keypad (0 to 9), **CLEAR**, **CANCEL**, ⌫ , **ENTER**, Contrast Test Flow Rate, Contrast Test Volume, Saline Test Flow Rate, and Saline Test Volume: 

Performing Test Injections (continued)

Step	Instruction
3	Select **Contrast Test Flow Rate** and enter a value (range: 0.0 mL/sec to 6.0 mL/sec; increment: 0.1 mL/secs; default: 2 mL/sec).
4	Select **Contrast Test Volume** and enter a value (range: 0 mL to 10 mL; increment: 1 mL; default: 10 mL).
5	Select **Saline Test Flow Rate** and enter a value (range: 0.0 mL/sec to 6.0 mL/sec; increment: 0.1 mL/secs; default: 2 mL/sec).
6	Select **Saline Test Volume** and enter a value (range: 0 mL to 10 mL; increment: 1 mL; default: 10 mL).
7	Select **ENTER**. The values will be saved and the keypad will disappear.

Note

If a saline chase is not required for the test injection, enter 0.0 mL/sec for Saline Flow Rate and 0 mL for Saline Volume. If only a saline test injection is required, enter 0.0 mL/sec for Contrast Flow Rate and 0 mL for Contrast Volume.

Powering Off the System

At the conclusion of a day's procedure load, power down the Remote (refer to page 26). The Hydraulic Controller will remain powered up and will enter Standby mode (low power consumption) after a period of inactivity.

Cleanup and Storage

WARNING

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

When preparing to clean and store the EmpowerMR® Injector System do the following:

Step	Instruction
1	Power off the Remote Control and the Hydraulic Controller as discussed under "Power Down Entire Injector System" on page 27. Disconnect the plugs from the electrical outlets. ***Note*** *The Injector Head receives power from the Hydraulic Controller and does not have a wall plug.*
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 EmpowerMR® Injector System. Never submerge either unit in water.
3	Clean the Remote Control with a soft towel and mild detergent. Clean the screen with a soft towel and a computer monitor cleaning agent.

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

5 Remote Control Operation and Programming

Introduction

The previous section, *Injection Procedure*, provided instructions for programming, modifying, and deleting a protocol while in the Main Screen.

This section provides more in-depth information describing the different screens that are presented during preparation and administering of injections. In addition, instructions for programming, saving, and retrieving stored protocols are discussed.

Remote Control Screens

Through a series of screens, the Remote Control provides the technologist with opportunities to create, modify, and delete protocols and to monitor status of injection procedures.

The following screens are discussed in the sequence that they occur starting with powering up to administering and pausing an injection:

- Power-Up Screen
- Main Screen
- ARM Mode Screen
- RUN Mode Screen
- PAUSE Mode Screen

The following screens can be accessed from the Main Screen:

- Program Screen
- Setup Screen
- Help Screen

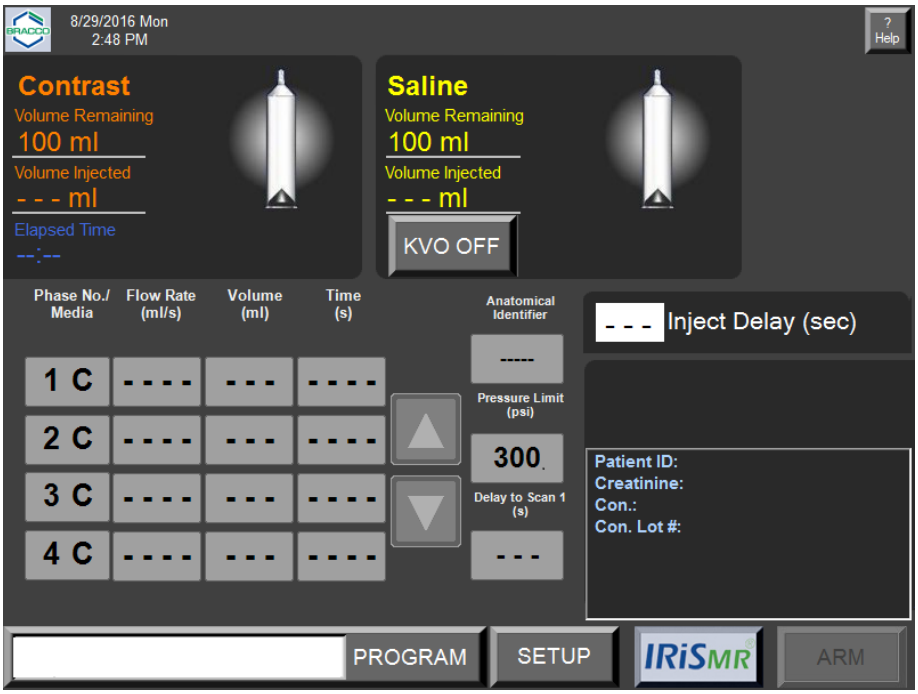
Remote Control Screens (continued)

Power-up Screen

The Power-Up Screen is displayed when the Remote Control is powered up. The displayed information is discussed under "Ensuring System is Powered Up" on page 29. Following internal diagnostics or five seconds, whichever is longer, the Main Screen will be displayed.

Main Screen

The Main Screen, shown below, is used to create injection programs, activate or deactivate the KVO (Keep Vein Open) function, and it is the starting point and returning point for all injection procedures:



From this screen, the technologist can also choose to enter the Program Screen, Setup Screen, the IRiSMR® functions, the online Help function, and the ARM mode.

KVO Function

When the KVO (Keep Vein Open) function is turned on (KVO ON, shown below), the saline syringe injects a bolus of 0.25 mL at 1 mL/s every 30 seconds. The saline Volume Remaining field will be automatically updated.

To turn on the function:

Step	Instruction
1	The KVO key must be active. Ensure the Injector is tilted down in the RUN position and the saline volume is greater than 1 mL.
2	Select the KVO key. The message on the key will change from KVO OFF to KVO ON.

Remote Control Screens (continued)

Select the **KVO** key again to turn off the function. The message on the key will change from KVO ON to KVO OFF. In addition, any of the following conditions will cause the KVO function to turn off:

- System starts injecting (RUN mode).
- Injector is tilted out of the RUN position.
- Saline volume drops to 0 mL.
- Any Injector Head membrane key is pressed.
- Loss of communication occurs.
- Overpressure occurs.

The KVO function will automatically resume after the completion of the injection. Injection parameters can be changed without interrupting the KVO. The screen saver will not come on if the KVO function is ON.

Main Screen User Controls, Information, and Messages

The Main Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- Programming phases (includes selecting contrast, saline, PAUSE, TIMED PAUSE, flow rate, and volume)
- Up/Down arrows to scroll phases
- Programming the Pressure Limit
- Programming an Inject Delay
- Programming a Delay to Scan
- Accessing the Program Screen
- Accessing the Setup Screen
- Initiating KVO
- Entering ARM mode
- Screen Saver (during STOP mode, a screen saver will be displayed if there has been no activity for 30 minutes. Touching any part of the Remote Control screen will stop the screen saver and return the Remote to the prior display)

Information:

- Volume remaining (contrast and saline)
- Volume injected (contrast and saline)
- Syringe graphic displaying orientation (contrast and saline)
- Selected program name (if applicable)

Remote Control Screens (continued)

- Current protocol parameters (contrast or saline, pause, flow rate, volume, time, pressure limit, delay to scan, anatomical identifier, if applicable)
- Help button
- Date, day, and time

Messages:

- **Use the Injector Keys to Load** – displayed when the Injector is powered up and the Injector Head is tilted up. The message disappears after the syringe is loaded.
- **Tilt Injector Up to Load** – displayed when the Injector is powered up and the Injector Head is tilted either in the RUN position or between the LOAD (up) and RUN (down) positions. The message disappears when the Injector Head is tilted in the LOAD position.
- **Injector Not Found** – displayed if the Remote loses communication with the Injector Head. The message disappears when communication is established. The Remote remains active when communication is lost, but the ARM key is not active.
- **Warning!!! Invalid Parameter. Please check allowable range** – displayed when an invalid flow rate, volume, delay to scan, or pressure limit value is entered via the pop-up keypad. The message disappears when OK is selected in the pop-up window.
- **Injection is complete** – when the injection is completed, the system annunciates this voice message. The system then returns to the STOP mode and displays this same message as text.
- **SYSTEM IS STOPPED** – this message is annunciated as a voice message and displayed as a text message whenever the system goes from ARM to STOP and from PAUSE to STOP.
- **Possible Full Occlusion** – when the KVO is On and the monitored pressure indicates that there may be a full occlusion in the connecting tube. The KVO will automatically be turned Off and the pop-up message "Possible KVO occlusion. Press OK to continue" will appear on the Remote. Acknowledge the message (select OK), check the fluid path for occlusions and turn the KVO back On. The user will be unable to Arm or turn the KVO back on until the message is acknowledged and the pressure drops below 50 psi (345 kPa, 3.4 bar).
- **SALINE FLUSH INJECTION WILL BE DISABLED, REMOVE SALINE SYRINGE, Press OK to Continue Injections Protocol Without Saline Flush** – this message is displayed if after Phase 1 and Phase 2 are programmed for contrast, the technologist attempts to also program Phase 3 for contrast (as shown on page 51). When the technologist acknowledges the instruction, the Remote Control will display SALINE FLUSH DISABLED, and the system

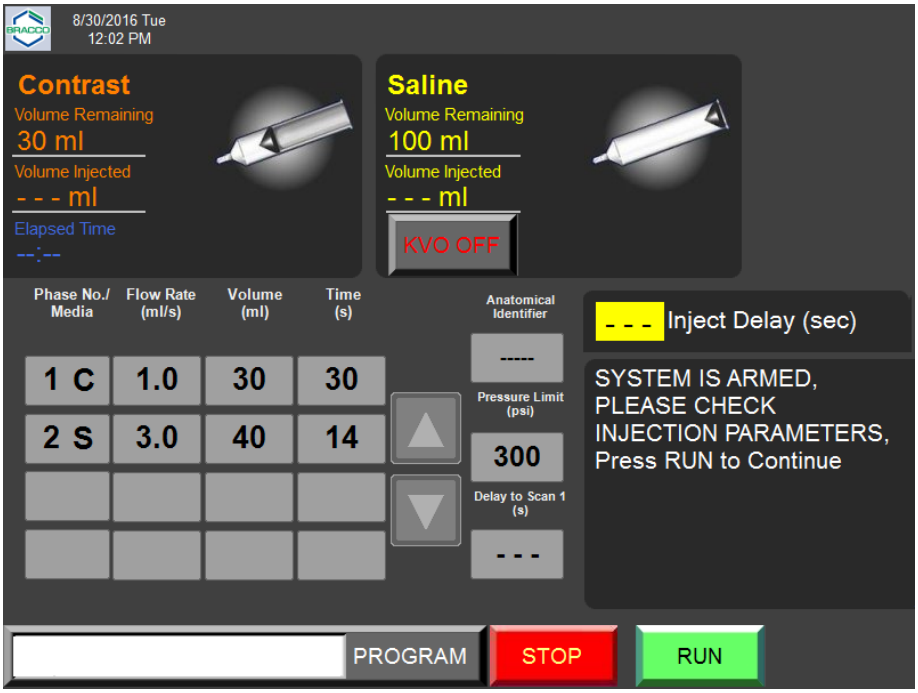
Remote Control Screens (continued)

will set itself up for three or more phases of contrast injection, only. The saline injection will be re-associated with the system if Phase 3 and all subsequent phases are deleted.

- **System is armed (voice) SYSTEM IS ARMED, PLEASE CHECK INJECTION PARAMETER, PRESS RUN TO CONTINUE (text)** – when the ARM key is selected, the voice message is annunciated and the text message is displayed. The ARM softkey is enabled on the Remote only when:
  - The Injector Head is tilted down in the RUN position.
  - Volume is greater than 1.0 mL.
  - Valid injection parameters have been entered.
  - If saline injection has been programmed, it is the second or third phase and no other phases follow it.

ARM Mode Screen

When the technologist selects the ARM key in the Main Screen, the Remote displays the ARM Mode Screen, as shown below:



From this screen the technologist can start the injection by selecting the RUN key, or stop the injection by selecting the STOP key.

Remote Control Screens (continued)

ARM Mode Screen User Controls, Information, and Messages

The ARM Mode Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- RUN key or INJECT DELAY key – selecting this key starts the injection.
- Down Arrow key – allows the technologist to scroll down if there are more than four valid phases; otherwise, the key is grayed out.
- STOP key – selecting this key will stop the injection and bring the system back to the Main Screen.
- Initiating KVO

Information:

- Volume remaining (contrast and saline). Each syringe must have more than 0 mL for Injector to arm.
- Volume injected (contrast and saline). Volume for each syringe will show --- mL once Injector is armed.
- Elapsed time will show up --:-- once Injector is armed.
- Syringe graphic displaying orientation (contrast and saline).
- Selected program name (if applicable).
- Current protocol parameters (contrast or saline, pause, timed pause, flow rate, volume, time, pressure limit, delay to scan, anatomical identifier, if applicable).
- Date, day, and time.

Messages:

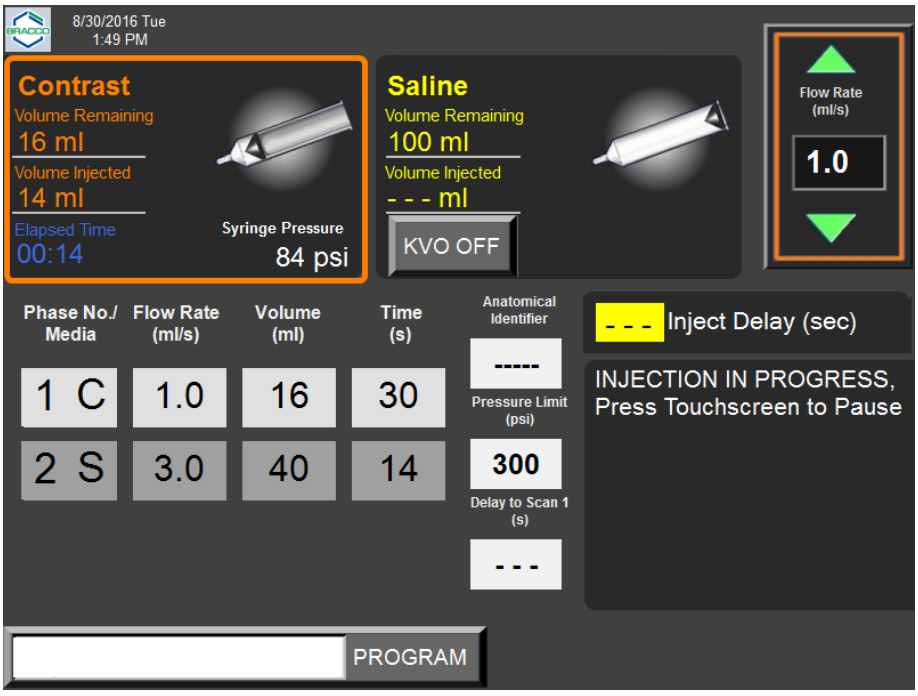
- **SYSTEM IS ARMED, PLEASE CHECK INJECTION PARAMETERS, PRESS RUN TO CONTINUE** – displayed if the remaining volume in the syringe is greater than or equal to the programmed volume. This message will disappear when the Injector goes into the STOP mode or the RUN mode.
- **SYSTEM IS ARMED, PLEASE CHECK INJECTION PARAMETERS, PRESS RUN (or INJECT DELAY) TO CONTINUE WITH XXX ML TOO LITTLE FLUID FOR INJECTION** – displayed if the syringe volume is less than the programmed volume (XXX represents the difference between the actual and programmed volume).
  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.

Remote Control Screens (continued)

- **TEST INJECTION IN PROGRESS, PLEASE WAIT** – displayed if the TEST INJECTION key (blue) on either side of the Injector Head handle is pressed while in ARM mode.
- **Possible Full Occlusion** – when the KVO is On and the monitored pressure indicates that there may be a full occlusion in the connecting tube. The KVO will automatically be turned Off, the system will return to Stop mode and the pop-up message "Possible KVO occlusion. Press OK to continue" will appear on the Remote. Acknowledge the message (select OK), check the fluid path for occlusions, select the ARM key and turn the KVO back On. The user will be unable to Arm or turn the KVO back on until the message is acknowledged and the pressure drops below 50 psi (345 KPa, 3.4 bar).

RUN Mode Screen

Injection occurs while in the RUN mode. The Injector will go into the RUN mode by selecting the RUN key (or the INJECT DELAY key) while the system is in either the ARM mode or the PAUSE mode. The RUN key (and INJECT DELAY key) disappears in the RUN Mode Screen, as shown below:



RUN Mode Screen User Controls, Information, and Messages

The Run Mode Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- Up/Down arrow keys in the flow rate box at upper right to increase or decrease the active flow rate during RUN mode.

Remote Control Screens (continued)

- Selecting any part of the Remote's screen (except in the flow rate box at the upper right) while it is in RUN mode, will cause the system to go into the PAUSE mode.

Information:

- Volume remaining (contrast and saline). Each syringe must have greater than 0 mL for Injector to go into RUN mode.
- Volume injected (contrast and saline).
- Elapsed time.
- Inject delay countdown (if applicable).
- Syringe graphic displaying orientation (contrast and saline).
- Selected program name (if applicable).
- Current protocol parameters (pressure limit, delay to scan, anatomical identifier, if applicable).
- Predecessor Phase Parameter (parameters of phase prior to current phase being executed). Not applicable when Phase 1 is being executed.
- Active Phase Parameter (parameters of current phase being executed).
- Successor Phase Parameter (parameters of phase to follow the current phase being executed). Not applicable if current phase is the final phase.
- Date, day, and time.

Messages:

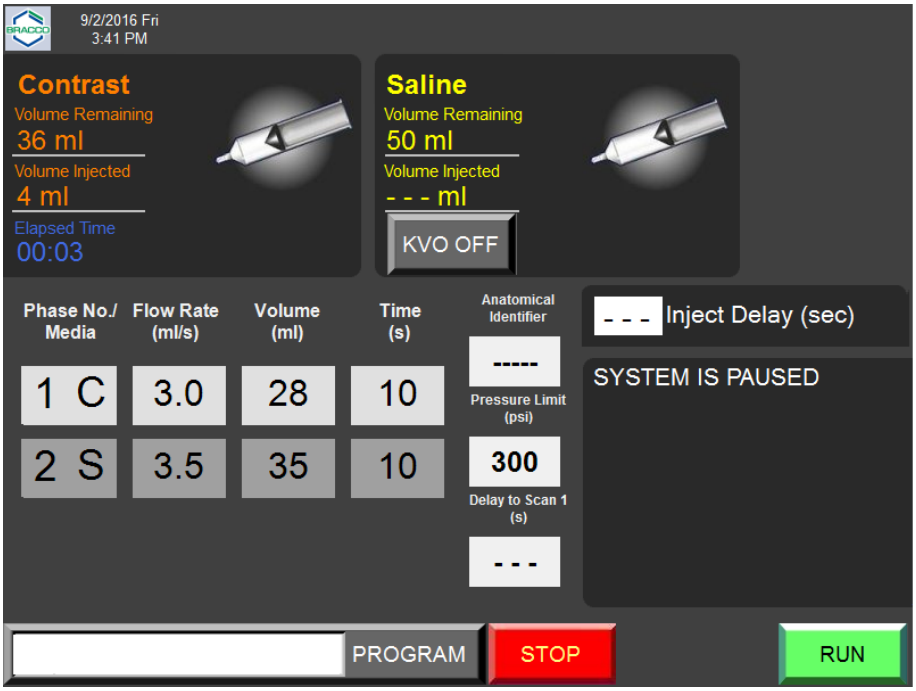
- **INJECTION IN PROGRESS, PRESS TOUCHSCREEN TO PAUSE** – displayed during injection. Message disappears when Injector goes into the PAUSE mode.
- **INJECT DELAY IN PROGRESS** – displayed during inject delay countdown. Message disappears when the countdown is finished and the injection begins.
- **Pressure Limit Occurring** – displayed if injection flow rate drops below 25% of its programmed rate due to pressure limiting. In addition, the pressure limited flow rate will be displayed and a one-second tone will sound every ten seconds.

Remote Control Screens (continued)

PAUSE Mode Screen

The Remote will Pause and display the PAUSE Mode Screen (shown below) if any of the following occurs:

- The phase being executed is programmed for Pause or Timed Pause.
- Touching the Remote's screen during RUN mode.
- Opening either Syringe door.
- Tilting the Injector Head out of the RUN position.
- Overpressure condition.
- Pressing a membrane key on the Injector Head.



PAUSE Mode Screen User Controls, Information, and Messages

The PAUSE Mode Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- RUN key – selecting this key returns the Remote to the RUN mode and an audio annunciation Injection in progress is sounded.
- STOP key – selecting this key will bring the system back to the Main Screen.

Remote Control Screens (continued)

Information:

- Volume remaining (contrast and saline).
- Volume injected (contrast and saline).
- Elapsed time (continues to increment while in PAUSE mode).
- Remaining Pause time (for Timed Pause), if applicable.
- Syringe graphic displaying orientation (contrast and saline).
- Selected program (if applicable).
- Current protocol parameters (pressure limit, delay to scan, anatomical identifier, if applicable).
- Predecessor Phase Parameter (parameters of phase prior to current phase being executed). Not applicable when Phase 1 is being executed.
- Active Phase Parameter (parameters of current phase being executed).
- Successor Phase Parameter (parameters of phase to follow the current phase being executed). Not applicable if current phase is the final phase.
- Date, day, and time.

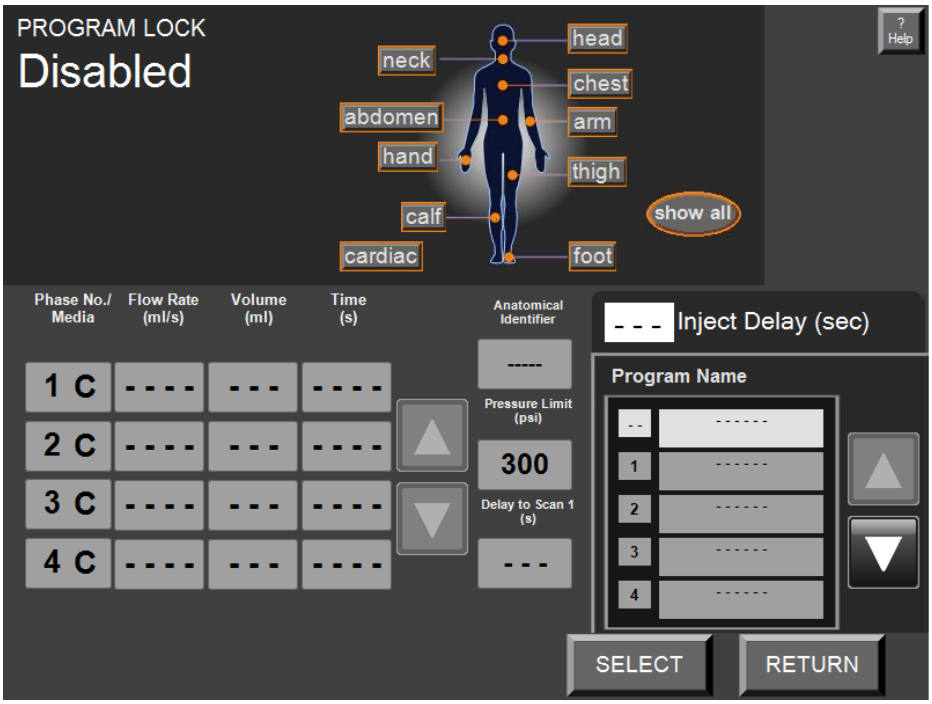
Messages:

- **SYSTEM IS PAUSED** – displayed with an accompanying tone when the Remote's screen is touched or a membrane key on the Injector Head is selected during RUN mode causing the system to Pause. Selecting the RUN key will remove the message and return the system to the RUN mode.
- **SYSTEM IS PAUSED, DOOR OPEN** – displayed with an accompanying tone when the syringe door is opened while the system is in RUN mode causing the system to Pause. Correcting the problem and selecting the RUN key will remove the message and return the system to the RUN mode.
- **SYSTEM IS PAUSED, TILT DOWN** – displayed with an accompanying tone when the Injector Head is tilted out of the RUN mode position while the system is in RUN mode. Correcting the problem and selecting the RUN key will remove the message and return the system to the RUN mode.
- **SYSTEM IS PAUSED, OVERPRESSURE** – displayed with an accompanying tone when the system is paused due to overpressure. This will occur if the pressure limited flow rate falls below 0.1 mL/sec for 5 seconds. Correcting the problem and selecting the RUN key will remove the message and return the system to the RUN mode.

Remote Control Screens (continued)

Program Screen

The Program Screen, shown below, is accessed by selecting the Program key in the Main Screen:

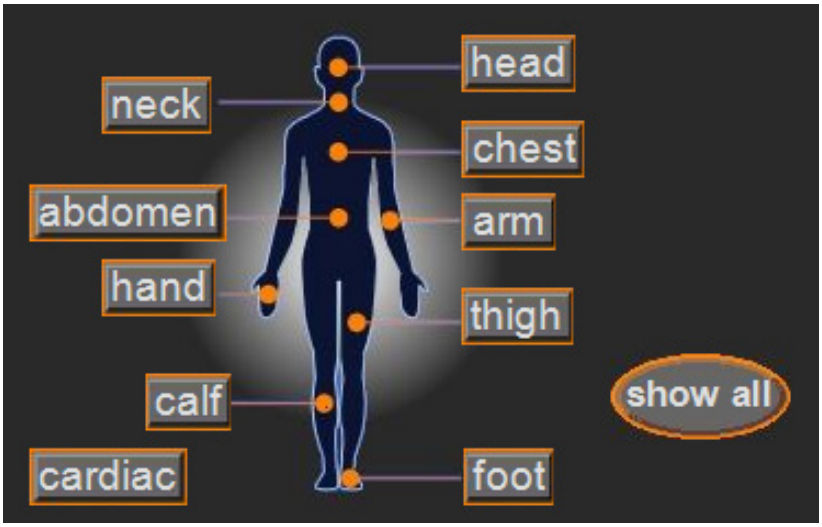


This screen allows the technologist to create, modify, and store programs for future use, and retrieve them when needed. Programs can also be sorted in accordance with anatomical identifiers.

Remote Control Screens (continued)

The Program Screen consists of three main areas:

Human Body Identifier area:



The Human Body Identifier area permits the technologist to associate an injection protocol with a specific part of the human anatomy.

- Anatomical Identifier Area:

The Anatomical Identifier area aids in retrieving a required program by selecting an anatomical identifier.

Remote Control Screens (continued)

- Program Name List:

This list allows for scrolling through program names.

Program Screen User Controls, Information, and Messages

The Program Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- Selecting and programming phases (includes selecting contrast, saline, PAUSE, TIMED PAUSE, flow rate, and volume).
- Up/Down arrows to scroll phases.
- Up/Down arrows to scroll stored programs.
- Programming Pressure Limit.
- Program Delay to Scan.
- Anatomical identifier keys to sort and recall stored programs according to human anatomy.
- Save modifications to a program (SAVE key).
- Save new programs (SAVE AS key).
- Delete programs (DELETE key).
- Retrieve programs into the Main Screen (SELECT key).
- Return to the Main Screen without retrieving program (RETURN key).

Remote Control Screens (continued)

Programs can be sorted and retrieved according to the following anatomical identifiers:

- Head
- Neck
- Chest
- Arm
- Hand
- Abdomen
- Thigh
- Calf
- Foot
- Miscellaneous
- Show All (retrieves all programs, up to 100, in numerical order)

Information:

- Program names (up to 100).
- Current protocol parameters (contrast or saline, pause, flow rate, volume, time, pressure limit, delay to scan, anatomical identifier (if applicable).
- Help button.
- Date, day, and time.

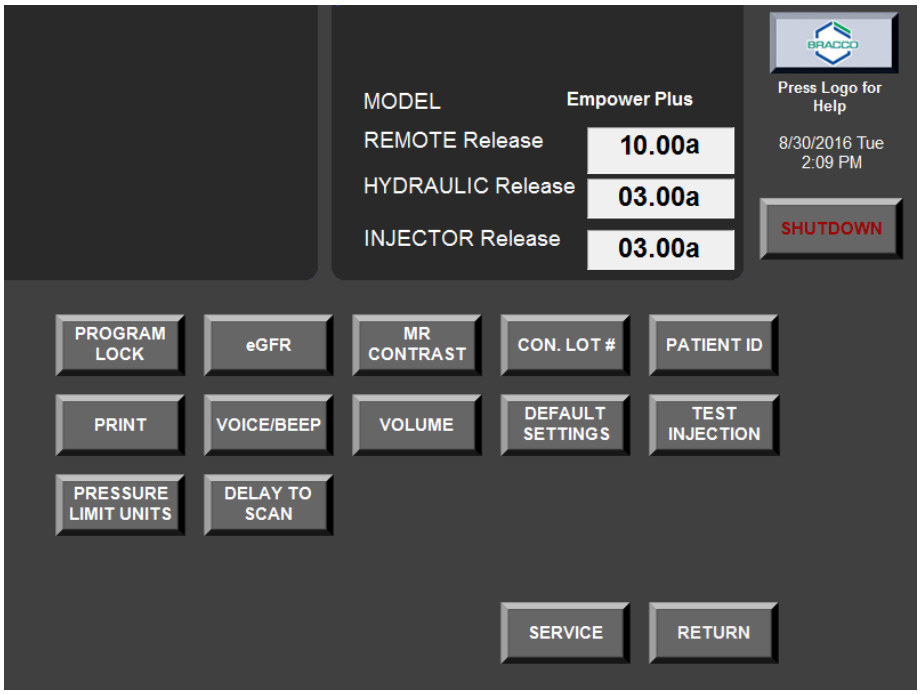
Messages:

- **All Program Locations Are Full** will be displayed if all program locations are filled and the technologist tries to save a new program. Up to 100 programs can be stored.

Remote Control Screens (continued)

Setup Screen

The Setup Screen (shown below) is accessed by selecting the Setup key in the Main Screen:



The Setup Screen allows the technologist to configure the system.

The Setup Screen provides the technologist with the following user controls, information, and messages:

User Controls:

- VOICE/BEEP key – toggle switch that enables/disables voice messages. The default setting is ENABLED.
- DEFAULT key – restores all settings in the Setup Mode Screen to the factory default settings.
- TEST INJECTION key – modifies settings for the Test Injection. Selecting this key causes a pop-up keypad to display allowing the technologist to enter flow rate and volume for contrast and saline to be administered when Test Injection is activated. When the system is armed, Test Injection can be initiated at the Injector Head by pressing the Test Inject key (blue) on either side of the Injector Head handle.
- PRESSURE LIMITS UNITS key – toggle switch that permits changing units for pressure limit (psi, kPa, bar). The default setting is psi.

Remote Control Screens (continued)

- VOLUME key – allows the technologist to adjust the volume for audio and beeper sounds, but not for fault signals. Selecting this will display a pop-up volume control screen. After adjusting the volume settings and selecting ENTER, the new settings are stored and the volume pop-up screen disappears.
- DELAY TO SCAN key – toggles between Enabled, Dual Enabled, and Disabled. This allows the technologist to select Delay to Scan (1), both Delay to Scan features, or disable both of them. The default setting is Disabled. One or both Delay to Scan key(s) will appear in the Main Screen only if enabled in the Setup Screen.
- PROGRAM LOCK - will lock out the ability to modify the programs stored in the Remote Control.
- SERVICE key – allows authorized Bracco Injeneering S.A. local personnel to access maintenance operations. It is password protected.
- RETURN key – returns to the Main Screen.
- GFR key - the user can select the method that the system will remember the type of GFR entry.
- CON. LOT# - the user can select to allow for the entry of the contrast lot code.
- PATIENT ID - the user can select if the user has the ability to enter the Patient ID.
- MR CONTRAST - the user can select the method that the system will remember the type of MR contrast entry.
- SHUTDOWN - safely powers off the Remote at the end of the day's activities.

Information:

- Help button.
- Date, day, and time.

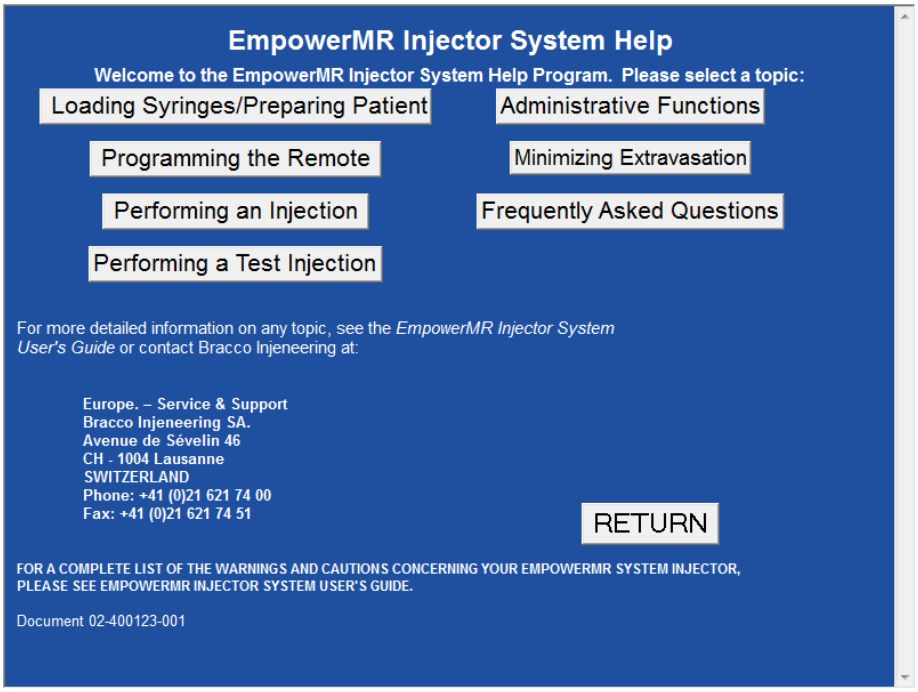
Messages:

- **Warning!!! Invalid Service Password. Please try again** is displayed if an incorrect password is entered after selecting the SERVICE key. This feature is reserved only to authorized Bracco Injeneering S.A. local personnel.

Remote Control Screens (continued)

HELP Screen

The EmpowerMR® Remote Control features a HELP Screen (shown below) to aid the technologist in the use of the EmpowerMR® Injector System. It is activated by selecting the Help button on the Main Screen, Program Screen, and Setup Screen. Selecting topic keys on the screens will display information pertaining to the selected topics. To exit, select the RETURN key as often as necessary to back out of selected topics and the HELP Mode Screen.



Advanced Programming Features

In addition to programming an injection procedure in the Main Screen, the technologist can use the Program Screen to create and store up to 100 separate programs. These programs can be identified by name or categorized according to anatomical identifiers and can be retrieved back into the Main Screen for injection.

To access the Program Screen, select PROGRAM in the Main Menu Screen.

Creating and Saving a New Program

Upon entering the Program Screen, the system will transfer the current program in the Main Screen to the Program Screen and the first entry in the Program Name area will be highlighted, as shown in this example:

To save a new program, refer to "Saving the New Program" on page 88; otherwise perform the following procedure for creating and saving a new program that can be retrieved for future use.

Advanced Programming Features (continued)

Programming Phases

When programming phases, remember these requirements:

- The first phase is always a contrast injection.
- A saline injection may be programmed for the second or third phase.
- Only one phase may be programmed for saline.
- No additional phases may be programmed following a saline phase.
- A phase may not be programmed for Pause or Timed Pause if the protocol includes a saline injection.
- Two consecutive phases may not be programmed for Pause or Timed Pause. This applies to any combination of Pause and Timed Pause.

To program phases, do the following:

Step	Instruction
1	Starting with Phase 1, program contrast as follows:

Step	Instruction
a	Select the **Flow Rate** key for Phase 1. A Flow Rate range data input pop-up window is displayed.
b	Enter the desired flow rate in mL/sec and select **ENTER**. The Remote Control will automatically enter one decimal place and display the value in the Flow Rate column (for example, if you enter 100, the Remote Control will show this as 10.0). To make corrections in the pop-up window, select ⌫ to erase one character at a time. The allowable flow rate range is 0.1 to 10.0 mL/sec in 0.1 mL/sec increments.
c	Select either the **Volume** or **Time** key for Phase 1. A Volume or Time range data input pop-up window is displayed.
d	Enter the desired volume in mL or time in seconds and select **ENTER**. The value will be displayed in the Volume or Time field. The Remote will also calculate and display the time interval in the Time column or the Volume interval in the volume column. The allowable volume range is 1 to 100 mL in 1 mL increments. The allowable time range is dependent on the flow rate entered.

Advanced Programming Features (continued)

Step	Instruction
2	To program contrast for Phase 2, repeat step 1 starting with Phase 2; to program saline in Phase 2, do as follows: **Step** / **Instruction** a – Select the Phase 2 key in the Phase column and select Saline in the pop-up window. An S will replace C in the Phase 2 key. b – Repeat steps 1a through 1d to program flow rate and volume for the saline.
3	Continue to program phases (maximum of 8 contrast phases). If necessary, press on the adjacent Up/Down arrows to scroll the phases.

Note

To modify a phase parameter, select the appropriate key, enter the new value in the pop-up window, and select **ENTER**. *To delete an entire phase, select the phase and select* **DELETE** *in the pop-up window and select* **ENTER**.

Programming the Pressure Limit

The default delivery Pressure Limit is 300 psi (2068 kPa, 20.7 bar). To enter a different value, do the following:

Step	Instruction
1	From the Program Screen or the Main Screen, select the **Pressure Limit (psi)** softkey displaying the current value. A pop-up **Pressure Limit Range** keypad is displayed.
2	Enter a new value using the keypad. Up to three characters may be entered. The allowable range is 40 to 300 psi (275.8 to 2068 kPa, 2.8 to 20.7 bar) in 1 psi increments.
3	Select **ENTER** on the keypad. The new value is entered and the keypad disappears.

Note

Invalid values will not be allowed, and the technologist will be alerted with a displayed message.

The pop-up Pressure Limit Range keypad also contains the following keys:

CLEAR – clears the entered value in the keypads preview pane.

 – erases previously entered digit.

CANCEL – removes keypad without making any changes to current value.

Advanced Programming Features (continued)

Programming a Pause

Programming a Pause is optional and is not available in procedures that include a saline injection. Review the requirements before programming a Pause (refer to "Requirements for Programming Pause and Timed Pause" on page 53).

To program a Pause, do the following:

Step	Instruction
1	Select a Phase number (except Phase 1) where the pause is to occur. A pop-up window is displayed.
2	Select **PAUSE** in the pop-up window.

Programming a Timed Pause

Programming a Timed Pause is optional and is not available in procedures that include a saline injection. The Injector will execute the next phase in the protocol after the Pause has timed out. Review the requirements before programming a Timed Pause (refer to "Requirements for Programming Pause and Timed Pause" on page 53).

To program a Timed Pause, do the following:

Step	Instruction
1	Select a Phase number (except Phase 1) where the pause is to occur. A pop-up window is displayed.
2	Select **TIMED PAUSE** in the pop-up window. A pop-up keypad is displayed.
3	Enter the number of seconds to pause and select **ENTER**. The keypad will disappear and the programmed time will be displayed in the selected phase key. Up to 3 digits may be entered allowing a range of 1 to 900 seconds in 1 second increments.

Programming Delay to Scan

The EmpowerMR® Injector System provides two Delay to Scan features. They must first be enabled in the Setup Screen in order to make them available in the Main Screen and the Program Screen (refer to "Setup Screen" on page 81). Delay to Scan (1) can be programmed from 1 to 300 seconds in 1 second increments. Delay to Scan (2) can be programmed from 1 to 900 seconds in 1 second increments.

Advanced Programming Features (continued)

To program a Delay to Scan, do the following:

Step	Instruction
1	From the Main Screen or the Program Screen, select a **Delay to Scan** softkey. A pop-up keypad is displayed, as shown:  *The pop-up keypad contains the following keys:* *CLEAR – clears the entered value in the keypads preview pane.* *– erases previously entered digit.* *CANCEL – removes keypad without making any changes to current value.* *RESET – sets the value to "---".*
2	Enter a new value using the keypad. Up to three digits may be entered. Do not exceed the allowable ranges.
3	Select **ENTER** on the keypad. The new value is entered and the keypad disappears.
4	Repeat, if applicable, for the other Delay to Scan.

Note

Invalid values will not be allowed and the technologist will be alerted with a displayed message.

Advanced Programming Features (continued)

Programming Anatomical Identifier

The anatomical identifier permits the user to associate an injection protocol with a specific part of the human anatomy (as shown under "Program Screen" on page 77). This aids in retrieving a required program. By selecting an anatomical identifier only the associated programs are displayed.

To associate the currently displayed program with an anatomical identifier, do the following:

Step	Instruction
1	Select the **Anatomical Identifier** key (located above the Pressure Limit key). The key's background color will turn white.
2	In the anatomical identifier area, select a body part name. The new name will be displayed in the Anatomical Identifier key.

Saving the New Program

New programs are saved using the SAVE AS key. You may save up to 100 programs. Save the program as follows:

Step	Instruction
1	Select the highlighted area in the Program Name List (as shown on page 79). A pop-up alphanumeric screen is displayed.
2	Enter up to 40 alphanumeric characters for the program name and select **ENTER**.
3	Select **SAVE AS** to save the new program. The program will be saved in the next available program number. If the program currently exists in memory with the same phases, anatomical identifier, and Delay to Scan parameters and values, the system will display **PROGRAM EXISTS IN MEMORY AS PROGRAM NUMBER XX. PROCEED?** Select **NO** to return the system to the Program Screen. Select **YES** to save the program into the displayed (XX) memory location.

Advanced Programming Features (continued)

Modifying and Saving an Existing Program

To modify or save an existing program, do as follows:

Step	Instruction
1	Retrieve an existing program by selecting a body name key in the anatomical graphic (as shown on page 78) or selecting **show all**. The **SAVE** key will be displayed and program names will be displayed in numerical order in the Program Name area. It will display all stored programs or just those programs associated with the selected anatomical identifier.
2	Use the adjacent Up/Down arrows to scroll the program names (as shown on page 79) until the desired program is found.
3	Select the program name. Its programmed parameters will appear for phase values, pressure limit, and Delay to Scan, if applicable.
4	Select the appropriate keys to modify their values. Refer to "Creating and Saving a New Program" on page 83 for instructions on entering values.
5	Select **SAVE**. The system will display **SAVE WILL OVERWRITE CURRENT MEMORY. PROCEED?** Select **YES** to save the program to its original numerical location or select **NO** to return to the Program Screen without saving the program.

Deleting an Existing Program

To delete an existing program, do the following:

Step	Instruction
1	Retrieve an existing program by selecting a body name key in the anatomical graphic or selecting show all. The **DELETE** key will be displayed if there is at least one program name in memory and program names will be displayed in numerical order in the Program Name area. It will display all stored programs or just those programs associated with the selected anatomical identifier.
2	Use the adjacent Up/Down arrows to scroll the program names (as shown on page 79) until the desired program is found.
3	Select the program name. Its programmed parameters will appear for phase values, pressure limit, and Delay to Scan, if applicable.
4	Select **DELETE**. The system will display **DELETE WILL REMOVE THE CURRENT PROGRAM FROM MEMORY. PROCEED?** Select **YES** to delete or select **NO** to return to the Program Screen without deleting the program.

Advanced Programming Features (continued)

Selecting an Existing Program

The SELECT key will transfer the currently selected program to the Main Screen. To select an existing program, do the following:

Step	Instruction
1	Retrieve an existing program by selecting a body name key in the anatomical graphic (as shown on page 78) or selecting show all. Program names will be displayed in numerical order in the Program Name list. It will display all stored programs or just those programs associated with the selected anatomical identifier.
2	Use the adjacent Up/Down arrows to scroll the program names (as shown on page 79) until the desired program is found.
3	Select the program name. Its programmed parameters will appear for phase values, pressure limit, and Delay to Scan, if applicable.
4	Select **SELECT**. The system will return to the Main Screen transferring the selected program.

Exiting the Program Screen

Select **RETURN** to exit the Program Screen and return to the Main Screen. Unsaved changes will be discarded and no program will be transferred.

IRiSMR® Features

The EmpowerMR® Remote Control has a software database module called IRiSMR® (Injector Reporting Information System for EmpowerMR®). This software records contrast and injection utilization. In addition to the above mentioned parameters, the software can store information related to Patient ID, Creatinine or GFR value, MR Contrast Brand, and MR Contrast Lot code. These additional fields further enhance the details of the IRiSMR® database.

MR Contrast and Lot Code Setup

The MR CONTRAST key on the SETUP screen allows the user to toggle the MR CONTRAST setting to one of the following settings:

MR Contrast Setting	Description
Off	In OFF mode, the IRiSMR option will not display the MR CONTRAST key.
Basic	In BASIC mode, the type of MR Contrast on every procedure will need to be selected for every patient.
Expert	In EXPERT mode, the type of MR Contrast can be selected once and the system will remember the type of MR Contrast for every procedure. The user can select a new type of MR Contrast as well. The default setting is EXPERT.

The CON. LOT# key on the SETUP screen allows the user to toggle the CON. LOT# to one of the following settings:

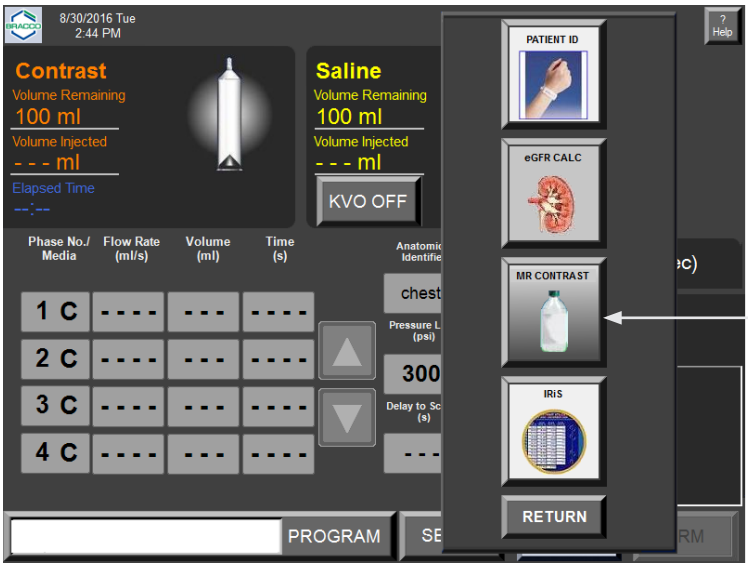
CON.LOT# Setting	Description
Enabled	The default setting is Enabled. In Enabled mode, the IRiSMR® MR CONTRAST option enables the user to enter the lot number of the Contrast. The MR CONTRAST setting via the SETUP screen must be set to Basic or Expert.
Disabled	In Disabled mode, the IRiSMR® MR CONTRAST option does not allow the user to enter the lot number of the Contrast.

IRiSMR® Features (continued)

MR Contrast and Lot Code Entry

From the Remote Control main screen, select the IRiSMR® key.

Then select the MR CONTRAST key from the IRiSMR® list, as shown below:



Next a choice of MR Contrast Brands are displayed as entries.

Select one of the specified MR Contrast by selecting the MR Contrast Brand to be used for the upcoming injection and enter the Lot number when prompted. The selected Brand along with the Lot Number will display at the bottom of the screen, as shown in the example below:

Verify that MR Contrast is correct as shown in the box at the bottom field and select **RETURN**.

IRiSMR® Features (continued)

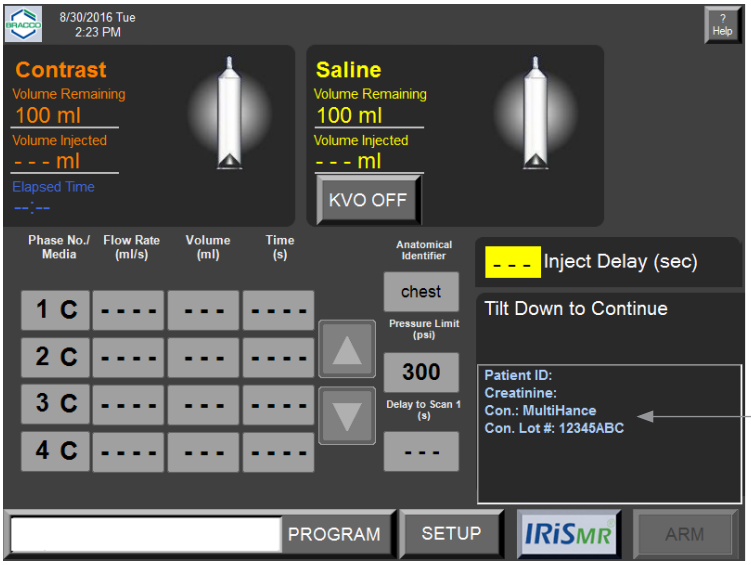
In addition, MR Contrast brands that are not displayed in the windows can be manually entered by selecting **OTHER** from the Brand list. A pop up keyboard will appear and the entry of a MR Contrast brand with up to 12 characters can be entered, as shown below. The entry will be recorded in one of the three user specified entries. The system will remember up to three user specified entries.

If the MR Contrast Lot code number (CON. LOT#) has been enabled, a pop-up keyboard will appear to allow entry of the MR Contrast Lot code using the pop-up alpha-numeric keyboard; you may enter up to 12 characters.

Once the MR Contrast Lot Code has been entered, verify that the MR Contrast type and MR Lot Code (if applicable) matches the type for the upcoming procedure and then select **RETURN**.

IRiSMR® Features (continued)

Once the RETURN key has been pressed, the Main Screen will be displayed. The MR Contrast Brand and Type selected will be displayed in the System Message Area, as shown below:



Contrast Brand and Lot Number

WARNING

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

Reminder: if the setup has been set to BASIC, the MR Contrast and MR Contrast Lot Code will be removed after the contrast syringe position is at REPLACE SYRINGE. If you are using EXPERT mode, the MR Contrast and MR Contrast Lot Code will only be changed if the user changes it or the Remote Control is re-powered.

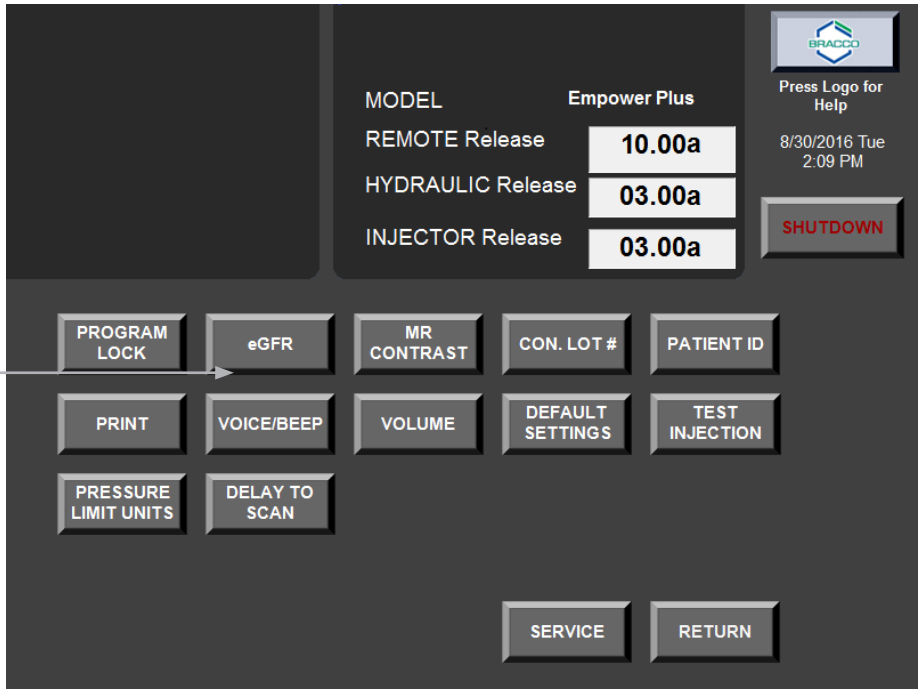
Creatinine and GFR Setup

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.

IRiSMR® Features (continued)

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.



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.

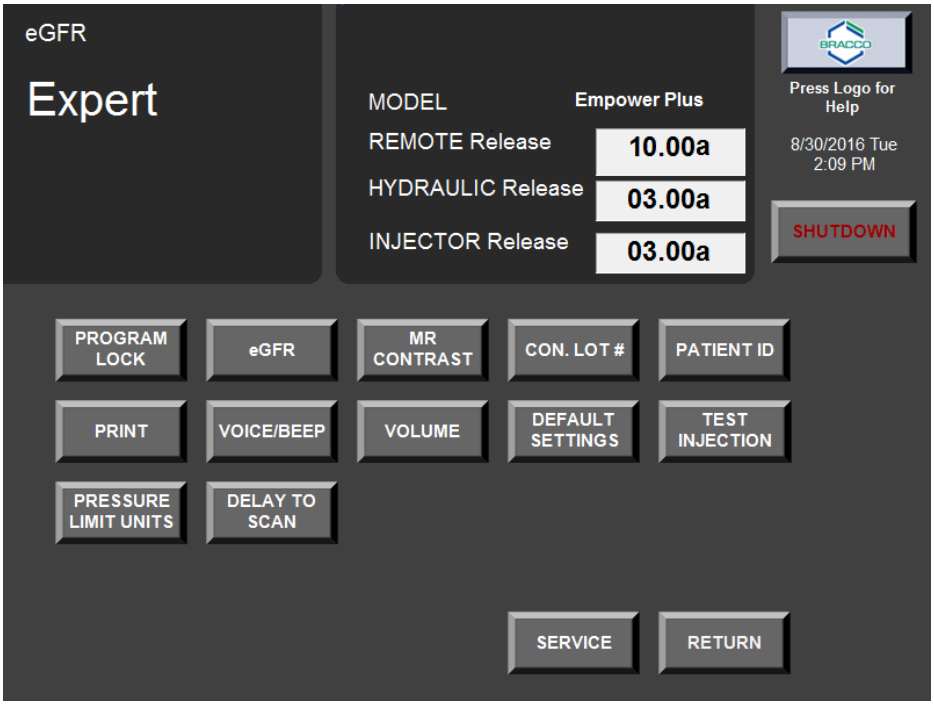
By utilizing the eGFR Calculator you are assuming responsibility for ensuring the accuracy of all information utilized in the eGFR calculation and making sure that all information represents the current condition of the patient.

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

IRiSMR® Features (continued)

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.



IRiSMR® Features (continued)

eGFR Calculation Setup

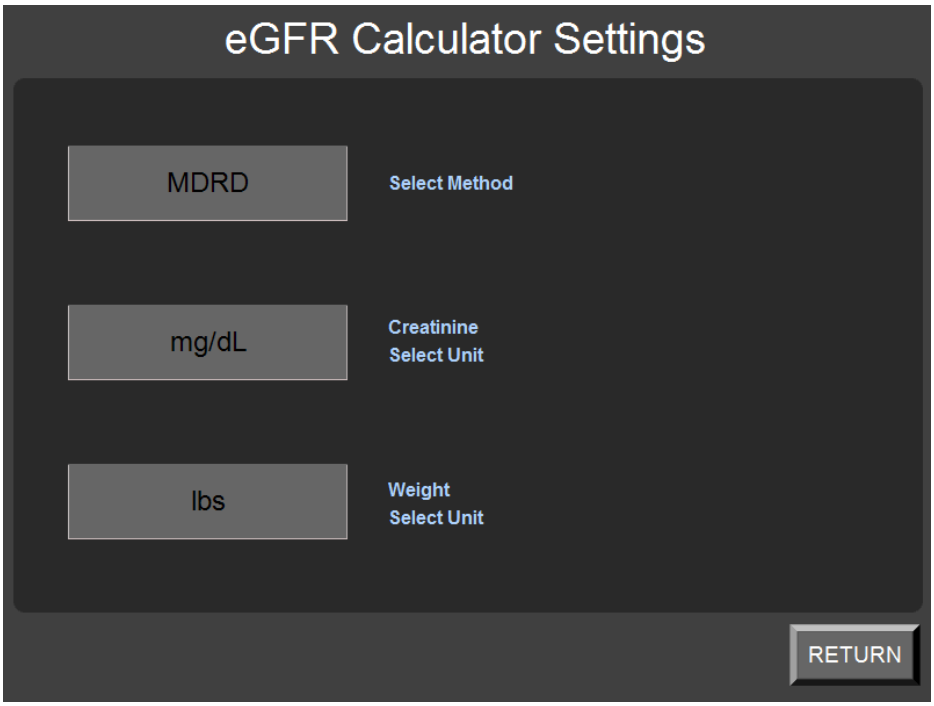
If the Expert mode was selected for the eGFR option, the next step is to set up the eGFR calculation, as follows.

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.

IRiSMR® Features (continued)

Setting the eGFR and the Creatinine Thresholds

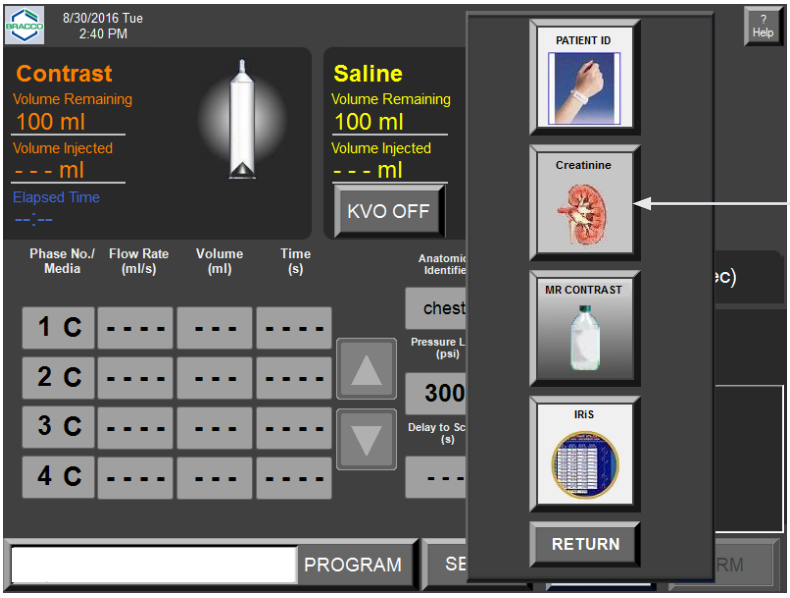
If the Expert mode was selected for the eGFR option, you can also set the eGFR threshold, as follows:

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.

IRiSMR® Features (continued)

Creatinine Entry

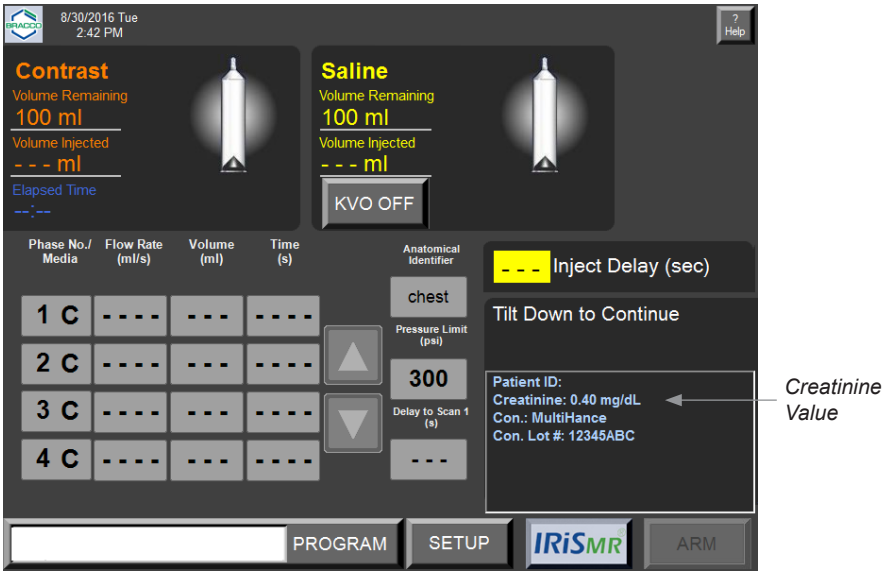
If the GFR has been set to BASIC only the Creatinine value will be stored in IRiSMR®. To store the value, select the IRiSMR® key followed by the Creatinine key, as shown below:



Next enter the value of Creatinine and select ENTER, as shown below:

IRiSMR® Features (continued)

If the value entered is below the user defined threshold, the value will be stored and displayed in the Patient Information area of the system message area as shown below:



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 and message text will be yellow and a cautionary symbol will appear near the end of the value. This value WILL NOT inhibit the use of the EmpowerMR® Injector System. It is the facility's ultimate responsibility to review this value and determine the best course of action for the patient.

WARNING

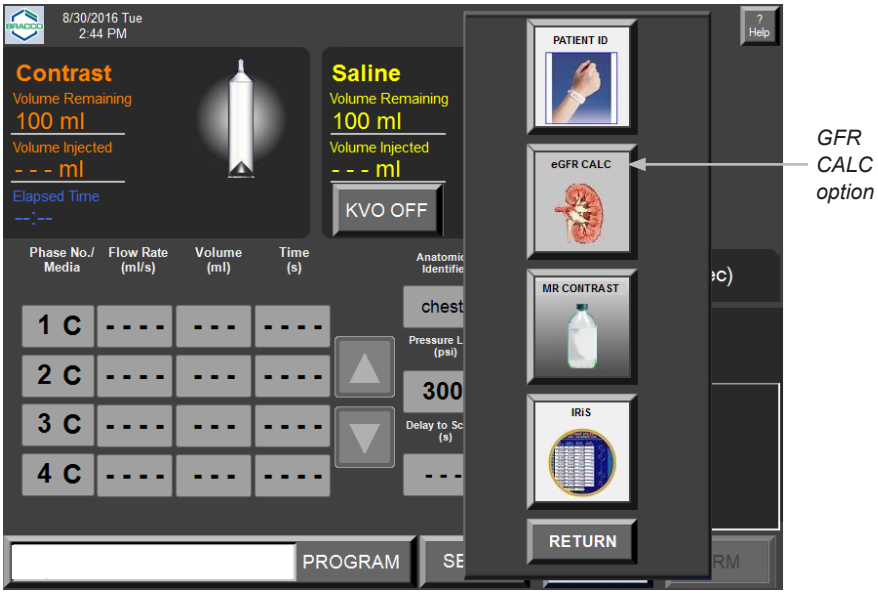
Prior to each injection, the creatinine value displayed should be reviewed for accuracy. It is the sole responsibility of the facility to assure that the value entered is accurate.

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.

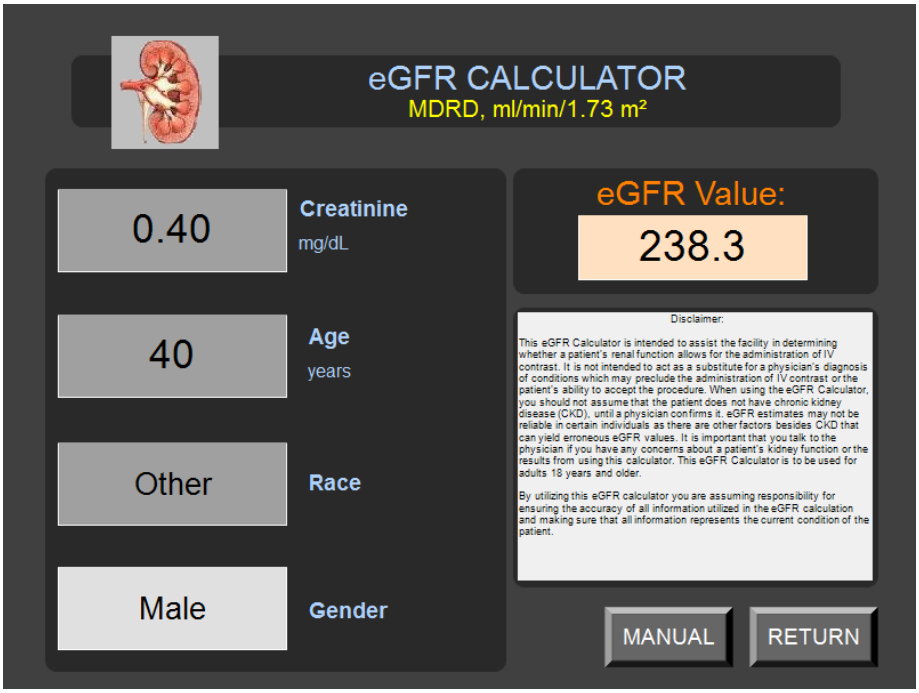
IRiSMR® Features (continued)

GFR Entry

If, in the Setup screen, the GFR has been set to EXPERT, the GFR value can be calculated and stored in IRiSMR. The GFR CALC option will be available in the IRiSMR® list, as shown below:



To calculate and store the GFR value, select **IRiSMR** followed by the **GFR** key. The system will display the GFR Calculator. In the following example, the GFR Calculator uses the MDRD equation and the units of creatinine for reference purposes only.

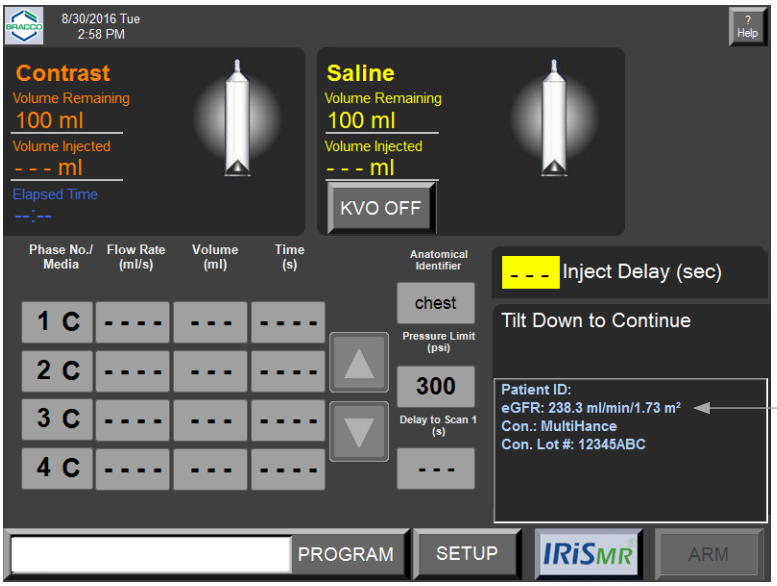


The equation and units used in the calculation are pre-set using the GFR Calculator Settings screen (accessible through the Service function on the Setup Screen as described on page 82).

IRiSMR® Features (continued)

Review the units and equation prior to any entry into the GFR CALCULATOR screen. Once the value has been calculated, review the value displayed on the screen and confirm by selecting the **RETURN** key.

If the GFR value calculated is greater than the user defined threshold, the value will be stored and displayed in the Patient Information area of the system message area, as shown below:



GFR Value is Displayed Here

If the GFR value entered is equal to or below the user defined threshold, there will be a message prompt alerting that the value is below the threshold. Select **OK** to confirm and to continue. Once accepted, the value will be displayed and message text will be yellow and a cautionary symbol will appear near the end of the value. This value WILL NOT inhibit the use of the EmpowerMR Injector System.

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 GFR can be manually entered by selecting the **MANUAL** key. 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 system message area.

WARNING

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

Once the contrast syringe is placed at the Replace Syringe position, the GFR value is removed from the screen. Prior to the next injection, the GFR value will have to be entered for this patient.

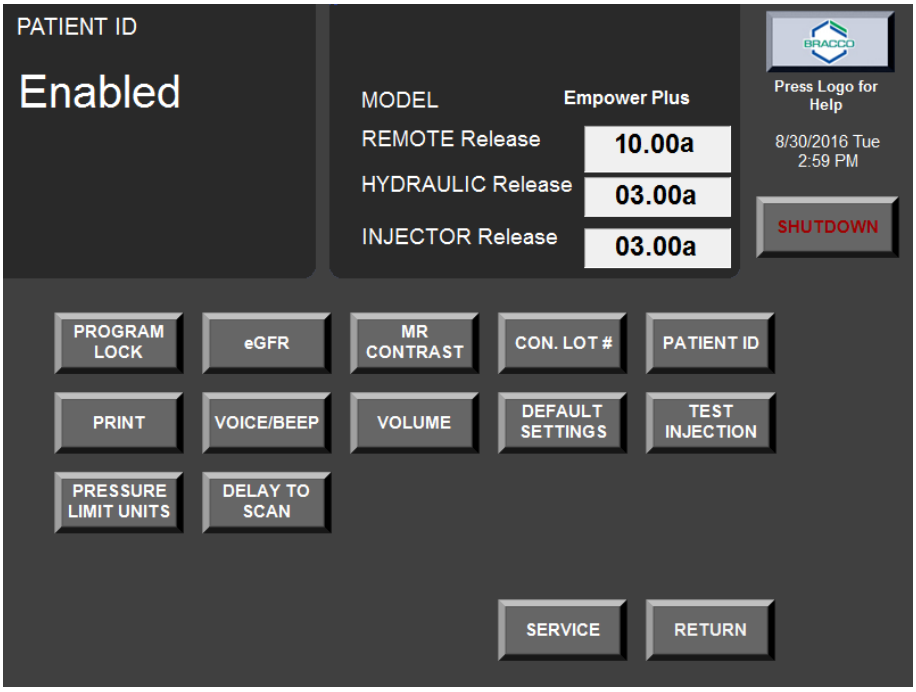
IRiSMR® Features (continued)

Patient ID Setup

The PATIENT ID option on the Setup screen enables the user to toggle the PATIENT ID setting to ENABLED or DISABLED.

When the Patient ID is enabled, the Patient ID option is available on the IRiSMR® list.

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

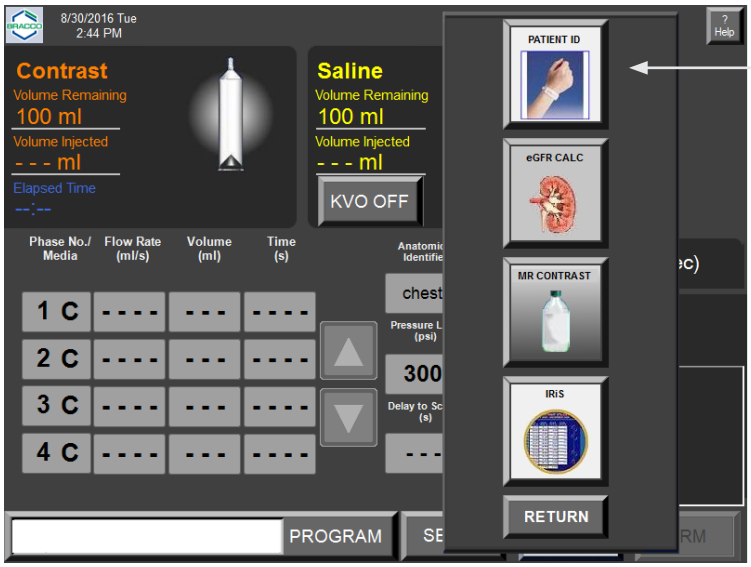


To disable the feature, select the **PATIENT ID** key again to disable the feature. The message in the upper left hand corner will indicate Disabled. Select **RETURN**.

IRiSMR® Features (continued)

Patient ID Entry

If, in the Setup screen, the PATIENT ID is set to ENABLED, the IRiSMR® list will display a PATIENT ID option, as shown below:

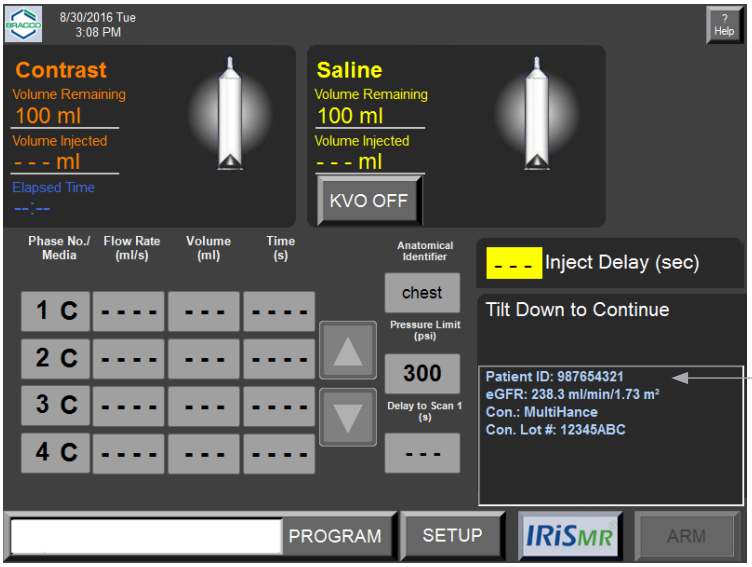


Select the **IRiSMR®** key followed by the **PATIENT ID** key. Once this key is selected, a pop-up keyboard will appear, as shown below:

Enter the alphanumeric value of the Patient ID up to 12 characters and select **ENTER** when completed.

IRiSMR® Features (continued)

The Patient ID will be displayed in the System Message area of the screen as shown below:



WARNING

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

6 Understanding Nexo® Connectivity

Using EmpowerMR® with Nexo®

Note

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

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

Nexo® is a self-contained software package distributed by Bracco Injeneering, aimed at networking 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 EmpowerMR® Injector System is compatible with Nexo® version 1.3. 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 right border of the main screen. According to the connectivity status:

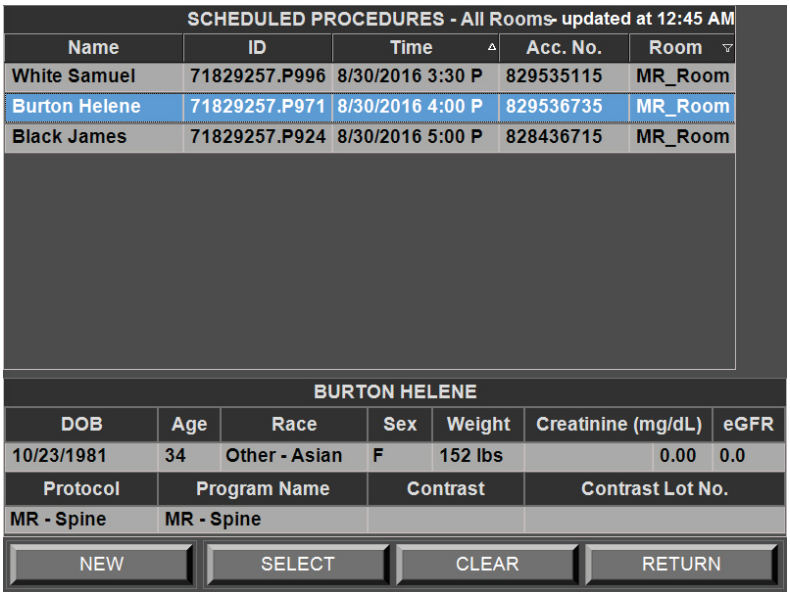
icon	Meaning
	Nexo® Connection Icon in green - The connection to Nexo®, PACS and RIS is working properly
	Nexo® Connection Icon in Yellow - The connection to Nexo®, PACS and RIS exists but there are synchronization issues between Nexo® and the injector. The data shown on the EmpowerMR® Injector may not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

Scheduled Procedures Screen

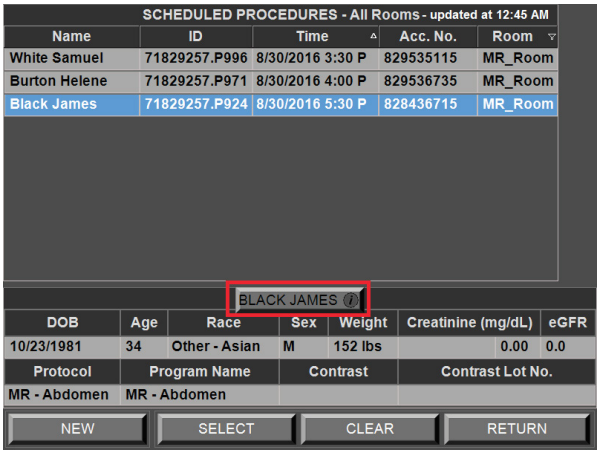
If the connection to the RIS is operational (green Nexo® Connection icon:) and if the hospital's work list has scheduled patient procedures, then when you select the **Current Patient** tab, the system will display the **SCHEDULED PROCEDURES - All Rooms** work list (<hh:mm> of last data update), and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



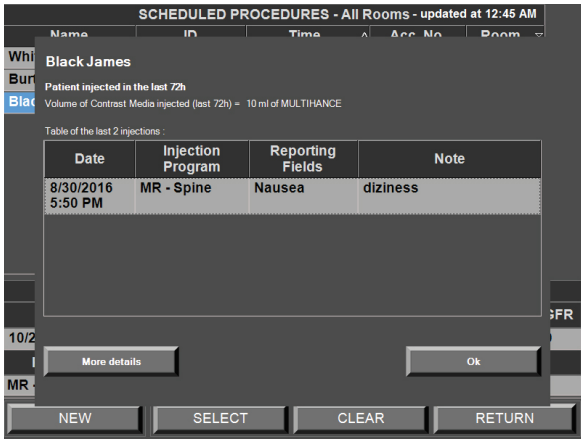
Note that depending on Nexo® configuration, the list may display only the patients scheduled for that injector, or also the patients scheduled in other rooms.

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. 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 Gadolinum). 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 at 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

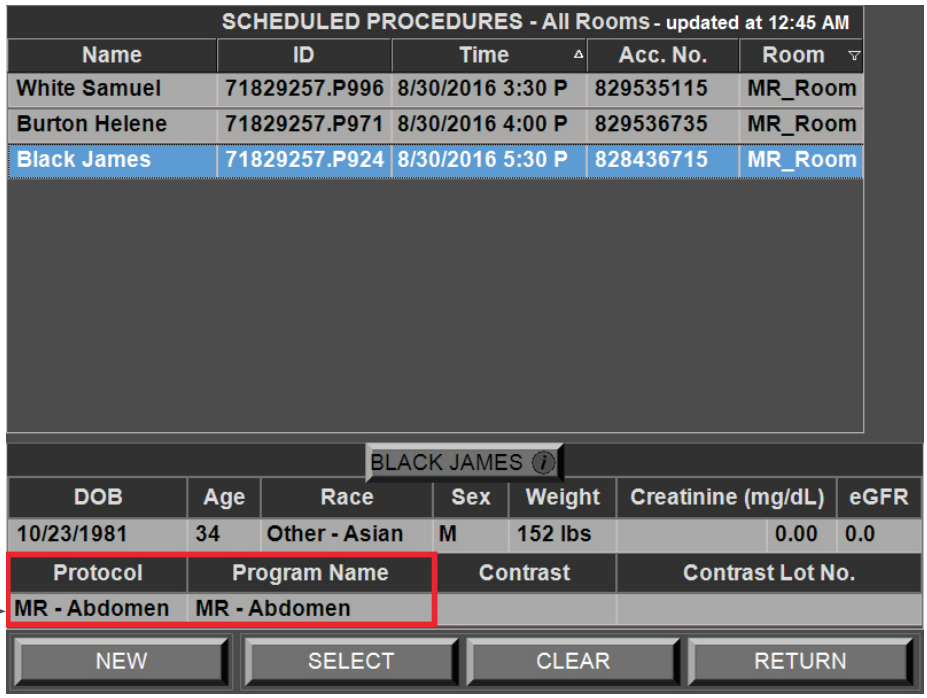
Data sorting options available on the Scheduled Procedures work list are as follows:

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

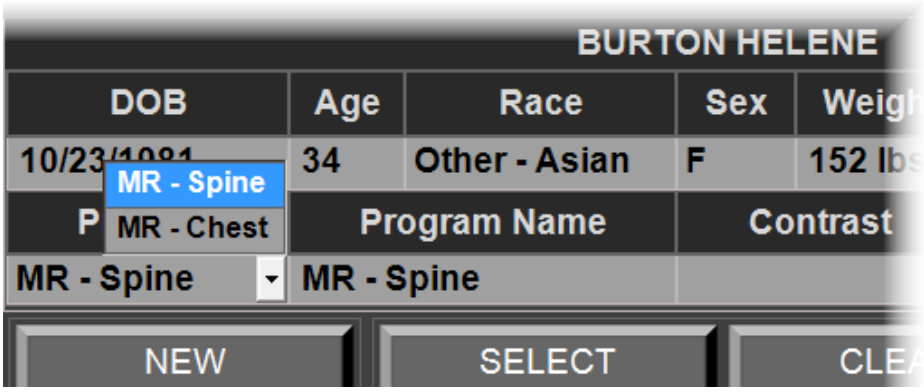
A patient's data on the SCHEDULED PROCEDURES work list includes an injection Protocol field.



Injection Protocol Field

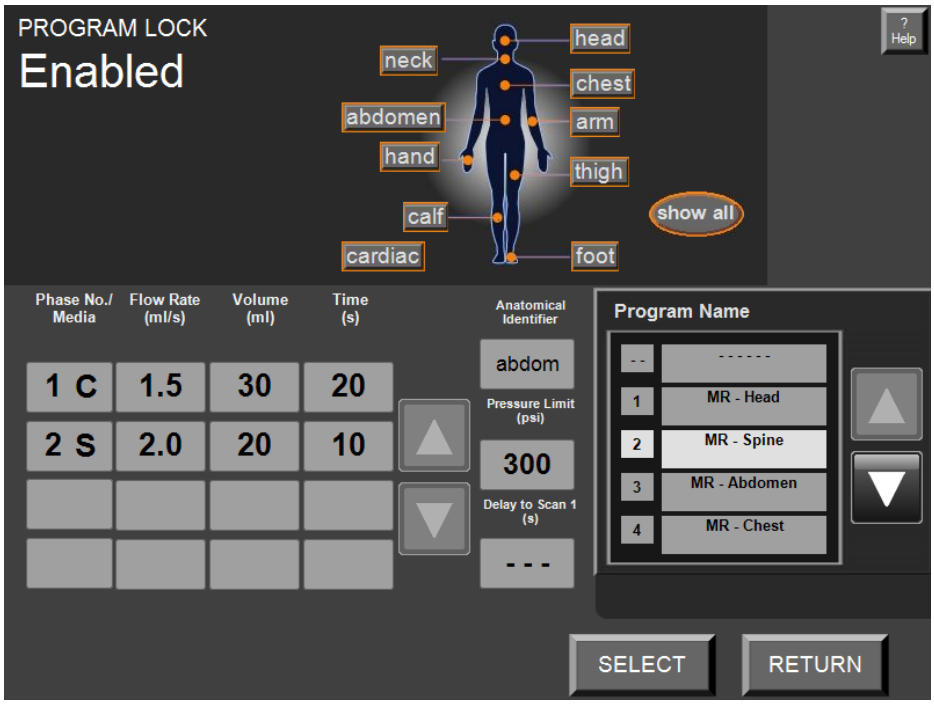
The protocol named in the Protocol field must correlate to an injection Program Name set up Nexo and also visible on the PROGRAM screen of the EmpowerMR® injector.

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:

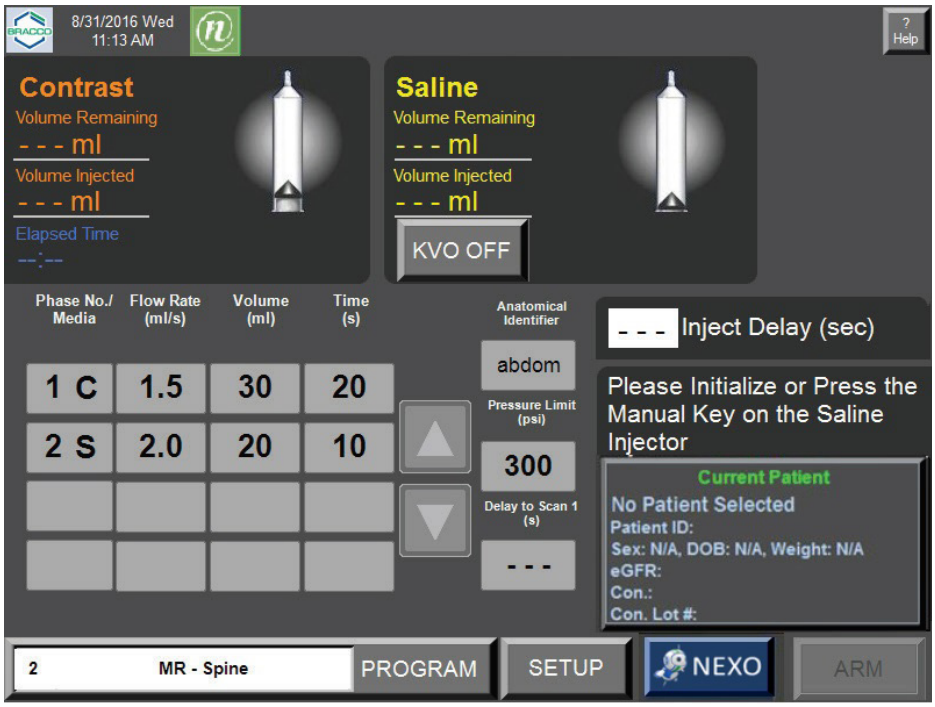


Protocol to Program Matching (continued)

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:



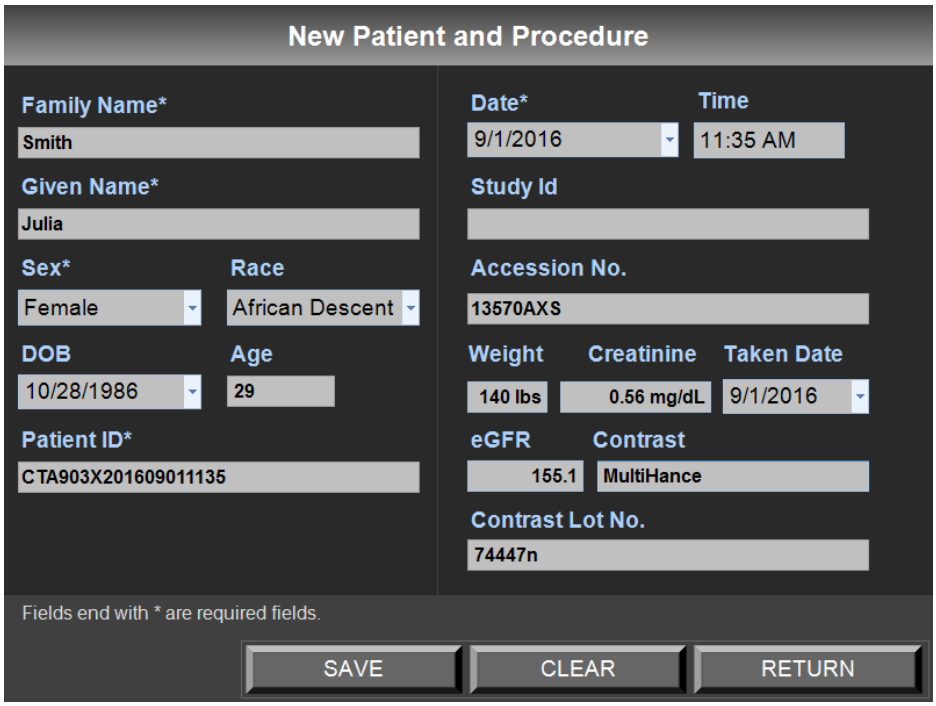
Using the Multi-programs Tab

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 116 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 icon 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*.

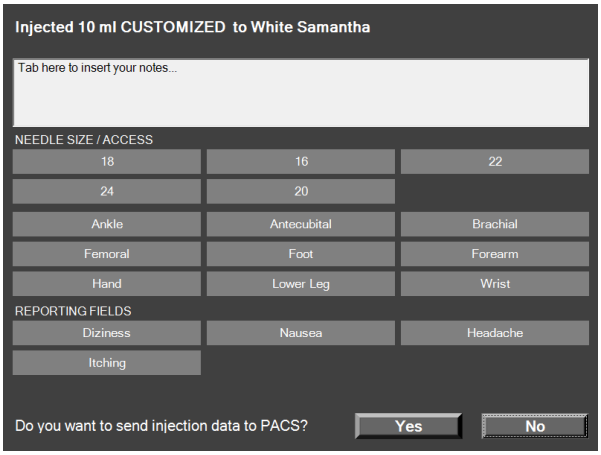
Once you have entered the required information on the New Patient and Procedure screen, you may choose one of the three options:

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 the following window:



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

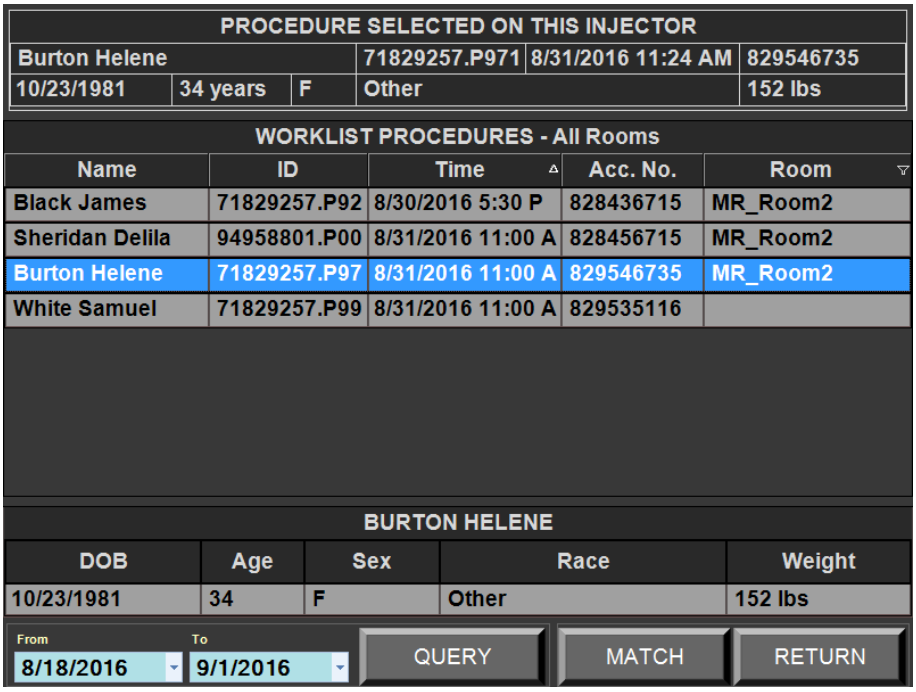
The **Injected Patients** tab may appear on the main screen if injections have been performed using the new patient feature and the injector is connected to the hospital's PACS network OR if the user decided not to send the injection report to PACS right after the injection procedure was completed.

Use the **Injected Patients** tab to correlate the patient data stored in the EmpowerMR® 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 EmpowerMR® injector and not yet stored in the hospital's PACS system, as shown in the example below:

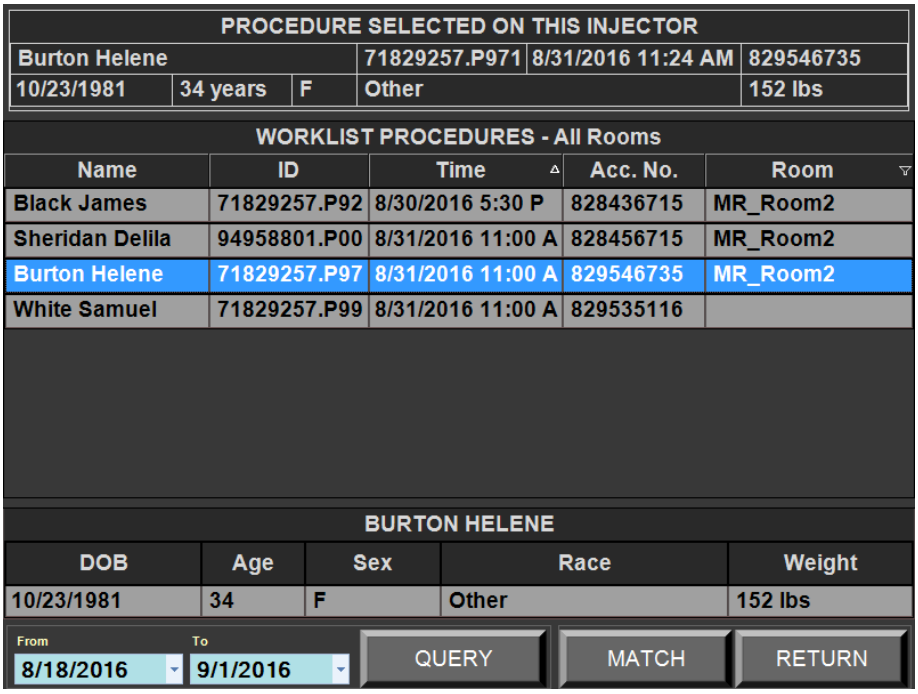


For each patient listed on the THIS INJECTOR PROCEDURES screen, you may:

- 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 EmpowerMR® system; or
- return to the main screen by selecting the **RETURN** button.

Using the Find Option

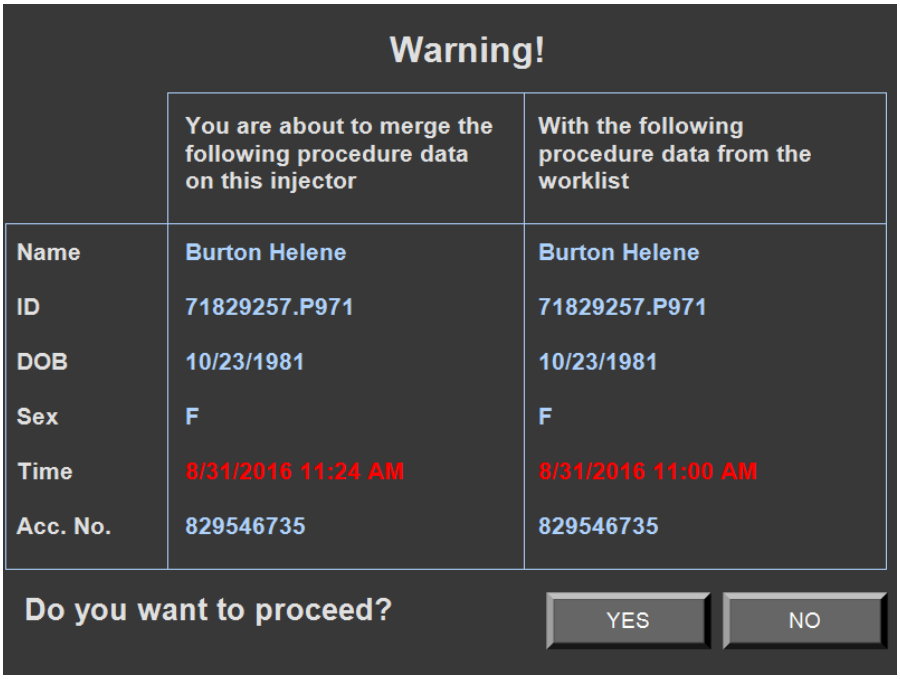
When you select the **FIND** button, the system displays a screen that shows the procedure selected on the injector, and the work list procedures for all rooms. For example:



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:

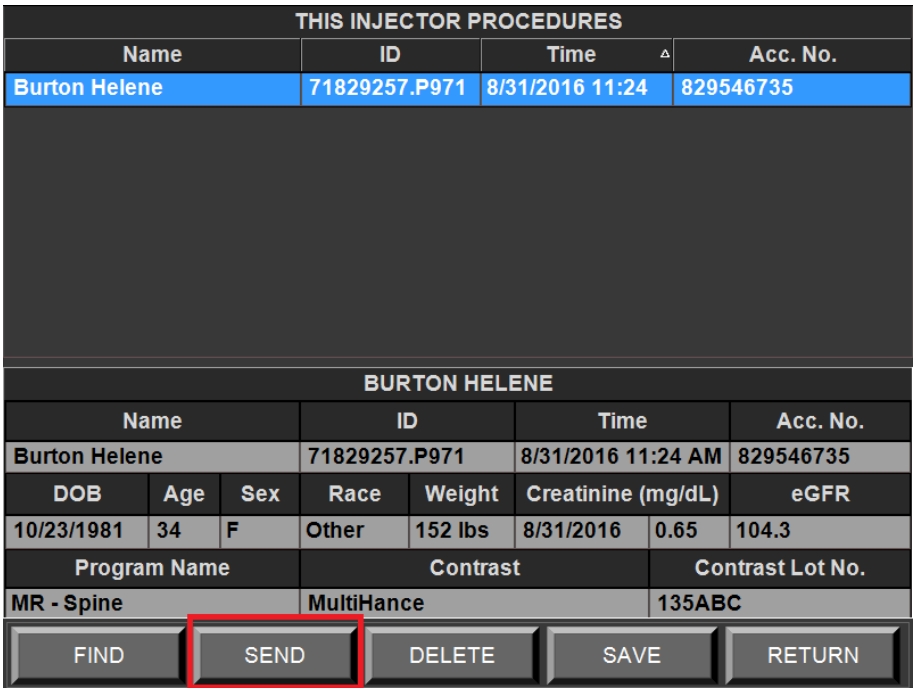


Note that the text that appears in red indicates that the procedure data in the injector does not match the data on the work list. If you select NO, the previous screen is displayed again. If you select YES, then the procedure data on the injector is merged with data coming from RIS and stored on the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

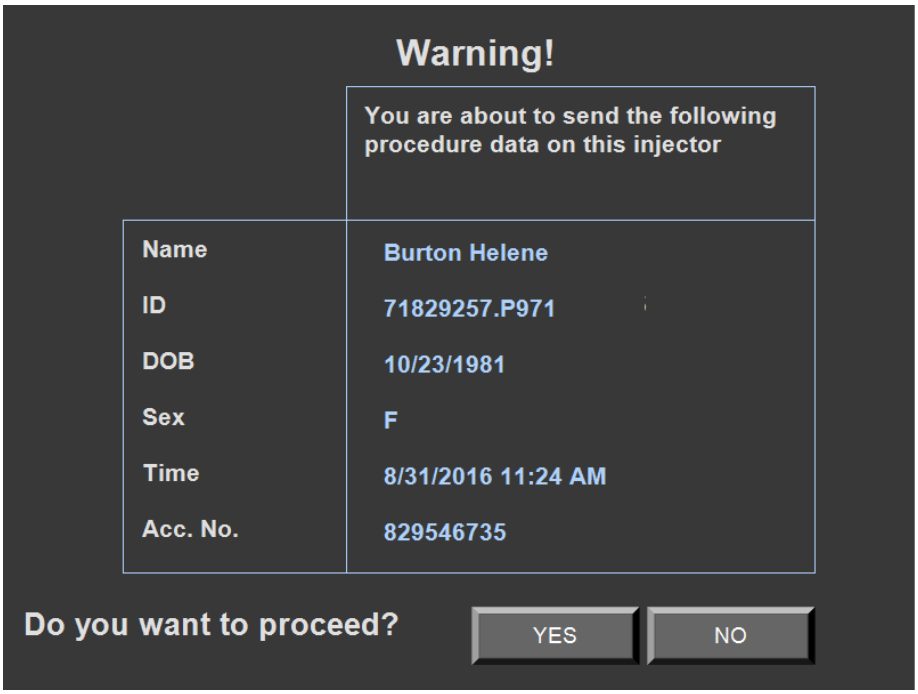
You must select the RETURN button to return to the main screen:

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):



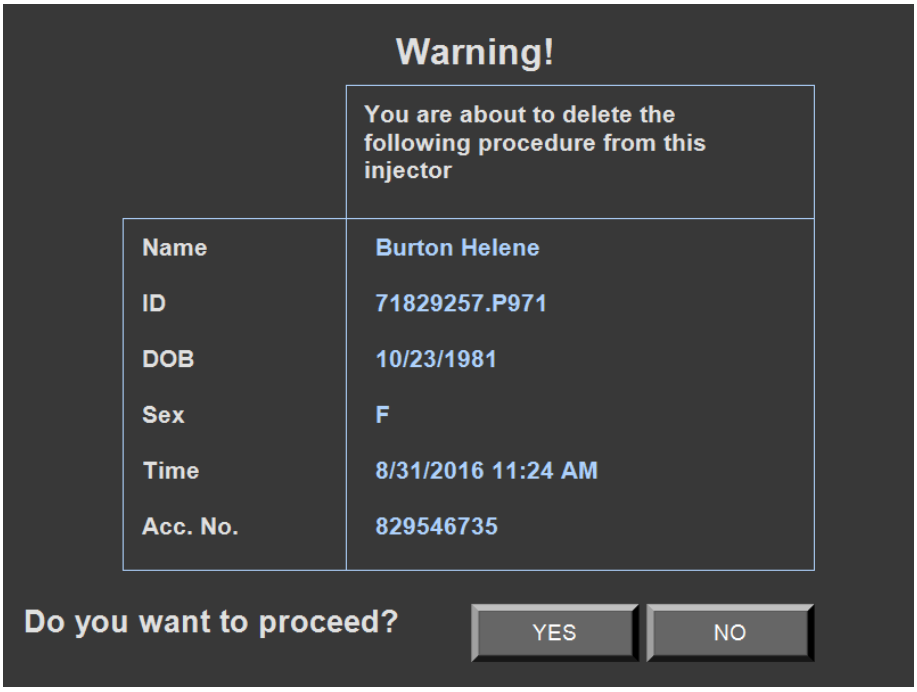
When you select the SEND button, the following type of screen displays:



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

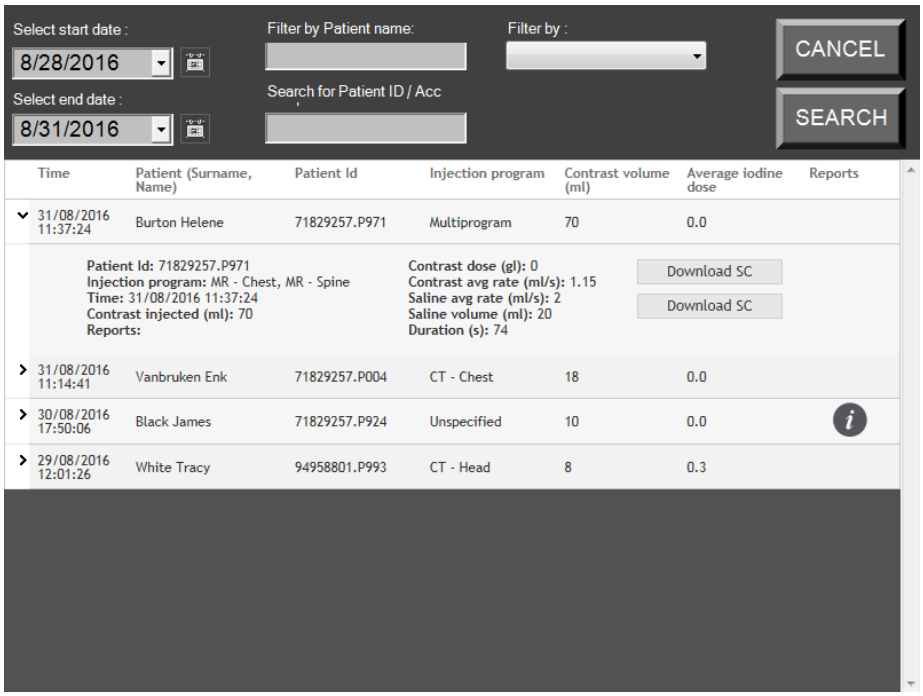
To delete procedure data stored on the injector, select the DELETE button from the THIS INJECTOR PROCEDURES screen. The system prompts you to confirm or decline, as shown below:



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 116 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.

7 Minimizing Extravasations

Suggested Techniques for Minimizing Extravasations

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

WARNING

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

- *Use a catheter that is 20 gauge or greater in the largest vein possible. Bracco Injeneering S.A. recommends an Angiocath®, Angio-Set® or equivalent. (Angiocath® and Angio-Set® are registered trademarks of Becton Dickinson and Company.)*
- *Minimize the effects of patient movement by taping the catheter firmLy to the patient's skin. Use of an Angiocath-type butterfly, Saf-T-Intima Ref #383335, permits easy insertion and secure taping.*
- *The ante-cubital 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 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 90-inch/2.4-meter, 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 heads 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 EmpowerMR® 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.*

8 Using the IRiSMR® Utility

Introduction

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

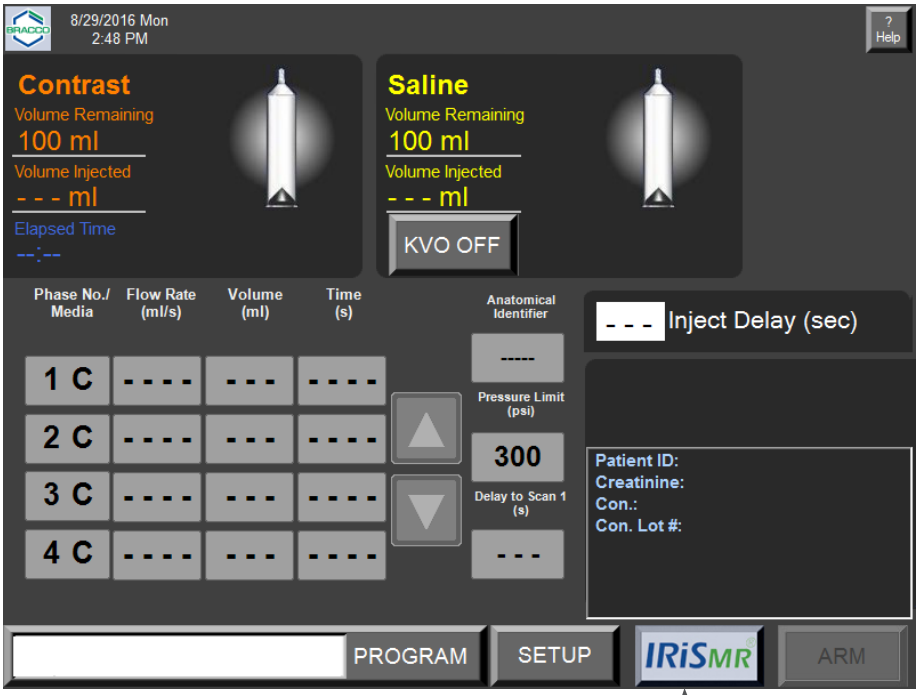
The IRiSMR® Viewer application resides on the Remote Control and will display information relative to that individual Injector System.

Note the following:

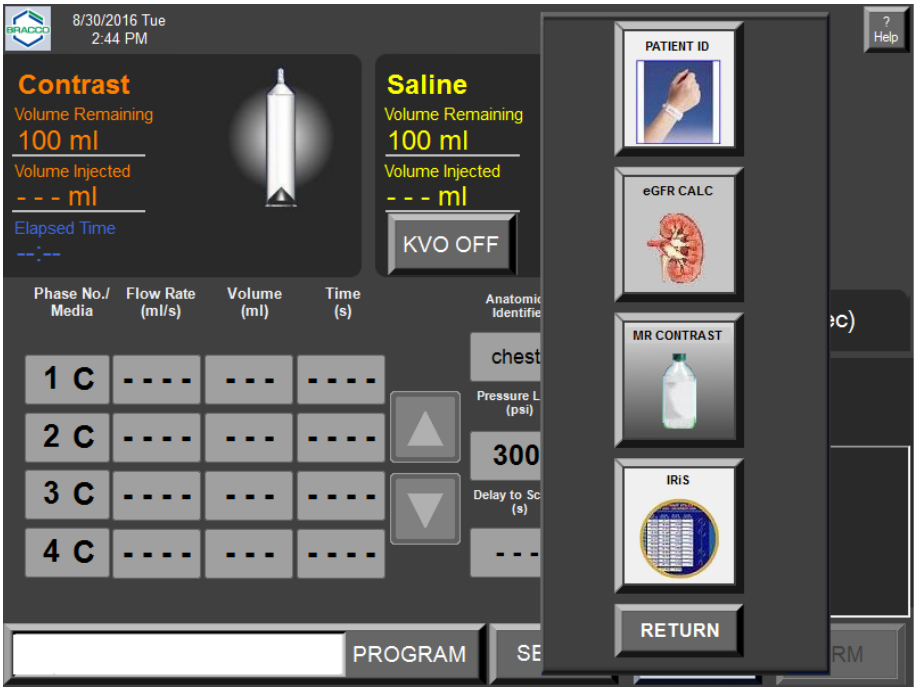
- No features of IRiSMR® affect the specified performance of the EmpowerMR® Injector System.
- Nexo® system provides all the functionalities of IRiSMR® with additional features and integration to the hospital information system. This is why IRiSMR® is disabled when Nexo® is used.

IRiSMR® Remote Viewer Navigation Instructions

To open the IRiSMR® Viewer application select the IRiSMR® key located at the bottom of the Remote Control Main Screen screen, as shown below (this key is available only on the main screen).



Once pressed, the system will display the IRiSMR® options list as shown below:



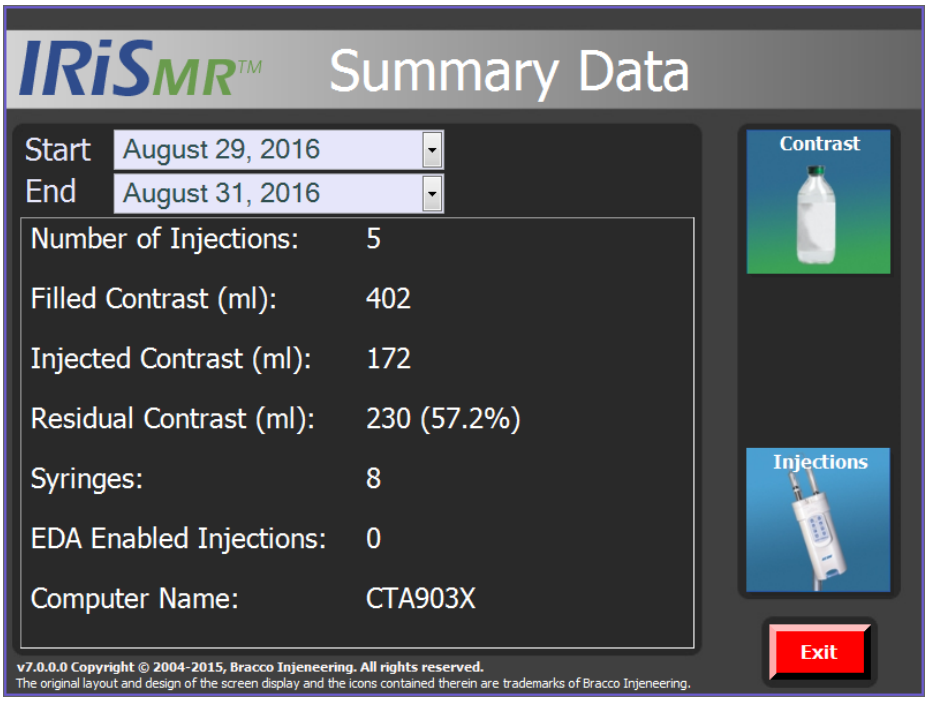
IRiSMR® Remote Viewer Navigation Instructions (continued)

Note

While the IRiSMR® 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 IRiSMR® key,

to display the IRiSMR® Summary Data screen, as shown below:



IRiSMR® has two main display areas:

- Contrast Utilization, and
- Injector Information.

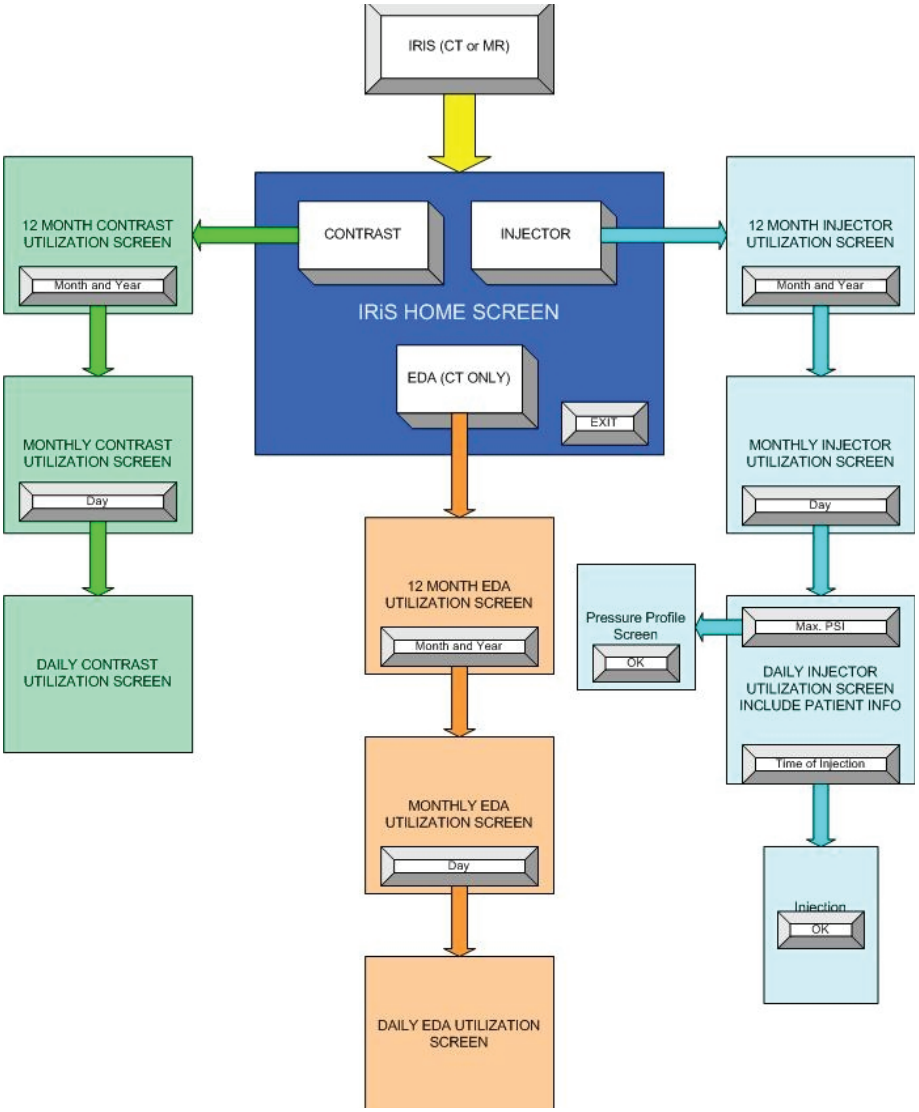
Navigation to either of these screens is performed by selecting the specific labeled key in the right panel of the screen.

The **EXIT** key will close the IRiSMR® application and display the Remote Control Main Screen.

Upon selecting one of the keys (Contrast or Injections) on the right panel, IRiSMR® will display a 12-Month Summary of the selected display area with

IRiSMR® Remote Viewer Navigation Instructions (continued)

the current month as the last displayed month. The following chart describes the flow and navigation of the various screens.



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

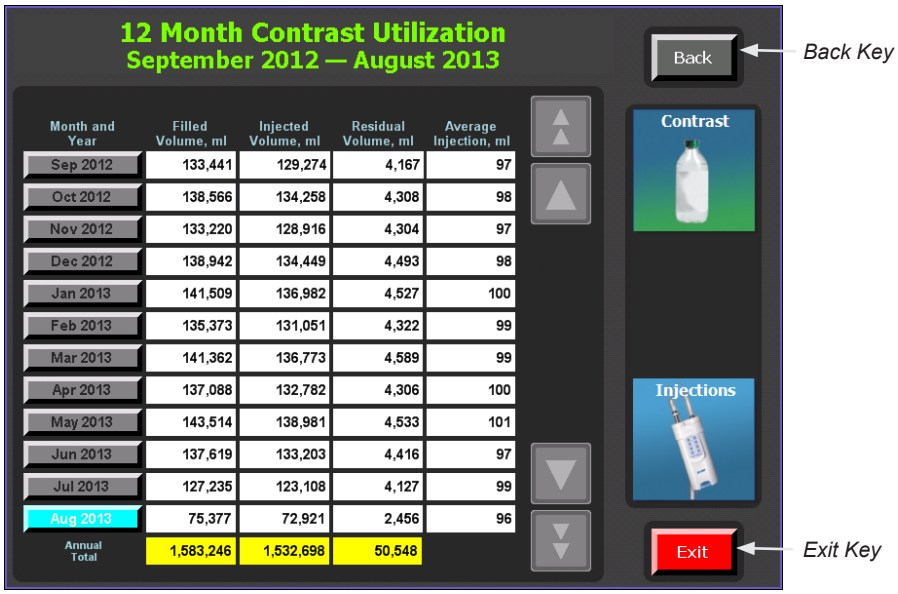
Each area begins by displaying a 12-Month view of the most current data. Access to the month summary is done by selecting one of the 12 highlighted displayed months.

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.

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

IRiSMR® Remote Viewer Navigation Instructions (continued)

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



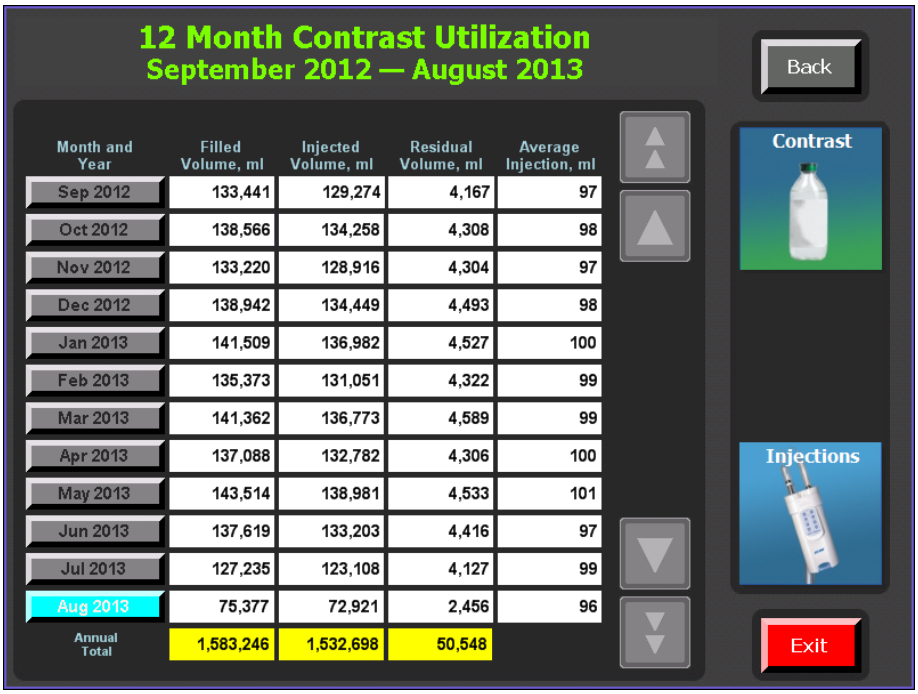
The chart below shows the arrow and its function on the various screens.

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



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	

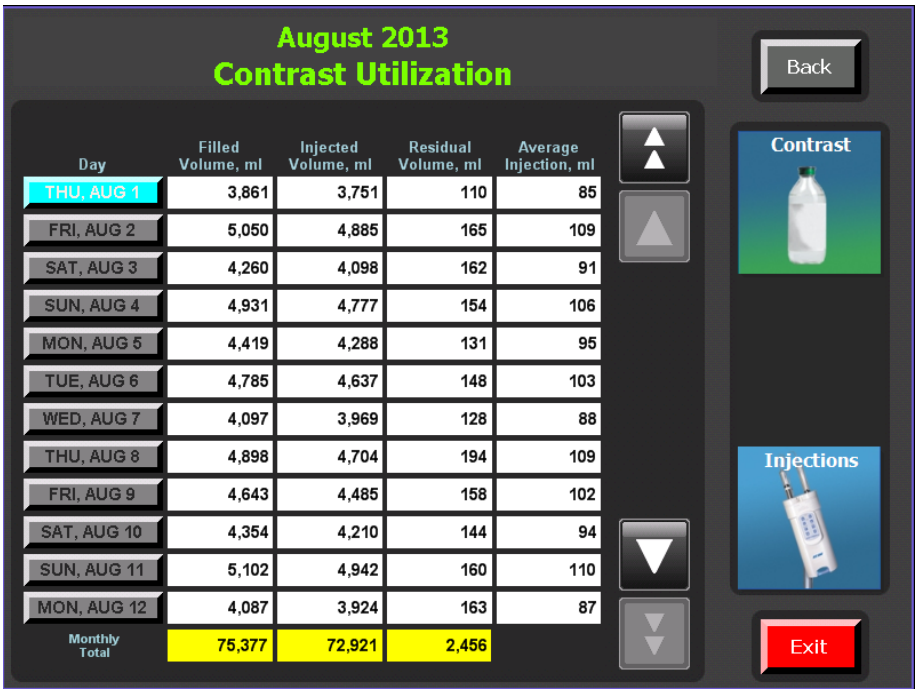
The definitions of the titles of the data columns for contrast utilization screens are as follows:

Title	Definition
Filled Volume, mL	The loaded contrast volume in the syringe when the system is at armed.
Injected Volume, mL	The total contrast volume injected into the patient.
Residual Volume, mL	The difference between the filled contrast volume and the injected contrast volume.
Average Injection, mL	The average injected contrast 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 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 at the bottom of the columns in yellow boxes. For example:

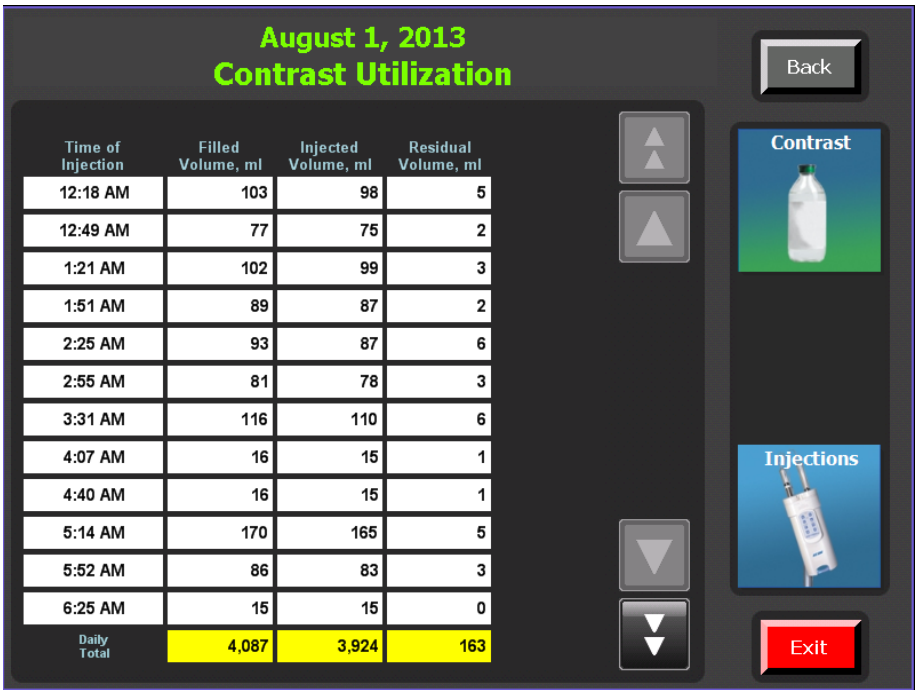


Day	Filled Volume, ml	Injected Volume, ml	Residual Volume, ml	Average Injection, ml
THU, AUG 1	3,861	3,751	110	85
FRI, AUG 2	5,050	4,885	165	109
SAT, AUG 3	4,260	4,098	162	91
SUN, AUG 4	4,931	4,777	154	106
MON, AUG 5	4,419	4,288	131	95
TUE, AUG 6	4,785	4,637	148	103
WED, AUG 7	4,097	3,969	128	88
THU, 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 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 at the bottom of the columns in yellow boxes. For example:

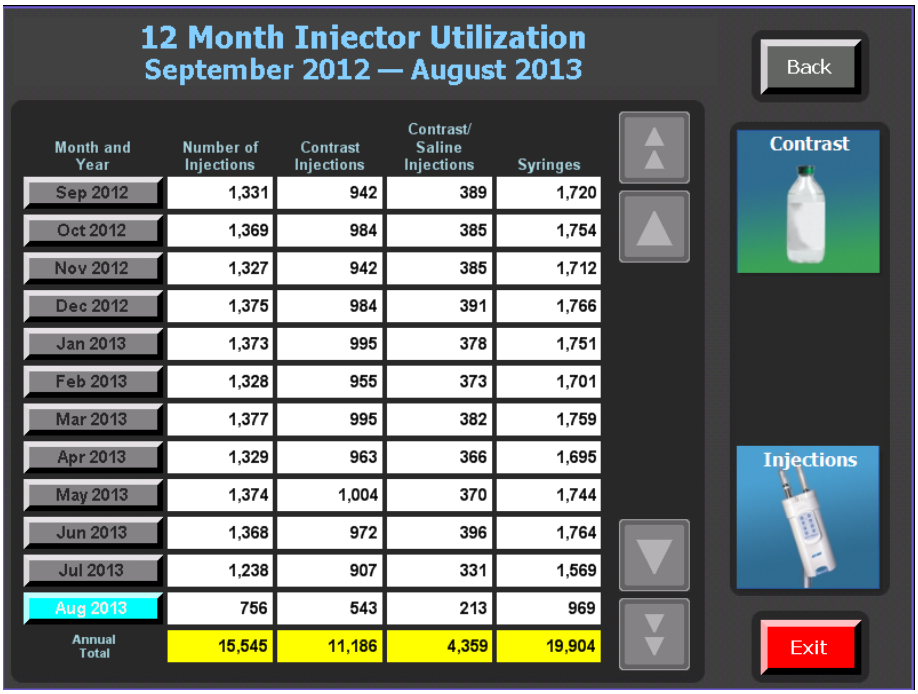


Time of Injection	Filled Volume, ml	Injected Volume, ml	Residual Volume, ml
12:18 AM	103	98	5
12:49 AM	77	75	2
1:21 AM	102	99	3
1:51 AM	89	87	2
2:25 AM	93	87	6
2:55 AM	81	78	3
3:31 AM	116	110	6
4:07 AM	16	15	1
4:40 AM	16	15	1
5:14 AM	170	165	5
5:52 AM	86	83	3
6:25 AM	15	15	0
Daily Total	4,087	3,924	163

Reviewing Injector Utilization

12-Month Injector Utilization

Select the Injections key 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 at 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

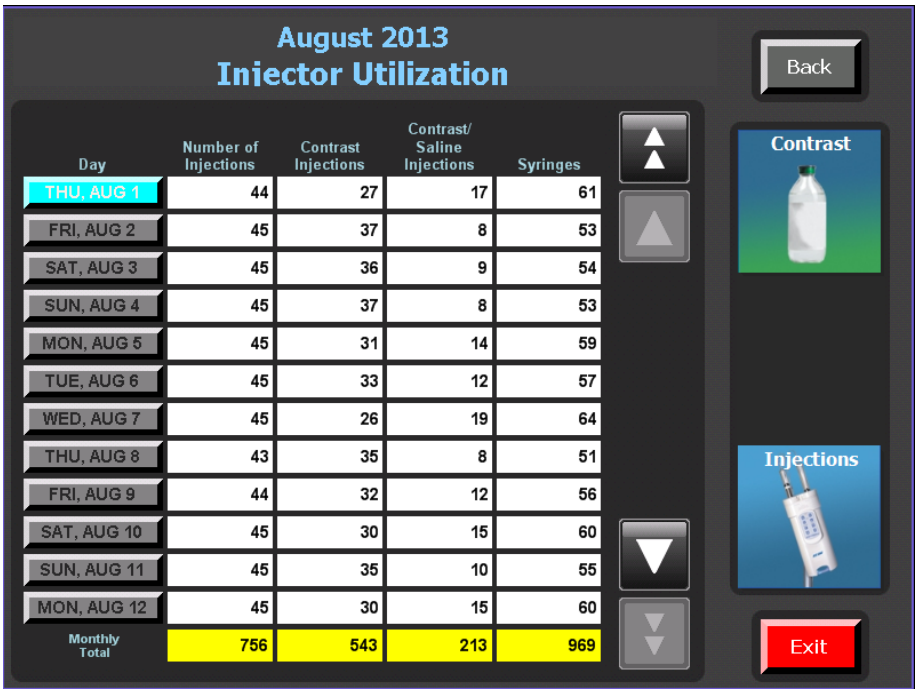
The definitions of the titles of the data columns for injector utilization screens are as follows:

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 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 at 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 at 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

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

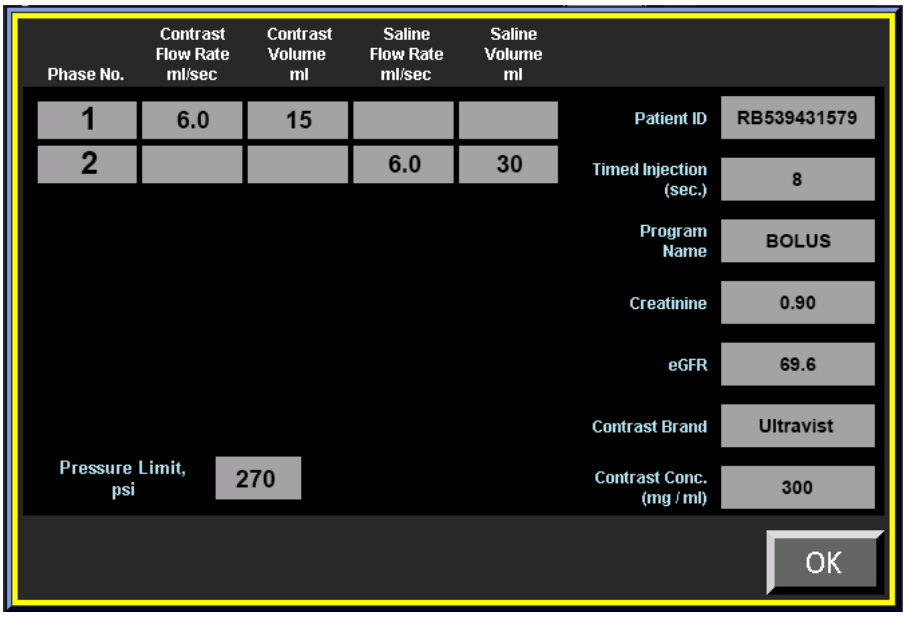
Title	Definition
Time of Injection	The time in 12-hour format that the injection took place.
Avg. Contr. Rate	The average of all of the contrast flow rates weighted with the contrast volumes (mL/s).
Contr. Vol.	The summation of all the contrast phase volumes (maximum displayed value of 200) (mL).
Saline 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 injection in units of PSI.

Reviewing Injector Utilization (continued)

Title	Definition
Max. PSI	The maximum pressure throughout the contrast injection in units of PSI If this value is selected, it will display a graph of the entire contrast injection (refer to "Pressure Profile" on page 139).
EDA Enab.	For IRiSMR® there will be an N (No).
Poss. Extrav.	For IRiSMR® there will be an N (No).

Injection and Patient Parameters

To display the injection parameters for a particular injection, select the time of injection from the Time of Injection column on the daily injection screen. A pop-up displays the programmed parameters for that particular injection. Select **OK** to close the pop-up window. For example:



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

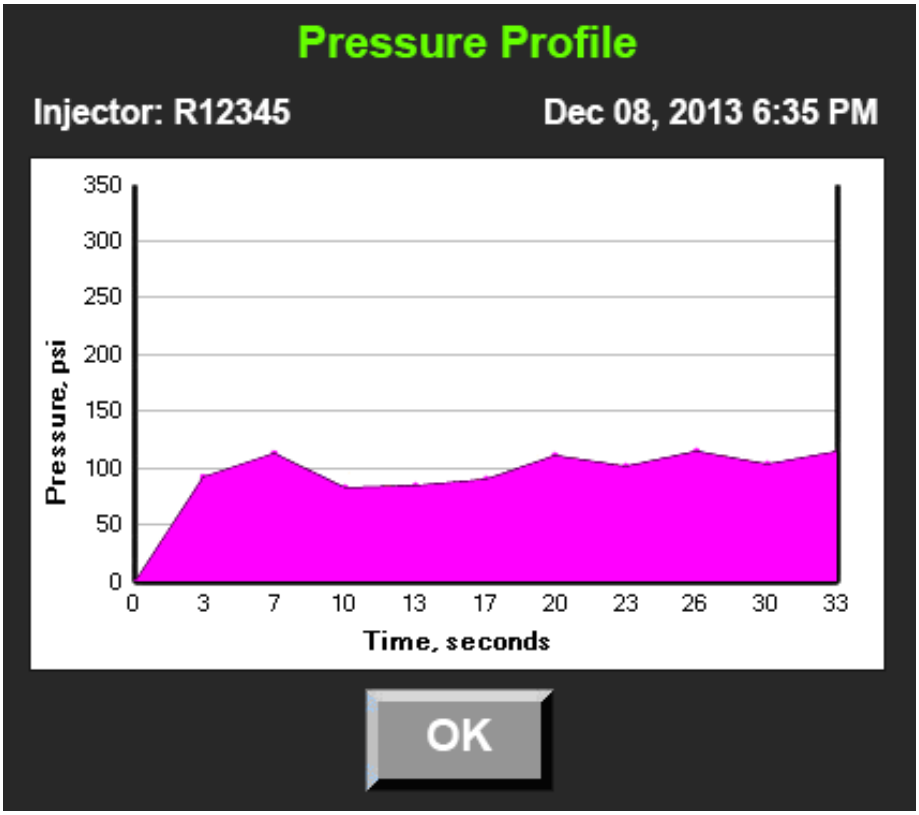
Title	Definition
Phase No.	The phase number.
Contrast Flow Rate	The programmed contrast flow rate for that phase in mL/s.
Contrast Volume	The programmed contrast volume for that phase in mL.
Saline Flow Rate	The programmed saline flow rate for that phase in mL/s.
Saline Volume	The programmed saline volume for that phase in mL.

Reviewing Injector Utilization (continued)

Title	Definition
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.
GFR	The calculated value of the glomerular filtration rate.
Contrast Brand	The selected MR contrast brand name.
Contrast Conc.	This field will be blank.
Pressure Limit, psi	The pressure limit for the specific injection.

Pressure Profile

To view the pressure profile for a particular injection, select the injection value in the Max PSI field on the Daily Injector Utilization window. A pop-up graph will show the profile for the entire length of the contrast injection. The x-axis is 10 equally-distributed time points in seconds representing the total contrast injection. The y-axis units are in PSI and range 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 injection. For example:



9 Limited Warranty

EmpowerMR® Injector System Limited Warranty

Bracco Injeneering S.A. warrants that the Bracco Injeneering S.A. EmpowerMR® 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 EmpowerMR® 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; 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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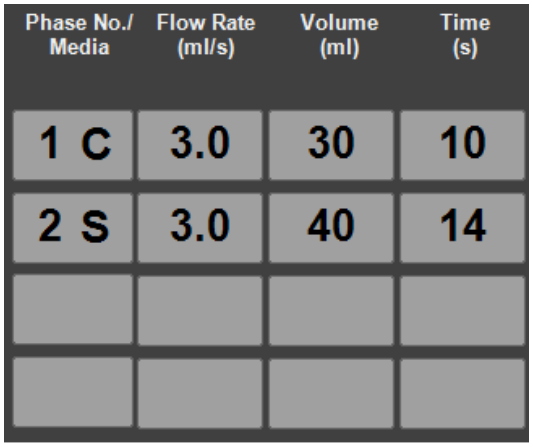
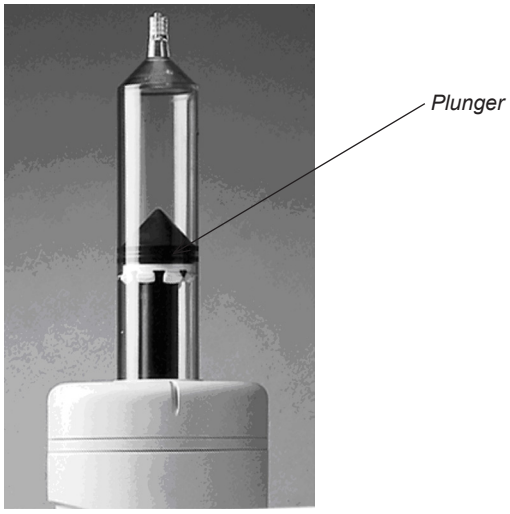
A charge will be applied for all repair service not covered under this limited warranty.

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 EmpowerMR® Injector System must be armed before an injection can proceed.
Contrast	Injectable agent used for MR image enhancement.
Connecting Tube	Used to attach both contrast and saline syringes to the patent's intravenous administration set.
Electro-hydraulic Interconnect	The Electro-hydraulic interconnect connects the Injector Head and the Hydraulic Controller. It is a flexible bundle that contains the fluid conduits, a fiber optic data link, and DC power connection.
Extravasation	The condition that results when contrast is injected primarily into the surrounding tissue resulting from a defect in the vein or misplaced catheter.
Flow Rate	The volume in milliliters of contrast or saline injected per second.
Hydraulic Controller	The part of the EmpowerMR® Injector System that contains the control electronics and hydraulic components to remotely actuate the hydraulic cylinders in the Injector Head.
Injector Head	The part of the EmpowerMR® Injector System that injects the contrast or saline and that will allow the user to arm and run the injection.
Overpressure	Condition caused by an occlusion in the administration set that essentially prevents any contrast 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.

Glossary (continued)

Glossary Term	Definition
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 at the bottom of the syringe, which is actuated by the Injector ram: 
Program (Injection Protocol)	A series of steps that the Injector System will perform, displayed on the Remote Control screen as a numbered list of flow rates, volumes, and durations.

Glossary (continued)

Glossary Term	Definition
Remote Control	One of the components of the EmpowerMR® Injector System. The Remote Control, located in the MR control room, allows the user to program and select the injection protocol, and to arm and run the injection from a remote location.
Syringe	The vessel in which the EmpowerMR® Injector System holds its contrast 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.

Appendix B – Troubleshooting

Frequently Asked Questions

This appendix contains frequently asked questions and their answers:

#	Question	Answer
1	The Remote Control is powered on, but the screen is completely black except for a randomLy blinking BRACCO 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 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 screen.
2	Someone knocked out the power cord. What should we do?	Turn off the component that was 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.*

Frequently Asked Questions (continued)

#	Question	Answer
3	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 doesn't 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 is not tilted fully downward. Look for the downward-tilted graphic on the Remote Control to confirm that the Injector is in the proper position. If it isn't, tilt it down further. • The syringe contains 0 mL of Contrast 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 System have lost communication with each other. Check the cables that run from the Remote to the Hydraulic Controller and from the Hydraulic Controller to the Injector. If the cables are tight, try powering both components off and then back on. • A system fault is displayed on the Injector and Remote Control. In this case, follow the instructions as listed on the Injector and Remote Control. In addition, the following conditions must be met to ARM at the Injector: • The Remote Control has one to eight valid phases programmed. • The Remote Control is in the Main Menu screen. • There has been no Remote Control activity for two or more seconds. If the situation persists, contact Bracco Injeneering S.A. local technical support.

Frequently Asked Questions (continued)

#	Question	Answer
4	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. To do this, tilt the Injector fully upright, then press the Contrast Reverse to Limit key (▼▼) or Saline Reverse to Limit key (▼▼). Acknowledge that the connecting tube set has been removed and 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 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 procedure under "Removing All Air from the Syringes and Tubing – KVO Not Used" on page 41. This is not recommended by Bracco Injeneering S.A. If you choose to do it, it is the responsibility of your institution to establish safety guidelines for this practice.

System Messages

The following table lists alert messages displayed by the EmpowerMR® 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?	The currently selected program has been changed, and the user has selected another program without saving the changes. The system is asking whether you want to automatically save the changes made to the previous program before opening another program.

System Messages (continued)

Message	Recommendation
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.
All Program Locations are Full.	EmpowerMR® 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 ACIST for support.	Please contact Bracco Injeneering S.A. local technical support 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.
Changing the Date or Time will affect the Remote Control functions, Do you wish to proceed?	Changing the date or time in the Super User screen will affect Remote Control functions such as a the Next Service Date and date and time stamps. To continue changing the date and time, select **YES**. To cancel and continue with the current date and time, select **NO**.
AN INJECTOR HARDWARE FAULT WAS DETECTED.	Please contact Bracco Injeneering S.A. local technical support 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, please contact Bracco Injeneering S.A. local technical support for assistance.

Appendix C – Technical Specifications

Power

Component	Voltage
Injector Head	1SELV (Safety Extra Low Voltage) supplied from the hydraulic controller.
Hydraulic Controller	100–240 VAC ± 10%. Internal switching power supply that auto-seeks to applied voltage.
Remote	100–250 VAC. Internal switching power supply that auto-seeks to applied voltage.
Label Printer	Input voltage: 100 – 240 VAC, 50/60 Hz, 1.6 Amps Output voltage: 24 VDC, 2.5 Amps
Badge reader	USB Connection, Current Consumption: 160 mA max.

Component	Wattage
Injector Head	2 VA maximum, supplied from hydraulic controller.
Hydraulic Controller	320 VA Typical when Running 1 VA Typical in Standby Mode
Remote	125 VA maximum

Component	Frequency
Injector Head	N/A (DC Power)
Hydraulic Controller	50 to 60 Hz ± 3 Hz
Remote	44 to 63 Hz

Weight

Component	Weight
Injector Head with Stand	42 pounds (19.1 kg)
Injector Head	16 pounds (7.3 kg)
Hydraulic Controller	47 pounds (21.5 kg)
Remote	13.85 pounds (6.3 kg)

Dimensions

Component	Dimensions
Injector Head with Stand	54 in high x 26 in wide x 26 in deep (1372 mm high x 660 mm wide x 660 mm deep)
Injector Head	17 in long x 8 in high x 12 in deep (432 mm long x 203 mm high x 305 mm deep)
Hydraulic Controller	19 in high x 7 in wide x 16 in deep (483 mm high x 178 mm wide x 406 mm deep)
Remote (without mounting kit)	17 in wide x 11 in high x 3 in deep (381 mm wide x 279 mm high x 76 mm deep)
Electro-hydraulic Interconnect	3/4 in (19 mm) diameter

Overall System Accuracies and Ranges

	Range	Accuracy
Volume	1 to 100 mL in user specified increments of 1 mL	± (2% of programmed volume + 1 mL)
Pressure	40 to 300 psi in user-specified increments of 1 psi 276 to 268 kPa in user-specified increments of 1 kPa 2.8 to 20.7 bar in user-specified increments of 0.1 bar	± (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	0.1 to 10.0 mL/s in user specified increments of 0.1 mL/s. When accelerating or decelerating between two flow rates that are different by more than 2.5 mL/s (with a stopped condition treated as 0 mL/s), the flow rate will uniformLy change under program control to its new rate within three seconds.	± (10% of programmed rate +0.1 mL/s), under conditions of stable flow rate control for at least 3 seconds. + (10% of programmed rate +0.1 mL/s), maximum instantaneous flow rate.

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	EmpowerMR® 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, second and third edition, Medical Electrical Equipment Part 1: Collateral Standard, Electromagnetic Compatibility.
Protection against ingress of fluids	IP21
Mode of Operation	Continuous operation with intermittent, stated permissible loading/rest time.
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 EmpowerMR® Injector Head, Power and Communication Cables, and Hydraulic Conduits.

Regulatory Requirements (continued)

Requirement	Description
Safety Certification	The EmpowerMR® Injector System has been tested to EN/IEC 60601-1, second and third edition, 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.

Environmental Requirements

Requirement	Standard
Operating Temperature Operating Humidity Operating Altitude Storage Temperature	Meets requirements set forth in EN/IEC 60601-1, second and third edition, Medical Electrical Equipment Part 1: General Requirements for Safety. Operation: • Temperature +18 to +30°C (+64.4 to + 86°F) • Humidity 30 % to 75 % • Altitude –200 m to 2000 m (-656.2 ft to 6561.7 ft) Storage and Transportation: • Temperature -29 to +60°C (-20.2 to 140°F) • Humidity 15 % to 85 % • Altitude –200 m to +4267 m (656 ft to 13999.34 ft)
Shock and Vibration	ASTM D4169

Software

Requirement	Description
Remote Control software version	10 and approved modifications (higher versions) thereof.
Compatibility	Injector Head 3.00a (and higher versions). Hydraulic controller 3.00l (and higher versions).
Operating system	Windows 7 embedded standard SPI

Accessories, Disposables, and Consumables

Catalog No.	Description
017348	FastLoad™ MR Syringe Pack This kit contains (2) 100mL Syringes, 96" connecting tube w/ (2) check valves and (2) non-seize Luer fittings, (1) large spike for saline bags and (1) small spike for contrast bottles. The syringe body is a translucent cylinder having its open end connected to the Empower injector pump via the wiper assembly. The spikes are used to fill the angiographic syringe with either contrast or saline. 

EMC Requirements

CAUTION

Use of EmpowerMR® Injector System adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, EmpowerMR® Injector System should be observed to verify that they are operating normally.

EmpowerMR® is suitable for professional healthcare facility environment, special environment such as inside the RF shielded room of a medical equipment for magnetic resonance imaging.

The EmpowerMR® 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:

Essential performancefor EmpowerMR® are the following:

- 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.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of EmpowerMR® Injector System could result in increased electromagnetic emissions or decreased electromagnetic immunity of EmpowerMR® Injector System and result in improper operation.

EMC Requirements (continued)

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
800663-001/002/003	Electro/Hydraulic Interconnect (Hydraulic Lines, DC Power, Fiber Optics) (inj to hc)
301022-001	Power Cable, Injector (Pivot Junction to PCBA)
301021-001	Fiber Optic Toslink Cable (Pivot Junction to PCBA)
301217-001	MR Interconnect COM Cable (Aaeon to Hydraulic Controller)
301125-001	Interconnect COM Cable, MR, 75 ft. (Advantech to Hydraulic Controller)
701014-001	COM Box (back of Advantech)
Nexo®-Ethernet	multiconductor, category 5U/UTP

Table 1: Cables

Portable RF communications equipment (including peripherals such as antenna cable and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EmpowerMR® Injector System, including cables specified by the manufacturer. Otherwise, degradation of the performance of EmpowerMR® Injector System could result.

Appendix D – 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).

The EmpowerMR® is intended for use in the electromagnetic environment specified below. The user of the EmpowerMR® should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1, Class B	The EmpowerMR® 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.
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 EmpowerMR® is intended for use in the electromagnetic environment specified below. The user of the EmpowerMR® should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The EmpowerMR® 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 EmpowerMR® 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).

The EmpowerMR® is intended for use in the electromagnetic environment specified below. The user of the EmpowerMR® 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 EmpowerMR® requires continued operation during power mains interruptions, it is recommended that the EmpowerMR® 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 EmpowerMR® is intended for use in the electromagnetic environment specified below. The customer or the user of the EmpowerMR® 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	± 2, ±4 ,± 6, ± 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*	±0.5, ±1, ±2 kV, 100kHz for power supply lines* ±0.5, ±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 EmpowerMR® 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	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

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)

<table>
<tr><td colspan="4">The EmpowerMR® is intended for use in the electromagnetic environment specified below.
The user of the EmpowerMR® should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance Level</th><th>Electromagnetic Environment – Guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the EmpowerMR®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 Vrms</td><td>$d = 1.2 \sqrt{P}$</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td><td>$d = 1.2 \sqrt{P}$ 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:  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">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 EmpowerMR® is used exceeds the applicable RF compliance level above, the EmpowerMR® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the EmpowerMR®.
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

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 EmpowerMR®, 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 EmpowerMR® is used exceeds the applicable RF compliance level, the EmpowerMR® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EmpowerMR®. Minimum separation distance shall be calculated by following equation: *E* is the immunity test level in [V/m] *d* is the minimum separation in [m] *P* is the maximum power in [W]
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	**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: 

*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 EmpowerMR® is used exceeds the applicable RF compliance level above, the EmpowerMR® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EmpowerMR®.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Bracco Injeneering S.A. EmpowerMR® 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)

The EmpowerMR® is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of the EmpowerMR® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EmpowerMR® 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 EmpowerMR® is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EmpowerMR® can help prevent electromagnetic.

The EmpowerMR® is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EmpowerMR® can help prevent electromagnetic interference by maintaining a miminum distance between portable and mobile RF communications equipment (transmitters) and the EmpowerMR® 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 *** $d = 1.0\sqrt{P}$	**80 MHz to 2700 MHz (for define RF Wireless transmitters see table before)** $d = 2.0\sqrt{P}$
0.01	0.20	0.10	0.20
0.1	0.63	0.32	0.63
1	2.0	1.0	2.0
10	6.3	3.2	6.3
100	20	10	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres [m] can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz.

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

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

The climatic environmental conditions could affect the life of critical components of the EmpowerMR®. The presence of transmitters near the EmpowerMR® could affect its performances. The distances mentioned in the tables prepared by manufacturer could help to prevent any disturbances of the equipment in normal operation.

Index

K

L

M

N

O

P

Q

R

S

T

U

V

902013-018,02 2023-03 ENGLISH

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