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Important Safety Notice to Users of the Medrad™ Intego™ PET Infusion System

This manual and the equipment it describes are for use only by qualified medical professionals with training and experience in Nuclear Medicine procedures. It is intended as a guide for using both the Intego™ PET Infusion System and dedicated Intego™ PET Infusion System disposables.

The Intego™ PET Infusion System contains a gross air detection feature, which is intended to assist qualified medical professional users/operators during the set up procedure to ensure that all air is out of the system.

The safe and effective use of the Intego™ PET Infusion System to a large degree depends upon factors solely under the control of the medical professionals using the system. There is no substitute for a properly trained and vigilant device user. It is important that the operating instructions and user warnings supplied with the Intego™ PET Infusion System be read, understood, and followed.

Before starting any PET infusion procedure, the device user should be trained in the particular procedures to be performed and should be familiar with the medical literature related to procedures and the potential complications and risks verses the benefits of utilizing radiopharmaceutical fluid infusion procedures.

This manual is intended as an extension of the user interface of the Intego™ PET Infusion System to provide procedural and technical information. Additional Intego training information is available in the following formats:

- On-Site in-service sessions
- Service manual
- Package inserts (IFU)

Please do not hesitate to contact MEDRAD if any of these resources are needed.
1 - Introduction

Certifications
The Intego™ PET Infusion System is equipped to operate at 100-240 VAC, 50/60Hz. Power consumption is 250 VA for the INT SYS 100 and 300 VA for the INT SYS 200. The INT SYS 100 complies with EN/IEC 60601-1, 2nd Edition. The INT SYS 200 complies with EN/IEC 60601-1, 2nd and 3rd Editions.

Intended Use
The Intego™ PET Infusion System is intended to deliver accurate doses of $^{18}F$-Fluorodeoxyglucose ($^{18}F$-FDG) or $^{18}F$-Sodium Fluoride ($^{18}F$-NaF) radiopharmaceuticals and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. The Intego™ PET Infusion System is also intended to provide effective radiation shielding to medical personnel from Fluorine-18 ($^{18}F$) radiation exposure during nuclear medicine diagnostic procedures.

Indications for Use
The Intego™ PET Infusion System is indicated for the administration of $^{18}F$-FDG, $^{18}F$-NaF, and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) procedures.

NOTE: The Intego™ PET Infusion System is intended for use with $^{18}F$-FDG or $^{18}F$-NaF. Intego™ PET Infusion System disposables intended for use with $^{18}F$-FDG may be used to deliver $^{18}F$-FDG or $^{18}F$-NaF. Please contact MEDRAD for more information.

Restricted Sale
The United States Food and Drug Administration (FDA) restricts sale of this system to physicians or those with written authorization from a physician.

Trademarks
MEDRAD and Intego are trademarks of MEDRAD, INC. Unless otherwise indicated, all trademarks are owned by MEDRAD, INC. Other trademarks that appear in this manual are the property of their respective companies.

Disclaimers
External wiring and modifications disclaimers: MEDRAD disclaims liability for any modifications or interfaces with other equipment that are not in conformity with the specifications and information contained within this manual.

Accessory equipment connected to the Intego™ PET Infusion System must be certified according to IEC 60601-1 standard. Furthermore, all configurations shall comply with system standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input or output port configures a medical system and is therefore responsible to ensure that the Intego™ PET Infusion System complies with the requirements of the standard IEC 60601-1-1. To obtain on-site consulting or consulting references, contact MEDRAD.

This manual applies to the Intego™ PET Infusion System, Catalog Numbers INT SYS 200 and INT SYS 100. Read all the information contained in this manual. Understanding this information assists in operating the Intego™ PET Infusion System in a safe manner.

Required Training
This device is intended to be used by individuals with training and experience in nuclear imaging studies.
Contact Information

The following is MEDRAD’s contact information:

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Definitions

The following are definitions of the terms WARNING, CAUTION, and NOTE found throughout this document.

WARNING
Indicates that the information is a warning. Warnings advise of circumstances that could result in injury or death to the patient or operator. Read and understand the warnings before operating the Intego™ PET Infusion System.

CAUTION
Indicates that the information is a caution. Cautions advise of circumstances that could result in damage to the system or improper functioning of the system. Read and understand the cautions before operating the Intego™ PET Infusion System.

NOTE
Indicates that the information that follows is additional important information, a tip that helps the clinician to recover from an error, or points to related information within the manual.

Symbols and Icons

The symbols and icons discussed in the sections below describe the requirements to which the Intego™ PET Infusion System conforms, how warnings are displayed in the manual, and the icons used on the equipment and equipment packaging.

Product Symbols

Indicates that this system conforms to requirements of the European Medical Device Directive 93/42/EEC.

Indicates that this system conforms to CSA requirements.

IPX1
IPX1 Code that specifies the degree of protection against vertically falling water drops (IEC 60529).
Indicates separate collection for electrical and electronic equipment per directive 2002/96/EEC.

The Intego™ PET Infusion System is a Class 1 electrical device as determined by IEC 60601-1.

Radiopharmaceutical ($^{18}$F-FDG or $^{18}$F-NaF).

Stop button.

On/Shutdown/Standby button.

Applied parts rating. The infusion system is a BF applied part device as determined by IEC 60601-1, indicating the degree of protection against electric shock.

Fuse rating. See Intego address label for specific fuse rating information.

This symbol informs the user of the correct manner of use.

This symbol informs the user of the incorrect manner of use.

Label showing the correct and incorrect routing of the Source Administration Sets (SAS) through the Saline Pump.

Label showing the correct and incorrect insertion of the Saline Spike into the Saline Container.

Label showing the correct and incorrect routing of the tubing through the RP Pump.
Label showing the correct and incorrect direction to attach the Needle Cartridge into the Needle Cartridge Holder.

Label showing the correct and incorrect insertion of the tubing into the Air Detector.

Label showing the correct and incorrect orientation of the T-Connector and the tubing in each of the Pinch Valves.

Label showing the correct and incorrect method of inserting the tubing into a Pinch Valve.

The following Product Symbols apply only to INT SYS 200 systems.

- Indicates Drive Speed Switch is in fast speed range position.
- Indicates Drive Speed Switch is in slow speed range position.

The following Product Symbol applies only to INT SYS 100 systems.

- Brake release triggers.

**Warnings**

Attention symbols used to identify warnings and cautions in product labeling.

- Pinch hazard. This symbol indicates there is the potential for pinch injury.

- Crush hazard. This symbol indicates there is the potential for crush injury.
See accompanying documentation. This symbol indicates the user should refer to the instructions-for-use to ensure safe operation.

Hazardous voltage. This symbol indicates there is a potential for electrical shock injury.

Radiation exposure hazard. Both symbols indicate that opening the Shielded Chamber when there is RP in the Intego™ PET Infusion System could expose the operator or patient to radiation.

DO NOT place greater than 1000 ml Saline Container on the Saline Hook.

Sitting on the unit is prohibited.

Display Icons

Radiation activity icon
- Not highlighted in yellow – Radioactivity may or may not be present within the Intego™ PET Infusion System.
- Highlighted in yellow – Radioactivity is present within the Dose Calibrator and assay information has been entered into the Intego™ PET Infusion System.

Fluid delivery battery status icon
- Not highlighted in yellow – Battery not present or battery is completely depleted.
- Highlighted in yellow – Unit is operating on battery power.

Plug icon
- Battery is present but the unit is operating on AC Power/Charging.

Fluid icon
- If present, fluid is currently being pumped within the Intego™ PET Infusion System.

Calendar icon. Touch this icon to enter the desired date.
Day selector icon. Toggles between today and yesterday.

Configuration icon. Located on the configuration button; used to open the Configuration screen.

Reset icon. Located on the reset button. Resets the RP field to the configured default value or the current scheduled dose and resets the patient infusion process back to entering patient information.

AM/PM icon. Press this icon to set AM or PM when entering time data.

Approximately icon. Used to identify estimated values.

Attention icon. Used to identify items that require clinician attention.

Partial infusion delivered.

Complete infusion delivered.

**Status Indicators**

The following Status Indicators are used on all Intego™ PET Infusion Systems.

**System Power and Dose Calibrator Status** (Green)

On – Intego™ PET Infusion System is On and Dose Calibrator is ready for use.

Blinking – Intego™ PET Infusion System is On and Dose Calibrator is warming up.

Off – Intego™ PET Infusion System is Shutdown.

**Fluid Delivery Battery Backup Status** (Amber)

On – Intego™ PET Infusion System is using battery backup.

Blinking – Only 5 minutes or less remain on battery before the Intego™ PET Infusion System will completely Shutdown. Connect the Intego™ PET Infusion System to AC power.

Off – Intego™ PET Infusion System is not using battery backup.
The following Status Indicators apply only to the INT SYS 200 systems.

**Drive System Status** (Blue)

On – Drive System is available for use.

Blinking – Low Drive System battery – Approximately 3 minutes or less remain before the Drive System becomes unavailable for use. Connect the *Intego™ PET Infusion System* to AC power.

Off – Drive System is not available for use.

**NOTE:** The Shielded Chamber Lid must be closed and latched in order to use the Drive System.

**System Battery Charging Status** (Violet)

On – Batteries are charging.

Off – Batteries are not charging.

---

**Packaging**

- **Catalog Number.**
- **Consult instructions for use.**
- **Single use only.**
- **For use with one vial of media only.**

**Do not use if package is opened or damaged.**

- **Lot number.**
- **Date of manufacture/sterilization.**
- **Non-pyrogenic fluid path.**

**Fluid path sterilized using gamma radiation.**
Medrad™ Integro™ PET Infusion System

Fluid path sterilized with Ethylene Oxide.

Use by date.

Atmospheric pressure range.

Humidity range.

Temperature range.

Contains DEHP.

Do not stack.

This side up.

Keep dry.

Fragile.
2 - System Basics

System Overview

The Intego™ PET Infusion System delivers $^{18}$F-FDG or $^{18}$F-NaF to patients during a PET or PET/CT diagnostic procedure. In addition, the system provides effective radiation shielding to medical personnel from $^{18}$F radiation exposure during nuclear medicine diagnostic procedures.

The Intego™ PET Infusion System meets the following clinical needs:

1. For a typical 555 MBq (15 mCi) infusion per patient, it limits $^{18}$F radiation exposure for medical personnel to less than 60 $\mu$Sv (6 mRem) finger dose and 3 $\mu$Sv (0.3 mRem) whole body dose.
2. Flexibility to program the required dose either by activity only or by activity per patient weight.
3. Ability to deliver $^{18}$F-RP within ±10% of the prescribed dose and within ±2% of the measured dose, excluding Dose Calibrator calibration factor.
4. Capability to retain and print infusion history and dispensing records.

The Intego™ PET Infusion System is a self-contained, self-powered (available only on INT SYS 200) mobile cart. A Multi-Dose Vial of RP (up to 27.75 GBq (750 mCi)) is stored within a Shielded Chamber within the body of the system. A SAS is installed within the Shielded Chamber at the same time a new Multi-Dose Vial of the RP indicated for use is installed. Just prior to an infusion, the system measures a dose of RP along with a saline flush in the Dose Calibrator. Once the correct radiation level is achieved, the RP dose and saline are infused into the patient via a PAS. Rechargeable batteries provide sufficient power to keep the Dose Calibrator warm so that the system can be unplugged and moved to a new location without having to completely power Off.

The Intego™ PET Infusion System consists of the following:

1. RP Pump
2. Saline Pump
3. Dose Calibrator
4. Air Detector
5. System Shielding
6. Vial Shielding

NOTE: Radiation shielding performance is achieved by using the Vial Shield designed by MEDRAD (or its equivalent).
The Intego™ PET Infusion System incorporates the following safety features to help protect patients and operators while the system is in use.

NOTE: These features are intended to augment the safety program of a site.

- The RP is stored in a Shielded Chamber within the Intego™ PET Infusion System. A patient’s dose of the RP indicated for use is created automatically while the dose remains within the Shielded Chamber, greatly reducing the operator’s exposure to radiation. Any waste material left over after an infusion remains within the Shielded Chamber until time for disposal. By employing a SAS, which is also contained within the Shielded Chamber, it is not necessary to replace the tubing set directly connected to the Multi-Dose Vial for each patient.
- Prior to infusing a dose of the RP indicated for use into the patient, the Intego™ PET Infusion System measures the dose activity to ensure that the correct dosage will be infused.
- The Intego™ PET Infusion System contains a Waste Container within the Shielded Chamber. If it is necessary to discard a dose of RP, the dose is transferred into this Waste Container to help prevent radiation exposure to the patient or operator.
- The Shielded Chamber Lid is secured by a heavy-duty latching system, which reduces the likelihood of unintentionally opening the Shielded Chamber while radioactivity is contained within. In addition, the Shielded Chamber Lid can be locked to prevent unauthorized access to the Shielded Chamber.
- The Intego™ PET Infusion System Display can be locked to prevent unauthorized access to the operating system.
- The Intego™ PET Infusion System has a saline test inject feature that may be used to check vein patency prior to an infusion.
- The Intego™ PET Infusion System features an air detection system that automatically disarms the Intego™ PET Infusion System if air is detected in the SAS.
- The Intego™ PET Infusion System PAS features a one-way check valve that prevents backflow of fluids into the SAS.

The following is available only on INT SYS 200 systems.

- The Intego™ PET Infusion System is intended for use with a powered Drive System. When the Drive System is being used, the system prevents test inject and dose delivery to the patient.

The following is available only on INT SYS 100 systems.

- The Intego™ PET Infusion System employs a hydraulic braking system that is continually engaged. The operator must continuously release the brakes to move the system.
Shielded Chamber Components

1. **SAS Track** – Recessed path used to hold the SAS and to prevent it from being damaged as the Shielded Chamber Lid is opened or closed.
2. **Vial Shield Compartment** – The chamber where the Vial Shield is placed.
3. **Needle Insertion Device** – A tungsten shielded lid with a fold-down handle that holds the SAS Needle Cartridge.
4. **RP Pump** – Precision pump used for RP dose preparation.
5. **SAS Confluence Holder** – Secures the SAS Confluence in the correct location and orientation.
6. **T-Connector Holder** – Secures the SAS T-Connector in the correct location and orientation.
7. **Dose Calibrator**
8. **Waste Pinch Valve** – Controls fluid flow to the Waste Container.
9. **PAS Pinch Valve** – Controls fluid flow to the PAS.
10. **Waste Storage** – The area where the SAS Waste Container is placed.
11. **Air Detector** – Used to detect air in the fluid as it passes from the SAS into the PAS.
12. **Air Detector Holder** – Secures the SAS within the Air Detector.
13. **Swabbable Valve Holder** – Secures the Swabbable Valve in the correct location for joining the PAS and SAS together.
14. **Saline Tube Holder** – Holds the Saline Tube in the PAS Compartment.
System Components

INT SYS 200

INT SYS 100
1. Display – Color touch screen display used to control the Intego™ PET Infusion System, view delivery data, and report radioactivity within the system.

2. USB Port – Provides the operator the capability of importing and exporting data.

3. Shielded Chamber – Lead shielded compartment that houses the SAS, RP, and various other system components.

4. Shielded Chamber Lid – A sliding lid that allows access to the components and RP contained in the Shielded Chamber.

5. Shielded Chamber Lid Latch – Used to secure the Shielded Chamber Lid from unintentional opening.

6. PAS Compartment – not shown – A separate compartment of the Shielded Chamber. Provides shielding for the PAS (located under the PAS Compartment Cover).

7. PAS Compartment Cover – Hinged cover to access the PAS Compartment.

8. On/Shutdown/Standby Button – Turns the Intego™ PET Infusion System On and Off. Also used to place the Intego™ PET Infusion System into and out of Standby. Also used to lock and unlock the system.

9. Stop Button – Used to stop current operation of the Intego™ PET Infusion System.

10. Power Switch – Rocker switch used to turn AC power On or Off.

11. Saline Pump – Peristaltic pump used to circulate saline in the SAS.


14. Cable Storage – Posts used for wrapping the power cable when the Intego™ PET Infusion System is being moved or when not in use.

15. Caster Brakes – Used to secure the Intego™ PET Infusion System from movement when parked.

The following apply only to INT SYS 200 systems.

16. Drive Controller – Thumb wheel to control forward/reverse variable speed.

17. Drive Engage Switch – Used to enable the Drive System.

18. Drive Speed Switch – Used to select the speed range of forward movement.

19. Drive Override – Mechanism to override the Drive System.

20. Status Indicators – Provides battery, Dose Calibrator, and Drive System status.

The following apply only to INT SYS 100 systems.

21. Brake Release – Located on each handle, used to release the primary brakes.

22. Status Indicators – Provides battery and Dose Calibrator status.
1. **Saline Spike** – Inserted into the Saline Container.
2. **Saline Tube** – Section of tube that is placed along the SAS Track and into the Saline Pump.
3. **RP Tube** – Section of tube from the Needle Cartridge to the Confluence that is placed in the RP Pump.
4. ** Needle Cartridge** – Contains the needles used to draw the RP into the SAS.
5. **SAS Coil** – Inserted into the Dose Calibrator. It holds the RP dose being measured by the Dose Calibrator.
6. **Pre-Coil Tube** – Section of tube from the Confluence to the SAS Coil.
7. **Post-Coil Tube** – Section of tube from the SAS Coil to the T-Connector.
8. **Waste Container** – Collects any discarded fluid.
10. **Waste Tube** – Section of tube from the T-Connector to the Waste Container.
11. **Patient Tube** – Section of tube from the T-Connector to the Swabbable Valve.
12. **Swabbable Valve** – Enables aseptic connection between the SAS and PAS.
13. **Saline Disconnect Luer** – Disconnects the Saline Tube from the Saline Container.
14. **Confluence** – Union of RP Tube, Saline Tube, and Pre-Coil Tube.
1. PAS Tubing
2. Removable Prime Tube – Captures excess saline during PAS priming.
3. One-Way Check Valve – Connected to the patient catheter or needle. Prevents fluid backflow.
4. Luer Connector – Connects the PAS to the SAS Swabbable Valve.
Vial Shield Components

1. **Vial Shield** – Multi-Dose Vial radiation shielding vessel designed to work specifically with the *Intego™ PET Infusion System*.
2. **Vial Cap** – Removable cap that provides access to the RP vial.
3. **Access Cap** – Removable cap that provides access to the RP vial septum.
4. **Carrying Handle** – Removable handle for transporting the Vial Shield and removing the Access Cap.

**NOTE:** For more information regarding Vial Shields, refer to the "Appendix D - Vials and Vial Shields."

Calibration Source Holder

**Calibration Source Holder** – Used to insert calibration sources into the *Intego™ PET Infusion System* Dose Calibrator.
Managing Power States

**Powering On the System**

**WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

**CAUTION:** DO NOT use the *Intego™ PET Infusion System* immediately after it has been brought indoors from extreme outside temperatures. Condensation may cause electrical damage to the system. Allow the *Intego™ PET Infusion System* to stabilize at room temperature before use.

1. Plug the *Intego™ PET Infusion System* power cable into an AC outlet and move the Power Switch to the On position.

2. Press and hold the **ON/SHUTDOWN/STANDBY** button until a beep sounds. The Introduction screen will appear.
**Medrad™ Intego™ PET Infusion System**

**Powering Off the System**
1. Press the **ON/SHUTDOWN/STANDBY** button.
2. A dialog box appears on the screen with the message “Intego Power and Security Options.” Press the **SHUTDOWN** button.

**NOTE:** If the Display is not functional, the **ON/SHUTDOWN/STANDBY** button can be pressed and held for 15 seconds to power Off the Intego™ PET Infusion System.

![Dosing Screen]

**Placing the System into Standby**
1. Press the **ON/SHUTDOWN/STANDBY** button.
2. A dialog box appears on the screen with the message “Intego Power and Security Options.” Press the **STANDBY** button.

**NOTE:** Placing the system into Standby eliminates the need to wait for the Dose Calibrator to warm up and allows the system to be driven (INT SYS 200 only). If the system is Shutdown, the user will need to wait up to 15 minutes to use the Dose Calibrator and the INT SYS 200 systems cannot be driven.

**NOTE:** If the Intego™ PET Infusion System is in Standby and the power cable is not plugged into AC power within 30 minutes, the system will completely power Off.

**NOTE:** If the power cable is removed from an AC outlet, the Display will remain powered for 60 minutes. After 60 minutes, the system will automatically go into Standby.

**Taking the System out of Standby**
1. Press the **ON/SHUTDOWN/STANDBY** button to activate the Intego™ PET Infusion System.
Securing the Intego™ PET Infusion System

The Device Lock feature secures the display and disables the Drive System (for INT SYS 200 only). A Standard lock can be used to secure the Shielded Chamber.

Locking the Device

NOTE: To enable the Device Lock feature, see "System Configuration."

1. Press the ON/SHUTDOWN/STANDBY button.
2. A dialog box appears on the screen with the message "Intego Power and Security Options." Press the LOCK button. A dialog box appears on the screen with the message "Device Locked."
Unlocking the Device

1. If the Intego™ PET Infusion System is powered Off or in Standby, press the ON/SHUTDOWN/STANDBY button.

2. In the “Device Locked” dialog box, enter the four digit security code and press the ENTER button.

NOTE: The factory set Security Code is 7237. It can be used to override any user configured code.
Locking the Shielded Chamber
A standard lock can be inserted in the mechanism shown below, if locking the Shielded Chamber is desired.

INT SYS 200

INT SYS 100
Navigating the User Interface

This section provides an overview of the main screens the operator will use with the Intego™ PET Infusion System.

Screen Overview

1. **Title Bar** – Located at the top of the screen. It identifies the current screen: System Preparation, Schedule, Dosing, or Configuration.

2. **Status Bar** – Located below the title bar. Information about the current state during operation is displayed here.

3. **Navigation Bar** – Located at the bottom left of the screen. It is used to move among the System Preparation, Schedule, and Dosing screens. Press the SALINE button or the RP button to access the System Preparation screen.

4. **Configuration Button** – Located at the bottom center of the screen. It is used to access the Configuration screen.

5. **Reset Button** – Appears only on the Dosing screen. Located at the bottom right of the screen. It resets the RP field to the configured default value or the current scheduled dose and returns the user to the Patient Information panel.

6. **Status Icons** – Located at the top right of the screen. Refer to "User Interface Symbols and Icons" section of this manual.

7. **Battery Meter** – Located at the top right of the screen. Indicates the amount of time that the system will operate on battery power.
**System Preparation Screen**

This screen enables the user to enter RP assay and saline information. The Multi-Dose Vial data, Saline Container remaining volume, activity in the SAS tubing, and the volume and activity contained in the Waste Container are monitored from the System Preparation screen. Daily QC and SAS priming are initiated from this screen.

![System Preparation Screen](image)

**Schedule Screen**

This screen enables the user to manually enter the Multi-Dose Vial schedule, import the Multi-Dose Vial schedule via a USB memory device, export the patient infusion history via a USB memory device, and clear the Multi-Dose Vial schedule.

![Schedule Screen](image)
**Dosing Screen**
This screen enables the user to monitor the Multi-Dose Vial schedule, prepare and deliver the patient dose using Personalized Dosing or Manual Dosing, enter patient and operator data, prime the PAS, perform test injections, change the flow rate, and monitor the RP activity being delivered to the patient.

**Configuration Screen**
This screen enables the user to set preferences, such as language, date and time, units, audio level, default values, security code, and Personalized Dosing formulas. Daily QC source assay information is entered on the Configuration screen. Dose Calibrator quarterly linearity and yearly calibration, and pinch valve calibration are performed from the Configuration screen.

**NOTE:** The Navigation Bar does not appear on the Configuration screen. To navigate from the Configuration screen, it is necessary to press the OK button. The user will be returned to the screen being used prior to the Configuration screen.
Moving the Intego™ PET Infusion System INT SYS 200

**WARNING:** Injury or damage to the system may occur if it is moved without the Shielded Chamber Lid secured. Do not move system unless the Shielded Chamber Lid is latched.

**WARNING:** Injury or damage may occur if the Intego™ PET Infusion System is used on steep inclines. Do not use the system on a floor with an incline greater than 10 degrees.

**WARNING:** Radiation exposure hazard. Do not move the Intego™ PET Infusion System unless the Shielded Chamber Lid is latched.

**WARNING:** Trip hazard. Injury may occur. Do not operate Drive System if the power cable is plugged into an AC outlet.

**CAUTION:** DO NOT plug the Intego™ PET Infusion System power cable into an extension cord or multi-outlet power strip. Only use the power cable supplied with the system.

**CAUTION:** DO NOT hang clothing or other pieces of equipment from the Intego™ PET Infusion System. Hanging clothes or equipment may impair the movement of the system.

**CAUTION:** DO NOT move any portion of the Intego™ PET Infusion System by force without disengaging the Caster Brakes or Brake Release.

1. Disconnect the PAS from the patient.

**WARNING:** Injury to patient may occur if system is moved without disconnecting the PAS from the patient. Disconnect the PAS from the patient prior to moving the Intego™ PET Infusion System.

2. Unplug the power cable from the AC outlet and wrap the power cable on the Cable Storage.

**NOTE:** If the Intego™ PET Infusion System is not placed in Standby and the power cable is unplugged from the AC outlet, the Display will remain powered for up to 60 minutes after which the system will go into Standby.

**NOTE:** If the Intego™ PET Infusion System is in Standby and the power cable is not plugged into AC power within 30 minutes, the Intego™ PET Infusion System will completely Shutdown.

3. Disengage the Caster Brakes

**NOTE:** The Intego™ PET Infusion System cannot be moved using the Drive System if the Device Lock feature is enabled and the Display is locked.

**NOTE:** The Intego™ PET Infusion System cannot be moved using the Drive System unless the Shielded Chamber Lid is closed and the Shielded Chamber Lid Latch is engaged.

**NOTE:** The Drive System cannot be engaged when priming the SAS or PAS, performing a test injection, preparing an RP dose, or delivering an RP dose to the patient or Waste Container.
**NOTE:** The *Intego™ PET Infusion System* must be powered On or in Standby to use the Drive System. If the system is powered Off, the Drive System will not operate.

**NOTE:** The battery must be charged for the Drive System to function. The blue Status Indicator will be illuminated when the Drive System is available for use. If the blue Status Indicator is blinking, plug the *Intego™ PET Infusion System* power cable into an AC outlet to charge the battery.

4. Choose either slow or fast on the Drive Speed Switch.

5. Firmly grip both of the handles on the *Intego™ PET Infusion System* at the Operator Position. Squeeze the Drive Engage Switch.

6. To move forward, use the thumb of the right hand to slowly rotate the Drive Controller forward while keeping the Drive Engage Switch pressed. To move backward, use the thumb of the right hand to slowly rotate the Drive Controller backward while keeping the Drive Engage Switch pressed.

**NOTE:** If the blue Status Indicator begins blinking while moving the *Intego™ PET Infusion System*, there are approximately 3 minutes remaining before the Drive System will stop functioning. When the blue Status Indicator begins blinking, move the system to an AC outlet and plug in the power cable.

7. Move the *Intego™ PET Infusion System* by carefully pushing the handles to the left and right to steer. The speed can be varied using the Drive Controller. The further the Drive Controller is rotated from the center position, the faster the system will move.

**CAUTION:** Avoid making fast turns or sudden starts and stops.

**NOTE:** Use forward motion to cross thresholds while moving the *Intego™ PET Infusion System*.

8. Once the *Intego™ PET Infusion System* is in its new location, release the Drive Engage Switch or the Drive Controller to stop.

9. Apply the Caster Brakes.

10. Unwrap the power cable from the Cable Storage and plug into an AC outlet.

**NOTE:** To ensure that the battery is fully charged and has the maximum capacity, keep the *Intego™ PET Infusion System* connected to AC power at all times except when the system is being moved.

**Moving the System Using the Drive Override (For Emergency Use Only)**

**NOTE:** If the Drive System is not available, the *Intego™ PET Infusion System* can be moved by using the Drive Override.

1. Disconnect PAS from patient.

2. Unplug the power cable from the AC Outlet. Wrap the power cable on the Cable Storage.
3. Pull the Drive Override out until it is fully extended (approximately 15 cm (6 inches)).

4. Disengage the Caster Brakes.
   
   **WARNING:** Crush hazard. Using the Drive Override disengages the Drive System brakes. Ensure the Intego™ PET Infusion System is not on an incline or left unattended when using the Drive Override and re-engage the Drive Override after moving the system and engage the Caster Brakes.

5. Firmly grip both handles on the Operator Position of the Intego™ PET Infusion System.

6. Move the Intego™ PET Infusion System using firm, steady force. Avoid making jerking movements or sudden starts and stops. Leave approximately 1 m (3 ft) per side to complete turns.

7. Once the Intego™ PET Infusion System is in its new location, apply the Caster Brakes.

8. Push the Drive Override in to the normal operating position.

9. Unwrap the power cable from the Cable Storage and plug into an AC outlet.

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**Moving the Intego™ PET Infusion System INT SYS 100**

**WARNING:** Injury or damage to the system may occur if it is moved without the Shielded Chamber Lid secured. Do not move system unless the Shielded Chamber Lid is latched.

**WARNING:** Injury or damage may occur if the Intego™ PET Infusion System is used on steep inclines. DO NOT use the system on a floor with an incline greater than 10 degrees.

**WARNING:** Radiation exposure hazard. Do not move the Intego™ PET Infusion System unless the Shielded Chamber Lid is latched.

**CAUTION:** DO NOT plug the Intego™ PET Infusion System power cable into an extension cord or multi-outlet power strip. Only use the power cable supplied with the system.

**CAUTION:** DO NOT hang clothing or other pieces of equipment from the Intego™ PET Infusion System. Hanging clothes or equipment may impair the movement of the system.

**CAUTION:** DO NOT move any portion of the Intego™ PET Infusion System by force without disengaging the Caster Brakes or Brake Release.
1. Disconnect the PAS from the patient.

   **WARNING:** Injury to patient may occur if system is moved without disconnecting the PAS from the patient. Disconnect the PAS from the patient prior to moving the *Intego™ PET Infusion System.*

   **NOTE:** If the *Intego™ PET Infusion System* is not placed in Standby and the power cable is unplugged from the AC outlet, the Display will remain powered for three minutes. If the power cable is not plugged into the AC outlet within three minutes, the system will go into Standby.

   **NOTE:** If the *Intego™ PET Infusion System* is in Standby and the power cable is not plugged into AC power within 30 minutes, the system will completely power Off.

2. Unplug the power cable from the AC outlet and wrap the power cable on the Cable Storage.

3. Disengage the Caster Brakes.

4. Firmly grip both handles on the Operator Position of the *Intego™ PET Infusion System.* Squeeze the Brake Release on each handle to disengage the brakes.

   **NOTE:** The Brake Release on each handle must be squeezed simultaneously to disengage the brakes.

   **NOTE:** To engage the brakes, stop squeezing either Brake Release.

5. Move the *Intego™ PET Infusion System* using firm, steady force. Avoid making jerking movements or sudden starts and stops. Leave approximately 1 m (3 ft) per side to complete turns.

6. Once the *Intego™ PET Infusion System* is in its new location, stop squeezing the Brake Release to stop.

7. Apply the Caster Brakes.

8. Unwrap the power cable from the Cable Storage and plug into an AC outlet.
3 - System Configuration

To configure the *Intego™ PET Infusion System*, press the **CONFIGURATION** button on the Navigation Bar.

**NOTE:** To save configuration changes, press the **OK** button. To return to the factory settings, press the **DEFAULT** button.

**System Settings**

On the left side of the Configuration screen, press the **SYSTEM** button to access the configuration options. Languages, Date/Time, Units, and Audio tabs will be displayed along the top.

1. Press the Languages tab to access the language configuration options.
   a. Configure the *Intego™ PET Infusion System* by pressing the button with the desired language.
2. Press the Date/Time tab to access the date and time configuration options.

   a. Configure the date format by pressing the Date Format field. Five date formats will be displayed. Press the button showing the desired date format.

   b. Configure the time format by pressing the Time Format field. A 12-hour and a 24-hour format will be displayed. Press the button showing the desired time format.

   c. Configure the current date and time by pressing the **EDIT** button. The current date is entered by pressing the Calendar icon. The current time is entered by pressing the Current Time field.

   **NOTE:** The system does not automatically adjust for Daylight Savings Time. The system time must be adjusted manually.

3. Press the Units tab to access the weight and activity unit configuration options.
a. Configure the weight units by pressing either the **POUNDS** button or the **KILOGRAMS** button.

b. Configure the activity units by pressing either the **CURIE** button or the **BECQUEREL** button.

4. Press the Audio tab to access the audio configuration options.

   a. Configure the audio level by pressing the **HIGH** button, **NORMAL** button, or **LOW** button.

**Dosing Settings**

On the left side of the Configuration screen, press the **DOSING** button to access the dosing options. RP, Saline, Case, and Printing tabs will be displayed along the top.

1. Press the RP tab to access the RP configuration options.
a. Configure the default dose by pressing the Default Dose field and entering the desired value via the keypad.

**NOTE:** If a vial schedule is entered using the Schedule screen, the Default Dose will be overridden with the schedule value. For more information on when the Default Dose is used and how a user may override it, refer to the "Patient Infusion" section.

b. Configure the Intego™ PET Infusion System to use Personalized Dosing by default by pressing the Default Setting **ON** button.

c. Configure the Intego™ PET Infusion System to use Manual Dosing by default by pressing the Default Setting **OFF** button.

d. Up to five Personalized Dosing formulas can be entered by pressing the **EDIT FORMULAS** button.
   i. Press the Multiplier field to enter the RP activity per unit weight and then press **ENTER** on the numeric keypad.
   ii. Press the Minimum field to enter the minimum RP activity that can be prepared regardless of the patient weight and then press **ENTER** on the numeric keypad.
   iii. Press the Maximum field to enter the maximum RP activity that can be prepared regardless of the patient weight and then press **ENTER** on the numeric keypad.
   iv. Press the **OK** button.

**NOTE:** If more than one formula is created, a formula name must be entered when entering the data. Press a **NEW FORMULA** button and enter the formula name via the keypad.

**NOTE:** At least one formula must be entered to use the Personalized Dosing.
2. Press the Saline tab to access the saline configuration options.

   - a. Configure the default Saline Container volume by pressing the Default Volume field and entering the desired value via the keypad.
   - b. Configure the additional flush volume by pressing the Additional Flush Volume field and entering the desired value via the keypad.

   **WARNING:** Injury or death may result from injecting air. If an additional flush volume is used with extension tubing, the *Intego™ PET Infusion System* will not prime the additional tubing automatically. Air may be injected into the patient if the extension tubing is not primed before use. The additional tubing must be primed before connecting to the patient by selecting the “Prime PAS” function until all air is purged from the PAS.

   **NOTE:** The additional flush volume is added to the fixed 35 ml saline flush used during a patient infusion.

   - c. Configure the test inject volume by pressing the Test Inject Volume field and entering the desired value via the keypad.
   - d. Configure the default flow rate by pressing either the **1.0mL/s** or **0.5mL/s** button.
3. Press the Case tab to access the Case configuration options.

a. Configure the Intego™ PET Infusion System by pressing the button with the desired default infusion site.

**NOTE:** If a default infusion site is not configured, the user will be given the option to select the infusion site when entering patient information on the Dosing screen. If a default infusion site is configured, it can be overridden when entering patient information on the Dosing screen.

4. Press the Printing tab to access the Printing configuration options.

a. Configure the Auto Print by pressing the ON or OFF button.

b. Press the Quantity field and enter the desired number of labels to automatically be printed if the Auto Print option is set to On.

**NOTE:** If the Auto Print option is not configured to be On to print labels, the user may still print manually.
Maintenance Settings

1. On the left side of the Configuration screen, press the MAINTENANCE button to access the maintenance options. Daily QC, Linearity, Calibration, and Service tabs will be displayed along the top.

2. Press the Daily QC tab to access the Daily QC configuration options.

   ![Configuration Screen](image)

   a. Press the Lot Number field and enter the lot number of the $^{137}$Cs calibration source to be used for Daily QC.

   b. Press the Activity field and enter the activity of the $^{137}$Cs calibration source to be used for Daily QC.

   c. Press the EDIT button to enter the assay date and time.

   d. Press the Calendar icon next to the Reference Date and enter the assay date of the $^{137}$Cs calibration source to be used for Daily QC.

   **NOTE:** When reading the date from the $^{137}$Cs calibration source assay information, be cognizant of the format. Some formats are dd/mm/yy and others are mm/dd/yy.

   e. Press the Reference Time field and enter the assay time of the $^{137}$Cs calibration source to be used for daily QC. If a time is not included with the assay information, enter 12:00.

   **NOTE:** Pressing the Linearity and Calibration tabs will access these configuration screens. Descriptions on how to perform linearity testing, pinch valve, and yearly calibration are provided in the Cleaning and Maintenance Appendix.
3. Press the Service tab to access the service configuration options.

   a. To configure a MEDRAD Service reminder, press the Calendar icon next to the Reminder Date field and enter the desired date.

   b. To export log files, insert a USB memory device into the USB Port. Press either the 30 DAYS or ALL LOGS button, then remove the USB Memory device after the Intego™ PET Infusion System indicates the export is complete.

   **WARNING: Shock hazard.** This port is intended for connection of USB-powered devices, such as memory sticks, having no other electrical power connections. Connection of devices having other electrical power connections to this port may result in an electrical shock hazard.

   c. MEDRAD contact information is on the Service Configuration screen.
Security Settings

1. On the left side of the Configuration screen, press the SECURITY button to access the security options. A Manage Security Code dialog box will appear.

2. Under Device Lock, press the ON button to enable the Device Lock feature. Press the OFF button to disable the Device Lock feature.

   NOTE: Locking the device prevents unauthorized use or movement of the Intego™ PET Infusion System (for INT SYS 200 only) and requires a user to enter the default or a user-specific security code after powering On.

3. To create a unique security code, enter the current security code by pressing the Current Code field. The factory set security code is 7237. It can be used to override any user configured code. If the current user code is unknown, enter 7237 in the Current Code field.

4. Press the Enter New Code field. Enter a unique four digit security code.

5. Press the Re-enter New Code field. Enter the same four digit security code.
6. Press the ENTER button. The OK button will appear. Press OK to accept the new code.
4 - Daily Setup

WARNING: Patient injury could result from using improper components. Use only components and options provided by MEDRAD designed for Intego™ PET Infusion System.

WARNING: Explosion hazard. DO NOT use the Intego™ PET Infusion System when flammable gases are present. Patient injury could result from using the system in the presence of flammable gases (such as anesthetics).

WARNING: Trip hazard. Injury may occur. Do not operate Drive System if the power cable is plugged into an AC outlet.

WARNING: No modification of this equipment is allowed.

WARNING: Do not use the Intego™ PET Infusion System in an oxygen rich environment (Environment in which the concentration of oxygen is greater than 25% for ambient pressures up to 110kpa).

Placing the System into Clinical Mode

1. Power On the Intego™ PET Infusion System.

   NOTE: If the Device Lock feature has been enabled, the Intego™ PET Infusion System will prompt the user to enter the Security Code. Press ENTER when complete.

2. The Introduction screen appears. Press the CLINICAL button.

   NOTE: The screen displays the current mode in the lower right corner of the Introduction screen.
3. If the Intego™ PET Infusion System was in Training Mode, the system will display the message “Changing from Training Mode to Clinical Mode requires a restart. Continue?” Press OK to proceed.

4. The Intego™ PET Infusion System will display a progress bar while switching to Clinical Mode. When complete, the system will display a message prompting the user to restart. Press the RESTART button to Restart the system.

5. At the Introduction screen, press the CLINICAL button.
NOTE: Only screens for $^{18}$F-FDG are shown here. When using $^{18}$F-NaF, the text “FDG” changes to “NaF” and RP-specific screen elements change from orange to green (e.g., the RP button on the Navigation Bar).

6. When the System Preparation screen appears, press the OK button to proceed. Allow up to 15 minutes for the Dose Calibrator to warm up before proceeding; the Status Bar indicates the warm-up time remaining.

Using the Schedule

To access the Schedule screen, press the SCHEDULE button on the Navigation Bar. The Multi-Dose Vial schedule can either be entered manually or imported via the USB Port. The user may edit the schedule as it changes throughout the day.

NOTE: The Intego™ PET Infusion System may highlight scheduled RP infusions. Refer to the "Vial Monitoring" section of this document for more information.
Manually Entering Schedule Information
1. Press the **ADD APPOINTMENT** button or a blank row in the schedule.
2. Press the Time field to enter the planned infusion time.
3. Press the Activity field to enter the planned dose activity.
4. Repeat steps 1 through 3 until schedule entry is complete.

**NOTE:** More than six appointments can be added. Use the scroll bar to view appointments not on the Schedule screen.

Importing the Schedule Information via the USB Port

**NOTE:** Importing a schedule replaces the existing schedule.

1. Create an electronic version of the schedule named “schedule.csv” and copy it to a USB memory device. There are three ways to create an electronic schedule:
   a. MEDRAD’s MVP software tool (Recommended).
   b. Select third party nuclear medicine management software packages.
   c. Using a spreadsheet program or text editor.

**NOTE:** Please contact MEDRAD for more information about creating an electronic schedule.

2. Insert the USB memory device into the USB Port on the Display.
3. Press the **IMPORT SCHEDULE** button. The time and activity information automatically populates for all scheduled RP infusions.
Editing the Schedule

1. To edit a scheduled RP infusion, press the Time field or Activity field and enter the new value.

NOTE: The Intego™ PET Infusion System automatically sorts the schedule by infusion time. Editing infusion time may reorder the schedule.

2. To delete a scheduled infusion, press the X button.

3. To remove the entire schedule, press the CLEAR SCHEDULE button.
Exporting the Infusion History

The Intego™ PET Infusion System creates an infusion history as each infusion is completed. The infusion history consists of a .csv file for each of the last 31 days the Intego™ PET Infusion System was used. To export the infusion history, insert a USB memory device in the USB Port and press the EXPORT HISTORY button. Remove the USB memory device when the system indicates the export has been completed.
Performing Daily QC

The Daily QC confirms proper operation of the Dose Calibrator. Daily QC can only be performed without a Multi-Dose Vial or SAS installed. It is possible to perform RP infusions without valid Daily QC results, but this is not recommended. An Attention icon is displayed on the DAILY QC button when the system is being used without valid Daily QC results.

**WARNING:** Using the *Intego™ PET Infusion System* without performing the necessary QC processes could result in the patient receiving an incorrect dosage of the RP indicated for use. Be certain to perform all necessary QC checks at the recommended intervals.

1. Access the System Preparation screen by pressing the SALINE button or RP button on the Navigation Bar.
2. Press the DAILY QC button.

**NOTE:** Nearby radiation sources may cause the zero adjustment to fail. Remove any nearby radiation sources before starting daily QC.
3. Press the **START** button. The *Intego™ PET Infusion System* will automatically proceed with all listed Daily QC tests and check the box next to each test as it completes.

![System Preparation](image)

**NOTE:** The Bias Adjustment may compensate for a failed Zero Adjustment. The Daily QC is valid if the Zero Adjustment fails but the Bias Adjustment is successful.

4. If the Zero Adjustment fails, check for and remove any nearby sources of radiation and repeat the Daily QC test from Step 3.

5. Daily QC will pause at the Constancy/Accuracy test and produce the prompt shown below.

   a. If the $^{137}$Cs calibration source is not available, press the **SKIP** button to bypass the Constancy/Accuracy test and proceed to step 10.

   b. If the $^{137}$Cs calibration source is available but the displayed assay information is incorrect, press the **EDIT** button, update the assay information, and proceed to step 6.
NOTE:  When the $^{137}$Cs calibration source lot number is changed, the Constancy check will establish a new reference activity for future Constancy checks instead of testing Constancy against the previous reference.

6. Grasp the Shielded Chamber Lid Latch to release it, and open the Shielded Chamber Lid to gain access to the Shielded Chamber.

7. Place the $^{137}$Cs calibration source into the Dose Calibrator using the Calibration Source Holder.

8. Close the Shielded Chamber Lid until the Shielded Chamber Lid Latch engages, then press the OK button.

9. When prompted, open the Shielded Chamber Lid, remove the test source from the Dose Calibrator, slide the Shielded Chamber Lid closed until the Shielded Chamber Lid Latch engages, then press the OK button.
10. At the conclusion of the Daily QC, the Intego™ PET Infusion System displays a summary screen. Print this screen to keep with the system’s records.

11. Press the SUMMARY button to return to the main System Preparation screen.

**Entering RP Assay and Saline Information**

**WARNING:** Radiation exposure hazard. Do not insert more than 27.75 GBq (750 mCi) into the Intego™ PET Infusion System.

**NOTE:** Entering RP Assay and Saline Information may be performed before or after installing the SAS or Installing the Multi-Dose Vial.

1. Access the System Preparation screen by pressing the SALINE or RP buttons on the Navigation Bar.

2. If a Multi-Dose Vial is loaded in the Intego™ PET Infusion System, remove the Vial Shield and SAS, then press the REMOVE button.

3. Press the NEW button to enter RP Assay information.
4. The Vial Assay Information screen appears. Press the respective fields to enter the Lot Number, Date, Reference Time, RP Type, Activity at Reference Time, and Volume. When all data is entered, press the OK button.

**WARNING:** Radiation exposure hazard. Do not insert more than 27.75 GBq (750 mCi) into the Intego™ PET Infusion System.

**NOTE:** If the level of radioactivity in the Multi-Dose Vial exceeds 27.75 GBq (750 mCi), the Intego™ PET Infusion System displays the message “Vial activity exceeds safe shielding level. Immediately return vial to protective container.” If this message appears, remove the Vial Shield from the system and return to hot lab or other storage capable of providing adequate shielding for the contained activity.

5. The System Preparation screen reappears with the usable activity in the Multi-Dose Vial displayed within the vial symbol. The total Multi-Dose Vial volume and activity are displayed to the right of the vial symbol.
6. Press the REPLACE button in the Saline section.

7. Enter the volume of the Saline Container using the keypad.

**NOTE:** The minimum recommended Saline Container volume is 750 ml.

**Installing the SAS**

**NOTE:** Always install a new SAS before installing a new Multi-Dose Vial.

**NOTE:** The *Intego™ PET Infusion System* is intended for use with $^{18}$F-FDG and $^{18}$F-NaF. *Intego™ PET Infusion System* disposables intended for use with $^{18}$F-FDG may be used to deliver $^{18}$F-FDG or $^{18}$F-NaF. Please contact MEDRAD for more information.

**NOTE:** Installing the SAS or installing the Multi-Dose Vial may be performed before or after entering RP Assay and Saline Information.

**NOTE:** In the following steps, it will be helpful to refer to the diagrams of the Intego Infusion System Components, Intego Shielded Chamber Components, and the SAS Components.

**WARNING:** DO NOT use the SAS with more than one Multi-Dose Vial. Using the SAS with more than one Multi-Dose Vial could result in injury to patient or operator.

1. Place the Saline Container onto the Saline Hook at the rear of the cart.
2. Open the PAS Compartment Cover.
3. Grasp the Shielded Chamber Lid Latch to release it, and slide the Shielded Chamber Lid towards the front of the cart to gain access to the Shielded Chamber.

**WARNING:** Severe operator injury can occur if care is not taken when opening or closing the Shielded Chamber Lid or the PAS Compartment Cover. Be certain that all fingers are clear before opening or closing the Shielded Chamber Lid or the PAS Compartment Cover.
WARNING: Radiation exposure hazard. Using the Shielded Chamber Lid as a work space may expose the operator to excess radiation. Do not use the Shielded Chamber Lid as a work space while there are radioactive materials present within the *Intego™ PET Infusion System*. Using the Shielded Chamber Lid as a work space or placing items on the Shielded Chamber Lid while it is open may damage the Shielded Chamber Lid, hampering its ability to provide an adequate radiation shield.

4. Open the SAS Disposable Package.

**WARNING:** Patient injury may result if disposable package is opened or damaged, or if damaged components are used. Visually inspect contents and package before use.

**WARNING:** This product contains DEHP, a chemical known to the state of California to cause birth defects or other reproductive harm. Please visit www.medrad.com/DEHP for more information regarding DEHP in MEDRAD products.

**WARNING:** Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components using aseptic techniques.

**WARNING:** Only the fluid path of the set is sterile and non-pyrogenic. Do not use in a sterile or aseptic area without proper precautions. Place the Saline Container onto the Saline Hook at the rear of the cart.

5. Load the Needle Cartridge into the Vial Shield Compartment:

**WARNING:** Puncture hazard. The SAS contains needles. To prevent injury, take care when handling the SAS to control the needles. Dispose of the needles per individual facility guidelines.

a. Grasp the Needle Insertion Device’s handle and lift the Needle Insertion Device straight up until it stops.

b. Rotate the Needle Insertion Device counter-clockwise until it stops. Release the handle. The Needle Insertion Device will remain in position.

c. Lift the hinged Needle Insertion Device cover to access the Needle Cartridge Holder.
d. Insert the Needle Cartridge into the holder so the RP Tube exits the cartridge away from the holder.

![Insert Needle Cartridge](image)

CAUTION: Incorrect installation of the SAS may result in improper functioning of the *Intego™ PET Infusion System*.

e. Stow the needles safely in the Vial Compartment until ready to install the Multi-Dose Vial by lowering the Needle Insertion Device cover, rotating the Needle Insertion Device clockwise until it stops, then pushing down on the Needle Insertion Device until it is back in its original position.

6. Insert RP Tube in the RP Pump:

   a. Open the RP Pump door.
   b. Insert the RP Tube into the RP Pump as shown in the left panel below. For proper installation, the tubing collar must rest immediately outside the RP Pump on the side closest to the Vial Shield Compartment.

![Insert RP Tube](image)

   c. Close the RP Pump door.

7. Insert the Confluence into the SAS Confluence Holder.
8. Insert the SAS Coil into the Dose Calibrator. Be sure the Pre-Coil Tube enters and the Post-Coil Tube exits on top of the SAS Coil and the SAS Coil is placed at the bottom of the Dose Calibrator.

![Image of SAS setup](image)

9. Route the Pre-Coil Tube into the SAS track between the SAS confluence holder and the Dose Calibrator. Be sure to press the tubing firmly into the SAS track.

10. Unroll the Waste Container and insert it into the Waste Storage.

11. Place the T-Connector into the T-Connector Holder.

12. Install the Waste Tube into the Waste Pinch Valve. Install the Patient Tube into the PAS Pinch Valve.

**NOTE:** To install tubing in a Pinch Valve, open the valve by pressing the button on the top. While holding the valve open and grasping the tubing on either side of the valve, pull the tubing in from the side. The tubing must be inserted completely as shown in the left panel below. Release the button on the valve to pinch the tubing in place.

![Correct and Incorrect Pinch Valve Installation](image)

**NOTE:** The left panel in the picture below shows the correct layout of the SAS when the tubing has been properly installed into the SAS T-Connector Holder, Waste Pinch Valve, and PAS Pinch Valve.
CAUTION: Incorrect installation of the SAS may result in improper functioning of the Intego™ PET Infusion System.

13. Firmly press the Patient Tube exiting the PAS Pinch Valve into the Air Detector Holder and Air Detector. Insert the Swabbable Valve into the Swabbable Valve Holder.

NOTE: Make certain the tubing is fully inserted into the Air Detector as illustrated below.

CAUTION: Incorrect installation of the SAS may result in improper functioning of the Intego™ PET Infusion System.

14. Insert the Saline Spike into the Saline Container. Verify the Saline Spike is fully inserted into the container as illustrated below.

CAUTION: Incorrect installation of the SAS may result in improper functioning of the Intego™ PET Infusion System.

15. Open the Saline Pump door, install the Saline Tube, then close the Saline Pump door.
4 - Daily Setup

a. Center the Saline Tube on the Saline Pump rollers. The Saline Pump will not pump fluid properly if the tubing falls below the rollers.

![Image of correct and incorrect installation of the Saline Tube on the rollers.]

**CAUTION:** Incorrect installation of the SAS may result in improper functioning of the **Intego™ PET Infusion System**.

b. Ensure the Saline Disconnect Luer rests against the edge of the Saline Pump.

![Image of correct and incorrect installation of the Saline Disconnect Luer.]

**CAUTION:** Incorrect installation of the SAS may result in improper functioning of the **Intego™ PET Infusion System**.

c. Center the Saline Tube in the Saline Pump door to prevent the tubing from being pinched when the door is closed.

![Image of correct and incorrect installation of the Saline Tube in the Saline Pump door.]

**CAUTION:** Incorrect installation of the SAS may result in improper functioning of the **Intego™ PET Infusion System**.

**WARNING:** Air embolism or improper injection dosage may occur if Saline Line is damaged. Make certain the Saline Tube is not pinched within the Saline Pump as this may damage the administration set.
16. Route the Saline Tube along the SAS Track, starting at the SAS Confluence Holder and moving towards the Saline Pump. Be sure to press the tubing firmly into the SAS Track.

17. Press the Saline Tube into the Saline Tube Holder between the Saline Pump and SAS Track.

**WARNING:** Improper injection dosage or radiation spillage may result if the Shielded Chamber Lid is closed onto the tubing set. Ensure that the tubing set and all administration set components are properly installed before closing the Shielded Chamber Lid.

18. Once the SAS has been installed, ensure all components are laying flat prior to closing the lid.
Installing the Multi-Dose Vial

![Image of Multi-Dose Vial]

**WARNING:** DO NOT use any RP other than $^{18}$F-FDG or $^{18}$F-NaF with the *Intego™ PET Infusion System*. Use of radiopharmaceuticals other than $^{18}$F-FDG or $^{18}$F-NaF may cause inaccurate dose measurement and/or excessive radioactive exposure.

**WARNING:** Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

**WARNING:** Severe operator injury can occur if care is not taken when opening or closing the Shielded Chamber Lid or the PAS Compartment Cover. Be certain that all fingers are clear before opening or closing the Shielded Chamber Lid or the PAS Compartment Cover.

**WARNING:** Radiation exposure hazard. Using the Shielded Chamber Lid as a work space may expose the operator to excess radiation. Do not use the Shielded Chamber Lid as a work space while there are radioactive materials present within the *Intego™ PET Infusion System*. Using the Shielded Chamber Lid as a work space or placing items on the Shielded Chamber Lid while it is open may damage the Shielded Chamber Lid, hampering its ability to provide an adequate radiation shield.

**WARNING:** Radiation exposure hazard. Do not insert more than 27.75 GBq (750 mCi) into the *Intego™ PET Infusion System*.

**NOTE:** Entering RP Assay and Saline Information may be completed before or after installing the Multi-Dose Vial. Installing the SAS should be completed prior to installing the Multi-Dose Vial.

**NOTE:** In the following steps, it will be helpful to refer to the diagrams of the Intego Infusion System Components, Intego Shielded Chamber Components, and the SAS Components.
1. Grasp the Needle Insertion Device’s handle, lift straight up until it stops, then rotate counter-clockwise until it stops. Release the handle; the Needle Insertion Device will remain in position providing access to the Vial Shield Compartment.

   **WARNING: Puncture hazard. The SAS contains needles.** To prevent injury, take care when handling the SAS to control the needles. Dispose of the needles per individual facility guidelines.

2. Insert the Vial Shield containing a Multi-Dose Vial of RP into the Vial Shield Compartment. DO NOT remove the Vial Shield’s Access Cap. Leave the carrying handle on the Vial Shield until ready to insert the SAS Needles into the vial.

3. When ready to insert the SAS Needles into the Multi-Dose Vial, remove the Access Cap: grasp the Vial Shield Carrying Handle and simultaneously push down and rotate counter-clockwise 1/8 of a turn. After completing the turn, lift the handle straight up. The Access Cap will lift from the Vial Shield, providing access to the Multi-Dose Vial septum.

   **WARNING: Radiation exposure hazard.** Radiation activity exposure is increased once the Access Cap is removed. The user should avoid working directly over the open Vial Shield to minimize exposure.

   **WARNING: Biological contamination may occur if aseptic techniques are not followed.** Follow facility guidelines to disinfect the vial septum.

4. Insert SAS Needles into the Multi-Dose Vial:
   a. Grasp the Needle Insertion Device’s handle and rotate it clockwise until it stops; the SAS Needles should be oriented over the Multi-Dose Vial septum.
   b. Press down on the Needle Insertion Device’s handle until the Needle Insertion Device is in its original closed position as shown in the Intego Shielded Chamber Components diagram. The SAS Needles will penetrate the Multi-Dose Vial as the Needle Insertion Device is lowered.
   c. Lower the Needle Insertion Device handle to rest on the cover.

5. Close the Shielded Chamber Lid until the Shielded Chamber Lid Latch engages and close the PAS Compartment Cover over the PAS Compartment.

The Vial Shield is keyed such that it can be properly inserted into the Vial Shield Compartment only one way. The posts in the Vial Shield Compartment must rest in the keyed areas located on one flat surface of the Vial Shield.
Installing the PAS

NOTE: A PAS must be installed to prime the SAS and to infuse a patient. A new PAS must be installed for each patient. The PAS installed to prime the SAS may be used for the first patient after SAS priming.

WARNING: Biological contamination can result from reusing the PAS or failure to follow sterile technique. DO NOT reuse or attempt to resterilize. Properly discard disposable items after use. If there is any possibility that contamination may have occurred during set-up or use, disassemble and set-up a new sterile product.

WARNING: Patient injury may result if disposable package is opened or damaged, or if damaged components are used. Visually inspect contents and package before use.

WARNING: Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components using aseptic techniques.

CAUTION: Component damage may occur if not installed properly. Ensure all connections are secure. DO NOT over-tighten.

NOTE: In the following steps, it will be helpful to refer to the diagrams of the Intego Infusion System Components, Intego Shielded Chamber Components, and the SAS Components.

1. Open the PAS Compartment Cover to expose the Swabbable Valve.
2. Clean the SAS Swabbable Valve following aseptic techniques described in facility guidelines.
3. Open the PAS disposable package, being sure not to remove the Removable Prime Tube.
4. Attach the PAS Luer Connector to the SAS Swabbable Valve.
5. Route the PAS from the PAS Compartment.

NOTE: INT SYS 200: Route the PAS out the left, right, or rear of the PAS Compartment, whichever is most convenient for connecting the PAS to the patient. INT SYS 100: Route the PAS out the left or right of the PAS Compartment, whichever is most convenient for connecting the PAS to the patient.

6. Close the PAS Compartment Cover back over the PAS Compartment. Make sure the PAS Compartment Cover does not pinch the PAS.

WARNING: Severe operator injury can occur if care is not taken when opening or closing the Shielded Chamber Lid or the PAS Compartment Cover. Be certain that all fingers are clear before opening or closing the Shielded Chamber Lid or the PAS Compartment Cover.
**Priming the SAS**

**NOTE:** Entering RP Assay and Saline Information, Installing the SAS, Installing the Multi-Dose Vial, and Installing a PAS must be completed prior to Priming the SAS. To prime the SAS:

1. Access the System Preparation screen by pressing the SALINE or RP buttons on the Navigation Bar.
2. Press the **PRIME SAS** button.

3. A dialog box appears with the following message: “Ensure that a PAS is connected to the SAS. Continue?” Install a PAS if necessary, then press the **YES** button.

4. SAS priming proceeds in three phases.
   
a. **Priming saline** - The *Intego™ PET Infusion System* fills the Saline Tube, Pre-Coil Tube, SAS Coil, Post-Coil Tube, Waste Tube, and Patient Tube with saline. All RP is still contained within the Vial Shield at this point, allowing safe correction of SAS installation errors detected during this phase.

   **WARNING. Radiation exposure hazard.** Once RP priming commences RP is in the SAS and no longer contained within the Vial Shield. To minimize radiation exposure, opening the Shielded Chamber Lid should be avoided once RP priming commences.

   
b. **Priming RP** - The *Intego™ PET Infusion System* fills the SAS Needles and RP Tube with RP.

   **WARNING. Radiation exposure hazard.** Once RP priming commences RP is in the SAS and no longer contained within the Vial Shield. To minimize radiation exposure, opening the Shielded Chamber Lid should be avoided once RP priming commences.

   
c. **Verifying Concentration** - The *Intego™ PET Infusion System* measures RP activity concentration to ensure RP assay information has been entered accurately.

**NOTE:** During each phase of SAS priming, the Status Bar indicates the phase being performed and displays a progress bar showing progress to completion.

5. When SAS Priming is complete, the *Intego™ PET Infusion System* will beep and the Status Bar will state “System is Ready.”

**NOTE:** The attached PAS is not primed during this process; it is primed when preparing for the first patient infusion. Excess fluid used during SAS priming is collected within the Waste Container inside the Shielded Chamber.

**NOTE:** To resolve any priming issues, refer to "Appendix C - Troubleshooting Tips."
5 - Patient Infusion

WARNING: Explosion hazard. DO NOT use the Intego™ PET Infusion System when flammable gases are present. Patient injury could result from using the system in the presence of flammable gases (such as anesthetics).

Patient and operator information is used for dose infusion record-keeping. All patient and operator information is optional. Fields that are not entered are left blank in the final dose infusion record.

1. Press the DOSING button on the Navigation Bar to go to the Dosing screen.
2. To enter patient information, press the EDIT button located on the Patient Information panel.

3. A patient information entry screen will appear.

NOTE: The patient information entry screen may appear with some or all patient information populated with valid data. Pre-populated patient information can be provided with an imported Multi-Dose Vial schedule or if retrying a patient for which patient information was already entered. Pre-populating patient information is a convenience feature to reduce the amount of hand-entry a user must perform.

NOTE: The Intego™ PET Infusion System will prevent initiation of a patient infusion with less than three minutes remaining on the battery meter.
4. Enter patient and operator information and update any information that is incorrect. To enter a Case Identifier, Alternate Case Identifier, or Operator Identifier, touch the corresponding data field and an on-screen keyboard will appear. To enter an Infusion Site, press the desired Infusion Site button. Press **OK** when finished entering patient information.

**NOTE:** The *Intego™ PET Infusion System* requires confirmation that the Patient Entry field has been reviewed, even if information was not entered. To proceed without entering information, press **EDIT**, then press **OK**.


5 - Patient Infusion

**Priming the PAS**

1. Install a PAS, if not already installed.
2. Hold the Removable Prime Tube on the PAS vertically so that the filter (white tip) is pointed upward.
3. Press the **PRIME** button.

**NOTE:** The *Intego™ PET Infusion System* will prevent priming with less than three minutes remaining on the battery meter.

4. When priming is complete, the *Intego™ PET Infusion System* will beep. Confirm that fluid is in the Removable Prime Tube and visually inspect the PAS for air.

⚠️ **WARNING:** Air embolism hazard. Injury or death can result from infusing air. Ensure air is expelled from the disposable sets before beginning infusion.

**NOTE:** If air is present within the tubing set after PAS priming is complete, evaluate the risk to the patient and reprime as needed by pressing the **PRIME** button. Repriming the PAS may overflow the Removable Prime Tube. Before repriming the PAS, remove the Removable Prime Tube and place the end of the PAS in an appropriate container for the excess fluid. If such a reservoir is not available, replace the PAS with a new one. A dialog box is displayed stating that PAS priming is already complete and asks whether the clinician wishes to prime again. Press the **YES** button.

5. Remove the Removable Prime Tube from the end of the PAS and discard.
6. Connect the PAS to the patient.

⚠️ **CAUTION:** Only catheters 24 gauge and larger, or steel needles 23 gauge or larger, should be used with the *Intego™ PET Infusion System*. The system performance may not be achievable if smaller gauge catheters or needles are used.

⚠️ **CAUTION:** Only use the *Intego™ PET Infusion System* PAS to connect to the patient catheter or needle. The system performance may not be achievable if tubing extension sets, additional tubing, or tubing other than an *Intego™ PET Infusion System* PAS is used.
Medrad™ Intego™ PET Infusion System

WARNING: Biological contamination can result from reusing the PAS or failure to follow sterile technique. DO NOT reuse or attempt to resterilize. Properly discard disposable items after use. If there is any possibility that contamination may have occurred during set-up or use, disassemble and set-up a new sterile product.

WARNING: Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components using aseptic techniques.

WARNING: Radiation exposure hazard. Higher residual radiation may occur when using an extension tube or additional tubing between the catheter and the PAS. The flush volume needs to be increased to account for additional tubing.

WARNING: Injury to patient may occur if system is moved without disconnecting the PAS from the patient. Disconnect the PAS from the patient prior to moving the Intego™ PET Infusion System.

Selecting the Flow Rate

1. The FLOW RATE button displays the currently configured flow rate. If this flow rate is not the desired flow rate, press the button and select the desired flow rate from the displayed list.

2. The selected flow rate will be displayed.
Performing a Saline Test Inject

**NOTE:** The TestInject is optional.

**NOTE:** The Intego™ PET Infusion System will prevent a Saline Test Inject with less than three minutes remaining on the battery meter.

1. On the Dosing screen, press the TEST INJECT button.

2. The Intego™ PET Infusion System displays a message asking the user to confirm that a check for air has been completed. Inspect the PAS Tubing for air.
   a. If the PAS contains air, press NO. Disconnect the PAS from the patient and return to the "Priming the PAS" section of the manual.
   b. If the PAS does not contain air, press YES. The Intego™ PET Infusion System will infuse the patient with a small, preset volume of saline. See "System Configuration."

**WARNING:** Patient Injury could result from not following standard extravasation minimizing techniques. To reduce the risks of extravasation conditions, follow all standard extravasation risk minimizing techniques.
Entering the Requested Dose Activity

The requested patient dose is displayed in the Requested Activity field. The requested patient dose may be entered by using a personalized dosing formula or manually.

**Personalized Dose Entry**
To select Personalized Dose Entry, press the dosing method button until it reads "Dosing: Personal." The requested patient dose is then established as follows:

1. The FORMULA button displays the currently selected formula. If this formula is not the desired formula, press the button and select the desired formula from the displayed list.

**NOTE:** See “System Configuration” to create formulas.

2. Press the Patient Weight field, enter the patient’s weight on the keypad, and then press ENTER.

3. The Intego™ PET Infusion System automatically calculates the requested patient dose using the entered weight and selected formula.

**Manual Dose Entry**
To select Manual Dose Entry, press the dosing method button until it reads “Dosing: Manual.” The requested patient dose is established via one of the following:

a. Default Dose: When there are no scheduled RP infusions, the requested patient dose is automatically set to the default value when initiating dosing for a new patient or when the RESET button is pressed.

b. Scheduled Dose: If there are scheduled RP infusions, the requested patient dose is automatically set to the current scheduled patient dose when initiating dosing for that patient or when the RESET button is pressed.

c. Direct Entry: Direct entry may be used to override either a default patient dose or a scheduled patient dose. Press the Requested Activity field and use the keypad to enter the activity value. The Intego™ PET Infusion System will only accept a value within the displayed Valid Range (the range of patient doses the system is capable of delivering at the time).
Requested Activity and the Activity Bar

Once the requested patient dose is established, it is displayed graphically on the Activity Bar below the Requested Activity field. The Activity Bar shows the requested patient dose, valid dosing range, and personalized dosing limits defined by the user selected formula within the total patient dosing range of the Intego™ PET Infusion System.

NOTE: The filled color portion covers the valid range of doses the Intego™ PET Infusion System can deliver under current conditions.

NOTE: The white dashed lines and pointers mark the upper and lower dosing limits imposed by the currently selected formula (only visible when using Personalized Dose Entry).
NOTE: If the requested dose activity is within the valid range, it is marked with a black line and pointer.

NOTE: If the requested dose activity is not within the valid range, it is marked with a yellow line and pointer. The valid range is also displayed within the Requested Activity field under the requested dose activity value.

Preparing an RP Dose

NOTE: When operating on battery power, the Intego™ PET Infusion System will prevent Preparing an RP Dose with less than three minutes remaining on the battery meter.

1. Press the PREPARE button to prepare the dose of RP to be infused.
2. If a test injection was not already performed, the Intego™ PET Infusion System displays a message asking the user to confirm that the PAS has been inspected for air (see the "Performing Saline Test Inject" section). Inspect the PAS Tubing for air:
   a. If the PAS contains air, press NO, disconnect the PAS from the patient, and return to the "Priming the PAS" section of the manual.
   b. If the PAS does not contain air, press YES. The Intego™ PET Infusion System will prepare the requested dose.

NOTE: Once a patient dose is prepared, the Requested Activity field displays the patient dose’s actual activity as measured by the Dose Calibrator. The Activity Bar changes to show the percent deviation of the measured dose with respect to the requested dose on a scale of +/- 10%. If the measured dose is beyond +/- 10% of the requested dose, the Intego™ PET Infusion System notifies the user by displaying the triangle at the end of the Activity Bar as color-filled. The Requested Activity field and Activity Bar continuously update as the prepared dose decays.

WARNING: Radiation exposure hazard. ¹⁸F-FDG or ¹⁸F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.
Infusing or Discarding the Dose

After the dose is prepared, the user may infuse the patient with the dose or discard the dose to the Waste Container.

**Start and Monitor Infusion**

**NOTE:** When operating on battery power, the *Intego™ PET Infusion System* will prevent Infusing or Discarding the Dose with less than three minutes remaining on the battery meter.

1. To infuse the dose, press the **INFUSE** button. To discard the dose, press the **DISCARD** button.

2. While infusing or discarding the dose, the *Intego™ PET Infusion System* displays a graph showing the percentage of the prepared dose activity remaining in the Dose Calibrator over the infusion or discard. The graph indicates whether activity is moving as expected or if there is a possible occlusion restricting the activity being delivered to the patient or Waste Container.
**NOTE:** The Intego™ PET Infusion System may detect an occluded line to the patient during an infusion. Appendix C, PAS Recovery, provides instructions for handling occlusions detected during an infusion.

**WARNING:** In case of occlusion, do not disconnect disposables before discarding dose, as liquid leakage can occur.

**Infusion Completion**

After an infusion completes, the Intego™ PET Infusion System displays a summary screen that shows the amount of RP delivered (both volume and activity), total fluid volume delivered, and any patient information provided.

1. Press the PRINT button to print this summary.
2. Press the OK button to update the infusion history and close the summary window.

**NOTE:** The Intego™ PET Infusion System should not be put in Standby before pressing the OK button.

**NOTE:** The printed label does not have all the information included on the Display.

**NOTE:** After the infusion completes, disconnect the PAS from the patient and Intego™ PET Infusion System. Although PAS residuals are negligible for infusions without occlusions, the PAS should be disposed of using the facility procedure for disposal of radioactive material.

**NOTE:** After pressing the OK button, the main Dosing screen appears.
NOTE: The Schedule Monitor will replace the last RP infusion schedule information with the actual infusion results and marked with a Complete Infusion Delivered icon to indicate a completed infusion.

NOTE: The Schedule Monitor on the left side of the screen will have moved its highlight to the next RP infusion in the Multi-Dose Vial schedule.

NOTE: On the right side, only the patient information panel is visible. To start the next patient, install a PAS, then proceed with "Entering Patient Information."

**Discard Completion**

After a discard completes, the Intego™ PET Infusion System displays a summary screen that shows the RP activity delivered, RP activity discarded, and any patient information provided.

1. To retry infusing the same patient, press the **RETRY** button. The main Dosing screen appears with the patient information panel visible on the right side. To start dosing the patient, install a PAS, then proceed with entering the patient information (all information will be pre-populated with previously entered patient information).

2. If the patient must be rescheduled or removed from the Multi-Dose Vial schedule, press the **RESCHEDULE** button. The Schedule screen appears, from which the scheduled infusion time can be changed or the RP infusion can be deleted.
   a. To delete a scheduled infusion, press the **X** button.
   b. To edit a scheduled RP infusion, press the Time field or Activity field and enter the new value.
3. To start the next patient, install a PAS, go to the Dosing screen, and proceed with "Entering Patient Information."

Monitoring the Vial

The Intego™ PET Infusion System continuously analyzes if the activity and volume of the currently loaded Multi-Dose Vial is sufficient to meet the dosing requirements of the Multi-Dose Vial schedule. When the Multi-Dose Vial schedule cannot be satisfied with the Multi-Dose Vial, the system alerts the user as follows:

1. On the Dosing screen: By displaying an Attention icon and message in the Status Bar, by displaying an Attention icon at the top of the Schedule Monitor, and by highlighting the unachievable RP infusions in yellow.
2. On the Schedule screen: By displaying an Attention icon and message in the Status Bar, by highlighting the unachievable RP infusions in yellow, and by displaying the valid dose range under the planned dose for the first unachievable RP infusions in the schedule.

While the Multi-Dose Vial is intended to meet the original Multi-Dose Vial schedule, there are several reasons a schedule may become unachievable:

- Scheduled infusions were delayed.
- More activity is used per RP infusion than originally planned.
- Unplanned RP infusions are added during the day.

Users may temporarily enter schedule changes under consideration to determine if sufficient RP activity is in the Multi-Dose Vial to support the new plan. Users should only commit to schedule changes if the Vial Monitor does not raise an alert. If changes that create an unachievable schedule cannot be avoided, the Vial Monitoring early warning alerts seek to provide information and time for the clinician to plan for the potential Multi-Dose Vial activity shortfall.
6 - Vial Shield and SAS Removal

Both the SAS and the Multi-Dose Vial may contain radiation even after the end-of-the-use period. If possible, allow the used SAS and Multi-Dose Vial to decay to background levels (at least 10 half-lives) before removing. If removal of the used SAS is required before decay to background has been achieved, take radiation precautions per facility radiation safety procedures.

**NOTE:** The Multi-Dose Vial and used SAS may be left within the Shielded Chamber until the radiation level has decayed sufficiently for safe removal.

**WARNING:** Radiation exposure hazard. 18F-FDG or 18F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

**WARNING:** Puncture hazard. The SAS contains needles. To prevent injury, take care when handling the SAS to control the needles. Dispose of the needles per individual facility guidelines.

**WARNING:** Radiation exposure hazard. The Intego™ PET Infusion System may contain radioactive materials. Do not reach under cart while the system contains activity. Do not remove access panels while the system contains activity.

**WARNING:** Severe operator injury can occur if care is not taken when opening or closing the lids over the Shielded Chamber or the Patient Administration Set compartment. Be certain that all fingers are clear before opening or closing the Shielded Chamber Lid or the PAS Compartment Cover.

1. Remove the Saline Tube from the Saline Pump and disconnect SAS from the Saline Container. The Saline Container and/or the Saline Tube may leak when disconnected. Take precautions to prevent spills.
2. Remove the Swabbable Valve and the Patient Tube from the Swabbable Valve Holder and Air Detector.
3. Open the PAS Compartment Cover. Release the Shielded Chamber Lid Latch and slide the Shielded Chamber Lid towards the front of the cart far enough to expose the two Pinch Valves.
4. Remove the Waste Tube from the Waste Pinch Valve and the Patient Tube from the PAS Pinch Valve. Press the button on top of the Pinch Valve and pull the SAS out.
5. Completely open the Shielded Chamber Lid and remove the RP Tube from the RP Pump.
6. To remove the SAS Needles from the Multi-Dose Vial, grasp the Needle Insertion Device’s handle, lift straight up until it stops, then rotate counter-clockwise until it stops. Release the handle and the Needle Insertion Device will remain in position.
7. Using the Vial Shield Carrying Handle, insert and attach the Vial Shield Access Cap by pushing down and rotating clockwise. Ensure that the Access Cap is fully engaged with the Vial Shield. Do not remove the Vial Shield at this time.
8. Lift the hinged Needle Insertion Device cover to access the Needle Cartridge holder. Remove the Needle Cartridge from the Needle Insertion Device.
WARNING. Puncture hazard. Do not attempt to recap needles.

9. Remove the SAS Coil from the Dose Calibrator.
10. Using tongs, lift the Waste Container from the Waste Storage and remove the SAS from the Shielded Chamber.
11. Discard the SAS in a designated hot waste disposal container per facility guidelines.
12. Using the Carrying Handle, remove the capped Vial Shield from the Shielded Chamber and return it to the hot lab or radiopharmacy.
7 - Training Mode

WARNING: Radiation exposure hazard. DO NOT install RP into the Intego™ PET Infusion System while in Training Mode. If the system detects radiation in the Dose Calibrator while operating in Training Mode, it will indicate an error and operation will stop.

WARNING: Explosion hazard. DO NOT use the Intego™ PET Infusion System when flammable gases are present. Patient injury could result from using the system in the presence of flammable gases (such as anesthetics).

WARNING: While in Training Mode, the Intego™ PET Infusion System should only be used for training purposes. Do not use the system to infuse fluid into a patient.

NOTE: The Intego™ PET Infusion System will simulate normal functionality in Training Mode. The user can perform all of the tasks detailed in the "Daily Setup and Patient Infusion" section of this manual. Saline or other non-radioactive fluid must be substituted for an RP to simulate an infusion.

NOTE: The Intego™ PET Infusion System cannot perform the Daily QC Constancy and Accuracy Test, Dose Calibrator Check, Linearity check, or Dose Calibrator Calibration while in Training Mode. MEDRAD recommends that the user performs these tasks prior to using the system in Training Mode.

NOTE: In Training Mode, the pinch valve calibration is simulated and not stored when the system is powered Off.

NOTE: The Intego™ PET Infusion System cannot simulate occlusions in Training Mode.

1. Power on the Intego™ PET Infusion System.
2. The Introduction screen appears. Press the **TRAINING** button.

**NOTE:** The screen displays the current mode in the lower right corner of the Introduction screen.

3. If the *Intego™ PET Infusion System* was in Clinical Mode, the system will display the message “Changing from Clinical Mode to Training Mode requires a restart. Continue?” Press **OK** to proceed.
4. The *Intego™ PET Infusion System* will display a progress bar while switching to Training Mode. When complete, the system will display a message prompting the user to restart. Press the **RESTART** button to Restart the system.

5. At the Introduction screen, press the **TRAINING** button.

**NOTE:** When the *Intego™ PET Infusion System* is in Training Mode, the Title Bar is colored red and the word “Training” is displayed.

6. At the conclusion of the training exercise, return the *Intego™ PET Infusion System* to Clinical Mode (See "Daily Setup"). Remove and discard the used disposable sets per site guidelines.
Appendix A - Cleaning and Maintenance

WARNING: Shock hazard. Patient or operator injury could result from worn cabling or unit disassembly. To avoid exposure to potentially hazardous voltages, DO NOT disassemble the Intego™ PET Infusion System in any way. Worn cabling also creates hazards. If any worn or damaged cables are detected, DO NOT use the system. Contact MEDRAD for service or replacement.

WARNING: Severe operator injury can occur if care is not taken when opening or closing the lids over the Shielded Chamber or the Patient Administration Set compartment. Be certain that all fingers are clear before opening or closing the Shielded Chamber Lid or the PAS Compartment Cover.

WARNING: Radiation exposure hazard. The Intego™ PET Infusion System may contain radioactive materials. Do not reach under cart while the system contains activity. Do not remove access panels while system contains activity.

WARNING: Radiation exposure hazard. Radiation activity exposure is increased once the Access Cap is removed. The user should avoid working directly over the open Vial Shield to minimize exposure.

WARNING: Radiation exposure hazard. Using the Shielded Chamber Lid as a work space may expose the operator to excess radiation. Do not use the Shielded Chamber Lid as a work space while there are radioactive materials present within the Intego™ PET Infusion System. Using the Shielded Chamber Lid as a work space or placing items on the Shielded Chamber Lid while it is open may damage the Shielded Chamber Lid, hampering its ability to provide an adequate radiation shield.

WARNING: Radiation exposure hazard. 18F-FDG or 18F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

WARNING: Puncture hazard. The SAS contains needles. To prevent injury, take care when handling the SAS to control the needles. Dispose of the needles per individual facility guidelines.

WARNING: Operator injury. Batteries are not user replaceable and must be replaced by MEDRAD personnel. Contact MEDRAD service.

CAUTION: Do not remove any covers or disassemble the Intego™ PET Infusion System. Periodically inspect for loose or frayed cables, loose covers, cracks, dents, or loose hardware. Contact MEDRAD for repairs.
Cleaning Guidelines

**CAUTION:** DO NOT use strong cleaning agents and solvents. Warm water and a mild soap solution are all that are required to clean the **Intego™ PET Infusion System**. Allow all components to dry thoroughly before using.

**CAUTION:** DO NOT soak or immerse any part of the **Intego™ PET Infusion System** or expose to excessive amounts of water or cleaning solutions while cleaning. Avoid allowing any fluids to leak inside system components. Improper or careless cleaning methods may result in equipment damage. Wipe components with a gauze pad dampened with a mild soap and water solution.

**NOTE:** Follow facility guidelines for the clean-up of spilled radioactive pharmaceuticals.

**NOTE:** For all body fluid spills, follow institutional decontamination procedures. If fluid has leaked inside any component of the **Intego™ PET Infusion System**, the affected subassembly should be disassembled and cleaned by MEDRAD personnel or returned to MEDRAD.

**Cleaning Guidelines**

Before beginning, disconnect the **Intego™ PET Infusion System** from AC power. If necessary, remove the SAS and the Multi-Dose Vial from the system by following the instructions outlined in the "Removing the Multi-dose Vial and SAS" section of the manual.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Cleaning Guidelines</th>
<th>Cleaning Tools</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interior of the Shielded Chamber.</td>
<td>Wipe clean and dry thoroughly.</td>
<td>A soft cloth or paper towel dampened with mild cleaning solution.</td>
</tr>
<tr>
<td>Exterior of the cart.</td>
<td>Wipe clean and dry thoroughly.</td>
<td>A soft cloth or paper towel dampened with cleaning solution or warm water.</td>
</tr>
<tr>
<td>Touch screen.</td>
<td>Wipe clean.</td>
<td>A soft, non-abrasive cloth or paper towel dampened with cleaning solution.</td>
</tr>
<tr>
<td>Vial Shield.</td>
<td>Wipe clean and dry thoroughly. Ensure the vial shield exterior is free from debris.</td>
<td>A soft cloth or paper towel dampened with cleaning solution or warm water.</td>
</tr>
<tr>
<td>Needle Insertion Guide.</td>
<td>Ensure that the needle insertion guide is free from debris.</td>
<td>A soft cloth or paper towel dampened with cleaning solution or warm water.</td>
</tr>
</tbody>
</table>
This section contains procedures for maintenance and operational checkout of the Intego™ PET Infusion System. Routine maintenance and inspection ensures continued performance of the system and reduces the possibility of equipment malfunction.

MEDRAD offers Preventive Maintenance programs in the United States, Canada, and Europe. These annual programs greatly assist in maintaining accuracy and reliability as well as extending the life of the system. Contact MEDRAD for details. In Europe, contact the local MEDRAD office or local authorized dealer for further information. Refer to the "Introduction" section of this manual for address, telephone, and fax information.

**WARNING:** Using the Intego™ PET Infusion System without performing the necessary QC processes could result in the patient receiving an incorrect dosage of the RP indicated for use. Be certain to perform all necessary QC checks at the recommended intervals.

**CAUTION:** Intego™ PET Infusion System malfunction may be caused by failure to perform regular maintenance. Regular preventive maintenance is recommended to ensure that the system functions properly. Refer to this manual or contact MEDRAD for additional information.

**NOTE:** Remove all radioactive fluids from the Intego™ PET Infusion System in preparation for a service call.

**NOTE:** Any problems detected during these or any other procedure should be corrected before using the Intego™ PET Infusion System in patient procedures.

**NOTE:** Local regulations or hospital protocol may require electrical leakage checks at more frequent intervals. If this applies, local regulations for leakage must be followed.

**NOTE:** Failures that occur due to lack of proper maintenance or abuse are not covered under warranty.

**NOTE:** MEDRAD Service makes on-site consulting or consulting references available upon request.

The Intego™ PET Infusion System must be properly maintained to ensure that it is meeting product requirements. The individual maintenance system and schedule depends upon how each system is used, the type of procedures performed, and the frequency of use. The following maintenance schedule is recommended for the system.

**Recommended Maintenance Schedule**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Guidelines</th>
</tr>
</thead>
</table>
| Daily     | 1. Perform the Daily QC procedure before the first use of the day. Refer to the "Daily Setup" section of this manual.  
2. (INT SYS 200) With the Intego™ PET Infusion System powered Off, check that the Forward/Reverse drive controller and drive engage switch are not broken or damaged and that they return to the rest position when pushed and released for both the forward and reverse directions. If there is a problem, contact MEDRAD.  
3. Thoroughly inspect the Intego™ PET Infusion System for any external damage, which could indicate damage to the radiation shielding. If severe damage is found, contact MEDRAD. |
### Medrad™ Intego™ PET Infusion System

<table>
<thead>
<tr>
<th>Weekly</th>
<th>(INT SYS 200) With the Intego™ PET Infusion System powered Off, put the Drive Controller to the full-speed forward position and power On the system. The system should not move. If the system moves, contact MEDRAD.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monthly</td>
<td>1. Inspect and clean the entire Intego™ PET Infusion System thoroughly, using the cleaning guidelines found earlier in this section. 2. Inspect the unit for any loose mechanical components and clean any fluid or debris from the SAS tray, bulk dose well, dose calibrator well, or waste container well. 3. Perform a complete operational checkout.</td>
</tr>
<tr>
<td>Quarterly</td>
<td>Perform the Dose Calibrator Linearity check. Refer to the &quot;Dose Calibrator Linearity Check&quot; section of this manual.</td>
</tr>
<tr>
<td>Annually</td>
<td>As part of an annual maintenance program performed by MEDRAD or an authorized dealer, MEDRAD recommends that the following checks and procedures be performed. 1. Perform the Electrical Leakage check. 2. Perform the Ground Continuity check. 3. Perform the Dose Calibrator Calibration check (Refer to the &quot;Dose Calibrator Calibration&quot; section of this manual). 4. Calibrate the Display. 5. Perform a complete system performance checkout. Contact MEDRAD for complete details.</td>
</tr>
<tr>
<td>As Needed</td>
<td>Perform Pinch Valve calibration. Refer to the &quot;Calibrating the Pinch Valves&quot; section of this manual.</td>
</tr>
</tbody>
</table>

### Dose Calibrator Linearity Check

To perform the Dose Calibrator Linearity check, follow these steps:

**NOTE:** The Dose Calibrator Linearity check is a required procedure to be performed during the quarterly maintenance schedule.

**NOTE:** Use $^{18}$F to perform the Dose Calibrator Linearity check. The activity should be higher than 925 MBq (25 mCi) to ensure the full range of programmable doses are checked.

**NOTE:** The Linearity check proceeds until the $^{18}$F activity decays to 3.7 MBq (100 μCi). If required, this limit can be configured by MEDRAD to be as low as 370 kBq (10 μCi).

**NOTE:** If the lower limit on the Linearity check is set to less than 3.7 MBq (100 μCi), the decay time will increase.
1. Press the **CONFIGURATION** button on the Navigation Bar to access the Configuration screen.

![Configuration Screen](image1.png)

2. The Configuration screen appears. Press the **MAINTENANCE** button and then press the Linearity tab.

![Linearity Tab](image2.png)
3. Press the **NEW MEASUREMENT** button to begin a new Linearity check.

![Configuration](image)

4. Enter the activity.

**NOTE:** The *Intego™ PET Infusion System* automatically measures the activity level. If the clinician enters a value for activity, that value will be retained for future reference and reporting.

   a. Press the Activity field.
   b. Using the keypad, enter the activity and reference time from the assay information. Press the **ENTER** button when complete.

![Configuration](image)

5. Using the Calibration Source Holder, place vial of $^{18}\text{F}$ into the Dose Calibrator and close the Shielded Chamber Lid.
6. Press the **BEGIN MEASUREMENT** button.

7. While the check is in progress, the *Intego™ PET Infusion System* provides a progress screen. To stop the Linearity check before it is complete, press the **ABORT** button.

**NOTE:** During the Linearity check, the system displays the measured activity every 10 minutes.
8. When the check is complete, the *Intego™ PET Infusion System* displays a summary screen (the screen shown is an example). Press the **PRINT** button for a hard copy of the results. Press the **DONE** button to exit.

9. To export the Linearity data, insert a USB memory device into the USB Port on the rear of the Display and then press the **EXPORT** button.

---

**Dose Calibrator Calibration**

> **WARNING:** Using the *Intego™ PET Infusion System* without performing the necessary QC processes could result in the patient receiving an incorrect dosage of the RP indicated for use. Be certain to perform all necessary QC checks at the recommended intervals.

**NOTE:** Dose Calibrator calibration requires $^{57}$Co and $^{137}$Cs sources.

**NOTE:** DO NOT use a rod calibration source to calibrate the system. Only a vial source should be used to calibrate the Dose Calibrator.
NOTE: MEDRAD recommends that the calibration source is greater than 3.7 MBq (100 μCi) with a 3% source uncertainty. If a 3% or better source is not available, contact MEDRAD.

1. Press the **CONFIGURATION** button on the Navigation Bar to access the Configuration screen.
2. The Configuration screen appears. Press the **MAINTENANCE** button and then press the Calibration tab.
3. Press the **BEGIN CALIBRATION** button.
4. The Intego™ PET Infusion System displays a dialog box prompting the clinician to insert the $^{57}$Co source into the Dose Calibrator. Using the Calibration Source Holder, insert the $^{57}$Co source into the Dose Calibrator and close the Shielded Chamber Lid.

5. Confirm the assay information listed for the first source is correct. If it is not, press the EDIT button to make changes. Once the information is correct, press the OK button.
6. The *Intego™ PET Infusion System* measures the source and displays a status window for the $^{57}$Co. Adjust the gain to achieve an error less than 1\% by clicking in the **GAIN** cell and entering the desired value using the keypad or by pressing the + and - buttons. The system will re-measure the source. Continue to adjust the gain until an acceptable (<1\%) error is achieved.

**NOTE:** MEDRAD recommends using the factory calibration gain located on the Dose Calibrator certificate as the initial gain value.

7. Remove the $^{57}$Co source.

8. Press the Cs-137 tab.

9. The *Intego™ PET Infusion System* then displays a dialog box prompting the user to insert the $^{137}$Cs source into the Dose Calibrator. Using the Calibration Source Holder, insert the $^{137}$Cs source into the Dose Calibrator. Confirm the assay information listed for the second source is correct. Press the **EDIT** button to make changes. Once the information is correct, press the **OK** button.
10. The Intego™ PET Infusion System measures the source and displays a status window for the $^{137}\text{Cs}$ source. Adjust the gain to achieve an error less than 1% by clicking in the GAIN field and entering the desired value using the keypad or by pressing the + and - buttons. The system will re-measure the source. Continue to adjust the gain until an acceptable (<1%) error is achieved.

**NOTE:** MEDRAD recommends using the factory calibration gain located on the Dose Calibrator certificate as the initial gain value.

11. If gain adjustments were made on either source, the user must re-measure both sources by performing the previous steps until no gain adjustments are needed to achieve errors of less than 1% for both sources.

12. Once no gain adjustments are needed on either source, press DONE to complete and exit the calibration.

**Geometry Check**

Acceptable geometry testing was demonstrated for the Intego Dose Calibrator in accordance with IEC61145: Calibration and Usage of Dose Chamber Systems for Assay of Radionuclides, and NRC Information Notice No. 93-10: Dose Calibrator Quality Control, Section 4.

The test report indicates that the licensee need not repeat geometry testing due to the following:

- The intended use of the Intego Dose Calibrator is for a single isotope: $^{18}\text{F}$.
- The location of the isotope in the Dose Calibrator is fixed based on the design of the Intego SAS.
Calibrating the Pinch Valves

1. Press the **CONFIGURATION** button on the Navigation Bar to access the Configuration Screen.
2. Press the **MAINTENANCE** button and then press the Calibration tab.
3. Press the **VALVE CALIBRATION** button.

4. The system displays a message prompting the user to remove all tubing from the Pinch Valves. Ensure that the tubing has been removed and Press **OK**.
5. When the calibration procedure is complete the system will display a message that calibration is complete. Press **OK**.

Replacing the Printer Paper

1. Depress the two locking catches on the sides of the printer (one on either side) and pull the printer cover away from the cart. The cover pivots forward and downward. Spread the two arms holding the roll of paper and remove the spent roll.

2. Place the new roll onto the arms so that the loose end of the paper rolls from underneath.
3. Insert the loose end of the roll into the paper guide.

4. Close the printer cover by pressing the release catch while lifting the printer cover back into place. The buttons on either side of the printer cover should both snap back into place.

Battery Maintenance and System Storage

For optimal battery life, keep the Intego™ PET Infusion System batteries fully charged by plugging the system into AC power whenever possible. This would include the following:

- Plug the system into AC power overnight.

The following apply only to INT SYS 200 systems.

- Plug the system into AC power immediately after it is driven every time.
- Plug the system into AC power immediately if the Drive System Status (Blue) Status Indicator begins flashing.
- Only drive the cart if the Drive System Status Indicator (Blue) is illuminated continuously.

NOTE: If the Intego™ PET Infusion System will not be used and cannot be powered for more than 1 week, the user should contact MEDRAD to prepare the system for storage.
Disposal of Equipment

When the Intego™ PET Infusion System is at the end of its usable life cycle, certain precautions should be taken prior to the removal of the system.

- Ensure that all calibration sources have been removed and properly stored.
- Interior and exterior wipe tests and area surveys should be performed, using the appropriate radiation detectors to determine any possible contamination of radioactive materials.
- The Dose Calibrator should be removed from the system and disposed of per manufacturer’s instructions.
- Lead is used as the primary shielding material for the Intego™ PET Infusion System. Lead is a hazardous waste regulated by the U.S. Environmental Protection Agency (EPA) and cannot be discarded in the regular trash or with the radioactive waste. Disposal should be made in accordance with federal, state, and local regulations. MEDRAD recommends end of life units be sent to reputable firms for electronic recycling in lieu of disposal.
- For equipment disposal information in accordance with European WEEE directives, please visit http://www.medrad.com/en-us/resources/Pages/WEEE.aspx.
- Remember to wear gloves when handling potentially contaminated items and wash hands thoroughly after handling lead items.
- Contact facility manager for instructions on proper removal or recycling of lead items and batteries.
Appendix B - Specifications

Mechanical

INT SYS 200
INT SYS 100

Nominal Value | Notes
--- | ---
Weight, INT SYS 200 | 355 kg (783 lb) ---
Weight, INT SYS 100 | 331 kg (730 lb) ---
Weight, Vial Shield | 8 kg (18 lb) ---
Vial Shield Radiation Profile

Exposure Rate at the surface with 27.75 GBq (750 mCi) in 30 ml saline in the vial.

Radiation Exposure Reduction Specification & Testing Results

NRC Code of Federal Regulations for Public Exposure: Do not exceed 0.02 mSv (2 mrem) in any one hour period.

Measured Exposure:

- Peak rate equal to or less than 0.014 mSv/hr (1.4 mRem/hr) at 30.5 cm (12 in) from any surface of the cart with 27.75 GBq (750 mCi) in the vial.
- Peak rate less than 0.001 mSv/hr (0.1 mRem/hr) at 30.5 cm (12 in) from the surface in the Operator Position with 27.75 GBq (750 mCi) in the vial.

Operator Exposure:

<table>
<thead>
<tr>
<th>Intego™ Radiation Exposure Reduction*</th>
<th>Product Specification &amp; Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Specification</td>
<td>Verification Testing Results</td>
</tr>
<tr>
<td>Body</td>
<td>% Exposure Reduction</td>
</tr>
<tr>
<td>Finger</td>
<td>0%</td>
</tr>
<tr>
<td></td>
<td>-20%</td>
</tr>
<tr>
<td></td>
<td>-40%</td>
</tr>
<tr>
<td></td>
<td>-60%</td>
</tr>
<tr>
<td></td>
<td>-80%</td>
</tr>
<tr>
<td></td>
<td>-100%</td>
</tr>
</tbody>
</table>

* Source MEDRAD® V&V data
### Environmental

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Non-Operating Conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature, maximum ambient</td>
<td>60º C (140º F)</td>
<td></td>
</tr>
<tr>
<td>Temperature, minimum ambient</td>
<td>-20º C (-4º F)</td>
<td></td>
</tr>
<tr>
<td>Humidity, maximum</td>
<td>100% R.H.</td>
<td>Non-condensing</td>
</tr>
<tr>
<td>Humidity, minimum</td>
<td>5% R.H.</td>
<td>Non-condensing</td>
</tr>
<tr>
<td>Pressure, maximum barometric</td>
<td>48 kPa (7 psi)</td>
<td></td>
</tr>
<tr>
<td>Pressure, minimum barometric</td>
<td>110 kPa (16 psi)</td>
<td></td>
</tr>
<tr>
<td>Vial Shield Temperature, maximum ambient</td>
<td>70º C (158º F)</td>
<td></td>
</tr>
<tr>
<td>Vial Shield Temperature, minimum ambient</td>
<td>-40º C (-40º F)</td>
<td></td>
</tr>
<tr>
<td><strong>Operating Conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temperature, maximum ambient</td>
<td>40º C (104º F)</td>
<td></td>
</tr>
<tr>
<td>Temperature, minimum ambient</td>
<td>10º C (50º F)</td>
<td></td>
</tr>
<tr>
<td>Humidity, maximum</td>
<td>90% R.H.</td>
<td></td>
</tr>
<tr>
<td>Humidity, minimum</td>
<td>20% R.H.</td>
<td></td>
</tr>
<tr>
<td>Pressure, maximum barometric</td>
<td>69 kPa (10 psi)</td>
<td></td>
</tr>
<tr>
<td>Pressure, minimum barometric</td>
<td>110 kPa (16 psi)</td>
<td></td>
</tr>
</tbody>
</table>

### Electrical

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mains Power Connection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mains supply voltage, maximum</td>
<td>240 VAC</td>
<td></td>
</tr>
<tr>
<td>Mains supply voltage, minimum</td>
<td>100 VAC</td>
<td></td>
</tr>
<tr>
<td>Mains supply frequency, maximum</td>
<td>60 Hz</td>
<td></td>
</tr>
<tr>
<td>Mains supply frequency, minimum</td>
<td>50 Hz</td>
<td></td>
</tr>
<tr>
<td>Power consumption, maximum, INT SYS 200</td>
<td>300 VA</td>
<td></td>
</tr>
<tr>
<td>Power consumption, maximum, INT SYS 100</td>
<td>250 VA</td>
<td></td>
</tr>
</tbody>
</table>

**Safety**

- Electrical leakage current, earth and chassis: < 100 µA  
  See note below.
- Electrical leakage current, patient connection: < 10 µA  
  See note below.
Appendix B - Specifications

Protection Against the Ingress of Fluids

Per IEC 60529, the Intego™ PET Infusion System has been classified as drip proof. This is indicated by the IPX1 designation.

Mode of Operation

Per EN60601-1, the mode of operation for the Intego™ PET Infusion System is continuous operation. The system is capable of operation under normal load for an unlimited period, without excessive temperature being developed.

Fluid Delivery

<table>
<thead>
<tr>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RP Vial</strong></td>
<td></td>
</tr>
<tr>
<td>Maximum vial activity for shielding effectiveness</td>
<td>27.8 GBq (750 mCi) ---</td>
</tr>
<tr>
<td>Maximum vial activity for dose preparation</td>
<td>25.9 GBq (700 mCi) System will not move fluid if vial activity exceeds this level.</td>
</tr>
<tr>
<td>Maximum RP vial volume</td>
<td>30 ml 30H vial. See note below.</td>
</tr>
<tr>
<td>Unextractable RP volume</td>
<td>0.64 ml 30H vial</td>
</tr>
<tr>
<td>Patient doses/vial</td>
<td>11 Based on 25.9 GBq (700 mCi) in vial, 555 MBq (15 mCi) patient doses and 30 minute interval between doses.</td>
</tr>
</tbody>
</table>

NOTE: A wide variety of vials from 10 ml to 30 ml are compatible with the system, with use of one of six different Vial Shields. See the "Appendix D - Vials and Vial Shields."

Concentration

<table>
<thead>
<tr>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum RP concentration</td>
<td>3.7 GBq/ml (100 mCi/ml) ---</td>
</tr>
<tr>
<td>Minimum RP concentration</td>
<td>12.3 MBq/ml (0.33 mCi/ml) ---</td>
</tr>
</tbody>
</table>
Nominal Value | Notes
--- | ---
**Dose Activity**
Maximum dose activity | 925 MBq (25 mCi) | Maximum Dose Activity is reduced for RP concentrations ≤ 308 MBq/ml (8.3 mCi/ml). See Concentration-Based Dose limits graph.
Minimum dose activity | 37 MBq (1 mCi) | Minimum Dose Activity is increased for RP concentrations ≥ 296 MBq/ml (8 mCi/ml). See Concentration-Based Dose limits graph.
Dose activity accuracy | ± 2% | Exclusive of Dose Calibrator calibration factor. See note below.
Half-life (^{18}F) | 109.74 min. | Value used for all decay calculations.

**Dose Volume**
Maximum RP dose volume | 3.0 ml | ---
Minimum RP dose volume | 0.125 ml | ---
Minimum dose fluid volume | 35 ml | Includes RP and saline flush. Additional Flush volume is added to this value. See note below.

**Test Injection**
Minimum saline volume | 5 ml | ---
Maximum saline volume | 30 ml | ---

**Additional Flush**
Minimum saline volume | 0 ml | ---
Maximum saline volume | 30 ml | ---
Appendix B - Specifications

Electromagnetic Compatibility (EMC)

US: The Intego™ PET Infusion System, although exempt per 47CFR15.103(c)(e), has been verified to conform to the requirements of 47CFR15 as a Class B digital device.

EU: The Intego™ PET Infusion System has been verified to conform to the requirements of the Medical Device Directive (93/42/EEC).

Mobility of INT SYS 200

Fluid to Patient

<table>
<thead>
<tr>
<th>Flow rate</th>
<th>0.5 ml/s</th>
<th>See note below.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow rate</td>
<td>1.0 ml/s</td>
<td>See note below.</td>
</tr>
</tbody>
</table>

**NOTE:** Dose activity and fluid delivery accuracies are only guaranteed if MEDRAD Intego™ PET Infusion System disposables are used and if the patient connection contains no restriction smaller than a 24 gauge, or larger, catheter, or 23 gauge or larger steel needle. Use of smaller catheters or needles will affect flow rate and delivered volume and may affect delivered dose activity.

Nominal Value Notes

<table>
<thead>
<tr>
<th>PAS</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extended length</td>
<td>155 cm (60 in) Approximate length.</td>
</tr>
<tr>
<td>Shelf life</td>
<td>5 years ---</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SAS</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste Container volume</td>
<td>375 ml or 100 mCi ---</td>
</tr>
<tr>
<td>Shelf life</td>
<td>3 years ---</td>
</tr>
</tbody>
</table>

Electromagnetic Compatibility (EMC)

US: The Intego™ PET Infusion System, although exempt per 47CFR15.103(c)(e), has been verified to conform to the requirements of 47CFR15 as a Class B digital device.

EU: The Intego™ PET Infusion System has been verified to conform to the requirements of the Medical Device Directive (93/42/EEC).

Mobility of INT SYS 200

<table>
<thead>
<tr>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Speed, maximum forward, high range</td>
<td>0.67 m/s (2.2 ft/s) ---</td>
</tr>
<tr>
<td>Speed, maximum forward, low range</td>
<td>0.4 m/s (1.3 ft/s) ---</td>
</tr>
<tr>
<td>Speed, maximum reverse</td>
<td>0.4 m/s (1.3 ft/s) ---</td>
</tr>
<tr>
<td>Recharging time</td>
<td>8 h See note below.</td>
</tr>
<tr>
<td>Braking</td>
<td>Automatic electric</td>
</tr>
<tr>
<td></td>
<td>Brakes are applied by the mobility controller when the driver controls are released.</td>
</tr>
<tr>
<td>Manual Override</td>
<td>--- Emergency use only. Pulling the handle releases the drives, allowing the system to be moved manually.</td>
</tr>
<tr>
<td>Caster Brakes</td>
<td>Manual User-applied to maintain position.</td>
</tr>
</tbody>
</table>
NOTE: Mobility battery recharge time is approximately 3x the discharge time. Users are advised to connect the Intego™ PET Infusion System to mains power whenever it is not moving.

### Mobility of INT SYS 100

<table>
<thead>
<tr>
<th>Braking</th>
<th>Nominal Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Braking</td>
<td>Manual hydraulic</td>
<td>Releasing brake handles applies brakes.</td>
</tr>
<tr>
<td>Caster Brakes</td>
<td>Manual</td>
<td>User-applied to maintain position.</td>
</tr>
</tbody>
</table>
Recovering from Priming Issues

If an error occurs during or after priming, the following should be checked for proper installation.

**WARNING:** Radiation exposure hazard. 18F-FDG or 18F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

**CAUTION:** Incorrect installation of the SAS may result in improper functioning of the Intego™ PET Infusion System.

- Ensure the Saline Container is sufficiently spiked.
- Confirm the tubing is placed correctly in the Saline Pump.
- Confirm the tubing is oriented on the Saline Pump rollers properly.
- Ensure the tubing is not pinched in the Saline Pump door.
- Ensure the Saline Disconnect Luer is against the Saline Pump.
- Confirm that the Needle Cartridge Clip is inserted with proper orientation into the Needle Insertion Device.
- Confirm the collar on the tubing is positioned properly in the RP Pump.
- Confirm the tubing is inserted into the Pinch Valves correctly.
- Confirm the tubing is fully inserted into the Air Detector.
- Confirm the RP Pump is closed and the tubing is in the pump.
- Confirm that all tubing is laying flat and not being pinched by the lid.

Recovering from Activation of Air Detector

**During Priming**

1. Confirm that the SAS is properly inserted into the Air Detector. If necessary, slide the Shielded Chamber Lid open to expose the Air Detector and properly insert the SAS.

   **WARNING:** Radiation exposure hazard. 18F-FDG or 18F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

2. Re-prime the system.

3. The Display displays a message stating that the SAS has already been primed. Press the YES button to continue.

**During a Saline Test Inject**

1. Confirm that the SAS is properly inserted into the Air Detector. If necessary, slide the Shielded Chamber Lid open to expose the Air Detector and properly insert the SAS.
WARNING: Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

2. Check the PAS for air, including the connection points with the patient catheter and the SAS.
3. If an air pocket is detected, disconnect the PAS from the patient catheter and prime the tubing set again.
4. Reconnect the PAS to the patient catheter and initiate the saline test infusion.

During an Infusion
1. Confirm that the SAS is properly inserted into the Air Detector. If necessary, slide the lid to the Shielded Chamber open only far enough to expose the Air Detector and properly insert the SAS.

WARNING: Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

2. Check the PAS for air, including the connection points with the patient catheter and the SAS.
3. If an air pocket is detected disconnect the PAS from the patient catheter and discard.
4. Press the DISCARD button, which discards the current dose.
5. Attach a new PAS.
6. Prime the new PAS.
7. Resume normal operation.

Recovering a Dose Due to a System Failure

With a Dose of RP in the Dose Calibrator
1. Restart the system. If the error condition does not persist, proceed with the infusion as normal.
2. If the error condition persists after the restart, the dose in the Dose Calibrator can be infused manually.
   a. Open the Saline Pump and remove the tubing from the pump.
   b. Disconnect the Saline Container from the SAS at the Saline Disconnect Luer adjacent to the Saline Pump.
   c. Insert the Saline Container tubing set into the Saline Pump to prevent saline from leaking onto the floor.
   d. Open the Shielded Chamber Lid only far enough to expose the PAS Pinch Valve and remove the SAS from the Pinch Valve.

WARNING: Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.
Appendix C - Troubleshooting Tips

With RP in the Vial Shield
1. Restart the system. If the error condition does not persist, proceed with the infusion as normal.

2. If the error condition persists after the restart, the RP in the Vial Shield can be used for hand injection.

WARNING: Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

Hand Injection Method - Option 1
a. Make certain that the Vial Access Cap is ready to be reinstalled onto the Vial Shield.
b. Open the Shielded Chamber Lid.
c. Using the handle of the Needle Insertion Device, immediately pull the needles directly out of the Vial Shield. DO NOT raise the shield lid over the Needle Insertion Device.

WARNING: Puncture hazard. The SAS contains needles. To prevent injury, take care when handling the SAS to control the needles. Dispose of the needles per individual facility guidelines.
d. Rotate the Needle Insertion Device counter-clockwise and immediately insert the Vial Access Cap onto the Vial Shield using the handle.
e. Remove the Vial Shield from the Vial Shield Compartment using the Vial Shield handle.
f. Rotate the Needle Insertion Device clockwise and lower it into place. Close the Shielded Chamber Lid.
g. Return the Vial Shield containing the RP directly to the facility hot lab where individual patient doses can be prepared.

Hand Injection Method - Option 2
a. Remove the PAS from the SAS and discard in the appropriate receptacle.
b. Clean the Swabbable Valve on the exposed end of the SAS using proper sterile technique.
c. Attach a sterile 10 ml syringe in a syringe shield to the Swabbable Valve.
d. Open the Shielded Chamber Lid.

e. Close the Shielded Chamber Lid.
f. Connect a syringe filled with 40 ml of saline to the free end of the SAS.
g. Manually infuse the 40 ml of saline into the SAS using the syringe to push the RP dose through the system and into the patient.
h. After the infusion, disconnect the patient from the tubing set.
i. If necessary, remove the SAS and the Multi-Dose Vial from the Shielded Chamber following the instructions found in the "Remove the Multi-dose Vial and SAS" section.
j. Secure the Intego™ PET Infusion System and contact MEDRAD.
**WARNING:** Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

e. Clamp off the Saline Line directly before the confluence using a slide clamp. (Some examples of appropriate slide clamps are Qosina 12053 and Qosina 12044).

f. Remove the tubing from the RP Pump and close the RP Pump lid.

g. Remove the tubing from the PAS Pinch Valve.

h. Close the Shielded Chamber Lid.

i. Using the syringe, extract 7 ml from the SAS. Assay the syringe. It should have only very low activity. Discard the syringe according to site policy. If the measured activity exceeds 740 MBq (20 mCi), skip to step m.

**WARNING:** Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

j. Load an empty, sterile 10 ml syringe into a syringe shield. Wipe the Swabbable Valve, connect the shielded 10 ml syringe to the Swabbable Valve, and extract an additional 7 ml. Assay the syringe. If the measured activity exceeded 740 MBq (20 mCi), skip to step m. Otherwise, discard the syringe according to site policy.

k. Load an empty, sterile 10 ml syringe into a syringe shield. Wipe the Swabbable Valve, connect the shielded 10 ml syringe to the Swabbable Valve, and extract 0.5 ml. (If it is not possible to measure 0.5 ml accurately near the start of the syringe, preload 5 ml of saline or WFI into the syringe before attaching to the Swabbable Valve.) Assay the syringe. If the measured activity exceeded 740 MBq (20 mCi), skip to step m. Otherwise, discard the syringe according to site policy.

l. Repeat step k. up to 3 more times (for a total of 4 x 0.5 ml). If significant activity has not been measured in an assay, there is a problem with the SAS or with the needles in the Multi-Dose Vial. In this instance, revert to “Hand Injection Method - Option 1.”

m. Once significant activity has been detected, individual doses of RP can be extracted by hand. Attach a shielded, sterile syringe to the Swabbable Valve.
Appendix C - Troubleshooting Tips

n. Extract the desired volume of RP and remove the syringe. Assay the syringe in a separate Dose Calibrator before injection.

o. Clean the Swabbable Valve and repeat steps m and n as necessary.

PAS Occlusion Recovery

This section describes how to identify a potential occlusion and details the method to recover from an occluded PAS during an infusion.

1. At the end of the infusion, if more than 5% of the dose activity remains in the Dose Calibrator, the system will allow the user to resume the infusion or discard the dose. MEDRAD recommends that the user check the lines for occlusions (clamped tubing, kinked crushed tubing, or high-gauge needles or catheters, closed valves between the PAS and the patient) prior to resuming.

![Image of Partial Infusion screen]

**WARNING:** Radiation exposure hazard. $^{18}$F-FDG or $^{18}$F-NaF emit gamma radiation. Operator should exercise extreme caution when handling radiopharmaceuticals. Doses may exceed maximum permissible dose if appropriate precautions are not properly exercised. Follow all individual facility guidelines for the handling and disposal of radioactive materials. DO NOT open the Shielded Chamber without first taking radiation precautions per facility procedures.

**NOTE:** During PAS Occlusion Recovery, the system will allow the clinician to attempt to infuse the remaining RP a total of 4 times. If the activity remains in the Dose Calibrator following 4 attempts to infuse, the RP will be discarded.

**WARNING:** In case of occlusion, do not disconnect disposables before discarding dose, as liquid leakage can occur.
2. If the user selects the DISCARD option or if activity remains in the Dose Calibrator after all attempts to resume, the remaining activity will be discarded into the Waste Container. The status bar will display any messages relating to the infusion.

The interface will show the activity that was infused. The user is given the option to “Retry the Patient” or try “Next Patient.”

a. If the RETRY PATIENT button is selected, the system will calculate the requested activity based on the amount of activity that was previously infused. The calculated activity can be edited by pressing the Requested Activity field and entering the new activity number.

b. The NEXT PATIENT button will allow the user to select the next appointment on the schedule or if the schedule feature has not been used to enter in new patient information.

3. The history will update and an icon will appear, indicating a partial infusion.

4. If the occlusion remains after the user attempts to resume the infusion or discard the dose, the user should check for occlusions in the Saline Container or Saline Line.
WARNING: In case of occlusion, do not disconnect disposables before discarding dose, as liquid leakage can occur.

**System Messages**

The following is a list of messages the *Intego™ PET Infusion System* could display and possible corrections:

**Critical Error Messages**

**NOTE:** These Errors Require the System to be Restarted

<table>
<thead>
<tr>
<th>Code</th>
<th>Error Messages</th>
<th>Explanation</th>
</tr>
</thead>
</table>
| E1000  | The measured concentration does not match the expected value based on the <Selected RP> assay information. | • Confirm that the assay information was entered correctly. Re-enter if needed.  
• Confirm that the assay information provided by the pharmacist is correct. Re-enter if needed.  
• If the assay corrections do not correct the problem, replace the Multi-Dose Vial.  
• If problem persists, recalibrate the Dose Calibrator.  
• If the problem continues, record the error message and contact MEDRAD. |
| E1055  | Activity detected while in Training Mode.                                      | • Remove activity from the Dose Calibrator and restart the *Intego™ PET Infusion System* in Training Mode.  
• If the problem continues, record the error message and contact MEDRAD. |
| Any other E code | N/A |

**Recoverable Errors / Messages**

| Error Messages                                                                 | Explanation                                                                                                                                                                                                 |
| A dose cannot be prepared from this vial. Replace vial. | • No activity is available to extract.  
• Replace vial. |
| Activity concentration is less than the acceptable minimum. | • Concentration may have decayed below minimum. Verify assay information was entered correctly and re-prime.  
• Verify SAS is installed properly and re-prime.  
• Replace vial and re-prime. |
| Activity concentration too high. Check assay information. | • Confirm that the assay information was entered correctly. Re-enter if needed.  
• Confirm that the assay information provided by the pharmacist is correct. Re-enter if needed.  
• If the assay was entered correctly, wait until the concentration decays to 3.7 GBq/ml (100 mCi/ml). |
| Additional saline flush required. Press OK to flush to waste. | • A prior dose infusion was aborted or high residual activity remains from priming the SAS.  
• It should not be necessary to re-prime the SAS, but if problem persists, re-prime the SAS. Refer to the "If an Error Occurs During or After Priming" section in the "Troubleshooting" Appendix. |
| Air detected in SAS. Need to prime. | • Confirm that the SAS is correctly inserted into the Air Detector.  
• Reprime the SAS. Refer to the "If an Error Occurs During or After Priming" and the "Recovering from Activation of the Air Detector" sections in the "Troubleshooting" Appendix. |
<table>
<thead>
<tr>
<th>Error Message</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assay information incomplete. Enter all required data.</td>
<td>• Enter all required information. Source lot number, activity, and date/time are all required. Refer to &quot;Daily QC&quot; section in the Clinical Use chapter and &quot;Dose Calibrator Calibration&quot; section of this manual.</td>
</tr>
<tr>
<td>Calibration already in progress.</td>
<td>• Wait until the measurement of the source is complete before proceeding to the next step.</td>
</tr>
<tr>
<td>Check printer paper.</td>
<td>• Check printer and replace paper as needed. Refer to the &quot;Replacing the Printer Paper&quot; section of this manual.</td>
</tr>
<tr>
<td>Date/Time write failure. Please try again.</td>
<td>• Re-enter the date/time. Refer to the &quot;System Configuration&quot; section of the &quot;System Basics&quot; chapter.</td>
</tr>
<tr>
<td>Dose Calibrator is detecting high background activity. Check for nearby sources.</td>
<td>• Check for nearby sources. • Check for the calibration source in the Dose Calibrator. Remove if still present. • Check for nearby sources of radiation. If necessary, remove the other source(s) or move the cart. • Check for contamination in the room or in the system, including possible radiopharmaceutical leak from the SAS. Clean the system per site guidelines and replace the SAS.</td>
</tr>
<tr>
<td>Dose Calibrator serial number mismatch. Recalibration required.</td>
<td>• Recalibrate the Dose Calibrator. Refer to the &quot;Dose Calibrator Calibration&quot; section of this manual.</td>
</tr>
<tr>
<td>Dose cannot be infused. Discard and prepare new dose.</td>
<td>• Discard the current dose and prepare a new dose.</td>
</tr>
<tr>
<td>Error reading preferences, resetting system to defaults.</td>
<td>• Re-enter system preferences on Configuration screen.</td>
</tr>
<tr>
<td>Infuse or discard current dose before preparing another.</td>
<td>• A patient dose is already prepared. Either infuse or discard the current dose before attempting to prepare another dose or perform a test injection.</td>
</tr>
<tr>
<td>Invalid date/time entered.</td>
<td>• Re-enter the date/time. Refer to the &quot;System Configuration&quot; section of this manual.</td>
</tr>
<tr>
<td>Measured activity is higher than expected. Check assay information and prime again.</td>
<td>• Confirm that the assay information was entered correctly. Re-enter if needed. Refer to the &quot;Entering Multi-Dose Vial Assay Information&quot; section of the &quot;Daily Use&quot; chapter. • Confirm that the assay information provided by the pharmacist is correct. Re-enter if needed. Reprime.</td>
</tr>
<tr>
<td>Measured activity is low. Ensure vial and SAS are properly installed. Replace if necessary.</td>
<td>• Confirm that the assay information was entered correctly. Re-enter if needed. Refer to the &quot;Entering Multi-Dose Vial Assay Information&quot; section of the &quot;Daily Use&quot; chapter. • Confirm that the assay information provided by the pharmacist is correct. Re-enter if needed. • Ensure vial and SAS are properly installed. Refer to the &quot;If an Error Occurs During or After Priming&quot; section in the &quot;Troubleshooting&quot; Appendix.</td>
</tr>
<tr>
<td>Operation will exceed Waste Container capacity. Replace SAS.</td>
<td>• The Waste Container is full. Replace the SAS.</td>
</tr>
</tbody>
</table>
### Appendix C - Troubleshooting Tips

<table>
<thead>
<tr>
<th>Troubleshooting Tip</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Pinch Valve error: &lt;Valve Error Details&gt;** See Operation Manual. | - Confirm that the SAS is properly installed into the Pinch Valves. Refer to the "If an Error Occurs During or After Priming" section in the "Troubleshooting" Appendix.  
  - Valve Error Details will be one of the following phrases:  
    - waste valve failed.  
    - patient valve failed.  
    - both valves failed.  
    - both valves open simultaneously.  
    - tubing absent from waste valve.  
    - tubing absent from patient valve.  
    - tubing absent from both valves.  
    - patient valve failure, tubing absent from waste valve.  
    - waste valve failed, tubing absent from patient valve.  
  - If necessary, restart the system. If the message reappears, record the error message and contact MEDRAD. |
| **Prime PAS.** | - The PAS has not been primed and the operation cannot be completed. Prime the PAS before proceeding. |
| **Printer error occurred.** | - Press the **OK** button and the system should correct the issue.  
  - If the message reappears, restart the system.  
  - If the message persists, record the error message and contact MEDRAD. |
| **Residual activity is higher than the acceptable background level. See Operation Manual.** | - High residual activity remains from priming the SAS.  
  - Refer to the "If an Error Occurs During or After Priming" section in the "Troubleshooting" Appendix.  
  - Re-prime the SAS.  
  - If re-priming does not resolve the issue, check for contamination and replace the SAS. |
| **Saline is low. Please replace.** | - Replace the Saline Container. Refer to the "Daily Setup" section. |
| **Saline prime failed. Ensure SAS is properly installed. replace if necessary.** | - Confirm that the SAS is correctly installed. Refer to the "If an Error Occurs During or After Priming" section in the "Troubleshooting" Appendix.  
  - Replace the SAS if necessary. |
| **SAS detected. Press Cancel to use or remove SAS and press OK.** | - The system requires that the vial and SAS be removed before the Multi-Dose Vial assay information can be reset.  
  - The SAS should only be used with a single Multi-Dose Vial. Change the SAS each time a new Multi-Dose Vial is installed. Refer to the "Installing the Multi-Dose Vial and SAS" section of the "Daily Setup" chapter.  
  - Press **CANCEL** if the **REMOVE** button was pressed by mistake. |
| **&lt;Selected RP&gt; or saline information missing. Enter all required data.** | - Enter all required information. Multi-Dose Vial Lot Number, Assay (or Reference) Date and Time, Total Activity, RP Volume, and Saline Volume are all required. Refer to the "Entering Multi-Dose Vial Assay Information" and "Entering Saline Data" sections of the "Daily Setup" chapter. |
| **&lt;Selected RP&gt; prime failed. Check SAS and vial installation, then re-prime.** | - Confirm that the SAS is correctly installed. Refer to the "If an Error Occurs During or After Priming" section in the "Troubleshooting" Appendix.  
  - Replace the SAS if necessary. |
<table>
<thead>
<tr>
<th>Issue Description</th>
<th>Recommended Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source not detected.</td>
<td>During calibration, the source was not inserted into the Dose Calibrator. Insert the appropriate source to continue with calibration. Refer to the &quot;Dose Calibrator Calibration&quot; section of this manual.</td>
</tr>
<tr>
<td>The date and time must be set.</td>
<td>Set the date/time. Refer to the &quot;System Configuration&quot; section of the &quot;System Basics&quot; chapter.</td>
</tr>
<tr>
<td>The process has been interrupted and must be restarted.</td>
<td>The STOP button has been pressed. To resume operation, do one of the following: During SAS and PAS Priming • Start the priming sequence again by pressing the PRIME button. During Dose extraction • Press the DISCARD button and then press the PREPARE button to extract a new dose. During Test Injection • Press the RESUME button to resume the test injection, or • Press the STOP button to stop the test injection. During patient infusion • Press the RESUME button to resume the infusion, or • Press the DISCARD button to discard the dose.</td>
</tr>
<tr>
<td>Process paused.</td>
<td>During Test Injection • Press the RESUME button to resume the test injection, or • Press the STOP button to stop the test injection. During patient infusion • Press the RESUME button to resume the infusion, or • Press the DISCARD button to discard the dose.</td>
</tr>
<tr>
<td>The supplier activity is too high to perform the requested operation.</td>
<td>• Activity exceeds 25.9 GBq (700 mCi). • Confirm that the assay information was entered correctly. Re-enter if needed. • Confirm that the assay information provided by the pharmacist is correct. Re-enter if needed. • If the assay was entered correctly, wait until the activity decays to 25.9 GBq (700 mCi).</td>
</tr>
<tr>
<td>This action is not allowed in Training Mode.</td>
<td>• Dose Calibrator calibration and the Linearity check cannot be performed while the system is in Training Mode. Restart the system in Clinical Mode to perform a Dose Calibrator calibration or a Linearity check.</td>
</tr>
<tr>
<td>Unable to detect printer. Press OK to retry.</td>
<td>• Press the OK button and the system should correct the issue. • If the message reappears, restart the system. • If the message persists, record the error message and contact MEDRAD.</td>
</tr>
<tr>
<td>Vial activity exceeds safe shielding level. Immediately return vial to protective container.</td>
<td>• Activity exceeds 27.75 GBq (750 mCi), which is the maximum safe shielding level for the system. • The Vial Shield should be removed from the system until the total activity in the Multi-Dose Vial decays to 27.75 GBq (750 mCi).</td>
</tr>
<tr>
<td>Waste activity will exceed shielding limit. Replace SAS.</td>
<td>• Activity in the Waste Container exceeds 3.7 GBq (100 mCi). • Replace SAS before continuing operations.</td>
</tr>
<tr>
<td>Residual activity exceeds 2% of original dose. Press OK to flush to waste.</td>
<td>• High residual activity remains after infusion. • Refer to the &quot;PAS Recovery&quot; section in the &quot;Troubleshooting&quot; Appendix.</td>
</tr>
<tr>
<td>PAS Occlusion Detected. WARNING PAS is pressurized and may leak if disconnected.</td>
<td>• If the infusion is stopped prematurely, do not disconnect disposables before discarding dose, as liquid leakage can occur. • Reference Appendix C - Trouble Shooting Tips PAS Occlusion Recovery.</td>
</tr>
</tbody>
</table>
Appendix D - Vials and Vial Shields

NOTE: Radiation Shielding performance is achieved by using the vial shield designed by MEDRAD (or its equivalent).

WARNING: Patient injury may result from using vials with other than a 20 mm diameter cap. Use of vials having other than a 20 mm diameter cap may create a particulate hazard.

WARNING: No modification of this equipment is allowed.

WARNING: Biological contamination may occur if aseptic techniques are not followed. Follow facility guidelines to disinfect the vial shield.

WARNING: Radiation Exposure Hazard. The Intego™ PET Infusion System Vial Shields must be transported in a container that complies with applicable transportation regulations.

CAUTION: If using an absorbent disc, place no more than one disc in the vial shield before installing an RP vial. Additional absorbent discs may result in improper fit and potential damage to the vial.

CAUTION: If using an absorbent disc, do not expose the absorbent disc to cleaning solutions or other fluids. Discard and replace the absorbent disc if it has been exposed to any fluid. Failure to replace the absorbent disc that has been exposed to fluids may result in improper fit and potential damage to the vial.

CAUTION: If using an absorbent disc, discard and replace the absorbent disc after each use. Failure to replace the absorbent disc may result in improper fit and damage to the vial.

CAUTION: Do not place labels, tags, or other materials on the exterior of the vial shield surface. Application of labels, tags, or other materials may cause the vial shield to fit incorrectly in needle insertion device and result in improper fit and functioning of the system.

CAUTION: Ensure that the needle insertion guide is clean and free of debris. Debris may cause the vial shield to fit incorrectly in needle insertion device and result in improper fit and functioning of the system.
Table 1: Vial Shield and Vial Specifications - Summary

<table>
<thead>
<tr>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight (lb)</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003 Size Specification</th>
<th>Body Diameter (mm)</th>
<th>Glass Height (mm)</th>
<th>Cap Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3017469 3038383</td>
<td>Silver</td>
<td>8.6</td>
<td>30-35 ml</td>
<td>36 ± 0.5 mm (1.417 ± 0.020&quot;)</td>
<td>62.8 ± 0.7 mm (2.472 ± 0.027&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3025071 3038384</td>
<td>Blue</td>
<td>8.6</td>
<td>20-25 ml</td>
<td>30 ± 0.25 mm (1.181 ± 0.009&quot;)</td>
<td>55 ± 0.7 mm (2.165 ± 0.027&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3027139 3038385</td>
<td>Gold</td>
<td>8.6</td>
<td>20-25 ml</td>
<td>32 ± 0.45 mm (1.259 ± 0.017&quot;)</td>
<td>58 ± 0.6 mm (2.283 ± 0.023&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3025939 3038382</td>
<td>Green</td>
<td>8.6</td>
<td>10-15 ml</td>
<td>24 ± 0.2 mm (0.944 ± 0.007&quot;)</td>
<td>45 ± 0.5 mm (1.771 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3025940 3038386</td>
<td>Brown</td>
<td>8.6</td>
<td>10-15 ml</td>
<td>24 ± 0.25 mm (0.944 ± 0.009&quot;)</td>
<td>60 ± 0.5 mm (2.362 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3027305 3038387</td>
<td>Black</td>
<td>8.6</td>
<td>10-15 ml</td>
<td>25 ± 0.25 mm (0.984 ± 0.009&quot;)</td>
<td>53.5 ± 0.5 mm (2.106 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3037589</td>
<td>Violet</td>
<td>8.6</td>
<td>10 ml</td>
<td>21.25 ± 0.2 mm (0.837 ± 0.007&quot;)</td>
<td>51 ± 0.5 mm (2.008 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Table 1 represents the vials and compatible vial shields for use with the Medrad™ Intego™ PET Infusion System. For additional vials not specified in this table, please contact MEDRAD Service.
### Table 2: Vial Shield and Vial Specifications - Silver

<table>
<thead>
<tr>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003 Size Specification</th>
<th>Body Diameter</th>
<th>Glass Height</th>
<th>Cap Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3017469 3038383</td>
<td>Silver</td>
<td>8.6 kg (18 lbs)</td>
<td>30-35 ml</td>
<td>30H</td>
<td>36 ± 0.5 mm (1.417 ± 0.020&quot;)</td>
<td>62.8 ± 0.7 mm (2.472 ± 0.027&quot;)</td>
<td>20 mm (0.787&quot;)</td>
</tr>
</tbody>
</table>

![Diagram of vial and vial shield specifications](image-url)
### Table 3: Vial Shield and Vial Specifications - Blue

<table>
<thead>
<tr>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003 Size Specification</th>
<th>Body Diameter</th>
<th>Glass Height</th>
<th>Cap Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3025071</td>
<td>Blue</td>
<td>8.6 kg (18 lbs)</td>
<td>20-25 ml</td>
<td>30 ± 0.25 mm (1.181 ± 0.009&quot;)</td>
<td>55 ± 0.7 mm (2.165 ± 0.027&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td>3038384</td>
<td>Blue</td>
<td>8.6 kg (18 lbs)</td>
<td>20-25 ml</td>
<td>30 ± 0.25 mm (1.181 ± 0.009&quot;)</td>
<td>55 ± 0.7 mm (2.165 ± 0.027&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
</tbody>
</table>

![Diagram of vial specifications](image-url)
### Table 4: Vial Shield and Vial Specifications - Gold

<table>
<thead>
<tr>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003 Specification Body Diameter</th>
<th>Glass Height</th>
<th>Cap Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3027139 3038385</td>
<td>Gold</td>
<td>8.6 kg (18 lbs)</td>
<td>20-25 ml</td>
<td>32 ± 0.45 mm (1.259 ± 0.017&quot;)</td>
<td>58 ± 0.6 mm (2.283 ± 0.023&quot;)</td>
<td>20 mm (0.787&quot;)</td>
</tr>
</tbody>
</table>

![Diagram of vial shield and vial]
## Table 5: Vial Shield and Vial Specifications - Green

<table>
<thead>
<tr>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003</th>
<th>Body Diameter</th>
<th>Glass Height</th>
<th>Cap Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>3025939</td>
<td>Green</td>
<td>8.6 kg</td>
<td>10-15 ml</td>
<td>10R</td>
<td>24 ± 0.2 mm (0.944 ± 0.007&quot;)</td>
<td>45 ± 0.5 mm (1.771 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
</tr>
<tr>
<td>3038382</td>
<td></td>
<td></td>
<td></td>
<td>10R</td>
<td>24 ± 0.2 mm (0.944 ± 0.007&quot;)</td>
<td>45 ± 0.5 mm (1.771 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
</tr>
</tbody>
</table>

![Diagram of vial specifications]
# Table 6: Vial Shield and Vial Specifications - Brown

<table>
<thead>
<tr>
<th>Vial Shield</th>
<th>Vial(s)</th>
<th>Medrad Part Number</th>
<th>Collar Color</th>
<th>Weight</th>
<th>Volume Range</th>
<th>ISO 8362-1:2003</th>
<th>Body Diameter</th>
<th>Glass Height</th>
<th>Cap Diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3025940</td>
<td>Brown</td>
<td>8.6 kg</td>
<td>10-15 ml</td>
<td>15R</td>
<td>24 ± 0.25 mm</td>
<td>60 ± 0.5 mm</td>
<td>20 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3038386</td>
<td>Brown</td>
<td>(18 lbs)</td>
<td></td>
<td>ISO 8362-4:2003</td>
<td>(0.944 ± 0.009&quot;)</td>
<td>(2.362 ± 0.020&quot;)</td>
<td>(0.787&quot;)</td>
</tr>
</tbody>
</table>

![Diagram of vial shield and vial specifications](image-url)
Table 7: Vial Shield and Vial Specifications - Black

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>3027305 3038387</td>
<td>Black</td>
<td>8.6 kg (18 lbs)</td>
<td>10-15 ml</td>
<td>----- 25 ± 0.25 mm (0.984 ± 0.009&quot;)</td>
<td>10H 25.4 ± 0.4 mm (1.000 ± 0.015&quot;)</td>
<td>53.5 ± 0.5 mm (2.106 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>----- 25.5 ± 0.25 mm (1.003 ± 0.009&quot;)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Diagram of vials and vial specifications](image-url)
### Table 8: Vial Shield and Vial Specifications - Violet

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3037599</td>
<td>Violet</td>
<td>8.6 kg (18 lbs)</td>
<td>10 ml</td>
<td>---</td>
<td>21.25 ± 0.2 mm (0.837 ± 0.007&quot;)</td>
<td>51 ± 0.5 mm (2.008 ± 0.020&quot;)</td>
<td>20 mm (0.787&quot;)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21.75 ± 0.25 mm (0.856 ± 0.009&quot;)</td>
<td>52 ± 0.5 mm (2.047 ± 0.020&quot;)</td>
<td></td>
</tr>
</tbody>
</table>
# Appendix E - Components and Catalog Numbers

## System

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medrad™ Intego™ PET Infusion System</td>
<td>INT SYS 200 or INT SYS 100</td>
</tr>
</tbody>
</table>

## Accessories

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power Cord - N. America</td>
<td>535-0243-012</td>
</tr>
<tr>
<td>Power Cord - International</td>
<td>535-0127-012</td>
</tr>
<tr>
<td>Power Cord - Brazil</td>
<td>3029224</td>
</tr>
<tr>
<td>Calibration Source Holder</td>
<td>3017468</td>
</tr>
<tr>
<td>Roll - Printer Labels - Thermal</td>
<td>3017517</td>
</tr>
<tr>
<td>Absorbent Disc</td>
<td>3036570</td>
</tr>
<tr>
<td>MEDRAD Vial Planner (MVP) Tool</td>
<td>Contact MEDRAD</td>
</tr>
</tbody>
</table>

## Disposables

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source Administration Set (SAS)</td>
<td>INT CSS</td>
</tr>
<tr>
<td>Patient Administration Set (PAS)</td>
<td>INT CPS</td>
</tr>
</tbody>
</table>

## Manuals

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation Manual</td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>3031103</td>
</tr>
<tr>
<td>Danish</td>
<td>3031188</td>
</tr>
<tr>
<td>Dutch</td>
<td>3031185</td>
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<tr>
<td>French</td>
<td>3031186</td>
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<tr>
<td>German</td>
<td>3031184</td>
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<tr>
<td>Italian</td>
<td>3031189</td>
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<tr>
<td>Spanish</td>
<td>3031187</td>
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<tr>
<td>Estonian</td>
<td>3031918</td>
</tr>
<tr>
<td>Russian</td>
<td>3033192</td>
</tr>
<tr>
<td>Turkish</td>
<td>3033193</td>
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<tr>
<td>Portuguese</td>
<td>3033194</td>
</tr>
<tr>
<td>Croatian</td>
<td>3032509</td>
</tr>
<tr>
<td>Finnish</td>
<td>3033504</td>
</tr>
<tr>
<td>Swedish</td>
<td>3036566</td>
</tr>
<tr>
<td>Slovak</td>
<td>3038038</td>
</tr>
<tr>
<td>Multi-lingual CD (includes the Operation Manual)</td>
<td>3031760</td>
</tr>
<tr>
<td>Service Manual - only available in English (For INT SYS 100, use 205947)</td>
<td>3031682</td>
</tr>
</tbody>
</table>

## Quick SAS Installation Guides

<table>
<thead>
<tr>
<th>Component</th>
<th>Catalog Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>English (For INT SYS 100, use DN-210202)</td>
<td>3031110</td>
</tr>
<tr>
<td>Danish (For INT SYS 100, use 3019948)</td>
<td>3031194</td>
</tr>
</tbody>
</table>
Dutch (For INT SYS 100, use 3019945) 3031191
French (For INT SYS 100, use 3019946) 3031192
German (For INT SYS 100, use 3019944) 3031190
Italian (For INT SYS 100, use 3019949) 3031195
Spanish (For INT SYS 100, use 3019947) 3031193
Russian 3033196
Turkish 3033197
Portuguese 3033198

Vial Shields
Silver 3017469 or 3038383
Blue 3025071 or 3038384
Gold 3027139 or 3038385
Green 3025939 or 3038382
Brown 3025940 or 3038386
Black 3027305 or 3038387
Violet 3037589
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