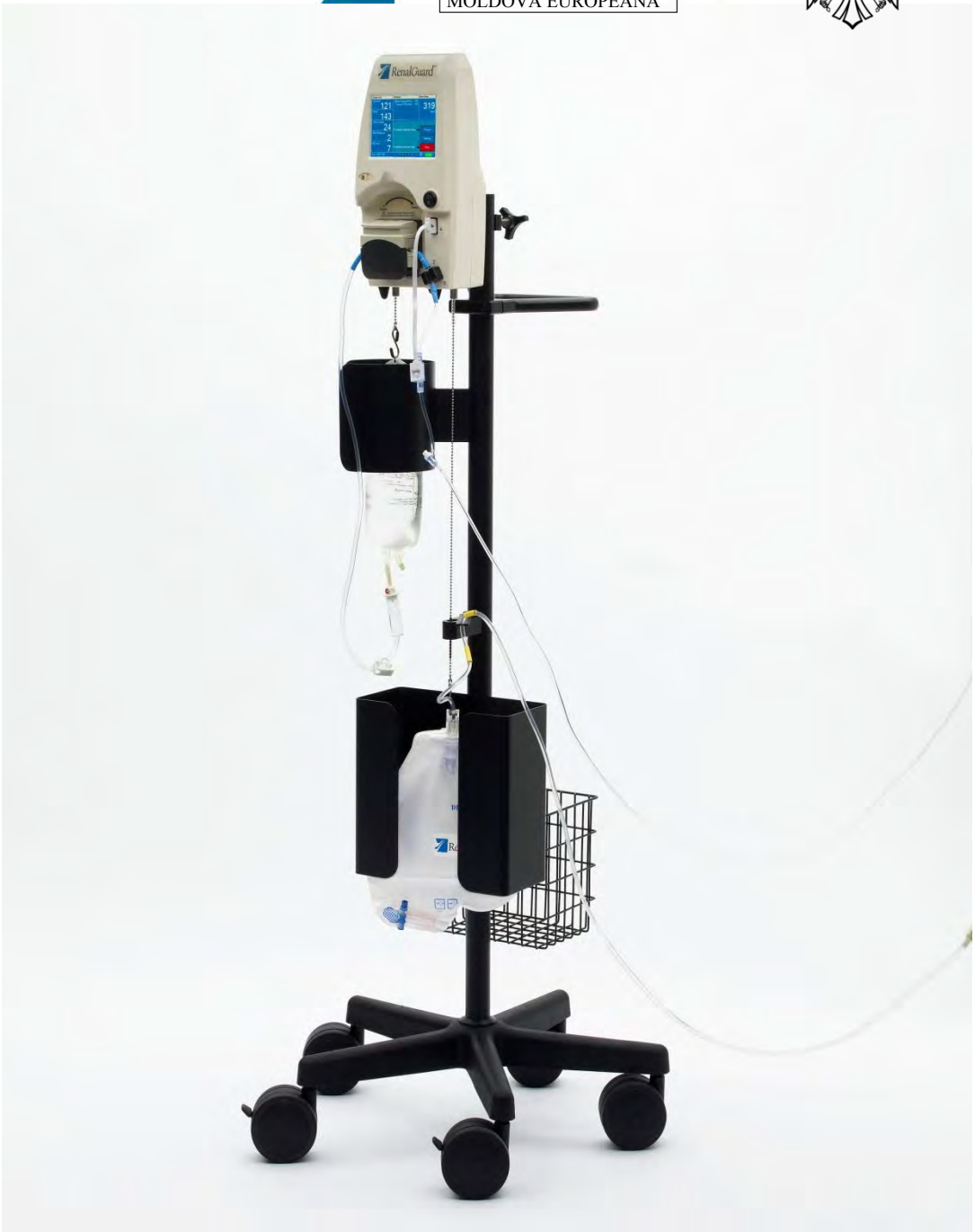
PLC Medical Systems, Inc.



RENALGUARD CONSOLE
Service Manual

LA00289

RENALGUARD CONSOLE
Service Manual

LA00289

PART ONE

OPERATOR MANUAL

RenalGuard®

Operator's Manual

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CE 0044

La00264, Rev I

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RenalGuard is manufactured by PLC Medical Systems, Inc. a subsidiary of RenalGuard Solutions, Inc.

RenalGuard Solutions, Inc.
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EC REP

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Table of Contents

1. Introduction

This Operator's Manual provides instructions necessary for the proper operation of the RenalGuard Solutions, Inc. (RGS) RenalGuard System™. It is not a guide to appropriate medical care. The use of the RenalGuard System and effective fluid management depends primarily upon the medical skills and knowledge of the medical team. Consequently, technical competence in operation of the RenalGuard System must be supplemented by a thorough understanding of the associated medical procedures.

The RenalGuard System maintains the vascular volume by measuring patient urine output and infusing hydration fluid (prescribed by physician) into the patient's IV to balance the fluid volume lost in urine.

The RenalGuard System consists of:

- the RenalGuard Console (Console),
- the RenalGuard Cart (Cart), and
- the RenalGuard Single Use Set (Set) that includes an Infusion Set and a Collection Set with an integrated urine collection bag.

The RenalGuard System neither controls nor regulates the patient's overall fluid or electrolyte balance. Total fluid balance includes all fluid intake (oral or IV) as well as all fluid output (feces, urine, chest tube or other drainage, etc.). It is the responsibility of the attending physician and the user to achieve the intended clinical results with proper choice of hydration rate, monitoring of appropriate clinical and laboratory data and any required concomitant pharmacological therapy to achieve appropriate hydration status and effective treatment.

Patient treatment must, at all times, be in accordance with the specific procedures prescribed by a qualified physician. Users must operate the RenalGuard System in accordance with the information detailed in this manual. RGS offers training in the use of the RenalGuard System based upon the contents of this operator's manual.

2. Before You Get Started

2.1 Indications for Use

The RenalGuard System is indicated for temporary[1] replacement of urine output by infusion of a matched volume of sterile replacement solution to maintain a patient's intravascular fluid volume.

The RenalGuard System is not intended for infusion of blood, blood components, medications, or nutritional fluids.

All treatments administered via The RenalGuard System must be prescribed by a physician.

2.2 Environment of Use

The RenalGuard System is intended to be used in a monitored hospital environment, such as an interventional lab or an intensive care unit, by medical personnel instructed in the use of the device.

[1] The RenalGuard System™ is intended for use no longer than 14 days with one patient. Individual RenalGuard Single Use Sets should not be used longer than 72 hours.

2.3 Compatibility

The RenalGuard System is designed to operate with:

1. All standard adult indwelling or short term urinary Foley catheters indicated for drainage of urinary bladder. (i.e. 16Fr Bard Foley catheter).
2. IV infusion needles and cannula intended for infusion of fluids into surface peripheral veins at rates of up to 6 liters/hour. It is required that needle sizes of Gauge 20 or larger bore size are used to prevent excessive resistance to flow (i.e. 20G BD Insyte™ Autoguard™). Use of smaller needles can result in alarms and suboptimal performance of the System.
3. Compatible fluids include crystalloid or colloid IV fluids in standard one liter bags. Incompatible fluids include medications, blood products and non-ionic fluids. Use of bags that are size other than 1 liter will result in alarms and suboptimal performance of the System. It is the responsibility of the prescribing physician to choose the appropriate fluid composition.
4. The Infusion Set is equipped with standard needle-less infusion port that can be used to connect to standard syringes and IV infusion sets. It is the responsibility of the prescribing physician and medical personnel operating the System to choose the appropriate infusion fluid and rate, control air bubbles and maintain sterility.

Caution: *The RenalGuard System is designed for use with 1 (one) liter infusion bags only. The System will not operate properly with other sized infusion bags.*

Warning: *The RenalGuard Infusion Set can only be used with the RenalGuard console. It cannot be used with any other device or as a standalone infusion set.*

2.4 Warnings and Cautions:

This manual contains important information concerning the prevention of bodily injury and the protection of the equipment. Such information may be designated as either Warning or Caution whereby:

Warning - designates information concerning the possibility of bodily injury to the patient, operator, or other individuals.

Caution - designates information concerning the possibility of damage to the equipment or to other property.

- Carefully read all warnings, precautions, and instructions before use. Follow all operating, maintenance, and installation procedures as described in this manual. Failure to do so can result in patient harm.
- RenalGuard Solutions, Inc. will not be responsible for patient safety if the procedures followed to operate, maintain, and calibrate the RenalGuard System are other than those specified in this manual. Anyone who performs the procedures must be appropriately trained and qualified.
- Use of accessory equipment not approved by RGS can result in patient injury or death.
- All electrical installations must comply with all applicable local electrical code and the manufacturer's specifications. Grounding reliability can only be achieved when the equipment is connected to an equivalent receptacle marked "HOSPITAL ONLY" or "HOSPITAL GRADE'. Use potential equalization (ground post) in accordance with national requirements. If the grounding reliability of the power cord is suspect, the cord must be replaced with an equivalent power cord with a receptacle marked "Hospital Only" prior to operating the equipment.
- All fluid flow paths in the RenalGuard Single Use Set are sterile and non-pyrogenic. Aseptic technique must be used throughout the procedure. Usual and customary infection control practices should be followed when replacing the Set to ensure the safety of the patient and clinician. Dispose of any residual fluids and urine remaining in the Set appropriately.
- Use only RenalGuard Single Use Sets with the RenalGuard Console. To prevent contamination, the Set must be used as soon as its package and sterilization caps are removed. Do not use the RenalGuard Single Use Set if the package is damaged, if the sterilization caps are missing or loose, or if the lines are kinked. Destroy the Set after a single use, using appropriate procedures for potentially contaminated material. Do not re-sterilize.
- The RenalGuard System is designed for use with 1 (one) liter infusion bags only. The System will not operate properly with other sized infusion bags.

- The RenalGuard Single Use Set's intended duration of use is up to 72 hrs. After 72 hours, replace the Single Use Set and re-run Prime on the new set. This can be repeated with one patient up to a total of 14 days, at which time use of the RenalGuard System must be discontinued.
- The use of other than RGS RenalGuard Infusion Sets or Collection Sets can result in patient injury.
- The RenalGuard Infusion Set can only be used with the RenalGuard console. It cannot be used with any other device or as a standalone infusion set.
- After use, the RenalGuard Single Use Set may be a potential biohazard. Handle and dispose of Infusion and Collection Sets in accordance with standard medical practice and applicable local, state and federal laws and regulations.
- During priming and operation, observe closely for leakage at joints and connections. If tightening the connections cannot stop leakage, replace the entire Set.
- Do not allow air to enter the RenalGuard Single Use Set after priming. If a large amount of air has entered and cannot be removed, the Set must be replaced.
- The Console may not be able to detect disconnections or occlusions of the Foley connector, urine set tubing, infusion tubing and/or venous access catheters. Carefully observe the RenalGuard Single Use Set and all operations of the RenalGuard System during patient treatment.
- The RenalGuard System uses positive displacement to infuse hydration fluid. If "gravity flow" infusion systems are attached to the infusion ports of a RenalGuard Single Use Set or to a common IV site, the flow of the "gravity only" infusion system may be impeded. Attaching additional infusion sets to the RenalGuard Single Use Set or to a common IV site risks infusing air into the patient. Hospital personnel should follow standard procedures for using "gravity flow" infusion systems in combination with positive displacement pumps. They should also ensure the accuracy of any additional infusion sets attached to the RenalGuard Single Use Set or to a common IV site.
- Do not modify the RenalGuard System in any way.
- Do not attempt to service any part of the RenalGuard System. Refer servicing to RenalGuard Solutions personnel only. If non-RenalGuard Solutions personnel perform repairs or adjustments, RenalGuard Solutions cannot guarantee the safety, reliability and performance of the system.
- ELECTRIC SHOCK HAZARD. Do not open the case of the RenalGuard Console due to the risk of electrical shock from the AC power or the internal batteries.

- Do not operate the RenalGuard System in the presence of flammable anesthetics or volatile substances, such as alcohol or elevated levels of oxygen. Under no circumstances should flammable gases be present when operating the RenalGuard System.
- Equipment that generates high energy radio interference (cellular phones, portable radios, electrosurgical equipment, etc) can cause false alarms. If this occurs, reposition the RenalGuard Console away from the source of interference and restart therapy.
- Store the RenalGuard Single Use Set in a dry place, between −10°C (14°F) and 45°C (113°F).
- The RenalGuard System has not been tested with patients with Congestive Heart Failure (CHF) or patients under sedation. These patients are at elevated risk of fluid overload and pulmonary edema, and therefore should be monitored closely when connected to the RenalGuard System.
- Patients with high urine flows are at risk of electrolyte imbalance and should be observed for these signs or symptoms of fluid or electrolyte imbalance: dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains, cramps, muscular fatigue, hypotension, oliguria, tachycardia, arrhythmia, or gastrointestinal disturbances such as nausea and vomiting.

Additional warnings or cautions applicable to specific sections of this manual are replicated in the following table:

Section	Warning or Caution Text
§ 2.3, § 4.4, § 4.12	***Caution:*** *The RenalGuard System is designed for use with 1 (one) liter infusion bags only. The System will not operate properly with other sized infusion bags.*
§ 2.3, § 2.8	***Warning:*** *The RenalGuard Infusion Set can only be used with the RenalGuard console. It cannot be used with any other device or as a standalone infusion set.*
§ 2.8	***Caution*****:** *Installing the RenalGuard Console on anything other than the RenalGuard Cart may introduce a hazardous situation. For example, installation on an IV pole that allows the upper portion of the pole to rotate separately from the lower half of the pole can interfere with the Console's ability to measure urine volume.*
§ 2.9	***Caution*****:** *Exercise care during cleaning to ensure that liquids do not enter the Console. (The RenalGuard Console has been tested per IEC 60529 IPX1 to be resistant to vertically dripping fluids but is not liquid-tight.)*
§ 4.3	***Caution:*** *The RenalGuard Console should be plugged in at all times. Failure to do so may result in decreased battery operation time.*
§ 4.4	***Warning:*** *The RenalGuard System will not operate properly if the urine bag is not hanging freely on the weight scale chain, or is interfered with in any way.*
§ 4.5	***Caution:*** *It is necessary to complete the priming procedure before connecting the patient for therapy. The RenalGuard Console performs required safety checks during the priming procedure.*
	Warning: *Do not connect the patient to the Infusion Set during the priming procedure. The air detector is disabled during priming. This could result in air being introduced into the patient.*

Section	Warning or Caution Text
	Caution: *The RenalGuard Single Use Set can only be primed using the following automatic priming procedure.*
§ 4.5, § 4.11, § 5.2	***Warning*****:** *Air detection is disabled during* ***Advance*** *button operation. The* ***Advance*** *button must not be pressed while the Infusion Set is connected to the patient.*
§ 4.6	***Warning:*** *Aseptic technique must be used throughout the procedure. Usual and customary hospital infection control practices should be followed when replacing the patient connected tubing to ensure the safety of the patient and clinician.*
	Warning: *Automatic air detection is disabled during manual connection operations.*
§ 4.7	***Warning*****:** *The RenalGuard System does not measure the total volume removed from or infused into the patient. The System only measures the urine output and system hydration rate. It is the user's responsibility monitor the patient's overall hydration status. If other fluids are infused or removed, the user is responsible for keeping track of the total amount of fluid infused or given orally.*
§ 4.7	***Warning:*** *This setting relies on the user input to calculate the total volume of fluid infused into the patient from other sources. It is the user's responsibility to adjust this setting if the other infusion rates are adjusted or terminated.*
§ 4.7.1.2	***Warning:*** *Both of these settings can cause the RenalGuard System to infuse fluid over and above the patient's urine output volume. It is the user's responsibility to confirm that this is an appropriate fluid balance for the patient.*
§ 4.7.2.1	***Caution:*** *This setting will cause the RenalGuard Console to infuse fluid either above or below the patient's urine output volume. It is the user's responsibility to confirm that this is an appropriate fluid balance for the patient.*
§ 4.7.2.2	***Caution:*** *This setting relies on the user input to calculate the total volume of fluid intake from other sources. It is the user's responsibility to adjust this setting if the other intake rates are adjusted or terminated.*
§ 4.8	***Warning:*** *Running with the infusion line clamped or leaving the Console in Stop mode risks underinfusing the patient and increases the risk of thrombosis.*
§ 4.9	***Caution*****:** *When the RenalGuard Console is in Pause mode, the Urine volume output is not being replaced. The Infusion rate is set to the minimum hydration rate until the user terminates Pause mode.*
	Caution: *Stay in Pause mode no more than is necessary. After the urine bag is drained in Pause mode, urine is not measured by the Console until Run mode is resumed. Resume Run mode as soon as possible after draining bag to ensure accurate urine measurement.*
§ 4.11	***Warning:*** *The RenalGuard System is designed for hydration with crystalloid and colloid hydration fluids only. It is not designed to infuse blood, blood products, or to deliver drugs.*
§ 4.12	***Caution:*** *Emptying the Urine Collection Bag during Run or Stop mode, or while the Console is powered off may result in incorrect urine measurement and alarms.*
§ 5.0	***Warning*****:** *Silencing and Clearing an Alarm may not eliminate the Alarm cause. Carefully investigate and correct all Alarms and Alerts.*
	Caution**:** *While the RenalGuard Console will provide information on the most likely causes of the alarm, the user must exercise caution and examine all possible options if the information displayed does not solve the problem.*
§ 5.2	***Warning:*** *It is the user's responsibility to ensure that air is removed from the infusion circuit before the system is restarted following air detection.*
	Caution: *Always enter Pause mode prior to draining urine. Remember to close the drain valve. Press the* ***Run*** *button again to resume therapy.*
	Caution: *Whenever the RenalGuard System is in the Pause mode, urine volume is not being replaced. The patient receives the user set minimum rate of hydration.*

2.5 System Components

The RenalGuard System consists of the Console, the Cart and RenalGuard Single Use Sets for infusion and urine collection.

Each Console is packaged with the following items:

- a detachable power cord
- a chain for suspending the infusion bag
- a chain for suspending the collection bag
- 2 chain guide tubes (only with Consoles that do not have permanently attached chains)
- an operator's manual

Each RenalGuard Cart is packaged with the following items:

- a pole
- base with casters
- handle with clamp
- 2 bag holders
- chain guide & tubing holder
- basket
- miscellaneous hardware
- assembly instructions

Each RenalGuard Single Use Set includes:

- an integrated Infusion Set with an IV bag spike
- a Luer-to-Foley connector for priming
- a urine Collection Set with an integrated urine bag
- a 3 foot extension set for the urine Collection Set
- directions for use

2.6 Electrical Requirements

The RenalGuard Console is supplied with a detachable power cord fitted with a hospital-grade plug.

- Power the Console only by a properly protected and grounded electrical supply that meets the following requirements: 100 - 240 VAC, 60/50 Hz, 50 VA
- Plug the power cord into an outlet labeled 'Hospital Only' or 'Hospital Grade' to ensure grounding reliability. If the grounding reliability of the power cord is suspect, the cord must be replaced with an equivalent power cord using a receptacle marked "Hospital Only" prior to operating the equipment.
- For non-US installations, an appropriate power cord satisfying local code and configuration requirements must be provided by the installing facility.

Fusing options within the power entry module:

- The power entry module incorporates a dual fuse carrier that will meet electrical safety requirements where both sides of the input line must be fused.
- For US (115 VAC) installations where electrical safety requirements dictate a single fuse on the input line, a removable metal clip occupies one of the two fuse locations.
- The fusing option that will satisfy local code requirements must be determined by the installing facility.

Other electrical connections include:

- An auxiliary ground post (potential equalization) for the device is on the rear panel.
- An RS-232 port intended for use by service personnel only. This connection is not designed to interface with any other hospital equipment.

2.7 Calibration Requirements

The RenalGuard Console operates by continuously monitoring the weights of the infusion bag and the collection bag and adjusting the performance of the pump in accordance to the user's instructions. Calibration of the internal weight scales is recommended once a year.

Calibration should only be performed by individuals familiar with adjusting medical equipment settings. Contact your service representative (refer to section 2.13 Service Information) for further information before proceeding.

Two hook weights each calibrated to the appropriate national standard and capable of being suspended from either the infusion bag or collection bag chain will be required to perform the calibration:

- a 1 kg weight
- a 2 kg weight

Weight scale calibration is performed by entering the Service mode and following the prompts displayed. Follow the instructions exactly as displayed to safeguard against calibration errors:

1. Ensure that the Console is installed on the RenalGuard Cart pole with the weight scale chains attached in accordance with section 4.2. The infusion and collection sets are not required for this process.
2. Turn off the Console then turn it on again.
3. When the Same Patient/New Patient Screen is displayed, touch the upper right corner of the display three times. The Service Screen will be displayed.
4. Touch the **Weight Calibration** button.
5. Carefully follow the step by step instructions displayed on the touchscreen. The weight calibration will be performed by the system as the weights are placed and removed in response to the instructions displayed.
    - Place and remove the weights carefully to minimize any swaying of the chains.
    - Failure to follow the instructions as displayed may cause a Calibration Error message to be displayed.
    - Reset the Console and restart the weight calibration if a calibration error message is displayed. Turn the Console power off and then back on to reset the Console.
    - A message to save the settings will be displayed when the weight calibration is successfully completed.
6. Touch the **Save** button to record the calibration results. The display will return to the Service Screen.
7. Turn the Console off and then back on again to exit the Service mode.

The RenalGuard Console is now calibrated and ready for normal use. Record the date of the calibration.

2.8 Placement Requirements

The RenalGuard Console must be installed on the RenalGuard Cart pole.

The Console should be placed on the pole so that:

- The urine collection bag will be attached to the chain such that it hangs freely within the rectangular urine bag holder.
- The urine collection bag will be below the level of the patient's bladder to facilitate urine drainage.
- The urine and hydration fluid bags will hang freely from the hooks and be neither obstructed nor impeded by the bag holders, urine bag chain guide or other obstacles.
- The chain supporting the urine collection bag will pass through the ring of the chain guide clamp to minimize excessive swinging of the bag.
- Neither the infusion nor the collection tubing is kinked or pinched; nor are they pulling or straining the weight measuring devices.

Caution**:** *Installing the RenalGuard Console on an IV pole, particularly one that allows the upper portion of the pole to rotate separately from the lower half of the pole can interfere with the Console's ability to measure urine volume.*

Warning: *The RenalGuard Infusion Set can only be used with the RenalGuard console. It cannot be used with any other device or as a stand alone infusion set.*

2.9 Cleaning

The following cleaning procedures should be performed following each patient treatment with the RenalGuard System, or as required during treatment.

Caution**:** *Exercise care during cleaning to ensure that liquids do not enter the Console. (The RenalGuard Console has been tested per IEC 60529 IPX1 to be resistant to vertically dripping fluids but is not liquid-tight.)*

2.9.1 Cleaning the Touchscreen Display

Glass cleaner is recommended for cleaning the touchscreen. To reduce the risk of damage to the touchscreen, perform the following steps:

1. Do not apply glass cleaner directly to the touchscreen.
2. Moisten a clean lint-free cloth or paper towel with glass cleaner.
3. Use the moistened cloth or towel to gently clean the touchscreen.
4. Use a dry lint-free cloth or paper towel to remove any moisture remaining on the touchscreen.

2.9.2 Cleaning the Console and Cart Surfaces

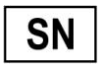
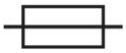
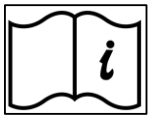
Conventional cleaners and disinfectants approved for general use by the facility should be used for cleaning or disinfecting the Console and Cart.

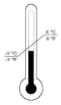
Note: Using a stronger bleach solution than recommended for general use can cause damage or discoloration.

1. Clean spills from the surface of the Console and Cart using mild conventional cleaners.
2. Disinfect the surfaces of the Console and Cart using appropriate cleaning solutions.

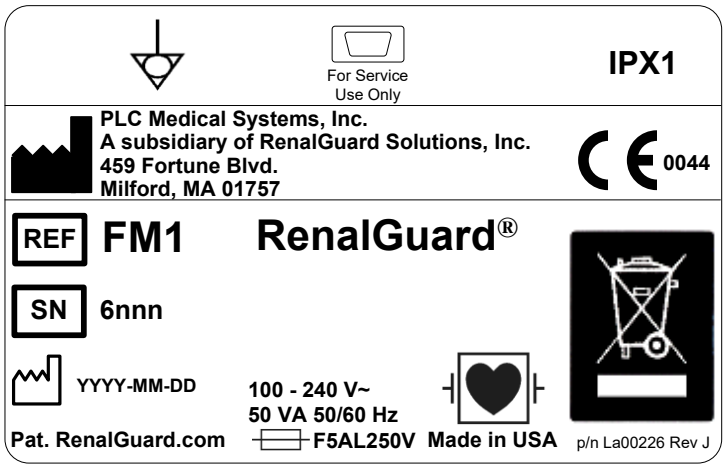
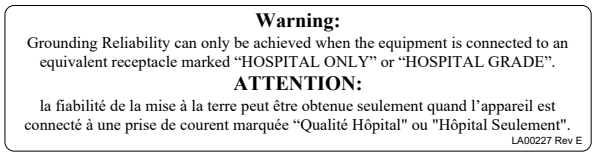
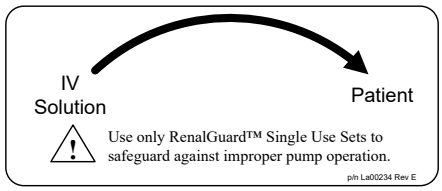
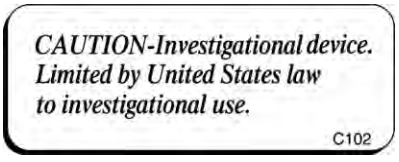
2.10 Symbols

The following symbols appear on the RenalGuard Console, the RenalGuard Single Use Set or the packaging.

Symbol	Description	Location	Reference
	"Attention!" Consult Operator's Manual or written warnings	Console label	ISO 15223-1
IPX1	Ingress protection rating per IEC 60529 - enclosure is resistant to vertically falling water drops.	Console label	IEC 60529
	Defibrillator-proof Type CF equipment per IEC 60601-1 equipment is electrically isolated from the patient.	Console label	IEC 60601-1
	Do Not Dispose compliant with the Waste in Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC	Console label	EN 50419
	Equipotentiality (identifies the equipotential ground stud located on the rear panel)	Console label	IEC 60601-1
	Serial Number	Console label	ISO 15223-1
	Fuse	Console label	
	Alternating current	Console label	IEC 60601-1
	RS-232 "For service use only"	Console label adjacent to the RS-232 port	n/a
	Consult Instructions for Use	Directions for Use Label	ISO 15223-1
	Catalog or Reference number	Console label and Single Use Set label	ISO 15223-1
	Date of Manufacturing	Console label and Single Use Set label	ISO 15223-1
	Manufacturer	Console label and Single Use Set label	EN 980

Symbol	Description	Location	Reference
	Lot number	Single Use Set label	ISO 15223-1
	Temperature limits to which the package can be subjected	Exterior of the shipping package	ISO 15223-1
	Battery charge symbol	Front panel adjacent to the battery charge indicator LED	ISO 15223-1
	On - enables Console operation	On/Off switch	IEC 60601-1
	Off - disables Console operation	On/Off switch	IEC 60601-1
	Use By (expiration date)	Single Use Set label	ISO 15223-1
	Sterilization using ethylene oxide	Single Use Set label	ISO 15223-1
	Do Not Resterilize (Reuse may result in infection)	Single Use Set label	ISO 15223-1
	Do not use if package is damaged	Single Use Set label	ISO 15223-1
	Humidity limit to which the package can be subjected	Single Use Set label	ISO 15223-1
	Authorized representative in the European Community	Single Use Set label	EN 980
	Latex free	Single Use Set label	n/a
	Non-pyrogenic	Single Use Set label	n/a

2.11 Label Images

Label Image	Description and Location
	System Label (located on the rear panel of the Console)
	Grounding Reliability Warning Label (located adjacent to the power inlet/cord receptacle on the rear panel of the Console)
	Fluid Flow Label (located adjacent to the pump head on the front of the Console)
	Loading Guide Labels (1), (2), (3) & (4) (located along the tubing path on the front of the Console)
	ETL Listed Label (located on the underside of the Console)
	Investigational Device Label * (located in the front of the Console) * USA units only

Label Image	Description and Location

Use only RenalGuard® Single Use Sets.

To Initiate Therapy:

Attach the RenalGuard Single Use Set to the Console according to the set's DFU
Turn the Console on
When asked, press **Begin New Patient**
Press **Start Prime** to begin Prime
When Prime has completed, inspect circuit for leaks or air bubbles
Attach the RenalGuard Single Use Set to the patient according to the set's DFU
Press **Run** to begin therapy

To Adjust Settings

Press **Settings**. Select the menu containing the setting you would like to change.
Press the desired setting you would like to change
Use arrows (▲▼) to change the setting
Press **Save Setting** to store the setting

To Empty Urine Bag

Press **Pause** button to enter Pause mode
Open clamp to drain urine collection bag
When draining is complete, ensure drain clamp is closed
Press **Run** to re-start therapy.

To Change Infusion Bag

Press **Stop** to enter Stop mode
Replace infusion bag
Press **Run** to re-start therapy

Handling Alerts or Alarms

Press **Silence** to silence the tone

To reset an alert, Press **Clear Alert**
If in Pause mode, correct the alert cause, then press **Run** to resume therapy

To reset an alarm, Press **Clear Alarm**
After correcting the alarm cause, press **Run** to resume therapy

La00256 Rev D

Directions for Use Label (located in the left side of the Console enclosure)

RenalGuard™

REF FM1

CE 0044

SN

LITHIUM BATTERY INSIDE
Do not damage or mishandle this package

-10°C 45°C

20% RH 90% RH

PLC Medical Systems , Inc.
A subsidiary of RenalGuard Solutions , Inc.
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La00248Rev H

Outer Package Label
(located on the outside of the shipping container)

RenalGuard®

RenalGuard Logo
(located in the front of the Console)

2.12 Abbreviations

cm	centimeter
Hz	Hertz
IV	intravenous
Kg	kilogram
KVO	Keep Vein Open
LED	Light Emitting Diode
ml	milliliters
ml/hr	milliliters per hour
psi	pounds per square inch
VAC	Volts Alternating Current

2.13 Service Information

For technical assistance, contact the address below:

Internationally:

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3. Device Description

3.1 Theory of Operation

The RenalGuard System maintains the hydration balance by measuring patient urine output and infusing hydration fluid (prescribed by physician) into the patient IV to balance the fluid lost in urine.

In addition to urine volume replacement, RenalGuard implements user-set Bolus, Percent Match, and Desired Fluid Balance. Bolus is defined as the amount of fluid in ml infused into IV in addition to the replaced volume of urine over a 30 minute period. The Percent Match setting adjusts the urine volume replacement from the default 100 % replacement to the user defined replacement ratio. This match is set as a percentage of the urine volume measured, with a range of 0% to 100 %. The Desired Fluid Balance Setting allows the user to adjust the goal of the RenalGuard System to achieve the desired fluid balance, which can be either positive or negative. Additionally, the Other Intake Rate allows the user to instruct the RenalGuard Console to take into account other fluid inputs when attempting the reach the set Fluid Balance or Percent Match goal.

The RenalGuard System is comprised of a Console, a Cart and a RenalGuard Single Use Set for infusion and urine collection. The Console is a microcontroller-based device that has a means for measuring urine and the ability to infuse hydration fluid into the patient. The rate of infusion of hydration fluid is controlled by the Console based on measured urine volume and user settings.

The Console is equipped with an internal battery that can sustain operation in the event of power outage or during short periods of time, when the patient is moved. The RenalGuard Console is to always be plugged into the AC outlet for operation and battery charging.

The Cart provides the mounting platform for the RenalGuard Console. The cart has a pole and a base with 5 wheels, 2 of them locking to restrict movement, if necessary. The cart includes containment housings for the infusion and urine collection bags.

3.2 RenalGuard System Overview

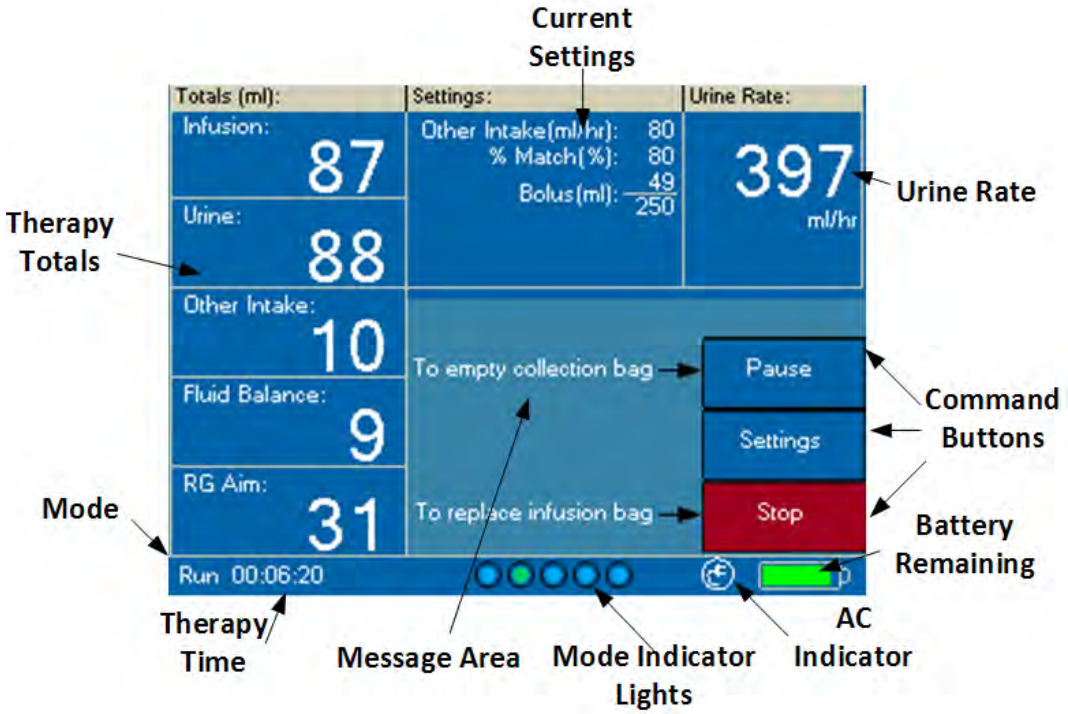
The RenalGuard System consists of the microcontroller-based Console, a Cart and a RenalGuard Single Use Set that is connected to the Console for therapy. The Console is mounted on the Cart.

The Console includes a roller pump, a user interface, two weighing scales, an air detector, a post-pump pressure sensor, an electrical connector for AC power, and mechanical interfaces for holding the Set in place. The Console controls the rate at which fluid is infused and monitors urine volume by weight measurement.

To initiate treatment, the RenalGuard System requires: a) peripheral IV access, b) a urinary Foley catheter and c) an appropriate number of one liter bags of the physician prescribed hydration fluid.

Priming of the RenalGuard Single Use Set is initiated by the user prior to treatment. During operation, the user is responsible for a) draining the urine bag when full, b) replacing hydration fluid bags when empty, and c) responding to alarms and alerts issued by the Console.

3.3 System Display



Explanation of RenalGuard Console System Display:

Urine Rate: Urine rate based on recent urine output.

Current Settings (see section 4.7 for more information on settings):

> **Bolus (ml):** The top number indicates the current bolus target added to the infusion goal (see RG Aim below). The second number indicates the total amount of bolus to be infused based on user settings. Only displayed if Bolus is set and currently being infused.
>
> **Other Intake (ml/hr):** User set rate of fluids from other sources that the patient is receiving. Only displayed if value is not 0.
>
> **Desired Fluid Balance (ml/hr):** User set desired hourly fluid balance. Only displayed if value is not 0.
>
> **Percent Match (%):** User set percent of the urine output that should be matched by hydration fluid. Only displayed if set value is not 100%.

Total Information (all units in ml):

Infusion: Total fluid infused since the start of the therapy. This includes fluid infused for Urine Volume replacement and fluid infused in response to all user settings.

Urine: Total urine collected since the start of the therapy.

Other intake: Total of the other fluids in ml that the patient has received since the start of therapy based on the user set "Other Intake" rate

Fluid Balance: Total Fluid Balance since the start of the therapy in ml. This is calculated using the formula:

Total Fluid Balance (ml) = Total Infused (ml) + Total Other Intake (ml) – Total Urine (ml)

RG Aim: Current target total fluid balance in ml which is calculated based on urine output and user settings, including Bolus, Percent Match, and Desired Fluid Balance.

RG Aim (ml) = Target Infusion Volume (ml) + Total Other Intake (ml) – Total Urine (ml)

Mode: Indicates the current mode of the RenalGuard Console (Run, Stop, Advance, or Pause, see sections 4.4 through 4.14 for more information).

Therapy time: This indicates the total time that the RenalGuard Console has been in Run mode since the start of the current therapy.

Message Area: This area is used to display user messages, alerts, and settings screens.

Mode indicator lights: The mode indicator lights provide a means to determine the mode of the RenalGuard Console even when the user is too far away to read the mode:

- Run mode: a green light will rotate through the indicator lights.
- Pause mode: all five indicator lights will flash orange.
- Stop mode: all five indicator lights are off.
- Advance mode: a green light will rotate through the indicator lights.

AC indicator: The symbol  indicates that the Console is connected to an AC supply. The symbol  indicates that Console is not connected to an AC supply.

If the Console is connected to an AC supply and the indicator is displaying the symbol  , confirm that the Mains AC switch located on the rear panel is in the On (|) position.

Battery remaining: Approximate battery charge remaining. Displays orange bar when less than 30 minutes of battery charge remain.

Command Buttons: Used to operate the RenalGuard Console. Section 4 explains all of the command buttons in greater detail.

3.4 User Settings

The RenalGuard Console allows the user to enter following parameters:

1. Minimum hydration rate in ml/hr

2. Desired Fluid Balance in ml/hr
3. Bolus Amount in ml
4. Percent Fluid to be Matched in %
5. Other Fluids being infused by external sources that need to be taken into account in ml/hr
6. Maximum allowed accumulated Positive Fluid Balance and minimum allowed Negative Fluid Balance for alert only
7. Minimum urine output in ml/hr for alert only

Refer to section 4.7 for additional information of the user settings.

3.5 Safety Features

The RenalGuard System includes the following features designed to protect the patient from potentially hazardous conditions. The operating system detects malfunctions and alarms the user as needed.

1. Air detector with automatic infusion pump shut-off
2. Post-pump downstream pressure sensor to detect occlusions
3. Pump motor speed monitoring by optical encoder
4. Weight scale monitoring of infusion fluid to detect leaks and pre-pump upstream occlusions
5. Weight scale monitoring of urine volume to detect leaks and urine Collection Set occlusions
6. Free flow protection device (pressure valve)
7. Pump door open detector with automatic motor shut off

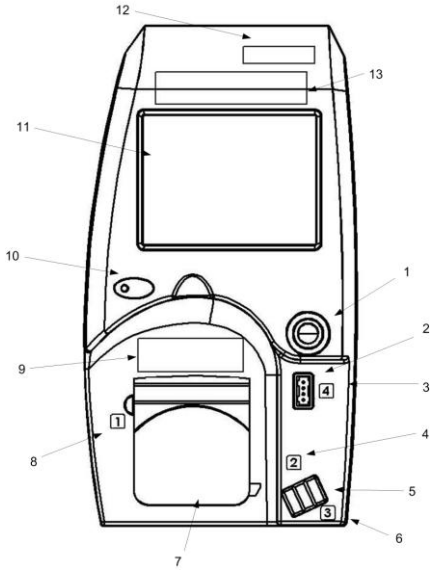
3.6 Audio Indicators

The RenalGuard Console uses different audio indicators to alert and inform the user of the status of the Console.

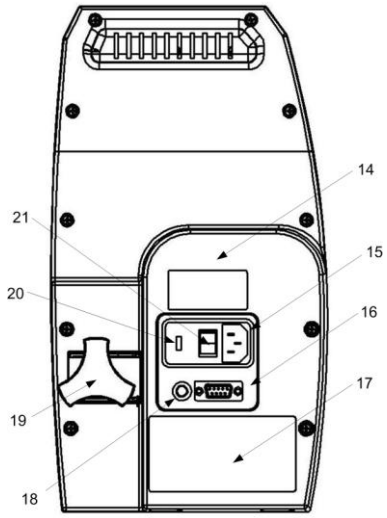
1. A solid tone indicates an alarm condition. Refer to section 5.0 for more information
2. A low-volume beep while the Console is in Run mode indicates that the Console has low battery power (less than 30 minutes remaining).
3. A low-volume beep while the Console is in Stop or Pause mode indicates to the user that the Console is not in Run mode.
4. A high-volume beep while the Console is in Stop or Pause mode indicates to the user that the Console has not been in Run mode for more than 15 minutes. The tone will not stop until the user enters Run or Advance mode.

4. Operation

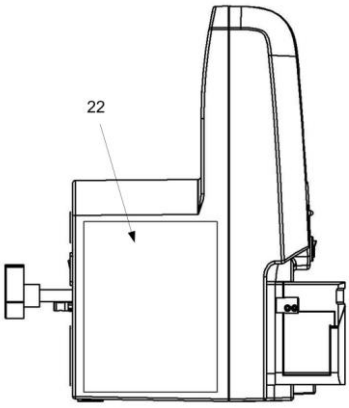
4.1 Features

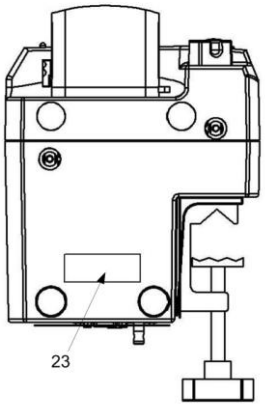


RenalGuard Console Front

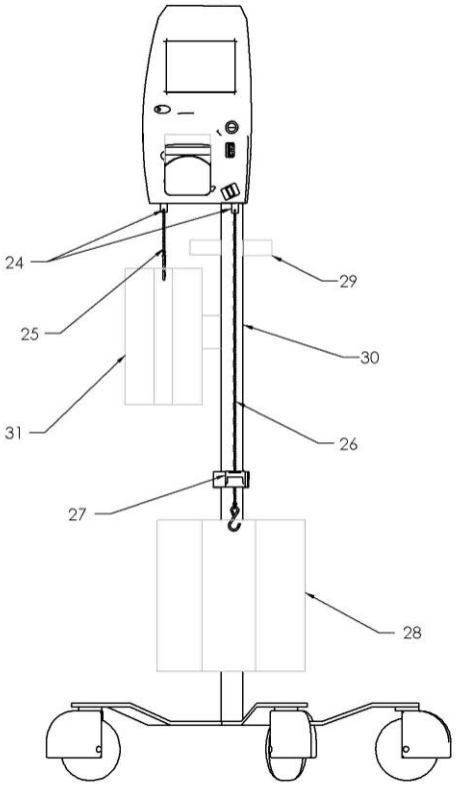


RenalGuard Console Rear





Console Left Side and Bottom



RenalGuard Console on the cart

#	Description	Function
1.	On/Off Switch	Turns the RenalGuard Console On or Off
2.	Pressure Sensor	Detects occlusions in the IV line.
3.	Loading Guide Label (4)	Location for the RenalGuard Single Use Set pressure sensor connection
4.	Loading Guide Label (2)	Location for the corresponding marker on the RenalGuard Single Use Set
5.	Bubble Detector	Monitors air bubbles passing through the RenalGuard Single Use Set
6.	Loading Guide Label (3)	Location for the corresponding marker on the RenalGuard Single Use Set
7.	Pumping Mechanism	Peristaltic pumping mechanism
8.	Loading Guide Label (1)	Location for the corresponding marker on the RenalGuard Single Use Set
9.	Fluid Flow Label	Indicates the direction of fluid flow through pump
10.	Battery LED	Constant yellow - indicates that the internal battery is charging
11.	Touch Screen Display	Performs all user interface functions of the RenalGuard Console
12.	Investigational Device	Identifies the RenalGuard Console as a US FDA investigational device *
13.	RenalGuard Logo	Identifies the RenalGuard Console
14.	Grounding Label	Informs the user to use only a hospital grade grounded outlet
15.	Power Entry Module	Includes the cord receptacle, the mains fuses and the mains on/off switch
16.	Serial Port	External communication port (For Service Use Only)
17.	Product Label	Includes Manufacturer, Model, and Serial # information
18.	Ground Equalization Stud	Provides the ability to ground external equipment through the system ground
19.	Pole Clamp	Clamps the Console to the Cart pole
20.	Mains Fuses	Replaceable fuses Type F5LA250V (the module back opens for fuse access)
21.	Mains switch	Switches the AC mains power On or Off.
22.	Directions for Use Label	Directions for Use
23.	ETL Listed Label	Identifies the ETL certification information
24.	Chain Guide Tubes	Protects the load cells (weight scales) from damage (only with Consoles that do not have attached chains)
25.	IV Chain Assembly	Hangs the IV Bag for monitoring by the load cell
26.	Urine Chain Assembly	Hangs the Urine Bag for monitoring by the load cell
27.	Chain Guide Assembly	Controls motion of urine bag during transit
28.	Urine Bag Holder	Restricts urine bag movement during transit
29.	Handle	For use during transit
30.	Pole	For mounting Console
31.	Infusion Bag Holder	Restricts infusion bag movement during transit

• USA units only

4.2 Installation and Setup

This section describes the initial installation procedure for the RenalGuard System.

4.2.1 Console Unpacking and Initial Inspection

When unpacking the RenalGuard System Console, follow these steps:

1. Inspect each container at the time of delivery for signs of damage or any indication of improper handling during shipment.
2. Ensure that the following components are included:
    - RenalGuard Console
    - Infusion chain with hook
    - Urine chain with hook
    - 2 chain guide tubes (only with Consoles that do not have attached chains)
    - AC power cord
    - This operator's manual
3. The RenalGuard Cart is packaged in a separate shipping box.
4. Immediately document and report any shipping damage or missing accessories to both the carrier and to an authorized RenalGuard Solutions representative. Failure to do so invalidates the warranty.

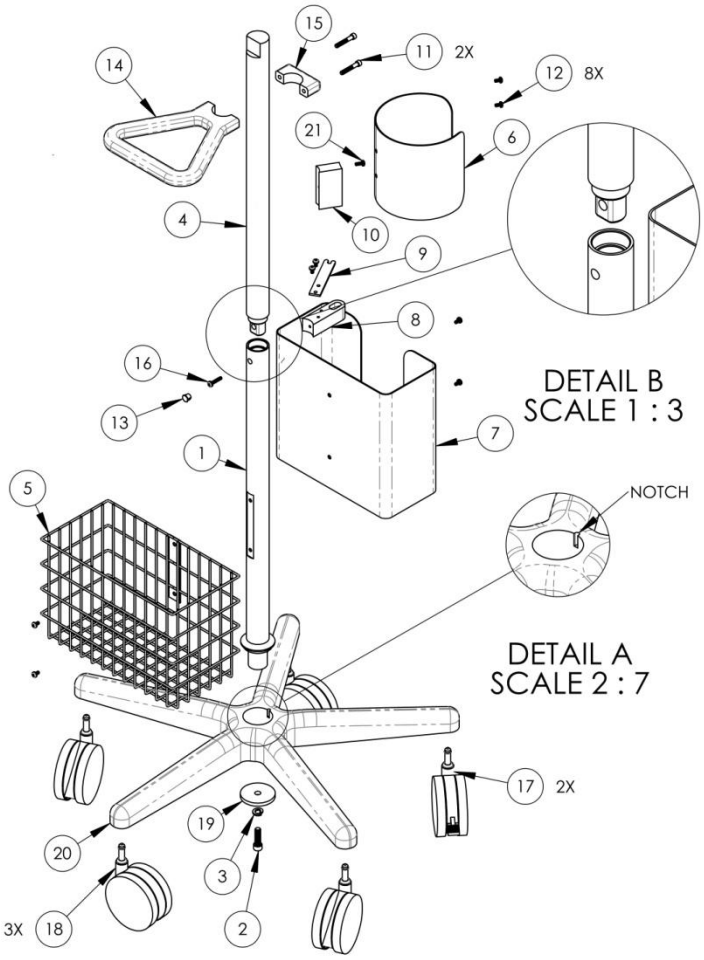
4.2.2 Cart Unpacking, Inspection and Assembly

The RenalGuard cart is shipped in a separate container. Assembly in accordance with the instructions below is required. RenalGuard cart is now shipped almost fully assembled. Unpack the RG cart components and inspect them against the exploded drawing to confirm the presence of all the parts. A Phillips screwdriver (not provided) will also be required.

Parts and Tools included:

- Wheel Base (20) with wheels (17 & 18) attached,
- Bottom Post (1) with Basket (5) and Rectangular Bag Holder (7) attached. (Hardware (2, 3 and 19) connected at bottom of pole.
- Top Post (4) with Handle (14) and Round Bag Holder (6) attached
- Chain Guide (8) with Tube Holder (9) attached. (Hardware (16) connected to chain guide. Cap (13) in bag containing chain guide)
- Two Allen wrenches (not shown)

1. Locate the notch in center hub of the 5-star wheel base (20). Casters are already attached to base.
2. Remove hardware (2,3 & 19) from bottom of bottom post (1). Align the roll pin at the base of the bottom post (1) with the notch (detail A) in the hub of the 5-star wheel base. Insert the post into the hub.
3. Stack the flat washer (19), lock washer (3) and the 3/8-16 x 1 1/4" screw (2) as shown. Using the larger Allen wrench, securely fasten the post to the base.
4. Install top post (4) into bottom post. Posts will only connect in one orientation (See Detail B) (1) Insert one 10-32 x 1" (16) Philips screw through the mounting hole in the post, to secure the chain guide (8) to the post, and insert plug (13).
5. The handle may be re-positioned as needed (using the smaller of the two Allen wrenches) when the Console is placed on the stand.



4.2.3 Initial Setup

This section details the initial setup of the RenalGuard System. The Console mounts to the assembled Cart.

To setup the RenalGuard System:

1. Remove the Console from its packaging.
2. Attach the Console to the pole of the assembled cart using the black clamp on the back of the Console.
3. If the weight scale chains are not attached when you unpack the Console, follow the step 3a instructions, otherwise proceed to step 4.
4. The chain guide clamp prevents the long urine chain from moving excessively.
   a. Pass the long urine chain through the opening of the hole in the chain guide.
   b. Ensure the urine bag is hanging freely.
5. Connect the medical grade AC power cord to the power entry module located at the rear of the Console. Plug the power cord into an outlet labeled 'Hospital Only' or 'Hospital Grade' to ensure grounding reliability. (Refer to section 2.6 for detailed electrical requirements).
6. Ensure that the **Mains** power switch located on the power entry module on the back of the Console is in the On (|) position. If this switch is Off, AC power will not be connected, even if the Console is plugged in, and the Console will run on battery power.
7. Set the **On/Off** switch on the front of the Console to the On position (|) to power up the Console and start the internal self-test. The Console will emit a short tone indicating that the diagnostic self-test has started. The message: Performing self test **…** will be displayed. The self-test takes approximately 20 seconds. Once the self-test has completed, the

3a For systems that do not have attached chains:

Attach the weight scale chains to the Console (refer to the image of the RenalGuard Console attached to the Cart Pole in section 4.1):

a. Slide a chain guide tube over the short Infusion chain, ensuring that the threads on the chain guide tube are facing away from the hook.
b. Facing the Console, screw the threaded end of the short Infusion chain into the left hole underneath the Console. Using a clockwise motion, continue until the chain is snug, but do not over tighten.
c. Screw the chain guide tube into the hole using a clockwise motion.
d. Slide the other chain guide tube over the long Urine chain, ensuring that the threads on the chain guide tube are facing away from the hook.
e. Facing the Console, screw the threaded end of the long chain assembly into the right hole underneath the Console. Using a clockwise motion, continue until the chain is snug, but do not over tighten.
f. Screw the chain guide tube into the hole using a clockwise motion. Proceed to step 4.

Continue with Same Patient and the **Begin New Patient** buttons will be displayed. This indicates that the self-test has completed successfully.

- If the self-test fails, the Console will emit an audible alarm and display an error message. Set the **On/Off** switch to the Off position (O). Wait 5 seconds and then reset the **On/Off** switch to the On position (**|**). If the error reoccurs, remove the system from use and contact service.

4.2.4 Powering Down and Storage

Set the front panel **On/Off** switch to the Off (O) position to power down the Console.

- Console may be stored on the RenalGuard Cart., or
- Console can be removed from the RenalGuard Cart. and stored on a flat surface.

The AC power cord should remain plugged in whenever the Console is in storage to ensure that the internal batteries remain charged.

4.2.5 Charging the Battery

Keeping the battery fully charged prevents unnecessary low battery alerts during operation. The system will operate on a fully charged battery for at least 30 minutes; however, it is advisable to recharge the battery whenever the battery remaining time shown in the battery icon on the bottom right corner of the display is less than half charged.

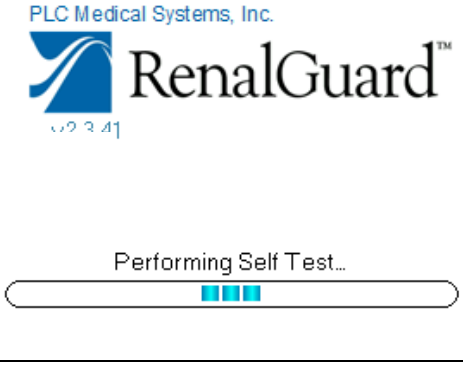
The remaining battery operation time is shown in the lower right corner of the display.

- To begin charging the battery, connect the Console to an appropriate AC outlet. Insure that the **Mains** switch located on the rear panel is in the On (|) position. The yellow battery LED on the control panel will remain illuminated while the battery is being charged.
- The Console will enter a 2 hour battery charge period after it is plugged in. The yellow LED will turn off when charging stops.
- The battery charging period may end before the battery is fully charged. The battery remaining time is displayed on the bottom right corner of the display. If the Console displays a less than half charge remaining, restart battery charging to fully charge the battery.
- To restart battery charging, insure that the Console is connected to an appropriate AC outlet. Turn the **Mains** switch located on the rear panel to the Off (O) position and then back to the On (|) position. The yellow LED will illuminate to indicate that battery charging has resumed.
- Depending upon the initial battery condition, it may be necessary to restart battery charging several times to fully charge the battery.

4.3 Therapy Setup

Caution: *The RenalGuard Console should be plugged in at all times. Failure to do so may result in decreased battery operation time.*

1. Connect the medical grade power cord to the power entry module located at the rear of the Console. Plug the cord into an outlet labeled 'Hospital Only' or 'Hospital Grade' to ensure grounding reliability. Ensure that the mains power switch located on the power entry module on the back of the Console is in the On (up) position.



Power on / Performing Self Test screen

2. Set the **On/Off** switch on the front of the Console to On. The Console will emit a short tone indicating that the diagnostic self-test has started. The message: **Performing self test …** will be displayed. The self-test takes approximately 20 seconds.
   If the self-test fails, the Console will emit an audible alarm and display an error message. Set the **On/Off** switch to Off. Wait 5 seconds and then reset the **On/Off** switch to On. If the error reoccurs, remove the system from use and contact service.

Power on self test (POST) failure screen

3. The Console will display the Same Patient/New Patient screen:

   a. Pressing the **Continue with Same Patient** button restores all previous information used for therapy before the power was turned off, including all settings, *Bolus Administration*, *Target Balance Value (RG Aim)*, *Elapsed Time, Other Fluid Intake, Urine Measured*, and *Fluid Infused*.

   b. Pressing the **Begin New Patient** button indicates that therapy on a new patient is to be started. All settings and therapy parameters are restored to zero or to the system defaults. If the **Begin New Patient** button is pressed accidentally, press the **Back** button to return to the patient selection screen.

Same Patient/New Patient Screen

4.4 Loading the Infusion Set

1. Visually examine the RenalGuard Single Use Set to determine that the package has not been opened or damaged during shipping. Once opened, preserve sterility.
2. Open the pump door and load the pump segment tubing over the rollers. Line up the loading guide markers [1] and [2] on the Infusion Set with the loading guide labels [1] and [2] on the Console. Assure that the clips on ends of the raceway are lined up with the tube segment. Close the pump door firmly until you hear a click. Check that the tubing is aligned correctly. Ensure that the tubing from the infusion bag side enters on the left side of the pump.
3. Line up the loading guide marker [3] on the Infusion Set with the loading guide label [3] below the air detector on the front of the Console. Insert tubing into air detector channel, ensuring that the tubing is firmly seated.
4. Plug the transducer connector marked [4] on the Infusion Set into the pressure transducer receptacle (labeled [4]) on the front of the Console. Ensure that the connector is fully seated.

Caution: *The RenalGuard System is designed for use with 1 (one) liter infusion bags only. The System will not operate properly with other sized infusion bags.*

5. Using the standard technique, spike a 1 liter infusion bag using the Infusion Set bag spike.
6. Facing the front of the Console, hang the full infusion bag on the Left chain hook. Ensure that the bag hangs freely and that its motion will remain unobstructed as it empties.

7. Facing the front of the Console, hang the empty Collection Set urine bag on the Right chain hook. To minimize excessive swinging of the urine collection bag, ensure that the chain supporting the bag passes through the ring of the chain guide assembly. Ensure that the bag hangs freely and that its motion will remain unobstructed as it fills.
8. Insert the collection set tubing into the notched hose holder on the chain guide assembly. Align the Yellow loading guides on the tubing to the right and left of the notch to prevent the tubing from pulling on the urine collection bag.
9. Confirm that the drain valve at the bottom of the urine collection bag is fully closed.

Warning: *The RenalGuard System will not operate properly if the urine bag is not hanging freely on the weight scale chain, or is interfered with in any way.*

4.5 Priming the RenalGuard Single Use Set

Caution*: It is necessary to complete the priming procedure before connecting the patient for therapy. The RenalGuard Console performs required safety checks during the priming procedure.*

Warning*: Do not connect the patient to the Infusion Set during the priming procedure. The air detector is disabled during priming. This could result in air being introduced into the patient.*

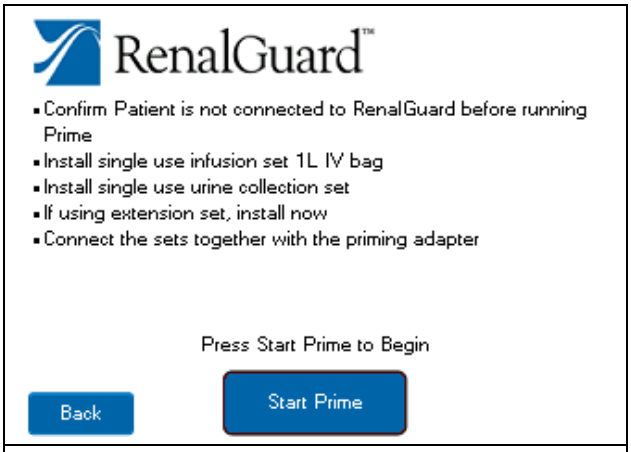
Caution*: The RenalGuard Single Use Set can only be primed using the following automatic priming procedure. The set cannot be primed by gravity flow.*

1. Use the Luer - to - Foley adapter to connect the end of the Infusion Set tubing to the end of the urine Collection Set tubing. The adapter is intended for priming only and is not to be used during patient therapy.
2. Support the tubing to ensure that tension is not exerted on either the hydration or collection bags or on their suspension chains. The Cart pole may be used to provide support.
3. Ensure that the clamp on the Infusion Set is open.

4. Once the RenalGuard Single Use Set is correctly installed, press the **Start Prime** button.

5. During Prime mode, inspect the Infusion Set for any leaks. If necessary, gently tap on the tubing and/or squeeze the drip chamber to release any air bubbles.

6. Prime mode will run the pump for approximately 2 minutes, and will stop automatically. Approximately 150 ml of fluid will be pumped from the hydration bag into the urine collection bag during Prime.



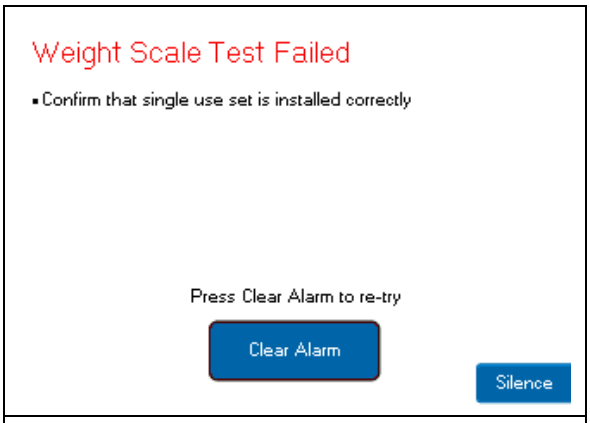
Start Prime Screen

   - Do not touch the infusion bag or urine bag during Prime. The weight scales monitor both the infusion and collection bags weights during Prime to confirm that the RenalGuard Single Use Set has been installed correctly.
   - If the Prime procedure fails, the Console will emit an audible alarm and display an error message. Press the **Silence** button to silence the alarm then follow these steps:

     a. Check the connections to the priming adapter and confirm that they are tight. Loose connections can cause leaks, resulting in Prime failures.

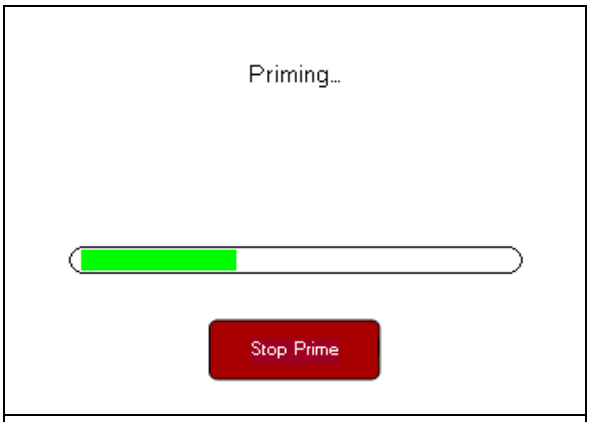
     b. Confirm that the set is installed correctly (i.e. bag obstruction, tubing leaks, inadequate connections, tube not in air detector, etc.). Once the visual check is complete, press the **Clear Alarm** button and repeat step 4.

     c. If the Prime procedure fails 3 or more times, discontinue use of the RenalGuard Single Use Set. It may be necessary to replace the RenalGuard Single Use Set or the RenalGuard Console. Contact your service representative (refer to section 2.13 Service Information).



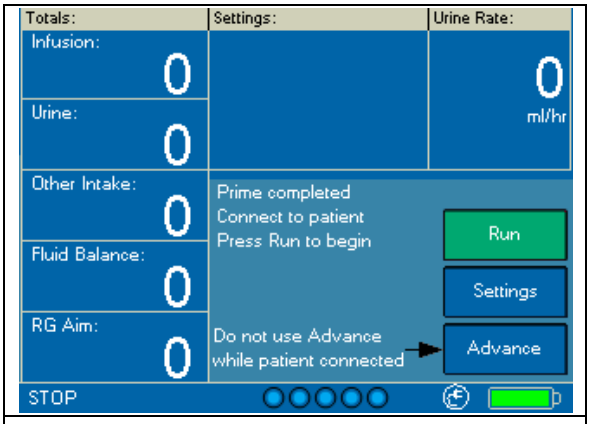
Prime Alarm Screen

7. Prime mode may be discontinued at any time by pressing the **Stop Prime** button. To restart, press the **Start Prime** button. Priming will restart from the beginning.



Prime Mode Screen

8. When the Prime procedure ends and the pump stops, carefully examine the entire Infusion Set to ensure that it is fully primed and that no air is present in the infusion tubing.
9. If air remains in the infusion tubing after Prime, use the **Advance** button to remove.
    d. Press and hold the **Advance** button to run the pump. Once the **Advance** button is released, the pump will stop within 2 seconds.
    e. The pump will automatically stop when the **Advance** button has been depressed for 30 seconds. It will be necessary to release and then re-press the **Advance** button to run the pump for as long as an additional 30 seconds.



Prime Completed Screen

***Warning**: Air detection is disabled during **Advance** button operation. The **Advance** button must not be pressed while the Infusion Set is connected to the patient.*

10. When the Console has determined that Prime has been successfully completed, the message: "Prime completed. Press **Run** to begin", will be displayed.

4.6 Connecting the RenalGuard System to the Patient

***Warning**: Aseptic technique must be used throughout the procedure. Usual and customary hospital infection control practices should be followed when replacing the patient connected tubing to ensure the safety of the patient and clinician.*

1. Ensure that both the Urinary Catheter and the IV Catheter have been successfully inserted into the patient and are prepared for use. The Urinary Catheter and IV Catheter should be flushed and flowing properly prior to connecting the RenalGuard Single Use Set.
2. Disconnect the Luer connector of the Infusion Set from the prime adapter. Remove the prime adapter which is only used during the priming procedure. The adapter should be discarded at this time. The priming adapter is not intended to be connected to the patient.
3. Connect the Luer connector of the Infusion Set to the inserted IV catheter. Ensure that no air enters the system. Turn the Luer connector until it is completely closed. Do not over tighten.

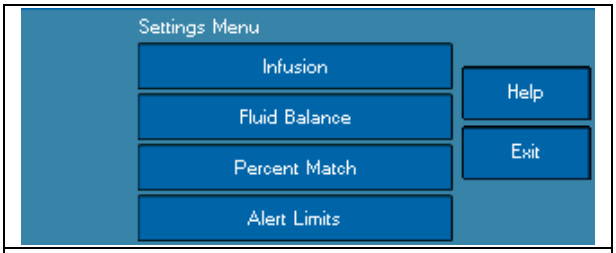
***Warning:** Automatic air detection is disabled during manual connection operations.*

4. Visually check for air in the Infusion Set.
    - If air is noted, disconnect the Infusion Set from the inserted IV catheter and use the Advance mode to purge the air.
    - Press and hold the **Advance** button to run the pump. Once the **Advance** button is released, the pump will stop within 2 seconds.
    - The pump will automatically stop when the **Advance** button has been depressed for 30 seconds. It will be necessary to release and then re-press the **Advance** button to run the pump for as long as an additional 30 seconds.
5. Connect the male Foley connector of the Collection Set to the inserted urinary catheter.

4.7 Setting and Changing Parameters

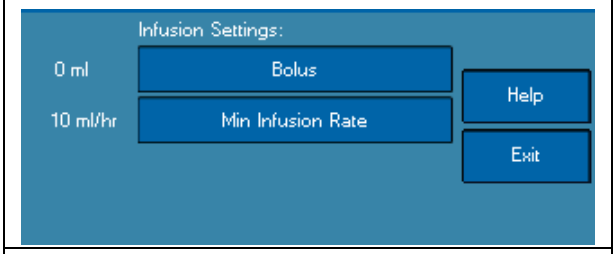
The RenalGuard Console has 4 user settings menus :

- Infusion Settings,
- Fluid Balance Settings,
- Percent Match Settings, and
- Alert Limit Settings.



Settings Menu Screen

- If a setting change is desired, press the **Settings** button from the main screen. The Settings Menu Screen will be displayed.
- Press the button for the desired settings menu and it will be displayed.
- Touch the **Help** button to display short explanations of each of the available settings

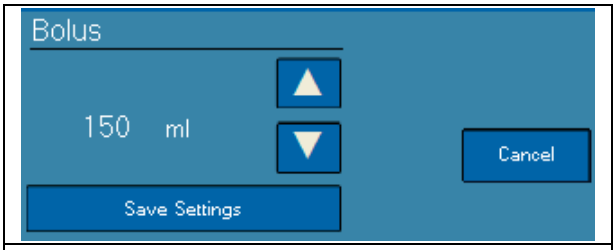


Infusion Settings Menu Screen

- Press the button for the setting to be changed. An adjustment screen similar to the one to the right will be displayed:

  Use the **Up and Down Arrow** buttons to adjust the setting.

- Press the **Save Settings** button to confirm the new setting. If the **Save Settings** button is not pressed, the previously stored setting will be used.



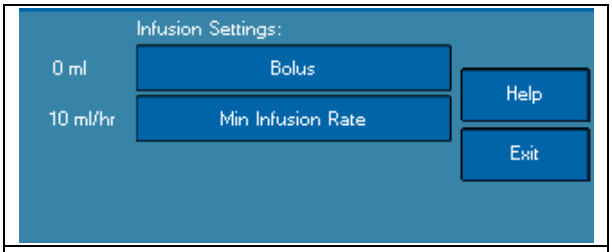
Adjustment Screen

***Warning*:** *The RenalGuard System does not measure the total volume removed from or infused into the patient. The System only measures the urine output and system hydration rate. It is the user's responsibility monitor the patient's overall hydration status. If other fluids are infused or removed, the user is responsible for keeping track of the total amount of fluid infused or given orally and adjusting patient settings accordingly.*

4.7.1 Infusion Menu

4.7.1.1 Bolus Deliver Setting

Units: milliliters
Range: 0 to 500 ml
Default: 0 ml



Infusion Settings Menu Screen

This setting allows the user to infuse additional fluid into the patient's IV when clinically indicated. Any volume set for the Bolus will be delivered over a 30 minute period.

- The Bolus Volume is infused in addition to the Fluid Balance Setting and the Urine Volume replacement amounts.
- If the Bolus delivery is interrupted by the Console entering Stop or Pause mode, Bolus delivery will automatically resume and complete as soon as the System is returned to normal operation.

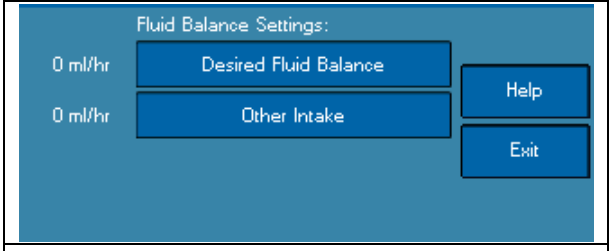
4.7.1.2 Minimum Hydration Rate Setting

Units: milliliters / hour
Range: 10 to 100 ml/hr
Default: 10 ml/hr

This setting establishes a minimum pump rate during Run and Pause mode. Regardless of the urine rate and other fluid balancing settings, the infusion pump will infuse hydration fluid at the set Minimum Hydration Rate. In Pause mode the infusion pump only runs at the Minimum Hydration Rate.

Warning: *Both of these settings can cause the RenalGuard System to infuse fluid over and above the patient's urine output volume. It is the user's responsibility to confirm that this is an appropriate fluid balance for the patient.*

4.7.2 Fluid Balance Menu



Fluid Balance Settings Menu Screen

4.7.2.1 Desired Fluid Balance Setting

Units: milliliters / hour
Range: -1000 to 500 ml/hr
Default: 0 ml/hr (balance)

The Desired Fluid Balance, in ml / hr, is the desired hourly fluid balance that the RenalGuard System attempts to achieve by adjusting the infusion pump. The Console takes the patient's urine output and the Other Fluid Intake setting into account when trying to achieve the Desired Fluid Balance. This setting can be positive or negative. If positive, the System attempts to balance the measured urine output and infuse the set rate of fluid over and above the match. If negative, the System attempts to replace the set rate less than the measured urine output. If the urine rate is too low to allow the System to reach the negative Desired Fluid Balance, the pump runs at the minimum hydration rate. Touching the Default Fluid Balance button will reset the setting to the default value.

Caution: *This setting will cause the RenalGuard Console to infuse fluid either above or below the patient's urine output volume. It is the user's responsibility to confirm that this is an appropriate fluid balance for the patient.*

4.7.2.2 Other Fluid Intake Setting

Units: milliliters / hour
Range: 0 to 2000 ml/hr
Default: 0 ml/hr

The Other Fluid Intake setting allows the user to inform the RenalGuard Console of the rate of other fluid intake into the patient. The Console then takes this setting into account when attempting to achieve the Desired Fluid Balance setting.

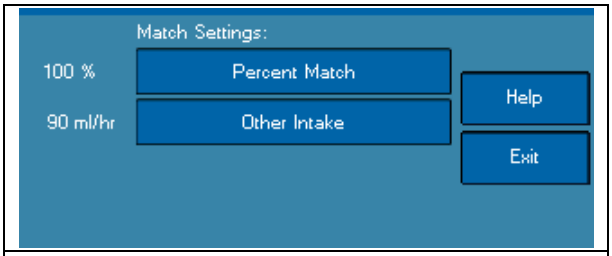
Caution: *This setting relies on the user input to calculate the total volume of fluid intake from other sources. It is the user's responsibility to adjust this setting if the other intake rates are adjusted or terminated.*

4.7.3 Percent Match Menu

4.7.3.1 Percent Match Setting

Units: percent
Range: 0 to 100 %
Default: 100% (balance)

The percent of the urine output that should be matched by hydration fluid. Touching the Default Percent Match button will reset the setting to the default value.



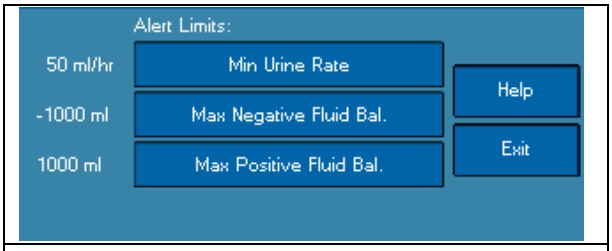
Percent Match Menu Screen

The Other Fluid Intake Setting is described in the previous section.

4.7.4 Alert Settings Menu

4.7.4.1 Minimum Urine Output Setting

Units: milliliters / hour
Range: 10 to 500 ml/hr
Default: 150 ml/hr



Alert Settings Menu Screen

This setting provides the ability to monitor for the minimum desired urine output level (in ml/hr). If the urine output is consistently below the set value, the user will be notified by an alert sound and the display message: "Minimum Urine Level Not Reached". This is a monitoring setting only and does not affect the System's performance.

4.7.4.2 Negative Alert Limit Setting

Units: milliliters
Range:-100 to -5000 ml
Default: -1000 ml

This setting provides the ability to monitor for a negative fluid balance beyond a set limit. If the fluid balance drops below this level, the user is informed with an alert. This is a monitoring setting only and does not affect the System's performance.

4.7.4.3 Positive Alert Limit Setting

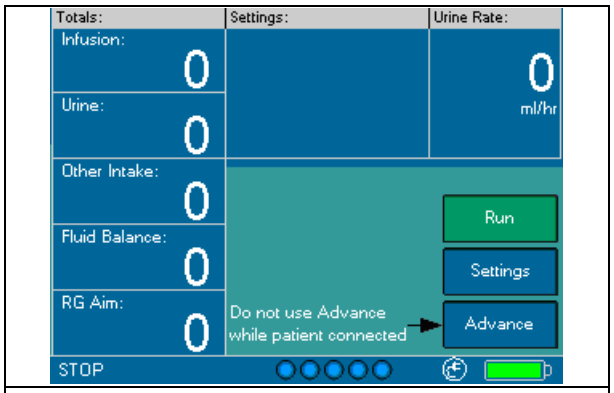
Units: milliliters
Range: 100 to 5000 ml
Default: 1000 ml

This setting provides the ability to monitor for a positive fluid balance beyond a set limit. If the fluid balance rises above this level, the user is informed with an alert. This is a monitoring setting only and does not affect the System's performance.

4.8 Initiation of Therapy

The RenalGuard System defaults to the matched hydration setting (Fluid Balance of 0 ml/hr). Other parameters are available (i.e. Bolus, Percent Match, and Desired Fluid Balance). See section 4.7 for information regarding these settings and parameters.

1. Before starting therapy, check to ensure that:
   - all patient connections are secure,
   - the urine bag is hanging freely, and
   - the clamp on the infusion line is open.
2. Press the **Run** button to start therapy.

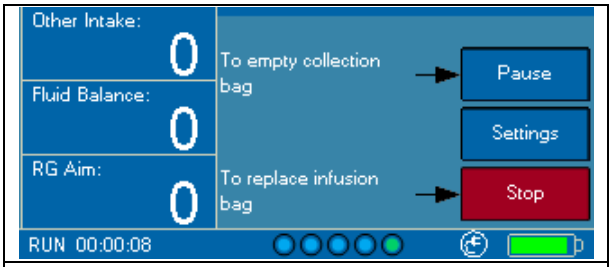


Run Initiation Screen

***Warning**: Running with the infusion line clamped or leaving the Console in Stop mode risks underinfusing the patient and increases the risk of thrombosis.*

4.9 Using Pause Mode

The Pause Mode is similar to the KVO (Keep Vein Open) mode frequently used in IV therapy. It is intended to allow the urine collection bag to be drained or to Pause therapy while the patient is moved or urine drainage is re-arranged.

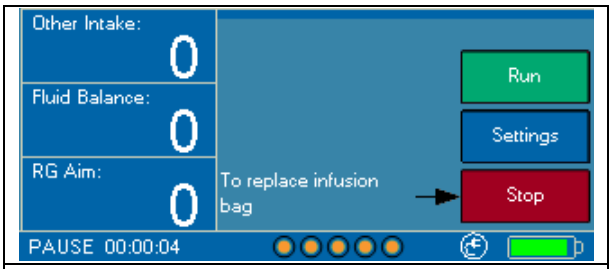


Run Mode Screen

Caution: *When the RenalGuard Console is in Pause mode, the Urine volume output is not being replaced. The Infusion rate is set to the minimum hydration rate until the user terminates Pause mode.*

Caution: *Stay in Pause mode no more than is necessary. After the urine bag is drained in Pause mode, urine is not measured by the Console until Run mode is resumed. Resume Run mode as soon as possible after draining bag to ensure accurate urine measurement.*

1. While in the Run Mode, press the **Pause** button to stop the urine volume replacement control.
   - While in the Pause mode, the System will run the pump at the minimum hydration rate to keep the vein open and to maintain minimum IV hydration.
   - During pause mode, the Console emits a low volume beeping. After 15 minutes, the Console will increase the volume of the beeping to high to alert the user that the patient is not receiving urine volume replacement.



Pause Screen

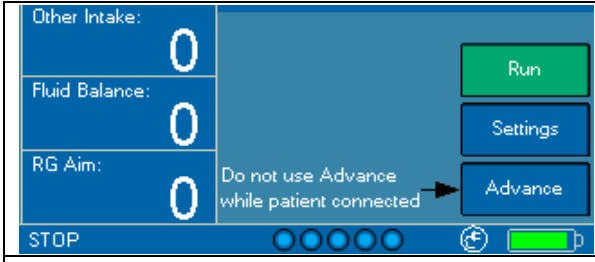
2. To resume Run mode operation, press the **Run** button.
3. Upon exiting from the Pause mode and entering the Run mode, the Console adapts to the infusion and collection bag weight changes to correctly resume hydration control.

4.10 Using Advance Mode

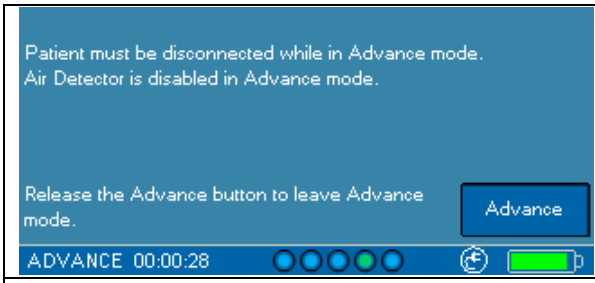
The Advance mode runs the pump at 60 ml/min to allow air bubbles to be cleared from the Infusion Set. The **Advance** button can only be activated while the Console is in Stop mode.

Warning: *Air detection is disabled during* ***Advance*** *button operation. The* ***Advance*** *button must not be pressed while the Infusion Set is connected to the patient.*

- Press and hold the **Advance** button to run the pump to displace fluid and air though the infusion set. Once the **Advance** button is released, the pump will stop within 2 seconds.
- The pump will automatically stop when the **Advance** button has been depressed for 30 seconds. It will be necessary to release and then re-press the **Advance** button to run the pump for as long as an additional 30 seconds.



Stop Screen



Advance Screen

4.11 Replacing the Hydration Fluid Bag

Caution: *The RenalGuard System is designed for use with 1 (one) liter infusion bags only. The System will not operate properly with other sized infusion bags.*

Warning: *The RenalGuard System is designed for hydration with crystalloid and colloid hydration fluids only. It is not designed to infuse blood, blood products, or to deliver drugs.*

1. The RenalGuard System is designed to automatically stop and sound an alarm when the Hydration Bag is nearly empty (i.e., when approximately 50 ml of fluid remains in the bag). The message: "Infusion Bag Empty" will be displayed. This alarm can be silenced for a 2 minute period using the **Silence** button.
2. Press the **Clear Alarm** button to reset the alarm.
3. If a hydration bag that is not empty requires replacement, press the **Stop** button to stop the pump and avoid allowing air into the circuit.
4. Remove the hydration bag from the Left chain hook. Disconnect the Infusion Set spike from the hydration bag.

5. Using the standard technique, spike a fresh 1 liter hydration bag using the Infusion Set spike.
6. Facing the front of the Console, hang the full hydration bag on the left chain hook. Ensure that the bag hangs freely and that its motion will remain unobstructed as it empties.
7. Press the **Run** button to resume Therapy.
8. The RenalGuard Console will automatically account for any weight changes and will automatically replace urine output by the patient while the pump was stopped.

4.12 Emptying the Urine Collection Bag

Caution: *Emptying the Urine Collection Bag during Run or Stop mode, or while the Console is powered off may result in incorrect urine measurement and alarms.*

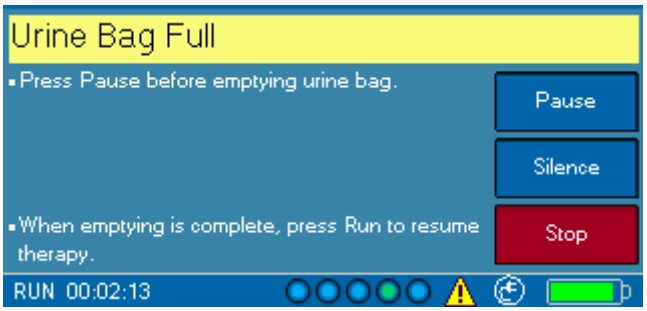
The Urine Collection Bag should only be emptied during Pause mode. Do not empty the Urine Collection Bag during Run or Stop mode, or while the Console is powered off. Accurate urine collection is a key component of RenalGuard Therapy. Draining the bag in any mode other than Pause may result in incorrect urine measurements and alarms.

There are two times the Urine Collection Bag emptying should be initiated:

a. After the Console has reported the alert "Urine Bag Full", or

b. During Operation (Run mode) whenever the user chooses to empty the bag

If the "Urine Bag Full" Alert is displayed:



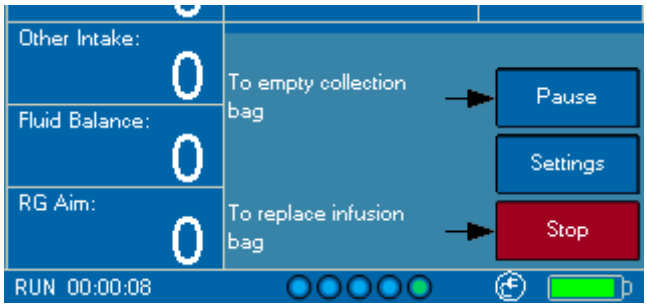
1.1 Press the **Pause** button to select the Pause Mode; this will also clear the alert.

1.2 Empty the Urine Collection bag by opening the valve at the bottom and draining the bag in accordance with established procedures.

1.3 When drainage is complete, close the urine collection bag drain valve.

1.4 Press the **Run** button to resume Therapy.

During Operation:



2.1 Ensure that the Console is in the Run mode prior to emptying the Urine Collection bag.

2.2 Press the **Pause** button to select the Pause Mode and clear the alert.

2.3 Empty the urine Collection bag by opening the valve at the bottom and draining the bag in accordance with established procedures.

2.4 When drainage is complete, close the urine collection bag drain valve.

2.5 Press the **Run** button to resume Therapy.

Therapy will not restart until the **Run** button has been pressed

4.13 Conclusion of Therapy

1. Once therapy is complete, press the **Stop** button to stop hydration.
2. Close the clamp on the Infusion Set to ensure that additional fluid is not infused into the patient.
3. Discard the Infusion Set and the urine Collection Set. Do not re-use.
4. Turn the RenalGuard Console off. Refer to section 4.2.4 for storage instructions and to section 4.2.5 for detailed battery charging instructions.

4.14 De-Installation and Packaging

This section details the steps followed to de-install the RenalGuard Console and to package the Console for shipment to RGS.

Contact service with any questions concerning the de-installation or return of Consoles. The numbers in parenthesis () refer to the identification numbers in the illustration and the table in section 4.1.

1. Set the On/Off switch (1) on the front of the Console to the "Off" position. Place a piece of tape over the switch to ensure that the switch will remain in the off position during shipment.
2. Disconnect the medical grade AC power cord from the power entry module (15) located at the rear of the Console. Place the power cord in the large plastic bag provided with the shipping box.
3. If the chains are attached to the Console by rings, it is a fixed-chain Console, proceed to step 4.

   Only for Consoles that do not have attached chains:

   a) Remove the chain guide tubes (24) from the underside of the Console by unscrewing them in a counterclockwise direction. The chain guide tubes are 1 inch pieces of metal tubing located where the chains for the infusion and urine collection bags exit the Console.

   b) Remove both the long (26) and short (25) chain assemblies from the underside of the Console by unscrewing their threaded ends in a counterclockwise direction. Place both chains and the two chain guide tubes in the small plastic bag provided with the shipping box.
4. Remove the Console from the pole by loosening the black pole clamp (19) at the rear of the Console. Ensure that the Console is adequately supported as you loosen the clamp.
5. Align the Console with the cutout foam in the shipping box. Place the Console into the foam in the box. The small plastic bag is intended to fit in the small foam cutout. The power cord fits into the open corner of the foam. If available the manual may be placed on top of the foam inside the box.
6. Ensure that the following components have been packed in the box:
   - RenalGuard Console
   - Short Infusion chain with hook
   - Long Urine chain with hook
   - 2 chain guide tubes (only with Consoles that do not have attached chains)
   - AC power cord
   - The operator's manual (if available)
7. Use shipping tape to seal the box. Follow the directions provided to return the product.
8. Do not return the cart with the Console.

5. Alarms and Troubleshooting

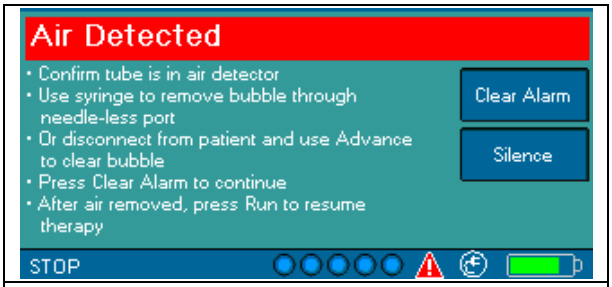
Warning: *Silencing and Clearing an Alarm may not eliminate the Alarm cause. Carefully investigate and correct all Alarms and Alerts.*

The alarms generated by the RenalGuard Console indicate the presence and severity of the condition detected. The Alarm bell on the bottom of the display and the volume of the sound emitted by the Console represent the general level of importance of the current alarm condition to the user.

Pressing the **Silence** button will silence alarm for a 2 minute period while corrective actions are performed.

Respond to the information displayed on the screen and correct the conditions that caused the Alarm.

Press the **Clear Alarm** Button to reset the alarm.



Typical Alarm Screen

- If the Console is still in the Run Mode and the alarm condition is still present, the Alarm will re-annunciate.
- If Console is in the Stop Mode, the Alarm condition may be cleared but the Alarm will re-annunciate if the condition has not been removed when Run mode is restarted.

Certain Alarms such as System Malfunction Alarms cannot be cleared or silenced unless the Console power is turned OFF and then back ON.

Depending on the cause of an Alarm or Alert the RenalGuard Console may respond in one of three ways:

1. Inform the user and stop the pump
   (for example if air is detected or if the hydration fluid bag is almost empty)
2. Inform the user and stop urine volume replacement while maintaining pump flow at the minimum hydration rate. (For example, if the urine bag has excessive motion).
3. Inform the user and continue urine volume replacement.
   (For example, if the minimum urine rate has not been reached).

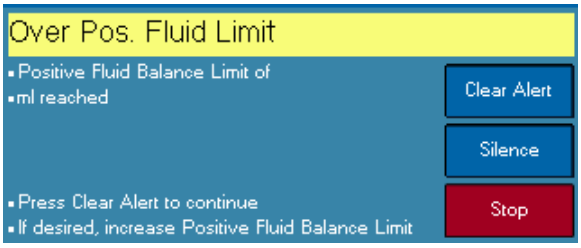
Caution: *While the RenalGuard Console will provide information on the most likely causes of the alarm, the user must exercise caution and examine all possible options if the information displayed does not solve the problem.*

5.1 Therapy Information Alerts

Positive Fluid Balance Limit Reached

This Alert is designed to inform the user that the positive fluid balance limit has been reached. This Alert is intended as in informational alert only and does not affect the System's operation.

This alert will recur after 15 minutes if the alert condition is still present.



Alert Message Displayed

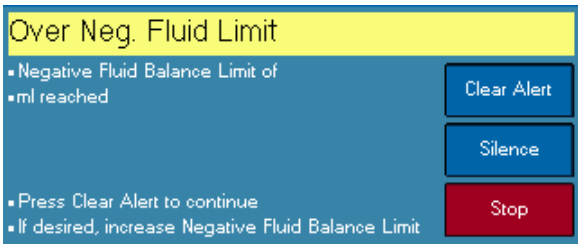
Recommended Action

1. Press the **Clear Alert** button to clear the alert
2. Confirm that current fluid balance is as desired
3. Adjust fluid balance settings (Desired Fluid Balance or Other Fluid Intake settings) if desired
4. Adjust Positive Fluid Balance Limit if desired (see section 4.7 for details).

Negative Fluid Balance Limit Reached

This Alert is designed to inform the user that the negative fluid balance limit has been reached. This Alert is intended as in informational alert only and does not affect the System's operation.

This alert will recur after 15 minutes if the alert condition is still present.



Alert Message Displayed

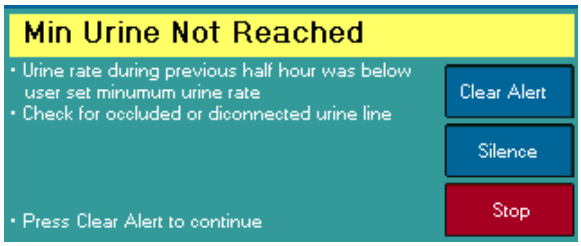
Recommended Action

1. Press the **Clear Alert** button to clear the alert
2. Confirm that current fluid balance is as desired
3. Adjust fluid balance settings (Desired Fluid Balance or Other Fluid Intake settings) if desired
4. Adjust Negative Fluid Balance Limit if desired (refer to section 4.7 for details).

Minimum Urine Not Reached

This Alert is designed to inform the user that over the previous 30 minutes the patient's urine output was below the user selected minimum level. This Alert is intended as in informational alert only and does not affect the System's operation.

This alert can also indicate blocked, kinked or clamped urine Collection Set. The user should check to ensure that the flow through the Collection Set flow is unobstructed.



Alert Message Displayed

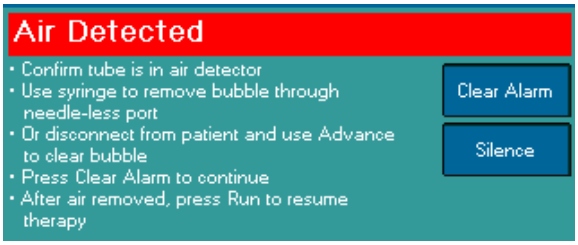
Recommended Action

1. Ensure that urine bag is hanging freely on the right hook
2. Check that the urine Collection Set is connected to the patient's Foley catheter
3. Ensure that the Collection Set is not blocked, kinked, or clamped
4. Press the **Clear Alert** button to clear the alert

5.2 Fluid Path Related Alarms and Alerts

Air Detected Alarm

Significant amount of air is detected by the ultrasonic air detection. The pump is stopped until the user initiates corrective action.



Alarm Message Displayed

This alarm can be caused by:

1. Air entrained from the damaged or disconnected tubing
2. Air entrained from the drip chamber
3. Tubing dislodged from the air detector slot

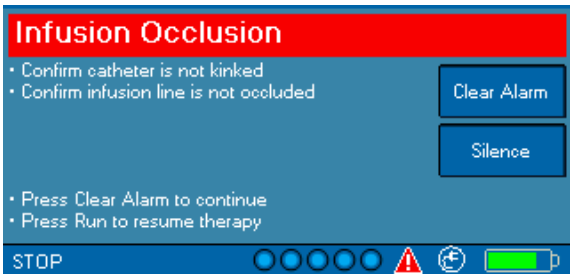
Recommended Action

1. Check for leaks and confirm that the drip chamber level is correct
2. Use the Advance mode to remove or aspirate any air bubbles
3. Confirm that the tubing is properly placed in the air detector slot
4. Press the **Clear Alarm** button to clear the alarm
5. Restart therapy by pressing the **Run** button after removing any air bubbles

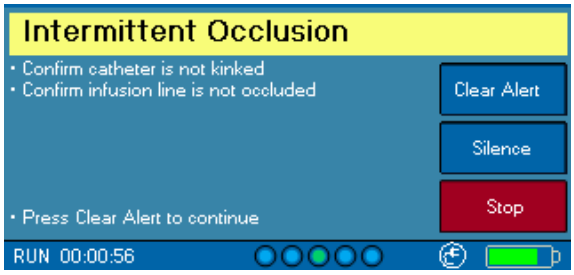
Warning: *It is the user's responsibility to ensure that air is removed from the infusion circuit before the system is restarted following air detection.*

Warning: *Air detection and occlusion detection are disabled during* ***Advance*** *button operation. The* ***Advance*** *button must not be pressed while the Infusion Set is connected to the patient.*

Infusion Set Occlusion Alarm



Alarm Message Displayed



Alert Message Displayed

The pressure sensor has detected a downstream occlusion of the infusion line. If a full occlusion is detected an alarm is reported, a red bar will be displayed, and the infusion pump is stopped pending corrective action. If an intermittent occlusion is detected an alert is reported, a yellow bar will be displayed, and the infusion pump will continue to operate.

This alarm can be caused by:

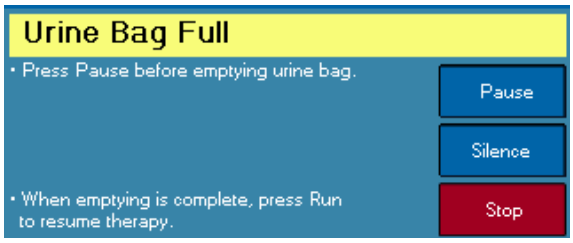
1. Closed clamp
2. Kinked tubing
3. Occluded IV

Recommended Action

1. Check clamps
2. Check tubing
3. Flush the IV in accordance with the accepted clinical technique
4. Press the Clear Alarm button to clear the alarm
5. Press the Run button to return the Console to the Run mode

Urine Bag Full Alert

Using the weight scale, the Console has detected that the Urine Bag is full.



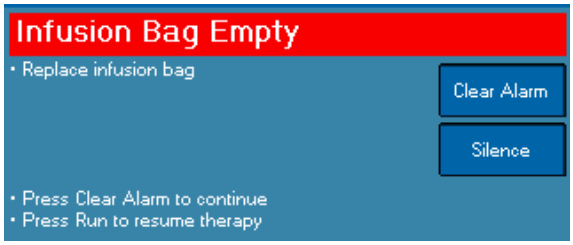
Alert Message Displayed

Recommended Action

1. Check the urine bag level
2. Press the **Pause** button to enter Pause mode and clear the Alert
3. Drain the urine bag in accordance with the accepted clinical technique
4. Close the urine bag drain valve
5. Press the **Run** button to return the Console to the Run mode

***Caution**: Always enter Pause mode prior to draining urine. Remember to close the drain valve. Press the **Run** button to resume therapy.*

Infusion Bag Empty Alarm



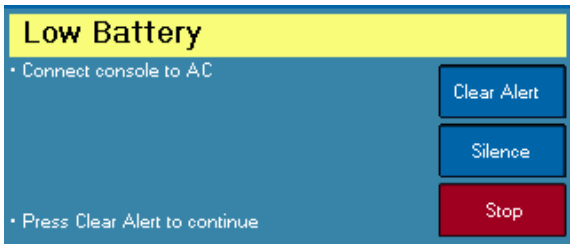
Alarm Message Displayed

The system has detected that the Hydration Fluid Bag is almost empty. There can be approximately 50 ml of fluid left in the bag. The system automatically stops the hydration pump.

Recommended Action

1. Check the fluid bag level
2. Replace the bag in accordance with the accepted clinical technique
3. Press the **Clear Alarm** button to clear the alarm
4. Press the R**un** button to return the system to the Run mode

Battery Low Alert and Alarm

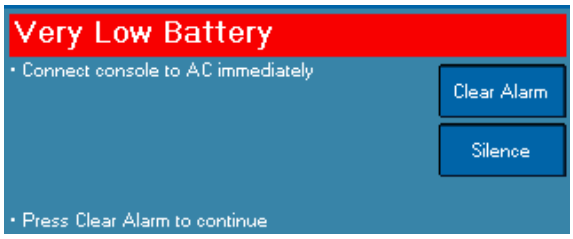


Alert Message Displayed

When there are fewer than 30 minutes of battery life remaining and the system is powered from the internal battery, the system generates an alert with a low volume and displays the message "Low Battery".

Recommended Action

1. Connect the Console to AC power
2. Refer to section 4.2.5 for detailed battery charging instructions
3. Press the **Clear Alert** button to clear the alert



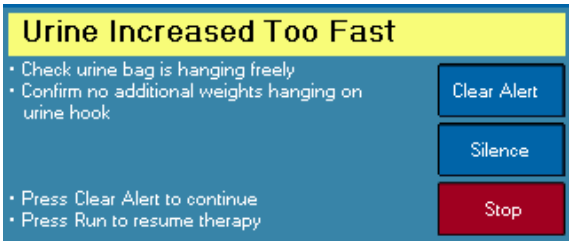
Alarm Message Displayed

When there are fewer than 3 minutes of battery life remaining and the system is powered from the internal battery, the system generates an alarm with a high volume and displays the message "Very Low Battery".

Recommended Action

1. Connect the Console to AC power
2. Refer to section 4.2.5 for detailed battery charging instructions
3. Press the **Clear Alarm** button to clear the alarm
4. Press the **Run** button to return the system to the Run mode

Excessive Urine Weight Increase Alert



Alert Message Displayed

The system monitors Urine Weight for abrupt increases that cannot be explained by normal urine output. If an abrupt increase of urine weight is detected an Alert message is issued to the user. The Console automatically switches to the Pause mode. Hydration continues at the minimum hydration rate. Urine volume replacement is disabled during this time. The user can clear this alert. The user must press the **Pause** button to restart therapy. The excessive increase in urine weight is not included in the total urine measurement.

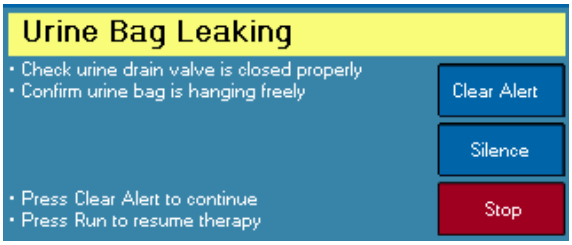
This alert can be caused by:

1. Object pulling on the urine scale hook
2. Additional weight added to urine bag
3. Hardware malfunction

Recommended Action

1. Ensure that the Urine collection bag is freely hanging on the right side hook
2. Press the **Clear Alert** button to clear the alert
3. Press **Run** button after correcting the condition to re-enter Run mode.

Urine Bag Leak Alert



Alert Message Displayed

The system monitors the urine bag for a decrease in weight. If such a decrease occurs during therapy an Alert is issued and the Console enters the Pause mode.

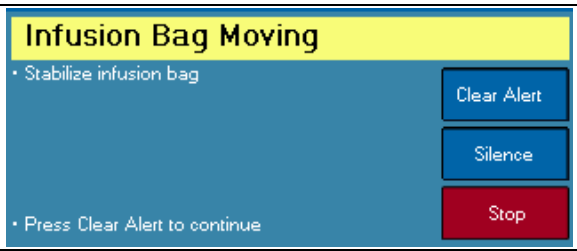
This alert can be caused by:

1. The urine bag was drained without pressing the **Pause** button
2. The urine bag is leaking

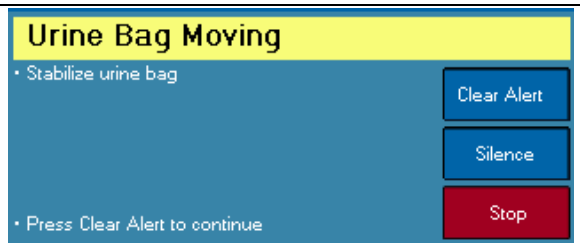
Recommended Action

1. Check for leaks
2. Check the tubing
3. Press the **Clear Alert** button to clear the alert
4. Press **Run** button to restart therapy.

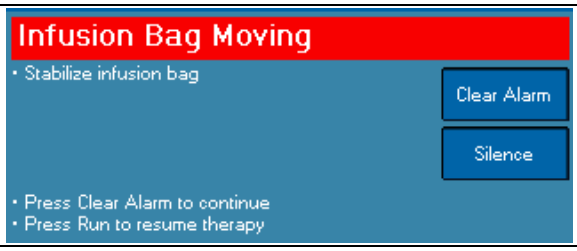
Unstable Scale Alarms and Alerts



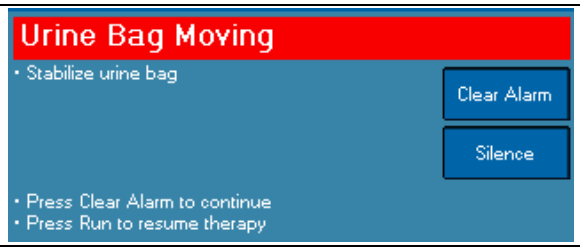
Alert Message Displayed



Alert Message Displayed



Alarm Message Displayed



Alarm Message Displayed

The system relies on weight scales to determine urine output and fluid replacement rate. If the device is excessively bumped, the weight scale readings become erratic and unreliable. The system automatically detects such conditions and issues an alarm. If the weight scale is not stable, the system will automatically enter the Pause mode.

Whenever the system is in the Pause mode, urine volume is not being replaced. Patient receives hydration fluid at the user set minimum hydration rate. When in the Pause mode, the Console will emit low rate and volume beeps. After 15 minutes, the system will increase the volume to high to bring to user's attention that the patient is receiving only the Minimum Hydration Rate of fluid.

If unstable scales are detected at the start of the Run mode, the Console issues an alarm and enters the Stop mode.

This alarm can be caused by:

1. Excessive Motion

Recommended Action

During the Start of Run

1. Bring the system to rest
2. Press the **Clear Alarm** button to clear the alarm
3. Press the **Run** button to start balancing

During Operation

1. Bring the system to rest
2. Press the **Clear Alarm** button to clear the alarm
3. Press the **Run** button to restart balancing

***Caution**: Whenever the RenalGuard System is in the Pause mode, urine volume is not being replaced. The patient receives the user set minimum rate of hydration.*

Infusion Weight Mismatch Alarm

During patient hydration the system monitors the weight of the hydration fluid bag and compares it to the pump flow rate. If serious mismatch is detected an alarm is issued and the pump is stopped.

Alarm Message Displayed

This alarm can be caused by:

1. Disconnected Tube
2. Kinked tube or other type of pre-pump occlusion
3. Leaky bag or tube

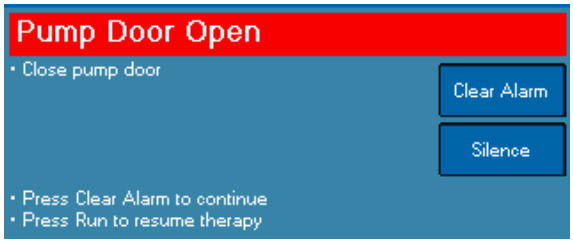
Recommended Action

1. Check for leaks
2. Check for occlusion
3. Press the **Clear Alarm** button to clear the alarm
4. Restart therapy if the condition is corrected by pressing the **Run** button

Pump Door Open Alarm

If the pump door is opened while the pump is running, the system generates a beep, displays an alarm message, and the pump is stopped.

If the pump door is opened when the pump is not running, a message indicating that pump door is open will be displayed. Whenever the Pump Door is opened, the pump rollers will not move and the pump will not run.



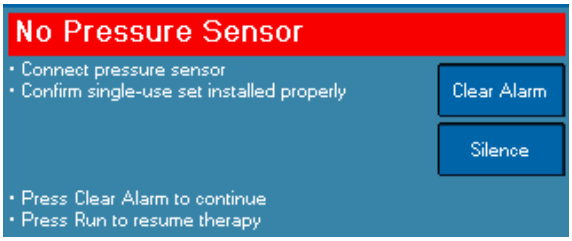
Alarm Message Displayed

Recommended Action

1. If Pump Door is open, close it
2. Press the **Clear Alarm** button to clear the alarm
3. Press the **Run** button to restart therapy.
4. If Pump Door is closed, cycle the power once. If the condition persists, notify service (refer to section 2.13 Service Information).

Pressure Sensor Disconnected Alarm

If the pressure sensor is disconnected while pump is running, the system generates a beep, displays an alarm message, and the pump is stopped.



Alarm Message Displayed

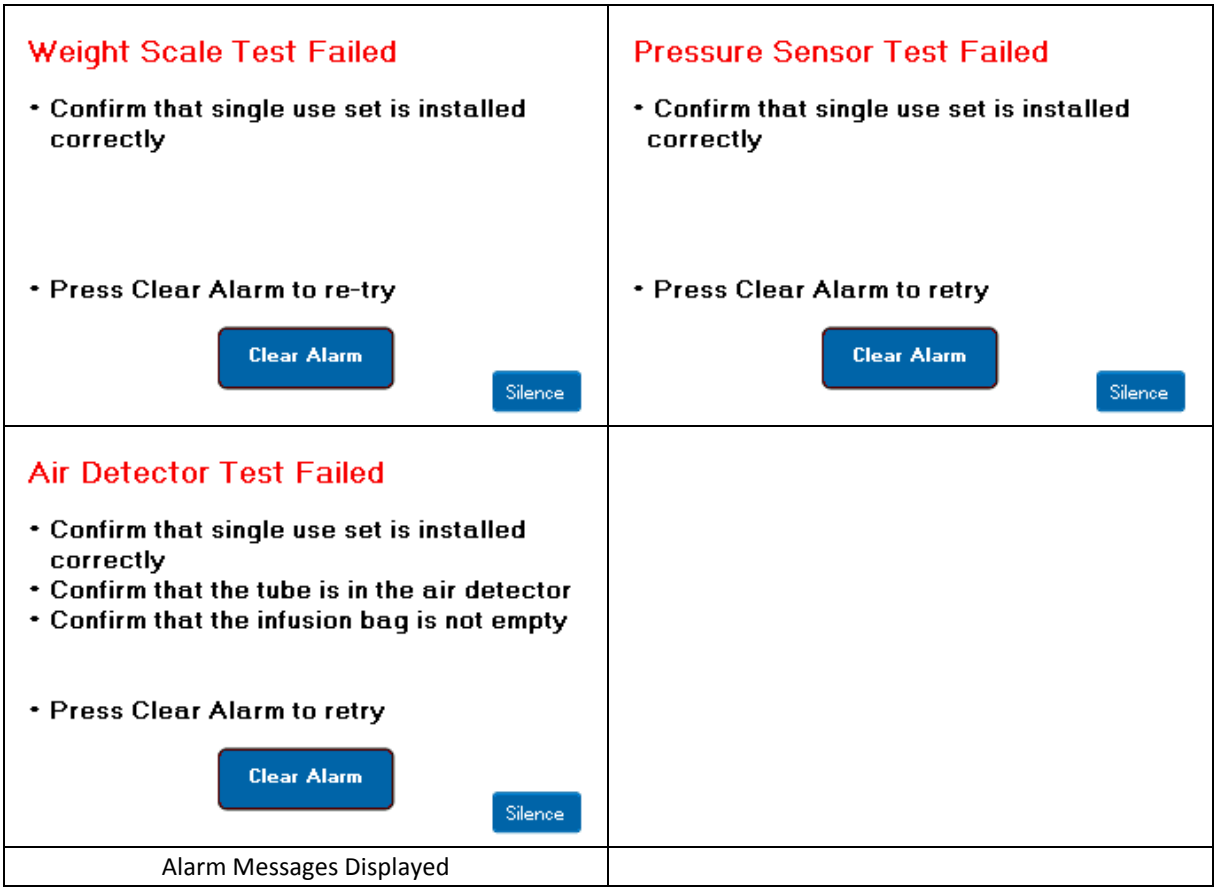
This alarm can be caused by:

1. Disconnected pressure sensor
2. Negative pressure in the infusion line

Recommended Action

1. If pressure sensor is disconnected, connect it
2. Press the **Clear Alarm** button to clear the alarm
3. Press the **Run** button to restart therapy.
4. If pressure sensor is connected, check that Infusion Set is installed correctly.
5. If alarm persists, open and close the infusion pump door. If the condition remains, notify service (refer to section 2.13 Service Information).

Prime Test Failure Alarms



Alarm Messages Displayed

These alarms may occur at the end of priming. The system checks the performance of:

1. Weight scales by comparing them to each other
2. Pressure Sensor
3. Air Detector

If this test does not pass, patient therapy will not be allowed. The following messages above are displayed, including steps to correct prime performance.

These alarms can be caused by:

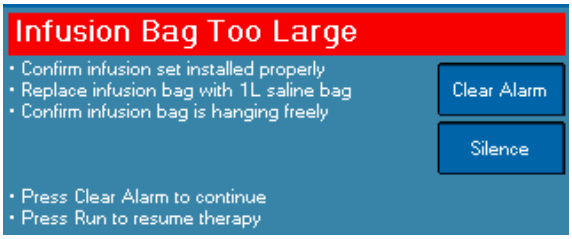
1. Incorrect connection of fluid path during priming
2. Bags not on hooks
3. Interference with weight scale measurements
4. Pressure sensor disconnected
5. Tubing not in the air detector slot
6. Hardware failure

Recommended Action

1. Ensure that the Infusion Set is connected to the Urine Collection bag
2. Ensure that Urine collection bag is freely hanging on the right side hook and the hydration fluid bag is freely hanging on the left side hook
3. Ensure that the tubing is correctly loaded into the pump.
4. Ensure that the pressure sensor is connected
5. Ensure tubing is in the air detector slot
6. Press the **Clear Alarm** button to clear the alarm
7. Repeat the procedure using the **Start Prime** button

Infusion Bag Oversize Alarm

If the weight of the infusion bag is greater than 1.5 Kg (larger than a standard 1 liter infusion bag) and the user attempts to go into Run mode, the system generates an audio alarm, displays an alarm message, and the pump is stopped.



Alarm Message Displayed

This alarm can be caused by:

1. An infusion bag greater than 1 liter being placed on the Console.

Recommended Action

1. Check the infusion bag and ensure that only a 1 liter bag is on the weight scale.
2. Press the **Clear Alarm** button to clear the alert
3. Press the **Run** button to restart therapy.

Urine Bag Not Detected Alarm

If the urine collection bag is not attached to the Console and the user attempts to go into the Run mode, the system generates an audio alarm, displays an alarm message, and the pump is stopped.

Alarm Message Displayed

This alert can be caused by:

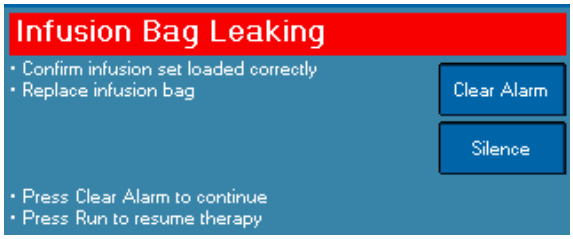
1. No urine collection bag attached to the Console.

Recommended Action

1. Check that the urine collection bag is properly attached on the weight scale
2. Press the **Clear Alarm** button to clear the alarm
3. Press the **Run** button to restart therapy.

Rapid Infusion Weight Decrease Alarm

The Console has detected that the weight of Hydration Fluid Bag decreased too rapidly. If such a decrease occurs during therapy, an Alarm is issued and the Console enters Pause mode.



Alarm Message Displayed

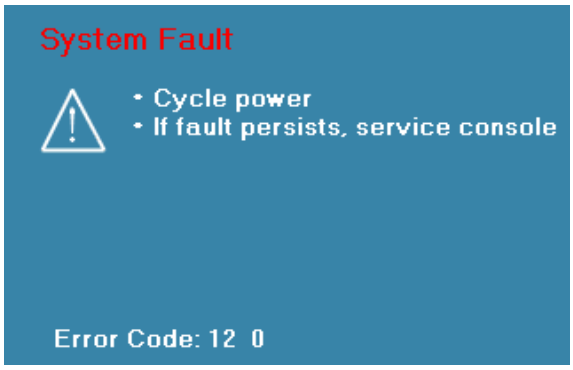
Recommended Action

1. Check that the Hydration Fluid Bag is on the left hook.
2. Confirm that the Hydration Fluid Bag is connected properly and is not leaking
3. Press the **Clear Alarm** button to clear the alarm
4. Press the **Run** button to return the system to the Run mode

5.3 System Malfunctions

System malfunctions result from internal system diagnostic tests that are continuously executed while the Console is in operation. They typically indicate a possibility of a component malfunction.

An Alarm is issued and the pump is stopped. System Malfunctions cannot be cleared. The user is advised to turn the power off and then on once. If the system malfunction condition remains, the system should not be used.



Fault Message Displayed

A system malfunction alarm may be accompanied by an error code. The user is advised to record the message and inform service (refer to section 2.13 Service Information).

6. Technical Information

6.1 Console Specifications

Feature	Description	
Model	FM1	
Dimensions	14 x 7 x 9 inches (35.6 x 17.8 x 22.9 cm) (H x W x D)	
Weight	9 lb (4.1 kg)	
Main Voltage	100-240 VAC, 60/50 Hz AC connection with grounded chassis	
Power	50 VA	
Fuse	5A fast-blow 250V, 5 mm X 20 mm (type F5AL250V)	
Internal Battery	Power Failure Backup Only Type: Lithium Polymer 30 minutes minimum at intermediate flow or maximum flow Charge: 4 hours to rated capacity whenever plugged into AC outlet. For best results, the AC should be cycled every 2 hours during charging. Replacement of the internal battery should only be performed by qualified service technicians.	
Enclosure Leakage Current	< 300 uA Normal Condition < 500 uA Single Fault Condition	
Flow Rates	Minimum Hydration Rate/ KVO Rate	10 ml /hr default, user adjustable from 10 – 100 ml/hr
	Normal Operating Rate	10 to 3,000 ml/hr. Based on user setting and measured urine output.
	Maximum Flow Rate	6000 ml/hr for up to 3 minutes.

Feature	Description
Bolus Flow Accuracy	±15% of setting or ±75 ml whichever is greater. Although the RenalGuard System injects fluid in response to urine flow, a bolus can be programmed for delivery in a 30 minute interval. The bolus can be set from 0 ml to 500 ml range in 50 ml increments. Bolus delivery accuracy for the 50 ml bolus setting is represented graphically in figure 1 for 25 replicate runs each. The extremes of the bolus delivery accuracy were found to be +11.5%, -11.4% for the 50 ml bolus. Bolus delivery accuracy for the 250 ml bolus setting is represented graphically in figure 2 for 25 replicate runs each. The extremes of the bolus delivery accuracy were found to be +2.0%, -5.3% for the 250 ml bolus setting.

Figure 1 Histogram of Bolus Volume at 50 ml setting

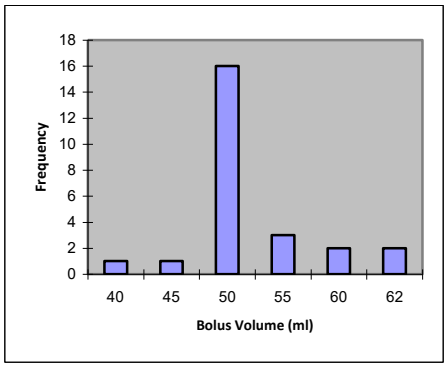
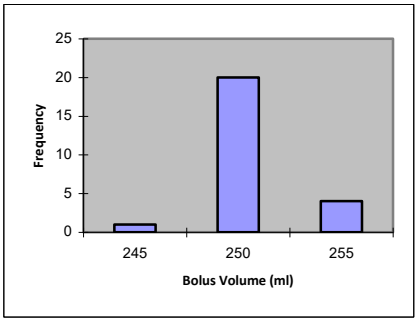


Figure 2 Histogram of Bolus Volume at 250 ml setting



KVO / Pause	10 ml /hr default, user adjustable from 10 – 100 ml/hr
Maximum Infusion	Under single fault conditions, a maximum of 1 L of hydration fluid can be infused. The fault can only occur while the Console is in Stop mode and the user then transitions into Run mode. However, the System will alarm during this time and the total of 1 liter will take a minimum of 17 minutes to infuse.

Feature	Description
Downstream Occlusion	Solid State Pressure Sensor. Alarm fixed at 15 psi. Maximum pressure 20 psi. At 50 ml/min, alert occurs within 45 s (± 15 s). When released, generates bolus volume of 6 ml (± 4 ml) At minimum flow, alert occurs within 3 minutes (± 1 minute)
Air Detector	Ultrasonic Detects 0.05 ml bubble at 100 ml/min
Operating Conditions	Temperature: 5°C to 40°C Humidity: 20%-90% non condensing
Storage and Transport Conditions	Temperature: -10°C to 45°C Humidity: 20%-90% non condensing
Enclosure	Plastic and coated metal.
Drip Proof	Enclosure provides IPX1 protection against the ingress of vertical dripping water in accordance with IEC 60529
Non-Volatile Memory	User settings and therapy data are stored indefinitely in the RenalGuard System's memory
Calibration	The RenalGuard Console scales should be calibrated annually by qualified service technicians. See Section 2.7 Calibration Requirements.
Over-infusion Protection / Under-infusion protection	The RenalGuard System uses two independent means to monitor the rate of fluid infusion to prevent over- or under- hydration. • the RenalGuard Console monitors the pump speed to ensure accurate flow. • the RenalGuard Console also monitors the change of weight in the infusion bag to add a redundant check of the hydration fluid infusion rate.
Audible Alarm	Can be muted for 2 minutes.

6.2 Guidance and Manufacturer's Declaration

Guidance and Manufacturer's Declaration – Emissions (for all equipment and systems)
The RenalGuard Console is intended for use in the electromagnetic environment specified below. The customer or user of the RenalGuard Console should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The RenalGuard Console RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The RenalGuard Console is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The RenalGuard Console has internal batteries which provide continued operation during power mains interruptions up to 30 minutes in duration.

Guidance and Manufacturer's Declaration – Immunity (for all equipment and systems)
The RenalGuard Console is intended for use in the electromagnetic environment specified below. The customer or user of the RenalGuard Console should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2 kV Mains	±2 kV Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles During the >95% Dip the EUT loses essential function.	Mains power quality should be that of a typical commercial or hospital environment. The RenalGuard Console has internal batteries which provide continued operation during power mains interruptions up to 30 minutes in duration.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Emissions (for non Life-supporting Equipment and Systems)
The RenalGuard Console is intended for use in the electromagnetic environment specified below. The customer or user of the RenalGuard Console should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile communications equipment should be separated from the RenalGuard Console by no less than the distances calculated/listed below:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1=3 Vrms	D=(3.5/V1)(Sqrt P)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	E1=3 V/m	D=(3.5/E1)(Sqrt P) 80 to 800 MHz D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz
			Where P is the max power in watts and D is the recommended separation distance in meters.
			Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).
			Interference may occur in the vicinity of equipment containing a transmitter.

Guidance – Recommended Separation Distances for the RenalGuard Console (for non Life-supporting Equipment and Systems)
The RenalGuard Console is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the Console as recommended below, according to the maximum output power of the communications equipment.

Maximum Output Power (Watts)	**Separation (m) 150 kHz to 80 MHz** **D=1.1667 (Sqrt P)**	**Separation (m) 80 MHz to 800 MHz** **D=1.1667 (Sqrt P)**	**Separation (m) 800 MHz to 2.5 GHz** **D=2.3333 (Sqrt P)**
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

7. Warranty

1. RenalGuard Solutions (RGS), Inc. warrants its Products to be free from defects caused by faulty material and poor workmanship. Liability under warranty is limited to the obligation to repair, or to replace without charge, any part found to be defective under normal use and service within the time period below, provided:
   a) RGS is promptly notified within the warranty period in writing upon discovery of such defects.
   b) The original parts are returned to RGS on RenalGuard Solutions prior authorization, transportation charges prepaid.
   c) Examination by RGS discloses to its satisfaction that such defects have not been caused by abuse after delivery.
   d) Warranties shall not apply to items which have been repaired or altered by other than RGS or its Representatives.
2. The period of warranty for RGS products is 12 months from the date of shipment.
3. RGS makes no warranties except as herein set forth. The warranties stated herein are in lieu of all other warranties, express or implied, and of all other obligations or liabilities on the part of RGS, and RGS neither assumes nor authorizes any other person to assume for it any other liability. The purchaser expressly waives any right, claim or cause of action that might otherwise arise out of the purchase and use of RGS products or service. RGS shall not be liable for special or consequential damages or any nature with respect to any merchandise or service sold, delivered or rendered.
4. All above warranties are contingent upon proper use of the Product. This warranty will not apply if:
   a) Adjustment, repair or parts replacement is required because of accidental, unusual physical, electrical or electromagnetic stress, neglect, misuse, failure of electric power, air-conditioning, humidity control, improper storage, transportation or causes other than ordinary use, or;
   b) if the Products have been modified without the prior written approval of RGS, or;
   c) where RGS serial numbers or warranty date decals have been removed or altered, or;
   d) where damage has occurred as the result of attaching accessories to the Product other than those approved by RGS, or;
   e) where damage has occurred as a result of not using an uninterrupted power supply (UPS) where specified by RGS, or;
   f) where damage has occurred as a result of not following the RGS operator's manual.

RENALGUARD CONSOLE
Service Manual

LA00289

PART TWO
THEORY OF OPERATION

TABLE OF CONTENTS

Definitions, Acronyms, & Abbreviations

Term	Definition
AC / VAC	Alternating Current / Volts Alternating Current
cm	centimeter
DC / VDC	Direct Current / Volts Direct Current
EMI	Electro Magnetic Interference
ESD	Electro Static Discharge
FMS	Fluid Management System
Hz	Hertz ~ Cycles per second
IV	Intravenous
l	liter
ml	milliliter
mm	millimeters
ms	milliseconds
PCB	Printed Circuit Board
rpm	revolutions per minute
SPI	Serial Peripheral Interface
µl	micro liter

RG System Visual Overview

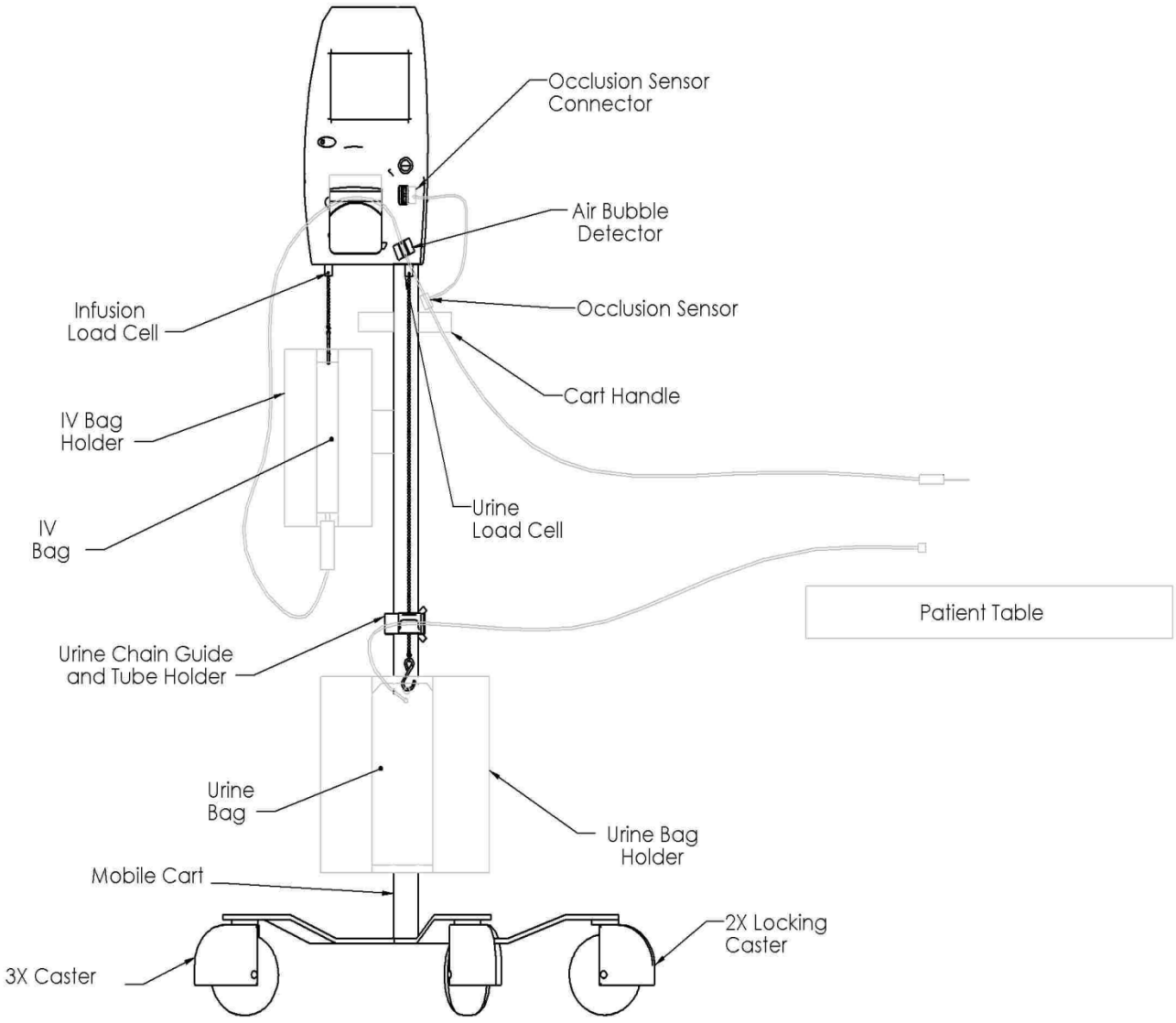


Figure 1 The RG System

System Architecture

- The RG system is comprised of four main components:
  - RG Console (hardware); RG Software; RG Cart; RG Single Use Set (SUS).

RG Console Hardware Modules

- The main components of the RG console are the Console Controller, the Power Manager System, the Control Panel Display and the Infusion Pump System. Figure 2 represents a simplified block diagram of the RG console.

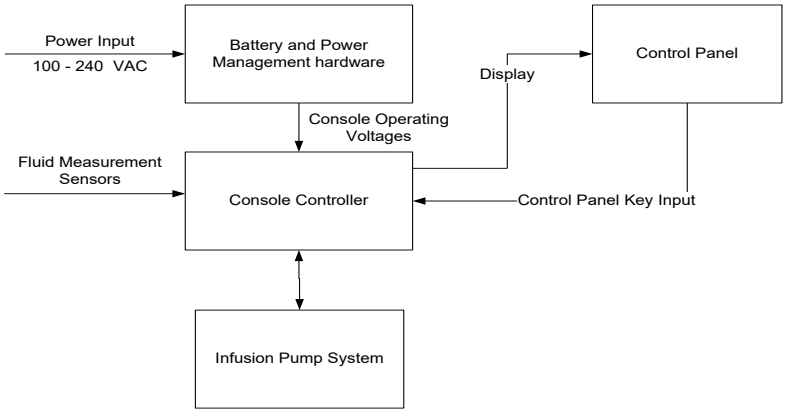


Figure 2 Block Diagram of the RG Console Hardware Modules

System Controller

- The RG System Controller which includes the system computer is contained within the MAIN printed circuit board (PCB). Figure 3 shows the central role of the controller in relationship with the rest of the RG.

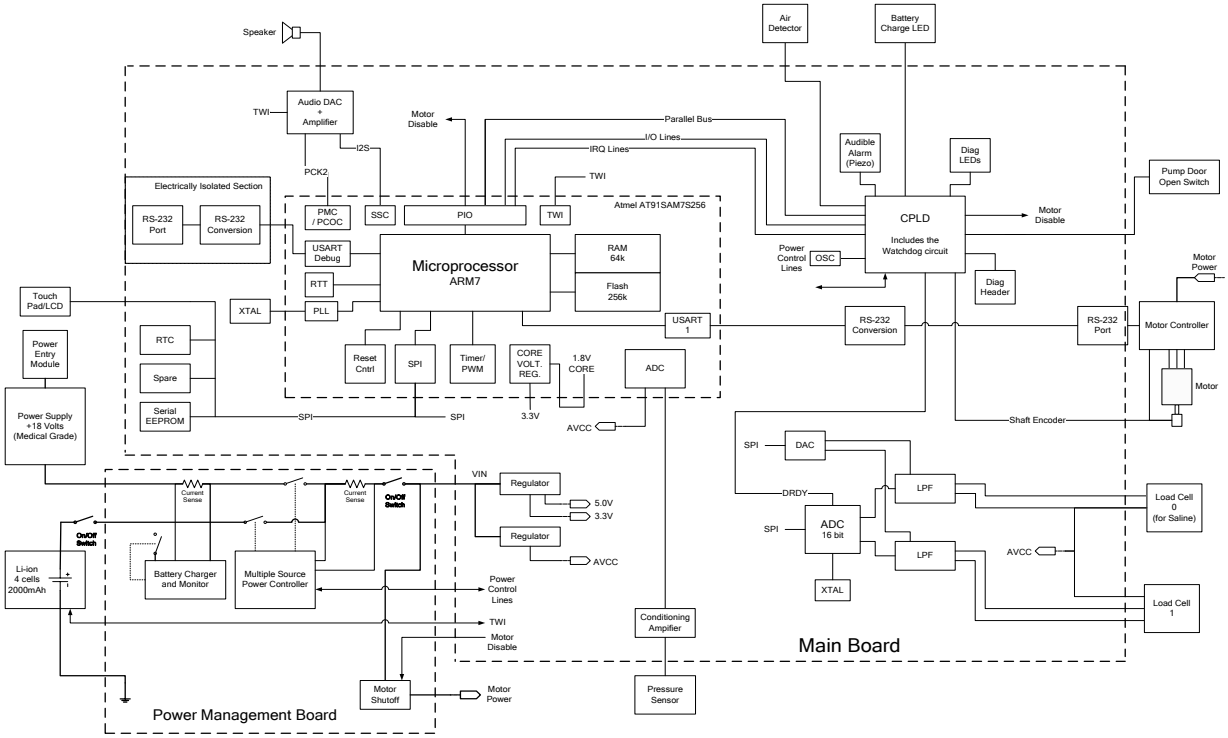


Figure 3 RG System Controller Block Diagram

RG Cart

- The mobile RG Cart is provided as part of the RG system and includes a pole for mounting of the RG Console (Figure 4).The cart has 5 wheels, 2 of them locking to restrict movement, if necessary. The 2 locking wheel should be position to the front of the cart. The cart includes containment housings for the infusion and urine collection bags which are designed to limit the movement of the bags during transport. The 12 inch basket can be used to store extra RG sets, IV fluid etc. The RG Cart passes the tip test outlined in IEC 60601-1.

Figure 4 RG Cart

RG Single Use Set (SUS) AC00050

The RG Single Use Set is an EO sterile package, containing the Infusion Set, Collection Set and Extension Set. Each set is individually packaged and held together inside the plastic tray with Tyvek lid. The RG Set is designed as a conduit for delivery of IV fluid from a standard IV solution bag to the patient and for collection of urine from a patient with a standard indwelling urological (e.g., Foley) catheter. The set is designed for one time use only.

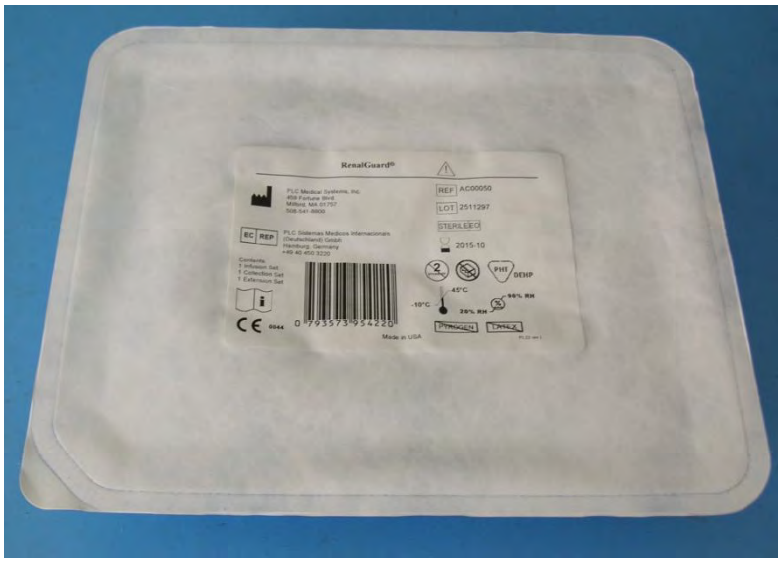
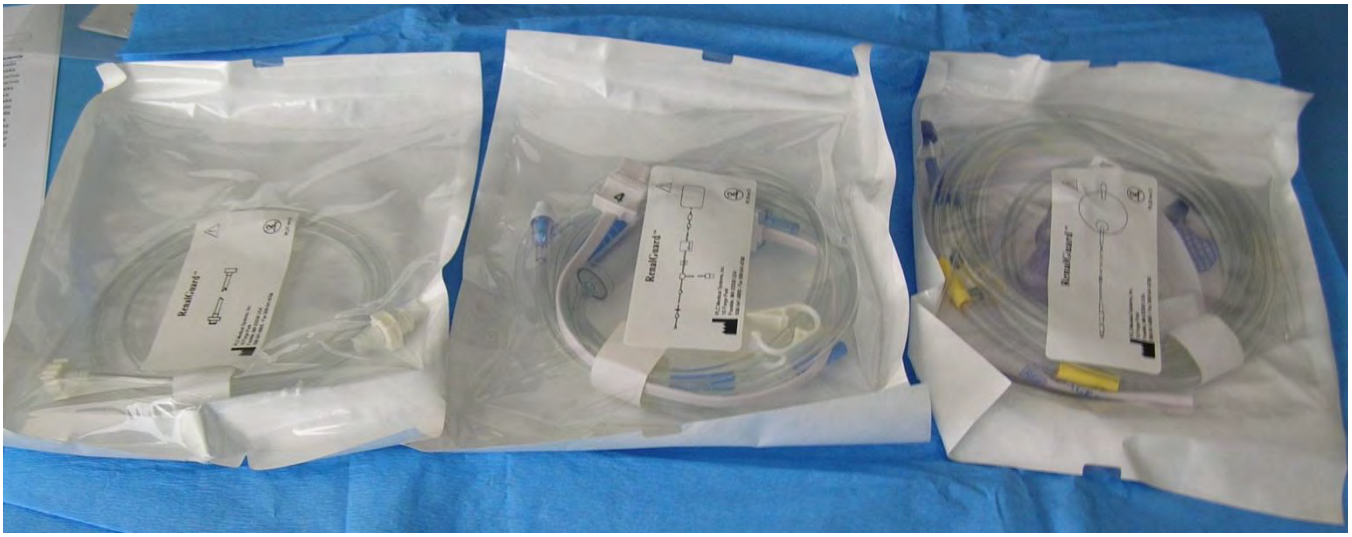


Figure 5 RG SUS AC00050 Outer Sterile Package

The FMS Disposable Set's three primary components are a sterilized disposable infusion set, a sterilized disposable collection set and sterilized disposable extension tubing:

- The infusion set will allow fluid to flow from an infusate bag, through the FMS console, to an IV needle set.
- The collection set containing a urine collection bag will attach to a urinary catheter and allow urine to flow to the FMS console.
- The extension tubing will connect to the collection set and allow for additional tubing length between the urinary catheter and the collection bag.



Extension Set Infusion set Collection Set

Figure 6 RG SUS AC00050 Individual Packaging

Infusion Set

The spike at one end of the infusion tubing is inserted into a standard pharmacy IV bag of normal saline which is hung on a weight scale. The infusion tubing is threaded through the console's roller pump mechanism and bubble detector with the other end connected to any standard IV catheter that was already placed in a patient's vein. This creates a circuit for administration of IV fluids into the patient.

Numbering on The Set guides the user on proper set installation. The console is designed to operate with 1 liter infusion bags only and will not operate with other larger sized IV bags. A disposable pressure sensor integrated into The Set allows the console to monitor occlusions in the infusion tubing or in the IV catheter. A one-way check valve in The Set prevents free-flow or reverse flow when the infusion set is disconnected from the pump. A manual clamp on The Set provides a second method to prevent free-flow. A needle-less access port allows air bubbles to be removed from the line as well as additional infusions without requiring the placement of additional IV access

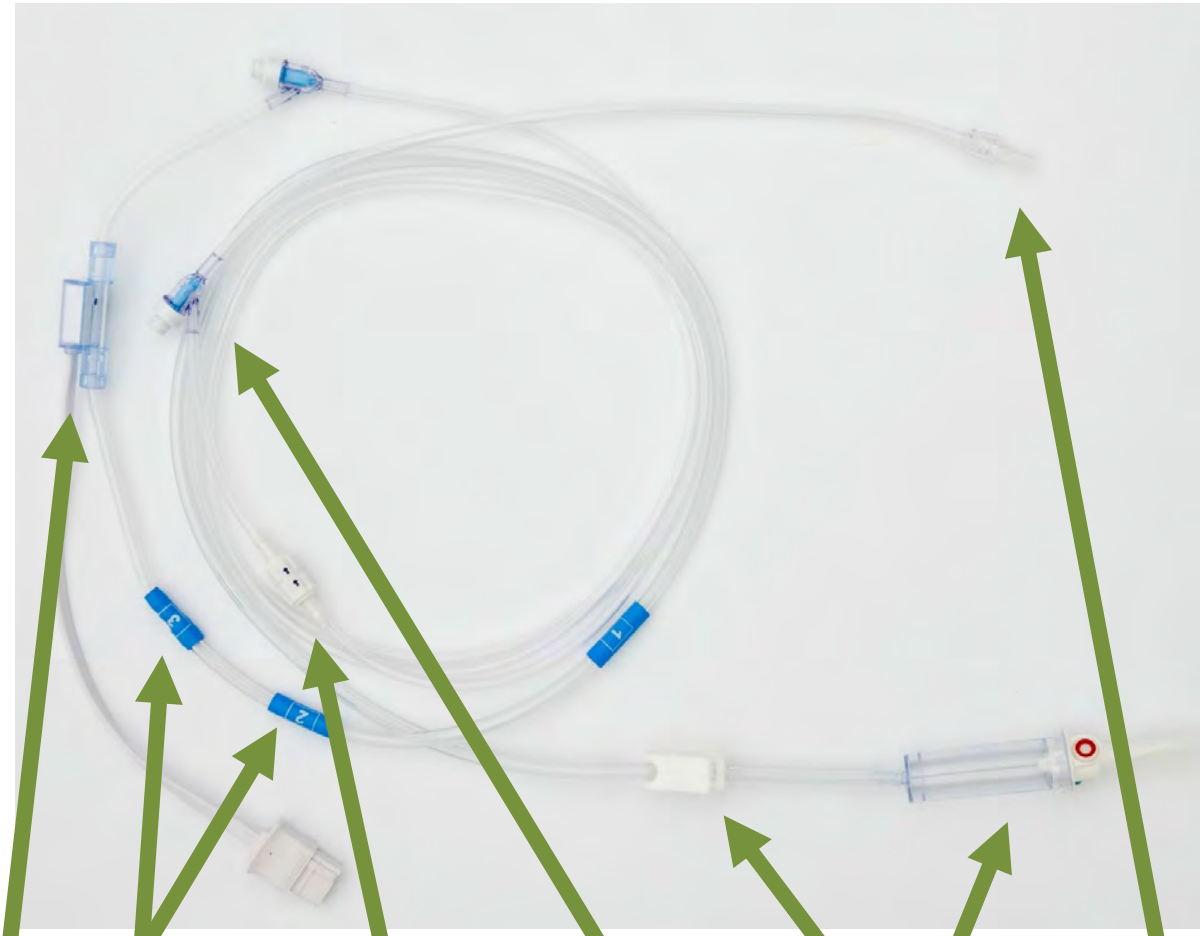


Figure 7 Infusion Set

Collection Set

The Urine Collection part of The Set consists of a standard urine drainage bag and tubing that is connected to a standard urinary indwelling catheter (such as a Foley catheter). After attachment to the patient's urinary catheter, the tubing and drainage bag are used for collection of excreted urine. The urine drainage bag is designed to hang on a weight scale located under the console and below the patient to allow gravity to assist with drainage. The urine bag is capable of holding more than 2 liters of urine and has a drain to allow for emptying the bag.

Figure 8 Collection Set

RG Console

- The RG console hardware design includes the electronics chassis, enclosures and mounting hardware also referred to the “mechanical package”. The Console modules described in the RG block diagram (Figure 2) are contained within the enclosure.

Electronics Chassis

- The electronics chassis provides a stable and rigid platform to securely mount the console component. Figure 9 shows an image of the electronics chassis. The chassis is made up of a left and right side which are held together by 5 screws which allow for easy serviceability.
- The chassis is constructed of aluminum with a conductive coating. The following components are chassis mounted:
  - Power entry module and fuse AC/DC power supply Load cells Battery
  - Pump motor controller Pole mounting clamp Ground equalization connector

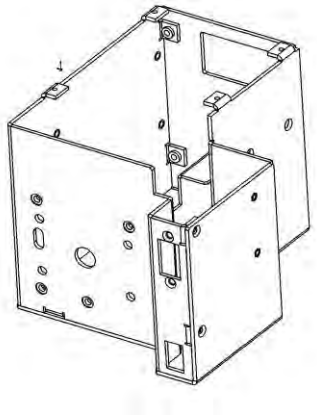


Figure 9 RG Electronics Chassis

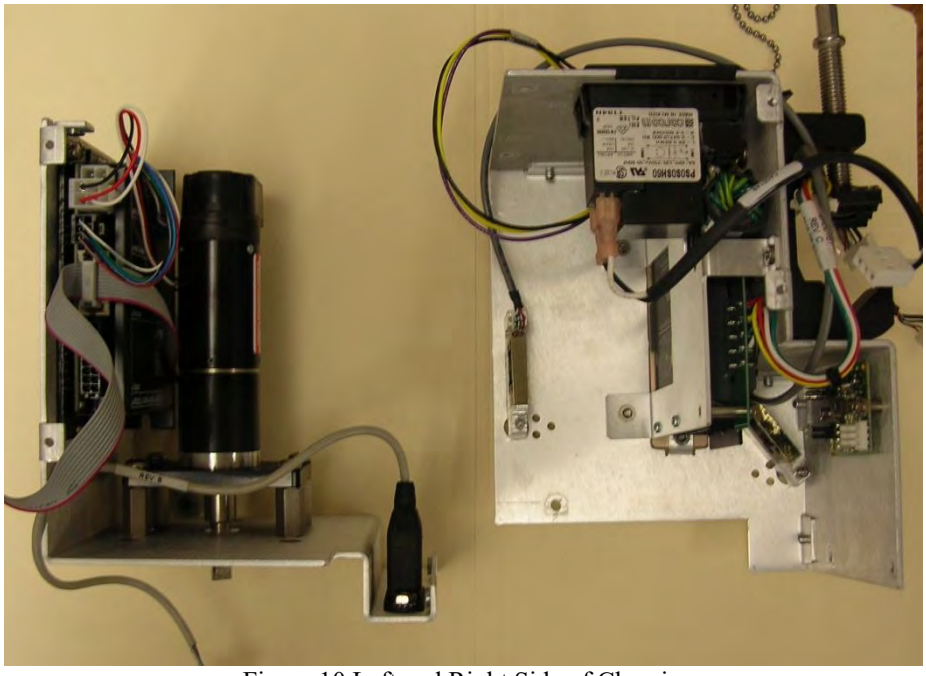
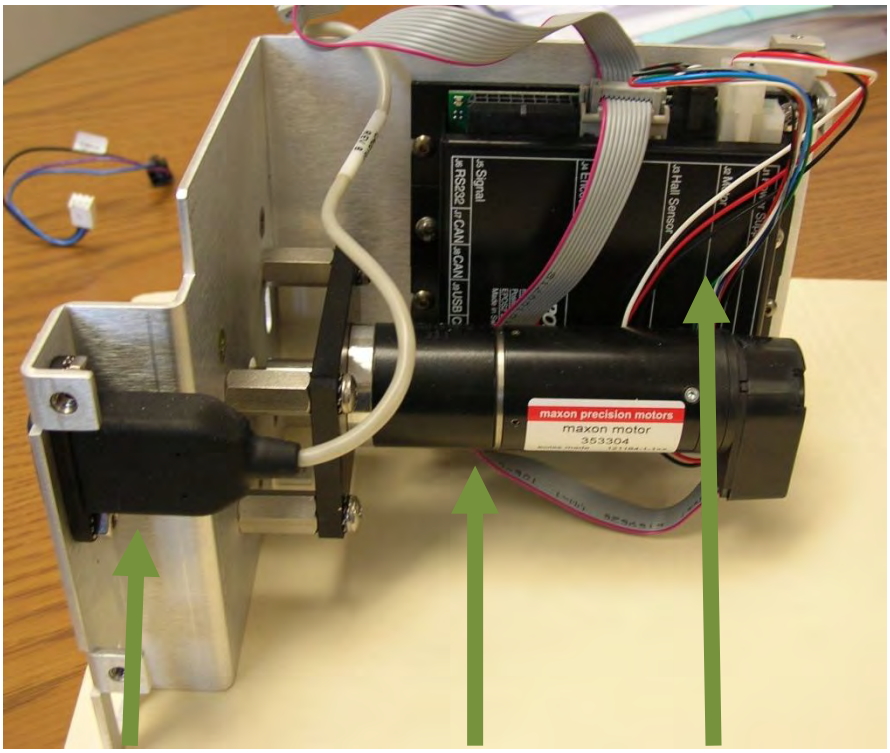


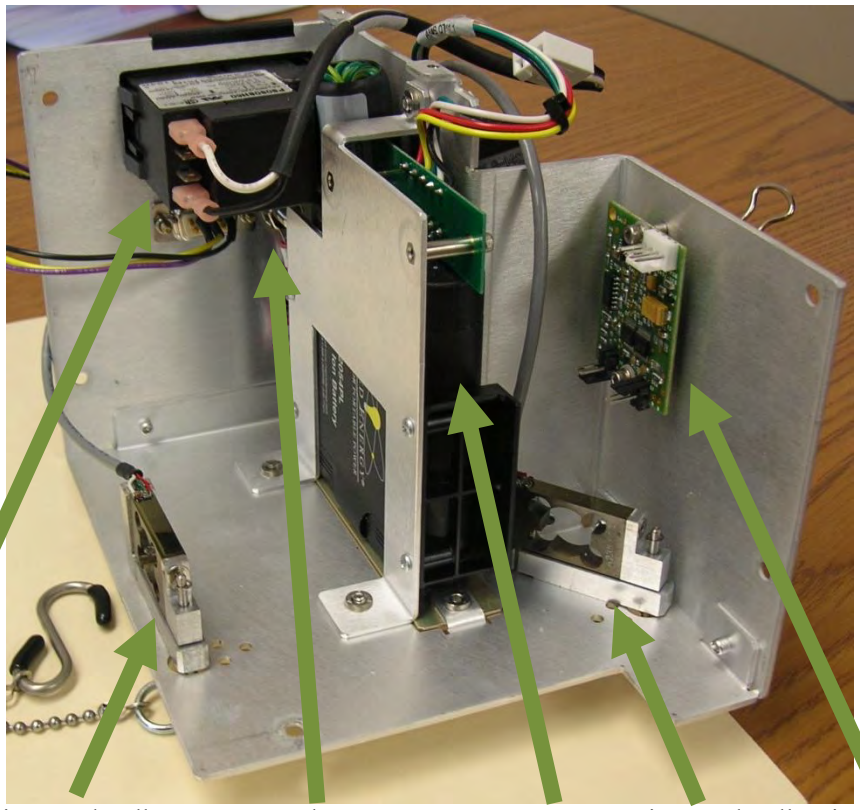
Figure 10 Left and Right Side of Chassis

Figure 11 Left Side Chassis



Pressure Sensor Motor Motor Controller

Figure 12 Right Side Chassis



Power Module Infusion Load Cell Ground Connector Battery Urine Load Cell Air Detect PCB

Console Enclosure

- The console enclosure provides external protection to the electronics chassis as well as providing an additional mounting platform. The enclosure is a two piece, snap together construction molded of 94V-0 flammability and 5V fume retardation rated material coated with conductive copper for EMI shielding per the UL 746C process. Fabrication is in accordance with the Front enclosure drawing MD00039 and the Rear Enclosure drawing MD00040.
- The following components are enclosure mounted:

Front enclosure PLC Part # MD00039	Rear enclosure PLC part # MD00040
• Touchscreen display (PLC # EP00201) • Battery Charging Indicator LED (PLC # EP00209) • Air bubble detector (PLC # EP00188) • Pump head (PLC # SB00305)) • Table top resting feet (PLC# SB00308) • Power on switch PLC # CA00169 • User interface labeling	• ID label PLC # LA00226) • Grounding Reliability label PLC # Lxx0227)* • ETL Safety approval label (PLC # LA00236) • Pole mounting clamp (PLC # MA00284) • 10 Phillips mounting screws (PLC # HA00509) *xx stand for language specific

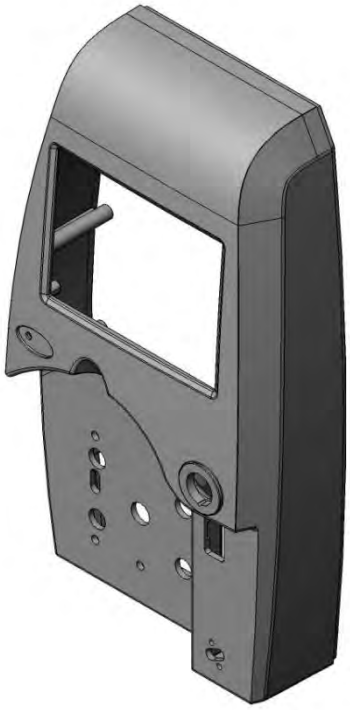
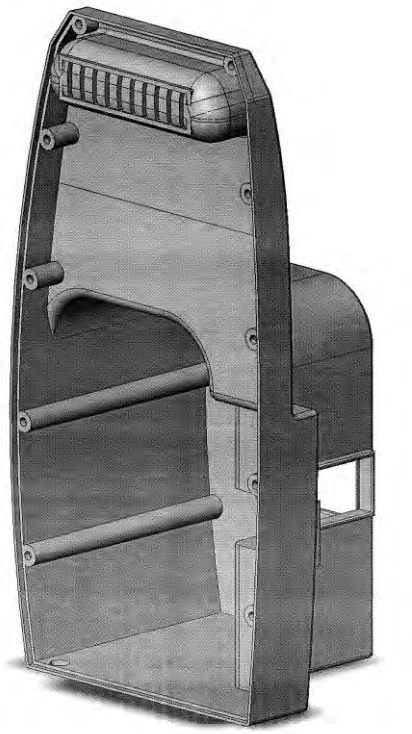

	

Figure 13 RG Front Enclosure	Figure 14 RG Rear Enclosure

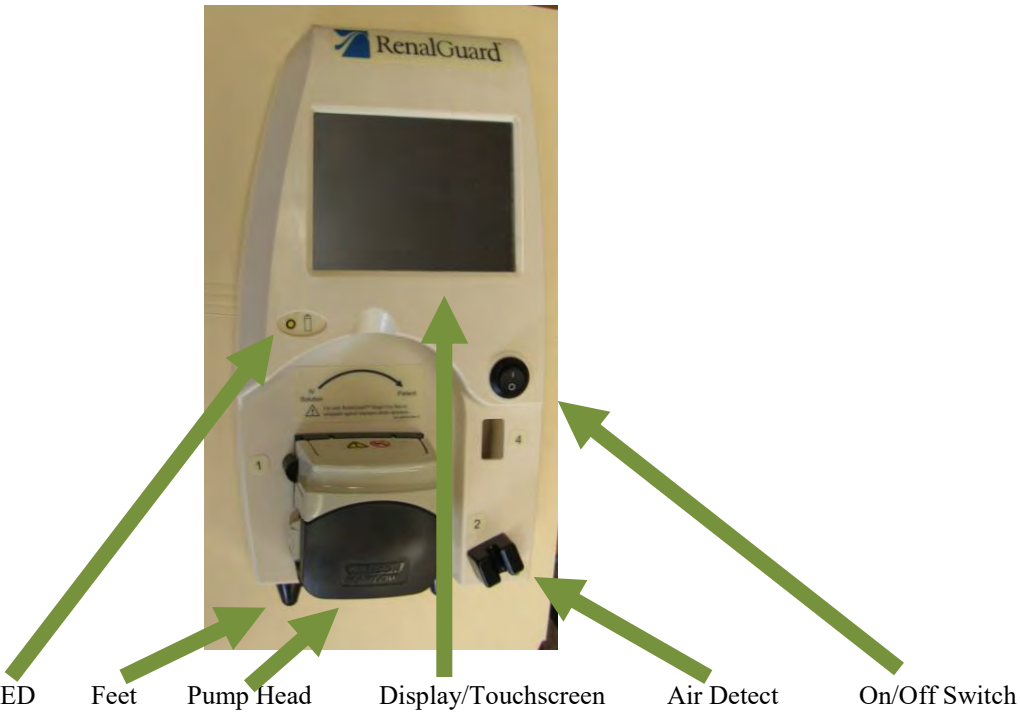


Figure 15 Front Enclosure

Figure 16 Front Enclosure (rear view)

Console Mounting

- A pole mounting clamp on the console provides the ability to position and securely mount the console on the mobile cart. PLC part number MA00284.

Figure 17 RG Mounting Clamp

Control Panel

Display / Touchscreen (PLC Part # EP00201)

- The RG Console touchscreen allows the entry of data by the operator. The touchscreen is a clear overlay on the LCD information display. Buttons for data entry on the touchscreen are generated by software.
- The touchscreen interfaces with the System Controller through an SPI communication bus. The connector signals and pin location are outlined in the following table.

LCD Display Interface Connector (PLC Part # CA00166)

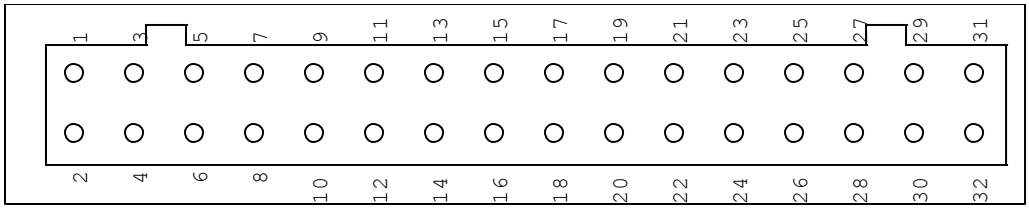


Figure 18 Touchscreen Display LCD Interface Connector

Table 1 Touchscreen/LCD Display Connector Pinout

	FUNCTION	PIN #	FUNCTION
2	+5V ext	1	+5V ext
4	+5V ext	3	+5V ext
6	GND pwr	5	GND pwr
8	GND pwr	7	GND pwr
10	DM	9	DP
12	DGND sig	11	VBUS
14	+3.3V out	13	+3.3V out
16	PROG#	15	ON/OFF
18	SCL	17	SDA
20	RS232 TTL TX	19	RS232 TTL RX
22	SS#	21	MISO
24	MOSI	23	SPCK
26	CAN TX	25	CAN RX
28	MCDA2	27	MCDA1
30	MCCDA	29	MCDA3
32	MCCK	31	MCDA0

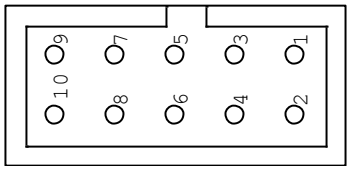


Figure 19 Main Board Display Interface Connector

Table 2 Main Board Display Interface Connector Pinout

PIN #	FUNCTION	PIN #	FUNCTION
1	No Connection	5	Data In
2	+3.3V	7	Clock
3	GND	8	Data Out
4	GND	9	+5V
5	Chip Select	10	+5V

- The RG console display consists of a 5.6” color TFT LCD panel. The display and touchscreen are an integrated assembly with common power supply. Refer to Tables 1 and 2 for the connector detail.

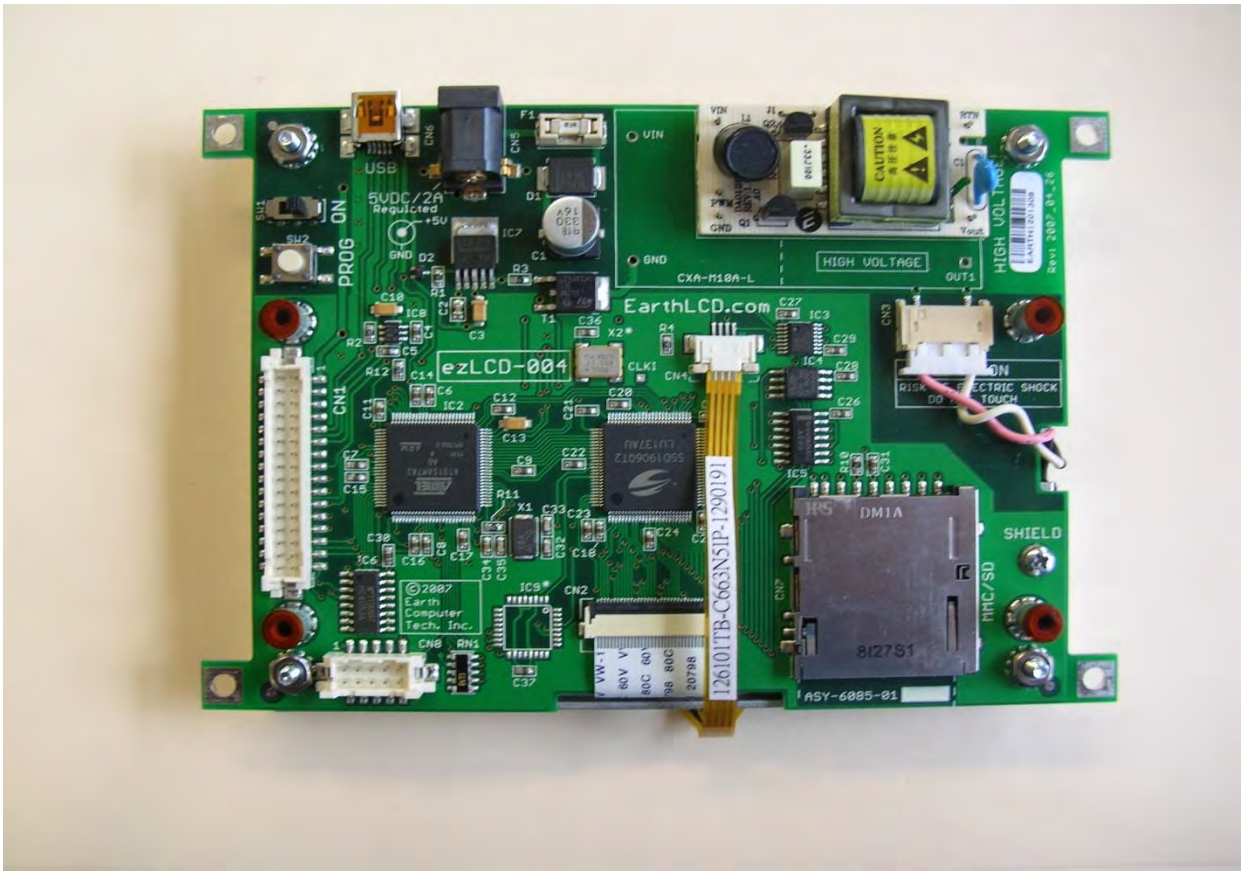
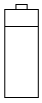


Figure 20 Rear of Touchcreen

Battery Charging Indicator (LED PLC Part # EP00209)

- A single, yellow LED is included on the control panel to indicate when the battery is receiving a charge.

Color	Function	Symbol
Yellow	Battery Charging Indicator (Continuous)	

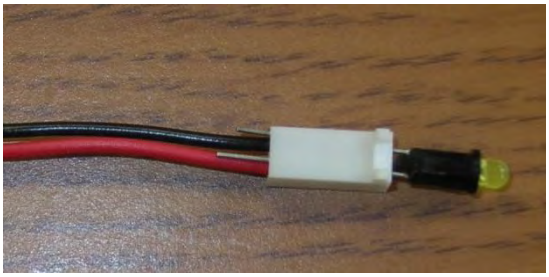


Figure 21

Infusion Pump System

- The Infusion Pump System consists of a peristaltic pump head assembly, motor assembly, pump motor driver, air bubble detector and two load cells which sense the weight of the infusion and collection bags. Figure 1 shows the general location of the RG components.
- If the pump is not running and the door is opened, the software shall report an open door condition to the user. If the door is closed the open door condition should be cleared

Peristaltic Pump Head Assembly PLC part # SB00305)

- The peristaltic pump head is selected to provide appropriate fluid flow (0 to 6000 ml/hr) for the selected pump motor speed and the single use infusion circuit tubing.). The head is designed to work with the following tubing characteristics:
  - Wall thickness: 1.6 mm
  - Bore size: 3.2 mm
- The pump head also incorporate a sensor to provide pump door status (open or closed) to the system controller. (PLC part # CA00152)
-

Figure 22 Pump Head Assembly Magnetic Holder Pump Rollers Pump head Door

- The pump head has a magnetic holder (PLC Part # MA00261) with magnet (PLC Part #HA00533) mounted to the left side of the pump head. When the pump head door opens the magnetic moves away from the sensor indicating the door is open.

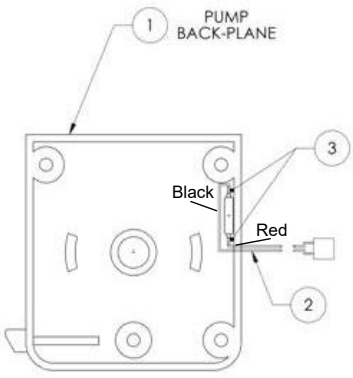


Figure 23

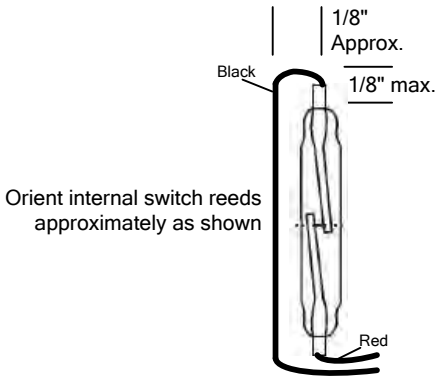


Figure 24

Pump Motor Assembly

- The pump motor assembly includes a DC brushless motor with Hall sensors, a speed reduction gearhead, and an encoder to provide motor data to the system controller.

Motor & Gear head (PLC part # MT00007)

- The DC brushless motor in conjunction with the gearhead is used to drive the pump head. The motor has internal windings for rotation and Hall effect sensors to report the position of the windings during rotation.
- The gearhead provides motor speed reduction and couples the motor to the pump head providing the speed/torque translation to achieve peristaltic action.

Figure 25 RG Motor & Gear Head

Encoder (PLC part # MT00006)

- The motor mounted encoder determines the speed and direction of the motor. The encoder data is connected through a 10-conductor IDC (Insulation Displacement Connector) cable (PLC part # CA00141) directly to the motor driver module. The signals and pin connections are listed below:

Table 3 Motor Encoder Pinout

Pin	Designation	Description
1	N.C.	Not Connected
2	+5V	+ 5 VDC max, 100 mA
3	GND	Ground
4	N.C.	Not Connected
5	A\	Inverted Channel A
6	A	Channel A
7	B\	Inverted Channel B
8	B	Channel B
9	I\	Inverted Channel I
10	I	Channel I

- The outputs of the encoder are two square waves in quadrature (channels A and B) and on index pulse which is generated once for each full rotation.

Figure 26 Motor controller

Incorrect Motor Rotation Direction

- The software shall generate an alarm if the motor speed and rotation direction, as measured by the CPLD, differs from the motor controller speed by more than 15 % or 10 ml/min, whichever is greater, for more than 3 seconds.

High Pump Rate

- If the software reads the pump speed to be greater than 100 ml/min for 3 minutes, it shall limit the speed to 50% of maximum speed. The software shall allow the maximum speed after the balanced Infusion controller output is less than 50% of the maximum speed for 3 minutes.

Pump Failure

- If the actual pump speed is greater than 120 ml/min or the change in infusion weight over a 4 minute period is greater than 400 ml, the software shall generate an alarm and disable the motor voltage.
- If the actual pump speed differs from the commanded pump speed by more than 15% or 4 ml/min whichever is higher, for more than 10 seconds, the software generates an alarm and disable motor

Air Bubble Detector (PLC part # EP00187) & PC Board (PLC part # EP00188)

- The air bubble detector is designed to detect bubbles in the infusion stream. It is a non-invasive type (no direct contact with the fluid) and poses no threat to the fluid integrity. Bubbles 50 µl or greater in size will be detected. The detector will be provided 5 V power from the main PCB and will output a logic signal change when air is detected. The detector is also tested for functionality during prime.
- The pin assignment for the detector to main PCB connection is as follows:

Table 4 Air Bubble Detector Pinout

Pin	Designation
1	5 V power
2	Output
3	Test Input
4	Ground

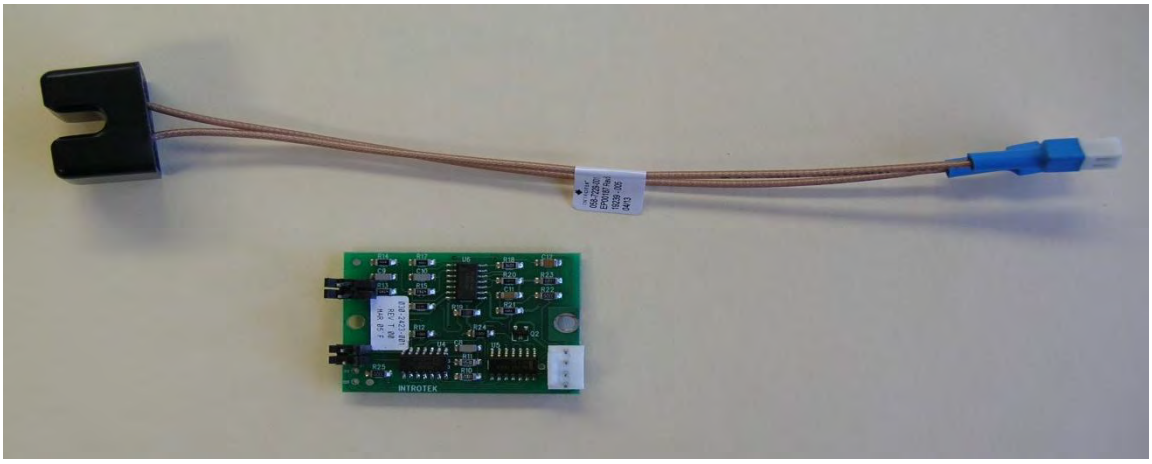


Figure 27 Bubble Detector with Sensor PC Board

- The RG Console detects bubbles larger than 50 uL at 11 ms samples. Alarm limit is 500 uL of bubbles over a 8 minute window. The system uses different limits based on the speed of the pump. The system stores the maximum speed of the pump based on the controlled speed and the tachometer over the previous 8 minutes. The limit of the samples is based on the following table. We use the limit corresponding to the max flow over the last 8 minutes. Each sample is 11 ms window where air is detected. When pump flow increases, the samples limit is reduced immediately (more sensitive). When pump flow decreases the samples limit remains in the bucket for the higher flow within last 8 minutes.

Table 5 Bubble Detection / Pump Speed

Max Flow (ml/min)	Min Flow (ml/min)	Limit	Bubble Size At Max (uL)	Bubble Size At Min (uL)	Bubble size in KVO (uL)
100	40	27	500.0	200.0	5.83
40	12	68	498.6	149.6	14.54
12	3	227	499.4	124.8	48.55
3	1.17	909	499.9	195.0	194.43

- This simple algorithm allows us to be less sensitive to small bubbles at lower flows, while still protecting the patient from air.

Load Cells / Weight Scales (PLC Part # EP00210)

- Load cell devices are utilized to measure the weight of fluid in both the infusion and collection bags. The measurements are in grams (corresponding to milliliters), have a maximum capability of 3000 grams and a linear signal output specified as mV per Volt of activation. The load cell elements are configured in a bridge of typical resistance of 10,000 ohms.
- Load cells communicate with the system controller using the following signals:

Table 6 Load Cell Pinout

Color	Signal	Description
Red	+ EXC	Positive Excitation Voltage
Black	– EXC	Negative Excitation Voltage
Yellow	+ OUT	Positive Signal Output
Green	– OUT	Negative Signal Output

- Figure 1 provides an overview showing the infusion and collection bags connected to the load cells using chains that exit the bottom of the console. On the older load cells the interface between each load cell and the corresponding chain has been made a different size to prevent the chains from being installed incorrectly.

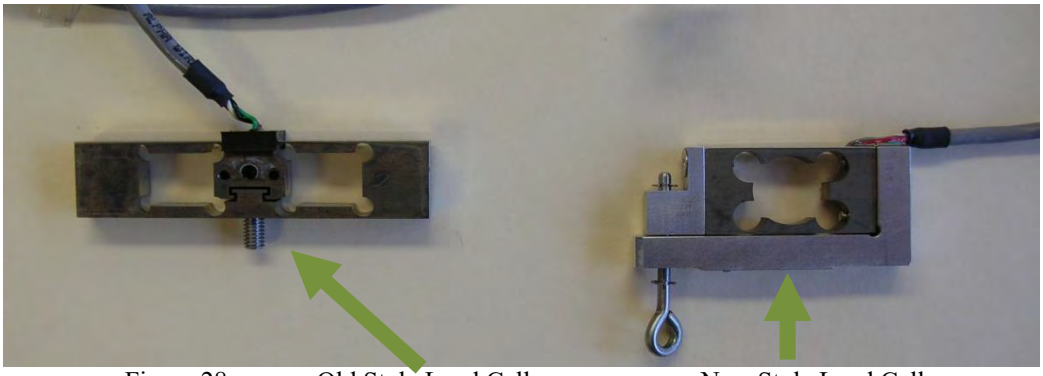


Figure 28 Old Style Load Cell New Style Load Cell

Weight Scale Stability

- The software is tolerant of the urine bag being lifted for ten seconds or less without causing a reading error.
- The software filters the weight scale readings such that if either the Infusion bag or urine bag is bumped, the operation of the system is not affected. "Bumped" is defined as an abrupt movement of about 6 inches.
- The infusion weight scale reading is filtered with a 10 second moving average filter.
- The infusion weight scale is declared unstable if it does not meet the stable criteria for 15 seconds. If the instability is detected the system should limit pump flow to the minimum Infusion rate up to 2 minutes. If the infusion scale remains unstable for a total of 2 minutes, the system should report an alarm and enter pause mode.
- The urine weight scale reading is filtered with a 60 second moving average filter. The urine weight scale is considered to be stable:
  - if half the samples are within ± 100 g of the previous filtered value, OR
  - if the difference between the minimum weight reading and the maximum weight reading in the filter window is less than 100 g.
- The urine weight scale is declared unstable if it does not meet the stable criteria for 60 seconds. If the weight scale is not stable, the system shall enter pause mode.
- If the weight scale readings are not stable, the software shall enter pause mode.

Weight Scale Calibration

- The calibration steps for a weight scale are shown below. Calibration involves measuring the weight scale reading with no weight attached, 1 Kg and 2 Kg weights attached. For each weight, the software averages 10 seconds of readings. The offset and gain of the input is then calculated and store in flash. Note that the user must cycle power to the unit after saving the data to flash.

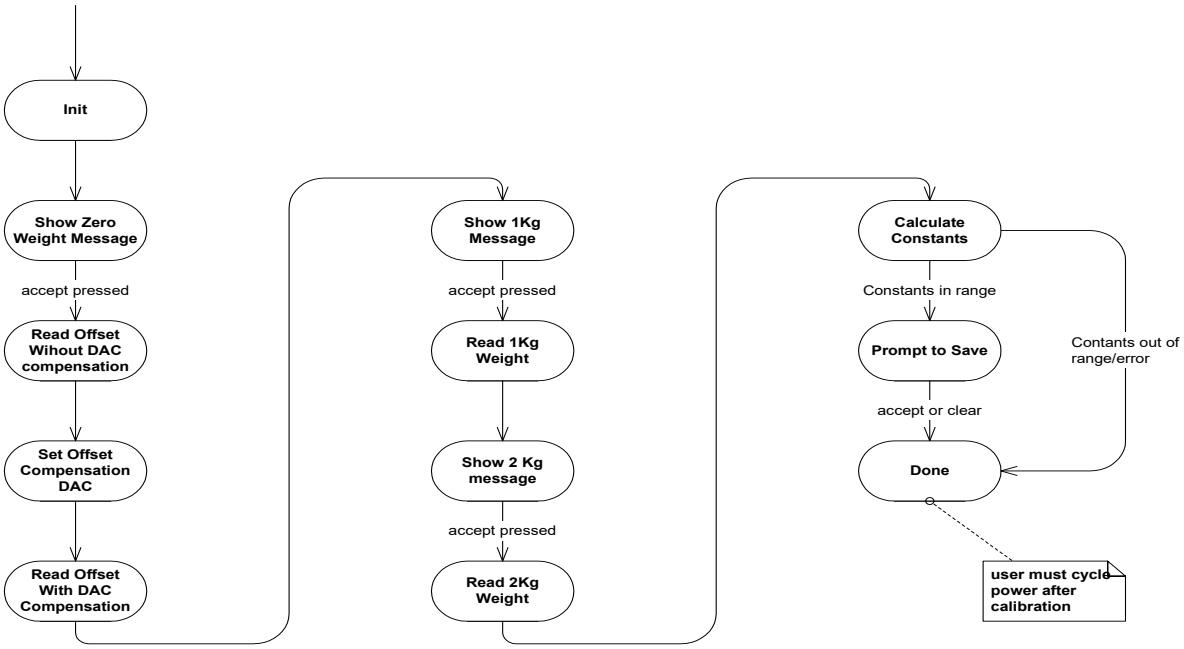


Figure 29 - Calibration Steps for an Input

- In order to calibrate a unit, the following steps must be executed.
  1. Using the service menu, select calibration mode.
  2. Follow screen directions to remove and attach weights on the infusion scale and the urine scale to allow the software to calculate the offset and gain for each scale. Ensure that the weights are still (not moving) during calibration.
  3. Save the calibration data when prompted by the software.
  4. Cycle power to the system

- After the software has executed the power on self tests, for each scale, verify the accuracy of the calibration by attaching 1 kg weight. On the service screen, it should read 1000 g +- 10 g. Remove the 1 Kg weight and attach the 2 kg weight. On the service screen it should read 2000 +- 20 g.

Pressure Sensor (Occlusion Detector)

- The single use set includes a pressure sensor used to detect occlusion in the infusion circuit. The sensor communicates with the system controller using a front enclosure mounted connector.

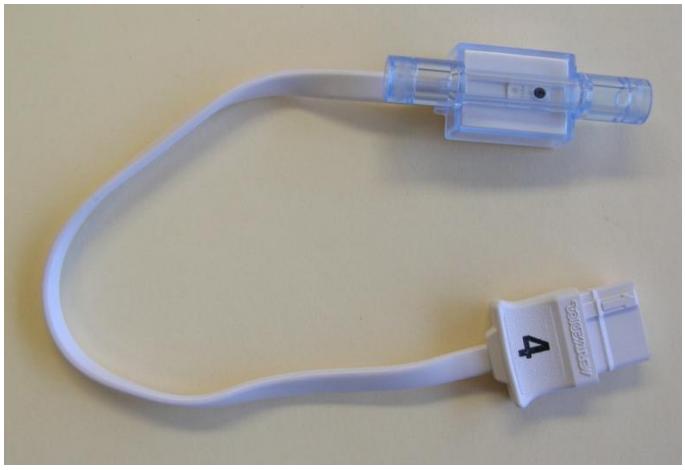


Figure 30 RG Single Use Set Pressure Sensor.

- Pressure sensor is considered disconnected below the value of -5.5. The average zero pressure offset is 0.55.

- During prime, the increase of average pressure from when the pump is not running to the average pressure when the pump is running should be at least 0.1 psi.

- The pressure sensor and its circuit can be calibrated from the external computer running any hyper terminal like software. The software checks for average pressure when the sensor is disconnected and stores the value in the NVRAM. The software also calculates average zero offset from the sensor connected two possible ways (reversed polarity – the connector is not keyed) and stores the value in the NVRAM. The threshold for the sensor disconnected alarm is set at the value of saved disconnected sensor value minus 1 psi.
- The software reads the pressure sensor to detect occlusions. If the pressure exceeds 15 psi for 30 seconds, the software reports an alarm condition “Occlusion Detected”. If the pressure exceeds 20 psi, the software reports an alarm condition “Occlusion Detected”. If the pressure exceeds 12 psi for 50% of the previous 2 minutes, the software reports an “Intermittent Occlusion” alert.
- While the pressure exceeds 12 psi, the software reduces the speed of the motor until the pressure reduces to a value less than the limit or an occlusion alarm is detected.
- If the pressure sensor is not detected, the software reports an alarm “Pressure Sensor Disconnected” and stop the pump.

Power Management System

The Power Management System of the RG Console consists of a power manager PCB, an AC power entry module, an AC/DC Power Supply, and a Lithium Polymer battery pack.

AC Power Entry Module (PLC Part # EP00192)

- The Power Entry Module provides connection to the AC power cord, a mains power ON/OFF switch, protective overload fuses and appropriate filtering for EMI suppression. The module meets all safety agency requirements and approvals.

Figure 31 Power Entry Module Clip Removed for International Use

AC/DC Power Supply (PLC Part # PW00029)

- The AC/DC power supply provides the RG Console required operating voltage of 18 VDC using universal input of 85-264 VAC at frequencies of 47-63 Hz. The power supply is rated at 100 W and supplies a maximum rated current of 5 A. The power supply meets the medical instrument EMC and safety requirements of the applicable standards.

Figure 32 AC/DC Power Supply

- The software generates an alarm “Bad +5V Supply“if the 5V supply, as read via the internal ADC, is less than 4.8 V or more than 5.2 V for at least 300 milliseconds. Note: This requirement also tests the internal ADC.

Battery Pack (PLC Part # EP00212)

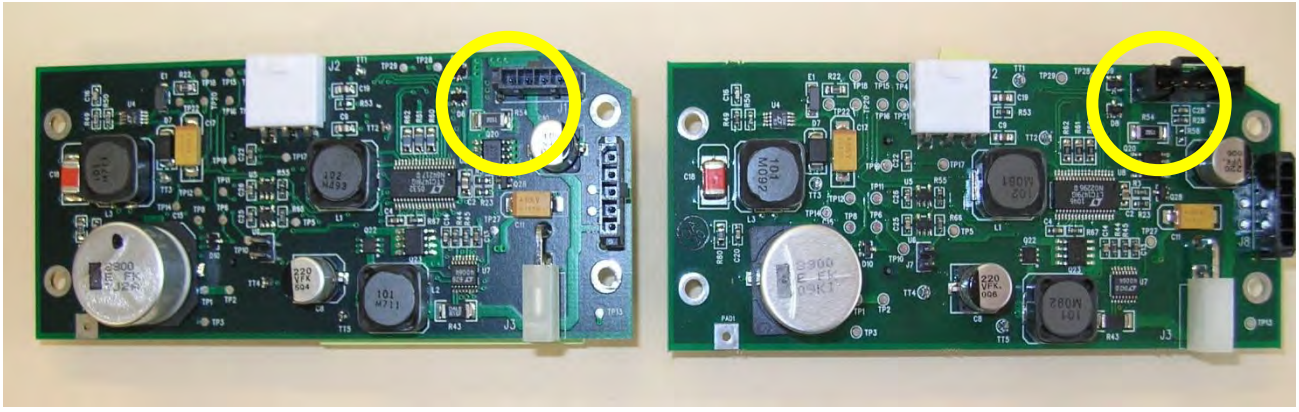
- The RG Console includes a battery which will run the instrument for up to 30 minutes at the maximum infusion rate. This mode of operation is primarily specified for use during patient transport. The battery pack consists of rechargeable Lithium Polymer batteries connected to deliver a minimum of 14-18 VDC at 1.6 A/hr and include the industry accepted battery state monitoring and protective circuits. Communication with the battery pack is through the industry standard System Management Bus (SMBus) protocol. The estimate for the remaining battery minutes is calculated from the battery remaining capacity and assumption that the average current when pump is running is 500mA. (2000mAh / 500 = 4hrs).

Figure 33 Old Style (Discontinued) New Style

- The software monitors the remaining battery capacity such that when operating off of battery, if there is a less than 30 minutes battery life remaining, the software shall generate an alert **"Battery Low"**.
- The software monitors the remaining battery capacity such that when operating off of battery, if there is a less than 3 minutes battery life remaining, the software shall generate an alarm **"Battery Critically Low"**.

Power Manager PCB (PLC Part #SB90325)

The Power Management PCB contains the charging circuits for the Lithium battery pack and a controller which manages the source of the system operating power. At turn-on we test the battery by reading the battery chemistry and verifying that it is either a lithium polymer battery or a lithium ion battery. (The battery type reported by the smart battery controller must be "LPOL" or "LION").



SB90310 (old style 4 pin on/off connector) SB90325 9 (new style 5 pin on/off connector)

Figure 34 Power Manager PCB:

Software

At turn on the first thing that software performs is a POST function

Power On Self Test (POST)

- The software performs a Power On Self Test (POST) of the hardware to check for proper operation. The software tests the following on power up:
  - External ADC
  - Internal ADC (5V supply monitor)
  - RAM
  - Flash
  - Motor Controller Interface
- Real Time Timer
  - CPLD Watchdog
  - CPLD Communication
  - Audio
  - Touchscreen communications
  - Integrity of weight scale calibration data
- If a failure occurs, the software generates a malfunction and displays a message indicating the failed test.

Prime System

Once post is completed, the system will prompt to “Continue With Same Patient” or “Begin New Patient”

If “Begin New Patient” is selected the system will prompt with Prime Screen and “Start Prime” button

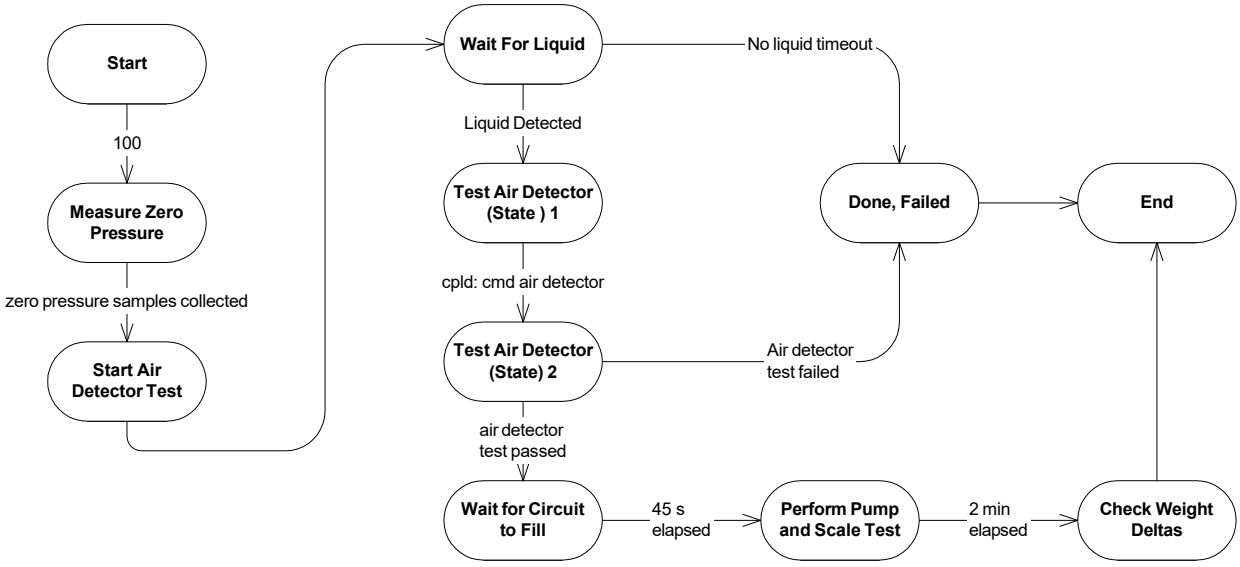


Figure 35 - Prime State Block Diagram

Run Mode

Once "Prime" is complete or if "Continue with Same Patient" is selected the software will.

- When the RUN button is pressed, the console displays "Reading Bag Weights. The bags need to remain stable during this time as the software is performing the following:
  - Check for stable scales. If a stability check fails, the test is repeated up to 5 times until it passes. If 5 tests in a row fail, the user is informed.
  - Check for oversized infusion bag. If infusion bag is more than 1.5kg the user is informed to use 1L bag.
  - Check for not attached urine bag. If the urine scale weight is less than 40g the user is informed to attach urine bag
  - If none of the above faults are detected the software checks scales for change, resets weight deltas, initializes pump speed check and the RUN mode is entered.
- In the RUN mode; if the test detects instability of the infusion scale for more than 30 seconds, the console limits pump flow to the default minimum Infusion rate for up to 2 minutes. If the infusion weight scale remains unstable for a total of 2 minutes, the console reports the "Infusion Bag Unstable" alarm and the console enters pause mode. If stability is detected during those 2 minutes, the console resumes normal operation.
- During stop and pause modes, the software generates a low volume beeping. After 15 minutes, the software increases the volume to high.
- The software monitors weight of the urine bag even after the "Urine bag full" (1.8 kg) alarm is reported. The software maintains a record of the total urine and uses that amount in the case of a drop in the urine volume. (Ex: Emptying the bag without going to the pause mode). Prevents any change in bag weight that is not in normal direction of flow.
- The software maintains a record of the total amount of infused saline and uses that amount to reinitialize balance in the case of emptying the bag without going to the stop mode. Prevents any change in bag weight that is not in normal direction of flow.
- The software displays alert when the maximum net gain is reached. The alert is suspended when the CLEAR button is pressed. Checking for maximum net gain is resumed when the new max gain is set.

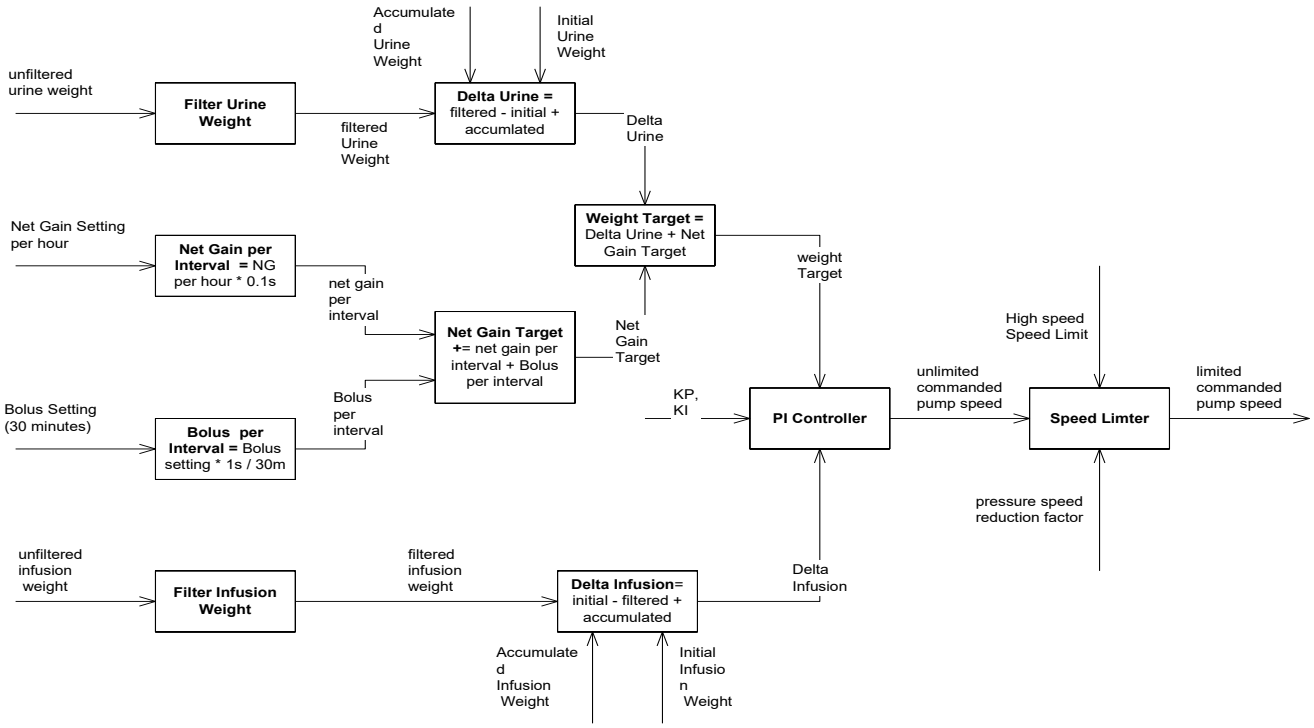


Figure 36 Control Loop Used to Balance Infusion.

Error Codes

There are two types of alarm codes, Power up Fault codes (POST codes) and System fault codes.

Post Faults

Table 7 Power Up (POST) Fault Code Reference Guide:

Error code	Title	Description/Resolution
0	Flash Fault	Flash is corrupt. Reprogram flash. If still fails, replace main board.
1	Audio Fault	Audio Fault
2	Configuration Data Corrupt	Configuration data is corrupt- re-calibrate.
3	Real Time clock fault	Power cycle. If failure remains, replace main board
4	CPLD fault	Reprogram CPLD. If still fails, replace main board.
5	Key Fault	Key stuck. Replace membrane panel
6	Pump fault	Check all cables connected properly.
7	Battery fault	Processor can't talk to battery. Ensure battery is connected. Replace Battery.
8	Internal ADC Fault	Internal ADC failure
9	EEPROM fault	Internal EEPROM failed
10	External ADC fault	Can occur when weights are adjusted during POST. Power cycle and do not touch weight hooks. Ensure both weight scales are connected.
11	Watchdog Fault	The CPLD cannot disable the motor
12	Touchscreen Fault	Touchscreen communication failure. Ensure touchscreen has latest firmware and is connected properly

System Faults

Once the system has passed post should a system fault occur the following message will be displayed to indicate what caused the fault?

Table 8 System Faults

Error code	Title	Description/Resolution
7	Pump control error	The pump has not followed the console's command. Can occur if motor is disconnected. Can also occur if the battery is very low and pump has to pump hard or fast.
12	Pump too fast	Pump went more than
20	Motor Running in Reverse	Motor ran backwards at >10ml/min
22	5V analog supply out of range	Hardware fault
23	ADC Test Fault	Replace main board
25	Software Malfunction	Report to engineering
26	Hardware Malfunction - See hardware Subcodes	Subcode 01 - motor speed out of range Subcode 02 - battery not detected Subcode 03 - Touchscreen not detected Subcode 04 - Audio DAC failed to initialize Subcode 05 - Audio DAC failed during operation
28	Software Error	Report to engineering
31	Motor Communication Failure	Motor Communication
40	EEPROM CRC Corrupt	Recalibrate console. If still fails, replace main board
41	Motor Communication Failure	Check connection / Replace motor controller

General Alarms / Alert Conditions

The alarms generated by the RenalGuard Console indicate the presence and severity of the condition detected. The Alarm bell on the bottom of the display and the volume of the sound emitted by the Console represent the general level of importance of the current alarm condition to the user.

Certain Alarms such as System Malfunction Alarms cannot be cleared or silenced unless the Console power is turned OFF and then back ON.

Depending on the cause of an Alarm or Alert the RenalGuard Console may respond in one of three ways:

1. Inform the user and stop the pump (for example if air is detected or if the hydration fluid bag is almost empty)

2. Inform the user and stop urine volume replacement while maintaining pump flow at the minimum hydration rate. (For example, if the urine bag has excessive motion).

3. Inform the user and continue urine volume replacement. (For example, if the min urine rate has not been reached).

Table 9 General Alarms / Alerts and Corrective Actions List

Code	Description	Comment
1	Maximum Net Gain Reached	Just clear
2	Minimum Urine Limit Not Reached	Just clear
3	Infusion scale not stable	Stabilize and press run again
4	Infusion Scale Not Stable (Run start)	Stabilize and press run again
5	Urine Scale Not Stable	Stabilize and press run again
6	Urine Scale Not Stable (Run start)	Stabilize and press run again
7	Pump Control Error	Cycle power
8	Air Detected.	Check if tube inserted. Clear air
9	Infusion Weight Mismatch.	Check for leaks, occlusion
10	Urine Bag Full	Empty urine bag
11	Infusion Bag Empty	Replace Infusion Bag
12	Pump Rotating Too Fast	Cycle Power
13	Weight Scale Mismatch (prime failed)	Try priming again
14	Not used	
15	Urine Scale Weight increased too rapidly	Check for extra weight and free chain
16	Urine Bag Leaking	Check for leak and free chain
17	Battery depleted	Connect AC. Cycle power.
18	Calibration Failed	Try again. Check raw ADC readings for saturation at 2kg and see if reading increases with weight increase.
19	Door Opened with Pump On	Check door
20	Bad Motor Direction	Cycle power
21	Occlusion Detected	Check for occlusion
22	Bad +5V Supply	Cycle Power
23	ADC Test Failed	Cycle Power
24	Power Up Test Failed	Failure code identifies the failure reason
25	Software Malfunction	Cycle power
26	Hardware Malfunction	Cycle Power
27	Prime Test Failed (Air Detector)	Check Air detector
28	Watchdog Failed	Cycle Power
29	Battery Low	Connect AC
30	Battery Critically Low	Connect AC
31	Motor Fault	Cycle power
32	Prime Test Failed (Pressure Sensor)	Check Pressure Sensor
33	Infusion Scale Weight decreased too rapidly	Check for leak and free chain
34	Pressure Sensor Disconnected	Connect pressure sensor
35	Infusion Bag To Large	Use correct bag and check free chain
36	Urine Bag Not Detected	Connect urine bag and check free chain

Infusion and Urine Faults and Warnings

Infusion Fluid Bag Weight Mismatch

During Run mode, the software compares the amount of volume delivered as determined by the pump rate against the amount of volume delivered as determined by the weight change of the Infusion fluid bag scale. If this difference over a 15 minute period is greater than 50% or 25ml, then the software generates an alarm **"Infusion Weight Mismatch"**.

Urine Bag Full

During infusion, if the urine bag weighs more than 1.8 kg, the software generates an alert **"Urine Bag Full".** The software continues to measure the weight of the urine. The software continues normal balancing.

Urine bag not attached detection

When entering the run mode, the software generates an alarm **"Urine Bag Not Detected"** if the urine bag is not attached (weight less than 40g). A normal empty urine bag from a RG SUS weights approximately 75 g.

Infusion Fluid Bag Empty

During infusion, if the software measures the Infusion bag weight to be less than 50 g or if the software measures the difference between the initial Infusion bag weight and the current bag weight to be greater than 950 g, it shall generate an alarm **"Infusion Bag Empty"**. If the weight of the infusion bag drops more than 500g over 15 seconds, the console generates an alarm **"Infusion Scale Weight decreased too rapidly"**.

Maximum Fluid Balance Limit Reached

In Run mode, the software generates an alert if the fluid balance (Infusion) exceeds the maximum fluid balance limit. This alert is informational only; balance settings shall not adjust automatically when this alert occurs. If this alert is cleared and the condition remains after 30 minutes have elapsed since the alert was initially annunciated, the alert shall recur.

The software allows the user to override this condition by increasing the maximum fluid balance limit setting.

Minimum Urine Output Detected

In Run mode, the software generates an alert **"Minimum Urine Limit Not Reached"** if the measured urine over a 30 minute period is less than the minimum urine output setting. Default setting is 150ml and is adjustable all the way down to 10 ml. discrete increments.

Urine Bag Leak / Urine Scale Fault

In Run mode, the software generates an alert "Urine Bag Leaking" and go to pause mode if the measure urine drops more than 50 g over a 5 minute period.

Urine Bag Abnormal Weight Increase / Urine Scale Fault

In Run mode, the software generates **"Urine Scale Weight increased too rapidly"** alert and goes to pause mode if the measured urine increases more than 500 g over a 5 minute period.

When entering Run mode, the software generates an alarm **"Urine Scale Weight increased too rapidly"** and goes to stop mode if the average urine rate since the last time the console was in Run mode is greater than 125 ml/min.

Maximum Negative Balance Limit Reached

In Run mode, the software generates an alert **(Maximum Net Gain Reached)** if the fluid balance (Infusion) drops below the minimum fluid balance limit. This alert is informational only; balance settings shall not adjust automatically when this alert occurs. If this alert is cleared and the condition remains after 30 minutes have elapsed since the alert was initially annunciated, the alert shall recur.

The software allows the user to override this condition by increasing the net gain setting.

Environmental

Operating Conditions Under Which Product will meet all Specifications (ENV1)

- Temperature: 5≤ T (° C) ≤ 40
- Relative Humidity: 20 ≤ RH(%) ≤ 90

Conditions of Storage and Transportation (ENV2)

- Temperature: -10 ≤ T (° C) ≤ 45
- Relative Humidity: 20 ≤ RH(%) ≤ 90 (includes condensation)
- Atmospheric Pressure: 10 ≤ P (hPa) ≤ 1060

Packaging and Transit

Packaging

- The console is packaged in a single cardboard carton with foam cut out to protect console during transit.
- The minimum accessories to be packaged with the console include:
  - medical grade power cord
  - operator's manual
- The mobile cart will be packaged in a separate cardboard box.

Transit

- ISTA Procedure 1A:2001, Packaged-Product weighing 150 lb (68 kg) or less

Compliance Standards

The system meets the requirements of the following standards:

- CAN/CSA C22.2 No. 601-1-M90, Medical Electrical Equipment – Part 1: General Requirements for Safety
- CISPR 11:1997+A1:1999, Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement
- IEC 878, Graphical symbols for electrical equipment in medical practice, 1988
- IEC 60601-1:1988+A1:1991+A2:1995, Medical electrical equipment - Part 1: General requirements for safety
- EN 60601-1-2:2001, Medical electrical equipment – Part 1: General requirements for safety - Part 2:Collateral standard: Electromagnetic compatibility requirements and tests
  - EN 61000-3-2:2000, Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions
  - EN 61000-3-3:1995, Electromagnetic compatibility (EMC) – Part 3: Limits – Section 3, Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment rated current < or = 16A.
  - IEC 61000-4-2:1995+A1:1998+A2:2000, Electromagnetic compatibility (EMC) – Part 4, Test and measurement techniques – Section 4.2 Electrostatic discharge immunity test – Basic EMC Publication
  - IEC 61000-4-3:2002+A1:2002, Electromagnetic compatibility (EMC) - Part 4, Test and measurement techniques – Section 3, Radiated, radio-frequency, electromagnetic field immunity test
  - IEC 61000-4-4:1995+A1:2000, Electromagnetic compatibility (EMC) – Part 4, Electrical fast transient/burst immunity test – Basic EMC Publication
  - IEC 61000-4-5:1995+C:1995+A1:2000, Electromagnetic compatibility (EMC) Electromagnetic compatibility (EMC) – Part 4, Testing and measurement techniques – Section 5, Surge immunity test
  - IEC 61000-4-6:1996+A1:2000, Electromagnetic compatibility (EMC) – Part 4, Testing and measurement techniques – Section 6, Immunity to conducted disturbances, induced by radio-frequency fields
  - IEC 61000-4-8:1993+A1:2000, Electromagnetic compatibility (EMC) – Part 4, Testing and measurement techniques – Section 8, Power frequency magnetic field immunity test – Basic EMC Publication
  - IEC 61000-4-11:1994+A1:2000, Electromagnetic compatibility (EMC) – Part 4, Testing and measurement techniques – Section 11, Voltage dips, short interruptions and voltage variations immunity tests
- IEC 60601-1-4:2000, Medical electrical equipment - Part 1-4: General requirements for safety – Collateral standard: Programmable electrical medical systems
- IEC 60601-2-24:1998, Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers

- EN 980:2003, Graphical symbols for use in labeling medical devices
- EN 1041:1998, Information supplied by the manufacturer of medical devices
- ISTA Procedure 1A:2001, Packaged-Product weighing 150 lb (68 kg) or less
- UL 60601-1:2003, Medical Electrical Equipment – Part 1: General Requirements for Safety

RENALGUARD CONSOLE
Service Manual

LA00289

PART THREE
HOW TO PROCEDURES

TABLE OF CONTENT

Battery Fuel Gauge Recalibration Procedure (EP00210)

A full charged Inspired Energy battery (EP00210) will have the following characteristics: These parameters can be seen from the RG service screen

Battery Des Cap: 2400 mAH
Battery Time: <150 Minutes
Battery Voltage: <16.50 Volts

Charging has virtually stopped when the current is below 50 mamp. Charging also stops after the RG console has been charging the battery for over 2 hours.

Batteries may require a recalibration to re-set the fuel gauge algorithms and re-calculate the actual capacity in the battery. This is performed using a smart charging station that communicates using the battery's SMBus data link. Allow up to 12 hours for each recalibration performed. If a fully charged battery does not have greater than 150 minutes of battery time available then the battery should first be re-calibrated. This procedure should be perfromed if after fully charging the battery with the RG console the above parameters have not been reached

Place the battery into the charger's battery bay ensuring that the 5-way connector is fully seated. The LEDs in the status window will provide information and the charger will automatically begin charging.

LED Indication:

Green flashing:	Battery charging
Green solid:	Battery fully charged
Blue flashing:	Battery in calibration mode
Blue solid:	Battery fuel gauge calibrated
Red flashing:	Battery fuel gauge in need of calibration
Red solid:	Error

The battery is ready for use when the Blue LED is solid.

Tag the battery as calibrated. Record the date calibrated on the tag.

Figure 1 Battery Charging Station

RG Software Upgrade Procedure

Parts Required: SW00023 Software Version being upgraded and the checksum value.

Tools Required:
Phillips Head Screwdriver medium size
Phillips Head Screwdriver long handle (10 inch long by ¼ inch wide shaft) small point
Windows PC with Serial Port (or USB-to-serial adapter)
Atmel SAM-BA 1.2 Software (available from PLC)
Two 1-kg hook weights (or a 1-kg weight and a 2-kg weight)
Pressure Simulator (optional)
AC00050 Single-Use Set
200 ml Graduated Cylinder (with 10 ml scale) or Scale (0-200 gram range)
1L Saline bag

Procedure

Event History Download:

- This software update will erase the current event history. Download the prior event history prior to updating software if you would like to retain the history.
- Ensure console is unplugged and console turned off.
- Remove rear cover (see figure 1).

Clear the Flash Memory of the SAM:

- Consoles with Programming buttons (serial number 6057 and higher and any console with an SB90347 main PC Bd installed):
  - Press and hold the reprogramming button (see Figure 2)
  - Turn the console front power switch ON for approximately 15 seconds then turn it OFF.
  - Release the reprogramming button.
  - Turn the console on. Touch screen should come on but no software version will appear on the screen, just the RG logo and PLC name will appear.
- Consoles without a programming button (older boards SB90323 and SB90309)
  - Connect a jumper from TT3 to J17 pin 1. Pin 1 is to the right.
  - Turn the console front power switch ON for approximately 15 seconds then turn it OFF.
  - Remove the TT3 to J17-1 jumper.
  - Turn the console back on. Touch screen should come on but no software version will appear on screen, just the RG logo and PLC name will appear.

Load ATMEL Software.

Open SAM-BA (See Section "**RenalGuard Software upgrade using SAM-BA" for more detail)**

-
  - Double click the SAM-BA icon on the desktop of the PC to launch the ATMEL SAM Boot Assistant application. When the "Choose protocol" window displays choose:
  - "Select COM port" as COM1 (or the appropriate COM port).
  - "Choose your board" select "AT91SAM7S256-EK".
  - Then click on the "DBGU connection" button.
  - Load the configuration file into the SAM:
    - When the SAM-BA 1.2 screen is displayed, click the "Browse" button next to the "Send File Name" window.
    - Find the file "C:\FMS Production Files\plcflash_verx-x.bin" in the "Send File name" window, click the "Send File" button. X-X stands for the software version to be loaded.
    - When the "At least one lock region is locked!" window opens and asks "Do you want to unlock involved lock region(s)" click the "Yes" button.
    - When the "Lock region(s) to lock" window opens and asks "Do you want to lock involved lock region(s)" click the "Yes" button.
    - To verify programming of the SAM, click the "Compare sent file with memory" button.
    - When programming has completed, close the window. Exit the SAM-BA application.

Power Cycle the Console.

- Confirm that:
  - The piezo device emits a <BEEP>. And the speaker emits a tone
  - The LCD/Touchscreen displays the “Performing Self Test” screen.
    - In most cases the RG console will fail Post the first time. If so Turn-off console and power back on.
  - After the test completes, press the top right corner of the screen three times to enter service mode
  - Confirm that that the software version (“SW Version”) displayed is **x-x.**
  - Confirm that that the software checksum (“Checksum”) displayed is **an exact match to that supplied by PLC**
  - Check the time and confirm that it is correct. If not, touch “Set Time” to set the time correctly.
  - Turn Console OFF. Re-attach rear enclosure.

Console Testing

- Test the console using the Field Test Data Sheet Doc 1601.

Pictures:

Figure 1:

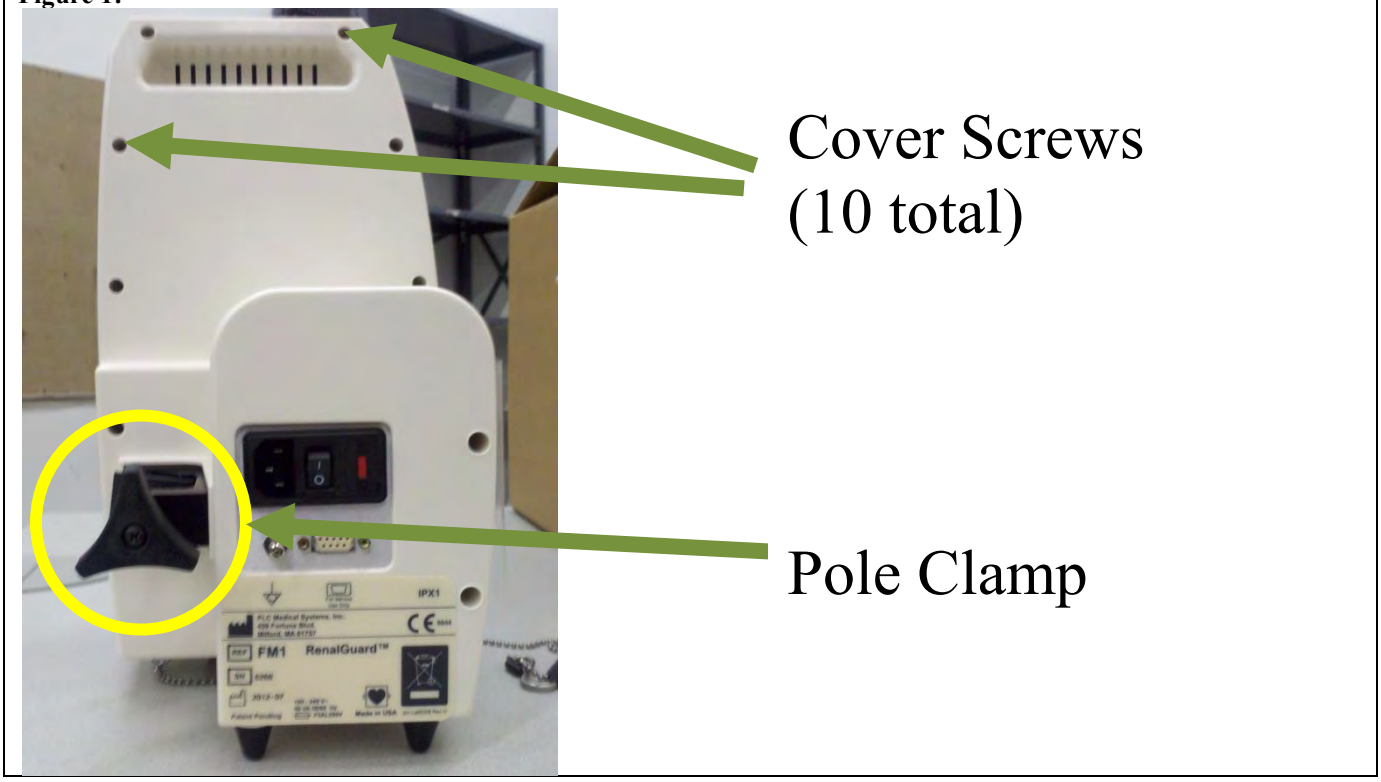
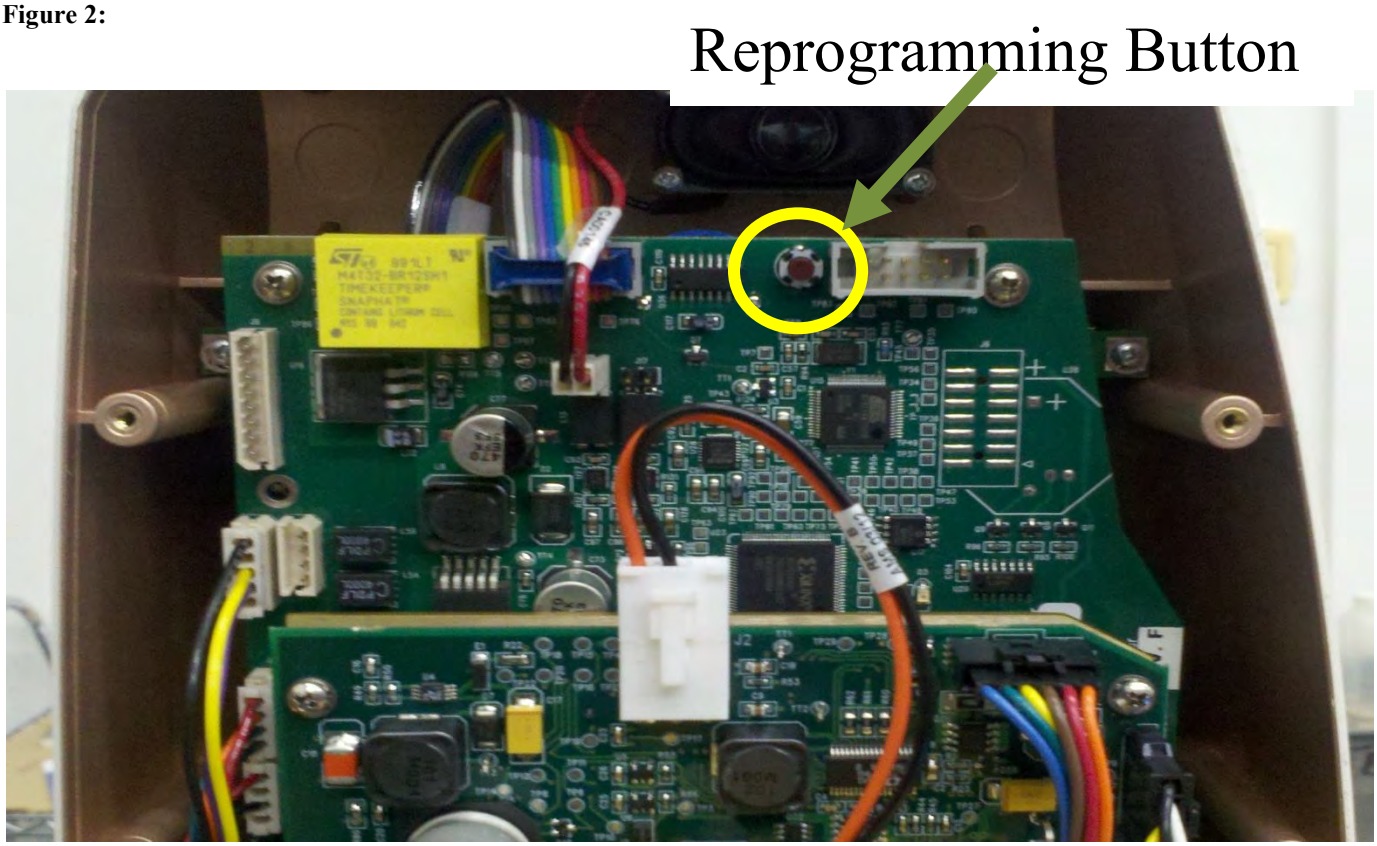


Figure 2:



Event History Download Procedure

Parts Required: None.

Tools Required: Windows PC with Serial Port (or USB-to-serial adapter)

Procedure

Event History Download:

Whenever new software is being loaded, the Event History will be deleted. In order to have a record of the Event history you must download the Event History prior to updating software.

Communicating with RG Console: (See Section "Connection for Event History Download for more details)

Turn on the computer that you will be downloading the RG event History file to.

Connect the computer to the RG console via the RS 232 cable.

Bring up the Hyper terminal program on the computer.

Turn the console front power switch ON and verify that the RG console and the Computer are communicating.
PLC Medical Systems and the current Rev of software will appear if the two are communicating.

Download Event History Data.

Press the "M" key:

Debug Port Menu Options screen will appear.
Open the File tab and click on "Log"
In the file name window enter the serial number of the RG console that you are down loading the event history from and use extension .txt. (example 6299.txt)
Then hit enter.
Debug Port Menu Options screen will re-appear.

Press "L" to copy the Event History to the file just created

Open Tera Term Log file that you recently created window from
Tera Term Log window will appear indicating the file name that you just created as well as the Bytes transferred.
Close window

File transferred and can be viewed by opening Notepad and selecting file that you created.

Understanding Event History Download

Alarms/Alerts

Title	Description/Resolution	Subcode	Data1	Data2
Max Net Gain Reached	User's set maximum net gain has been reached. Balancing continues, but net gain and bolus stop. To restart net gain or bolus, increase Max Net Gain.	0	0	0
Min Urine Not Reached	Urine measured over previous half hour is below user's set minimum urine rate. Alert is only informative. Therapy is unaffected.	0	0	0
Infusion Scale Not Stable	Infusion scale has been unstable for over 2 minutes. Stabilize scale and continue.	0	0	0
Infusion Scale Not Stable when Run Started	Console requires scales to be stable to start run. Stabilize scales and re-enter RUN.	0	0	0
Urine Scale Not Stable	Urine scale has been unstable for at least 1.5 minutes.	0	0	0
Urine Scale Not Stable when Run Started	Console requires scales to be stable to start run. Stabilize scales and re-enter RUN.	0	0	0
Air Detected	Greater than 0.5ml of air volume detected.	0	0	0
Infusion Weight Mismatch	Console compares pump rotations to weight scale change over previous 15 minutes. This alarm indicates that they differ by more than 50%.	0	Pump Expected Volume	Infusion Weight Delta
Urine Bag Full	Urine bag is full. Press PAUSE first, then clear alert. Once in Pause mode, empty bag.	0	0	0
Infusion Bag Empty	Replace infusion bag.	0	0	0
Prime Failed Weight Scale Test	Ensure prime was run on fresh circuit that has been installed properly. If alert persists, check pump head and weight scales.	0	Infusion Error (g)	Urine Error (g)
Urine weight increased too rapidly	Weight increase greater than 500g in 5 minutes. The weight increase is ignored.			
Urin bag leaking	Urine bag drop of more than 50g over 5 minutes			
Door Opened while running				
Occlusion	Pressure exceeds 15 PSI for 30 seconds or 20 PSI for a short time.			
Intermittent Occlusion	Intermittent occlusion for 2 minutes			
Air detector test failed during Prime	Ensure tube is in air detector and tube is filled with saline. Check air detector is alarm recurs.			
Battery Low	Less than 10 minutes left on battery			
Battery Critically Low	Less than 4 minutes left on battery			
Prime Presssure Test Failed	Test expects pressure to vary during Prime. If this occurs while circuit is setup correctly, replace infusion set to replace pressure sensor.			
Infusion Scale weight decreased unexpectedly	Infusion weight dropped by more than 500g over short period of time			
Pressure Sensor Disconnected	Pressure sensor is disconnected, or the pressure in the line is very negative			
Urine bag not detected	No weight is detected on urine scale hook			
Infusion Bag Too Large	Infusion bag weight over 1.5kg measured. Replace with 1L saline bag or replace infusion load cell.			

Other Events in the Event Log:
Events are printed: Hour: Minute Mode Event_Code Event_Description Subcode Data1 Data2

		Subcode	Data1	Data2
"Infusion Bag Changed",	Infusion Bag Changed,	0	Weight of infusion bag after change	0
"Urine Bag Changed",	Urine Bag Changed	0	Weight of urine bag after change	Weight of urine bag before change
"Urine Bag Changed",	Mode Change	New Mode #	Infusion Bag Weight	Urine Bag Weight
	Power Up	Encoded Date and Time		
	Power Down	Not used		
	Prime Complete	Pressure change between pump running and not running in .1 psi	Change in urine weight during Prime test	Change in infusion weight during Prime test
	Fluid Reading	Filtered pressure in PSI	Urine Weight in g	Infusion Weight in Grams
	Pressure Read	Not used		
	Motor Controller Reset	0	Bit Fault Counter	0
	AC/DC Changed	1 if running on AC, 2 if battery	Battery voltage in .01 V	Estimated battery minutes remaining
	POST Failed	Post failure code	0	0
	Max Pos. Setting	0	Old Setting	New Setting
	Min Urine Setting	0	Old Setting	New Setting
	Bolus Setting	0	Old Setting	New Setting
	Min Inf Rate Setting	0	Old Setting	New Setting
	Max Neg. Setting	0	Old Setting	New Setting
	% Match Setting	0	Old Setting	New Setting
	Desired Bal Setting	0	Old Setting	New Setting
	Other Fluid Setting	0	Old Setting	New Setting
	Spd Delta Dtctd	Seconds commanded speed of pump and actual speed disagree	Actual Speed	Filtered Speed
	Motor Comm Intrpted	Number of times motor controller reported failure	Motor Error Code	Motor Velocity
	Motor Comm Intrpted2	Number of times communication with motor controller failed	Error Code	Number of words expected from controller
	Motor Rate At Limit	Count of times Motor Speed	Commanded motor speed	Motor speed read by cpld

		read by cpld outside limit		
	Motor Drn Detected	Count of times motor turning backwards detected	Speed of motor in reverse	
	High Pump Speed	Count of times pump speed over limit after the 3 minute window	Pump speed	
	Screen Comm Intrped	Count of times communication to the touchscreen has been lost		
	1st NVRAM History CRC Crptd	0	Event log count from 1st log	Event log count from 2nd log
	2nd NVRAM History CRC Crptd	0	Event log count from 1st log	Event log count from 2nd log
	1st NVRAM CRC Crptd	0	0	0
	2nd NVRAM CRC Crptd	0	0	0
	1st FLASH Copy Crptd	0	0	0

Mode Strings:

INIT	System initialization
W_CAL	Weight calibration
PRM_S	Prime stop
PRM_A	Prime accept
RUN	System is in run mode
PRIME	System is primed
STOP	Stop mode
ADV	System is in Advance mode
RUN_I	Initializing run mode
PAUSE	System is in Pause mode
SERV	System is in Service mode
CAL_P	Pressure calibration
SET_T	Set time
SETSN	Set serial number
EVENT	Display event history
LANG	Set Language

RealTime Data Explanation

1. Mode
2. Infusion Weight (g)
3. Urine Weight (g)
4. Motor Speed feedback
5. Accumulate infusion weight
6. Accumulated urine weight
7. Net gain target

8. Last Run mode urine weight
9. Filtered Weight (Infusion)
10. Filtered Weight (Urine)
11. Pressure
12. Infusion weight stable
13. Urine weight stable
14. Air detected
15. User settings – Maximum Fluid
16. User settings – Minimum urine
17. User settings – Net gain
18. User settings – Bolus
19. Alarm ID
    a. Error subcode
    b. Error data 1
    c. Error data 2
20. Power source (AC or battery)

The columns below can be copied into an Excel spreadsheet

Mode	Infusion Weight (g)	Urine Weight (g)	Motor Speed feedback	Accumulate infusion weight	Accumulated urine weight	Net gain target	Last Run mode urine weight	Filtered Weight (Infusion)	Filtered Weight (Urine)	Pressure	Infusion weight stable	Urine weight stable	Air detected	User settings - Maximum Fluid	User settings - Minimum urine	User settings - Net gain	User settings - Bolus	Alarm ID	Error subcode	Error data 1	Error data 2	Power source (AC or battery)
4	####	73	0	2.4	0	0	72	####	72	0.5	1	0	0	####	150	0	0	0	0	0	0	1

Main PCB Mechanical Setup: (refer to figures 1 & 2 for images)

If not already installed, install the Battery/Crystal module (item 22, EP00205) in the U34 socket of main PC BD (item1, SB90347).

Using four nylon nuts (item 7, HA00256) secure the four 1/2" aluminum standoffs (item 4, HA00546) that will support the power management PCB.

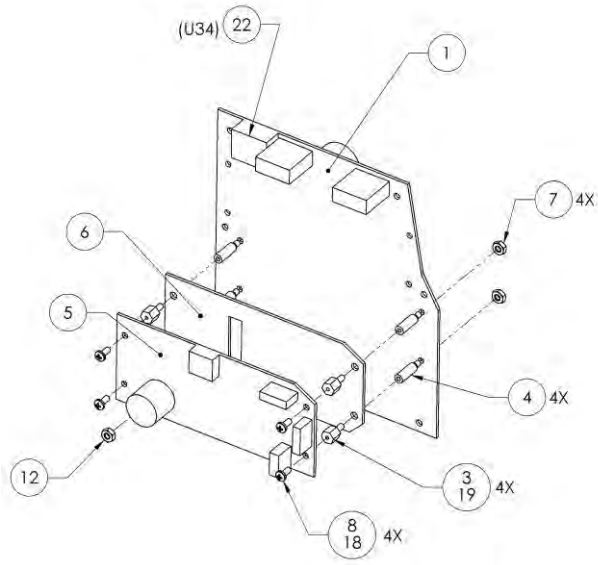


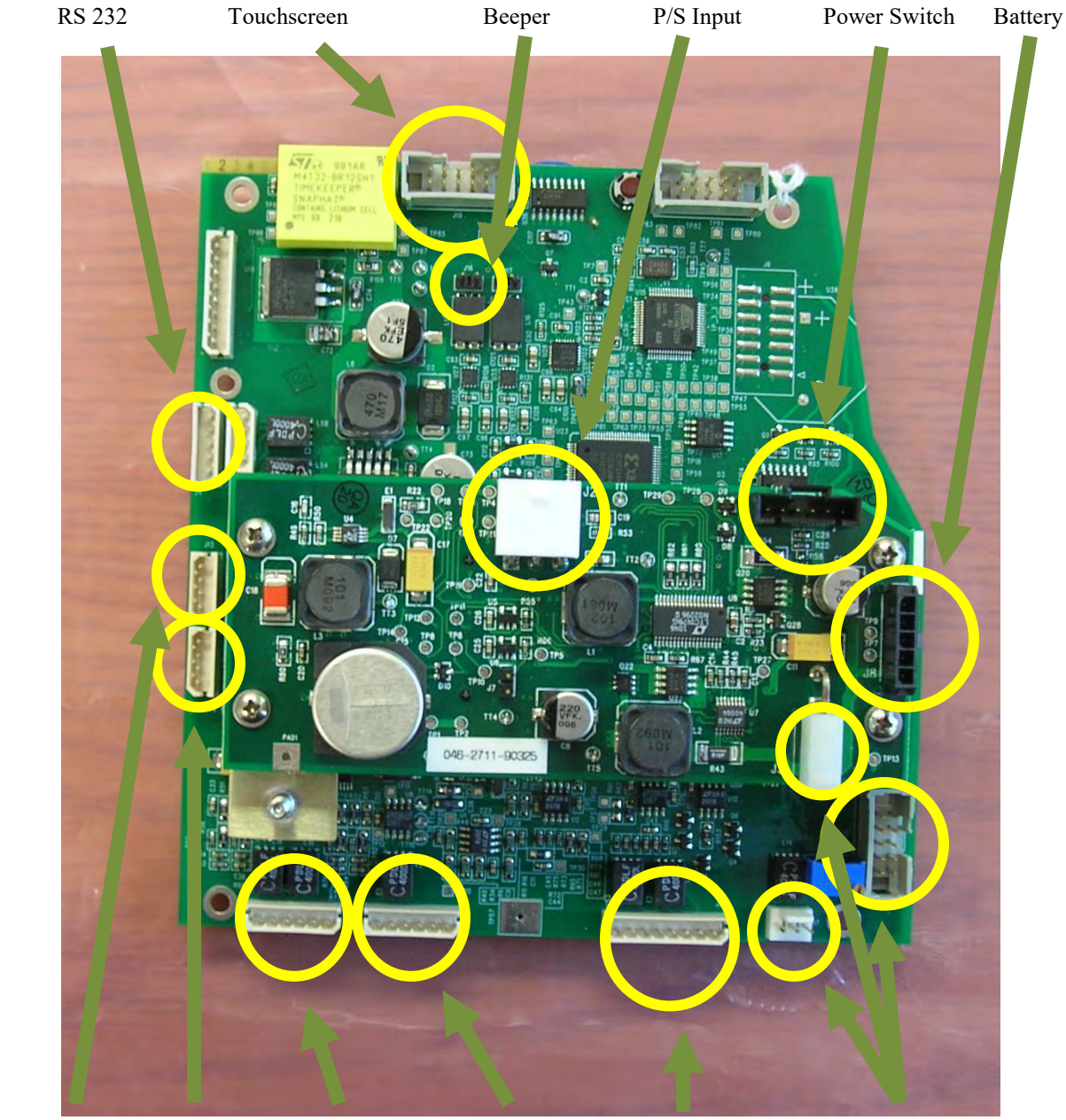
Figure 1

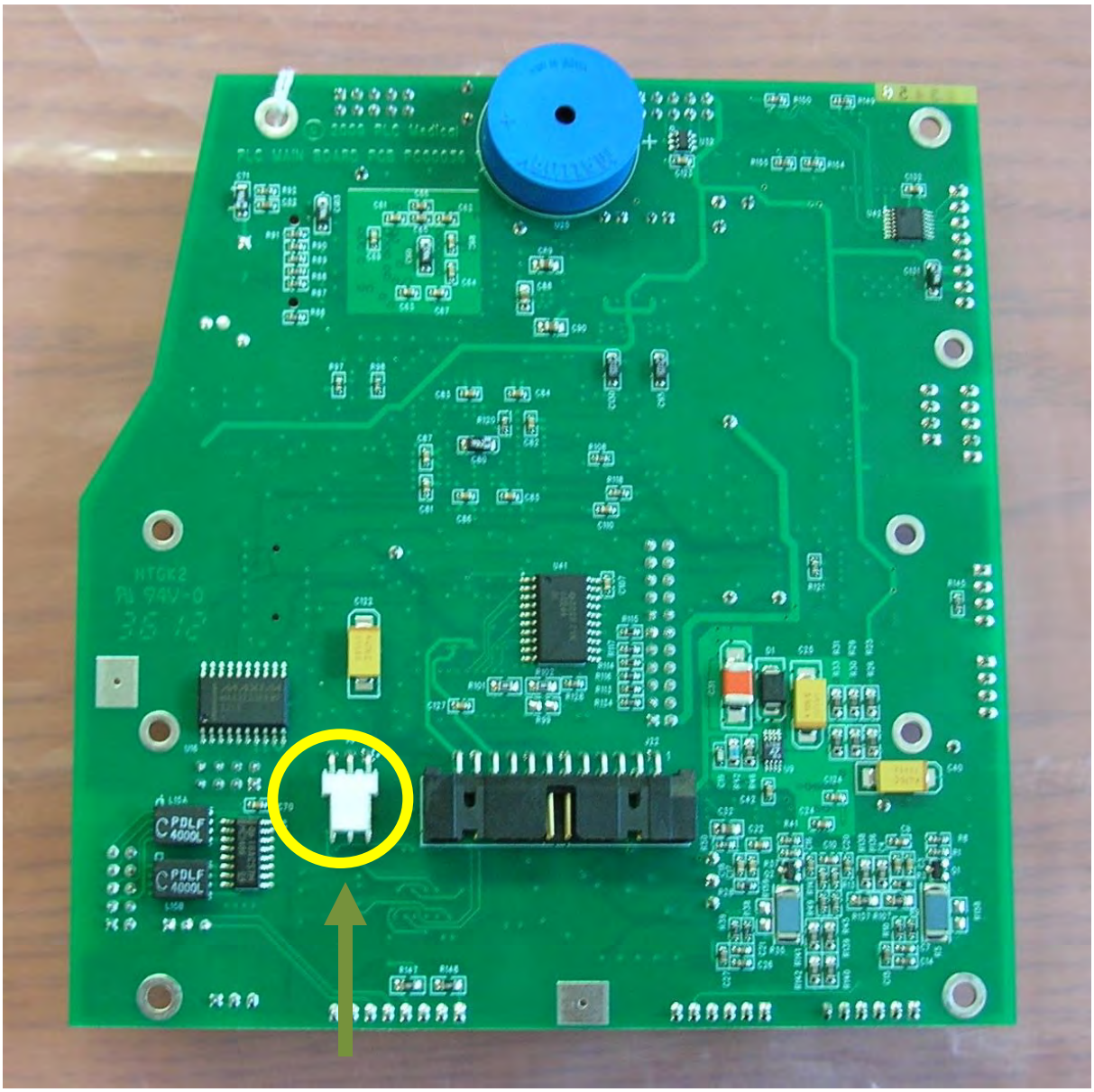
Power Management PCB Mounting: (refer to figure 1 & 2)

- Secure the power management shield (item 6, SM00139) to the standoffs on the Main PCB using four 1/4" aluminum male/female standoffs and Loctite 242 (items 3, HA00505).
- Secure the power management PCB (item 5, SB90325) to standoffs using four each screws and star washers (items 8, HA00232 & item 18, HA00462).
- Secure the ground cable (item 13 (not shown)) to the ground stud on the shield using the hex KEPS nut (item 12, HA00525).

Figure 2

Main PC Board / Power Management Cable Connections





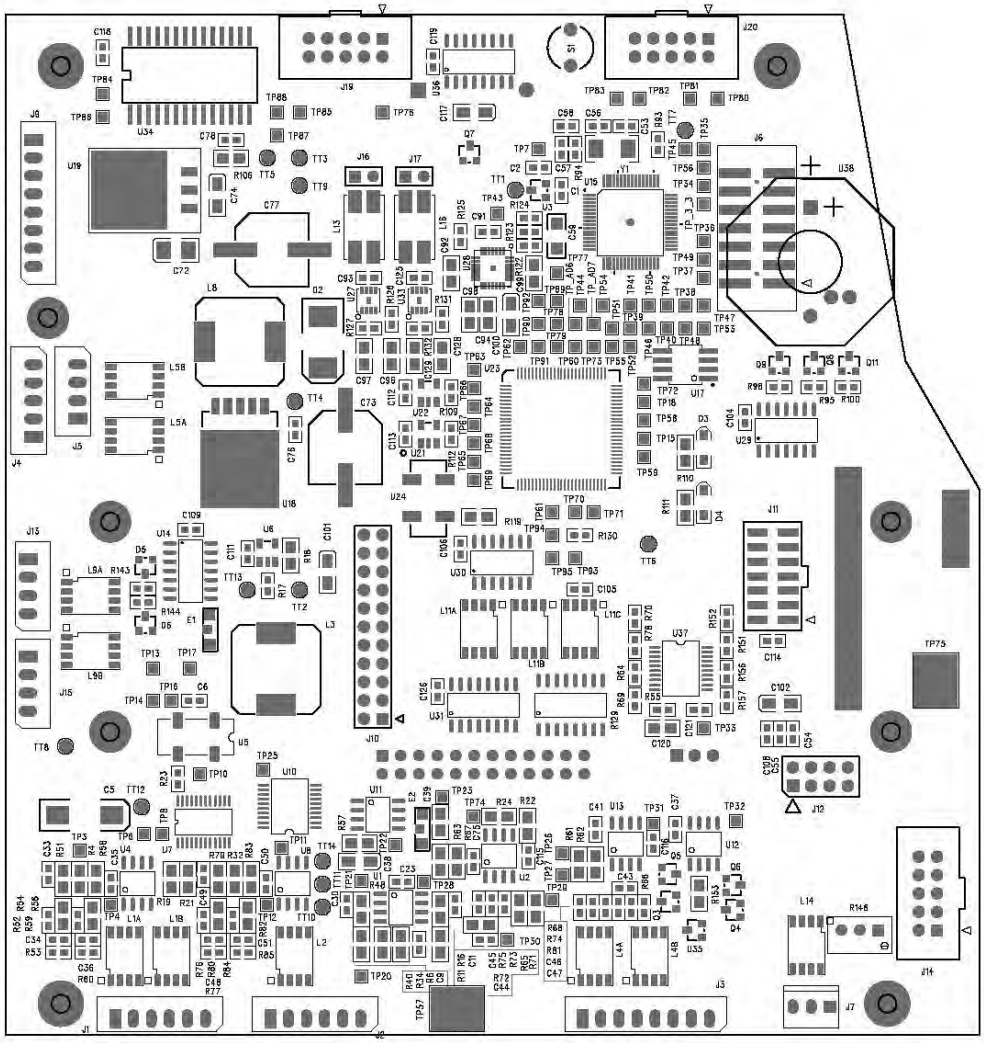
Battery Charge LED

RG Main PC BD Electrical Set-Up

If the Main PC Bd in the RG Console is replaced the following adjustment will need to be made:

- Confirm electrical voltages Re-calibration of both load cells (infusion and urine).
- Re-calibration of pressure sensor. Serial number entry Date and time entry

Confirm Electrical Voltages



Value	From	To	Acceptable Range
+ 7 VDC	TT2 (location 8F)	GND TP57 Location 0L or TP75 Location 6X	6.5 VDC to 7.5 VDC
+ 5.0 VDC	TT5 (location 15E)		4.75 VDC to 5.25 VDC
+ 3.3 VDC	TT3 (location 15F)		2.135 VDC to 3.465 VDC
+ 5 V REF	TP23 (location 4H)		4.90 VDC to– 5.10 VDC
+ 1.25 V REF	TP30 (location 1L)		1.15 VDC to 1.32 VDC

Load Cell Calibration

Turn on Console

If the load cell has been replaced, before first time calibration, pre-load both load cells by hanging a 3 Kg weight on the chains for a period of 1 minute.

Touch the upper right corner of the display three times to enter the Service screen.

Once the service screen appears select “Weight Calibration” Follow the instructions displayed to:

- Calibrate the infusion load cell (left chain)
- Calibrate the urine load cell (right chain)

At various steps during calibration, the display will prompt for:

- the hanging of either a 1 kg or 2 kg weight on the load cell chains, or
- the removal of weights from the load cell chains.

Follow the instructions exactly as displayed to safeguard against calibration errors.

Terminate the test if errors occur.

If no errors occurred during calibration, the display will prompt for either saving or discarding the calibration parameters. Touch **Save Settings** to store the parameters.

Load Cell Calibration Check

Remove all weights from the Infusion Load Cell chain. Displayed value on service screen (acceptable value: -5 grams to 5 grams):

Place the 1 kg weight on the Infusion Load Cell chain. Displayed value on service screen (acceptable value: 990 grams to 1010 grams)

Place the 2 kg weight on the Infusion Load Cell chain. Displayed value on service screen (acceptable value: 1980 grams to 2020 grams)

Remove all weights from the Urine Load Cell chain. Displayed value on service screen (acceptable value: -5 grams to 5 grams)

Place the 1 kg weight on the Urine Load Cell chain. Displayed value on service screen (acceptable value: 990 grams to 1010 grams)

Place the 2 kg weight on the Urine Load Cell chain. Displayed value on service screen (acceptable value: 1980 grams to 2020 grams)

If any values are out of range repeat the load cell calibration outlined above.

Pressure Calibration Setup

CAUTION: Electrical shock hazard!

The pressure calibration trimmer is difficult to access and must be adjusted in close proximity to the console's DC power supply. If the pressure calibration trimmer needs to be adjusted disconnect the AC power cord from the console. Allow the console to run on battery power during the pressure sensor calibration.

Turn console on. Enter the Service Screen by touching the upper right corner three times. Set the pressure calibration box switch to 10 and connect it to the console. If value displayed is 9.85 to 10.15 psi proceed to last step. If not continue on.

Access the sensor gain trimmer (R146) on the main PCB. R146 is located below the J3 header connector.

Adjust the trimmer until the pressure displayed is between 9.85 psi and 10.15 psi.

Set the Calibration Box to zero. Touch **Pressure Calibration** button and run the pressure calibration. Follow the instructions on the screen and when finished reboot the console.

Pressure Accuracy Check

Touch the upper right corner of the display three times to enter the Service screen.

Disconnect the calibration box from the console and record the disconnected sensor pressure value. Confirm that the pressure value displayed is –5.50 or less.

Connect the calibration box to the console and set the switch to 0. Confirm that the pressure value displayed is between − 0.2 psi and + 0.2 psi.

Set the calibration box switch to 10. Confirm that the pressure value displayed is between 9.8 psi and 10.2 psi.

Set the calibration box switch to 20. Confirm that the pressure value displayed is between 19.0 psi and 21 psi.

If any of the values are out of the acceptable range, repeat the Pressure Calibration Set-up

Record Serial Number

Enter console service screen and touch **Set Serial #** button.

Using the touchscreen number pad enter the four digit serial number found on the top of the pick list. Touch **Save Settings** button to store the serial number.

The console serial number is displayed at the top right corner of the service screen. Confirm that the value has been entered properly.

Set Time and Date

Enter the service mode then press **Set Time** button

Using the touchscreen number pad enter:

- the current time using the *hhmm* format {two digits for hours (24-hour time format) and two digits for minutes}.
- the current date using the *mmddyy* format {two digits for month, two digits for days and two digits for year}.

Press **Save Settings** to store the time and date information.

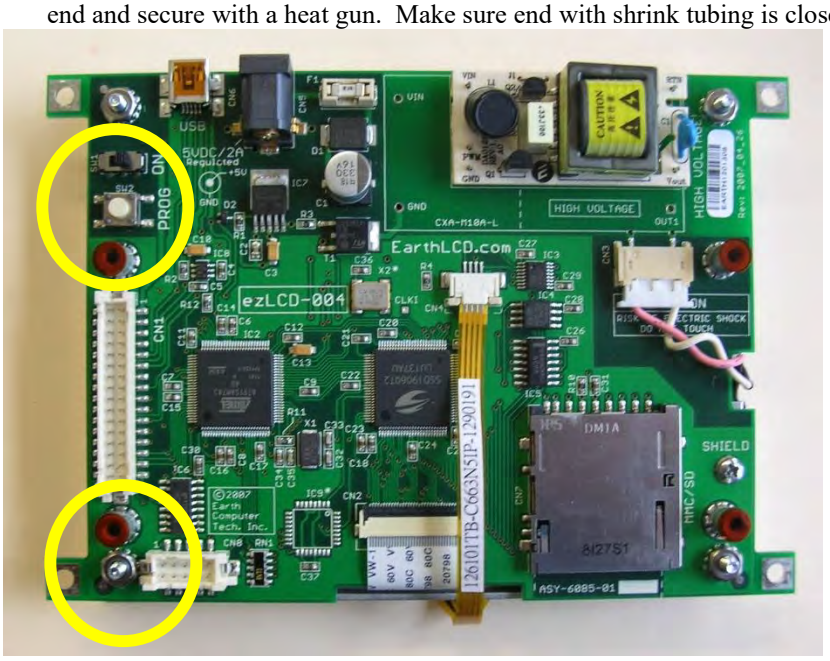
Power cycle the console and re-enter service mode.

Confirm that the values have been stored properly by viewing the Service screen.

Touchscreen Replacement

(Note: The Touchscreen (EP00201) is ESD-sensitive. ESD safeguards must be observed throughout.)

- Remove the 5” long piece of braid and a ring terminal (CA00087 & EH00135), from the old Touchscreen.
  - On older version of touchscreens, remove the mask and solder the braid to touchscreen PCB.
  - On new versions remove the mounting screw from the touch screen and attach the braid to touchscreen PCB as shown. Tighten the screw to hold the braid secure.
- If not already on the braid slide a 3” length of shrink tubing over the terminal ring and push it all the way to the solder end and secure with a heat gun. Make sure end with shrink tubing is closest to the touch screen.

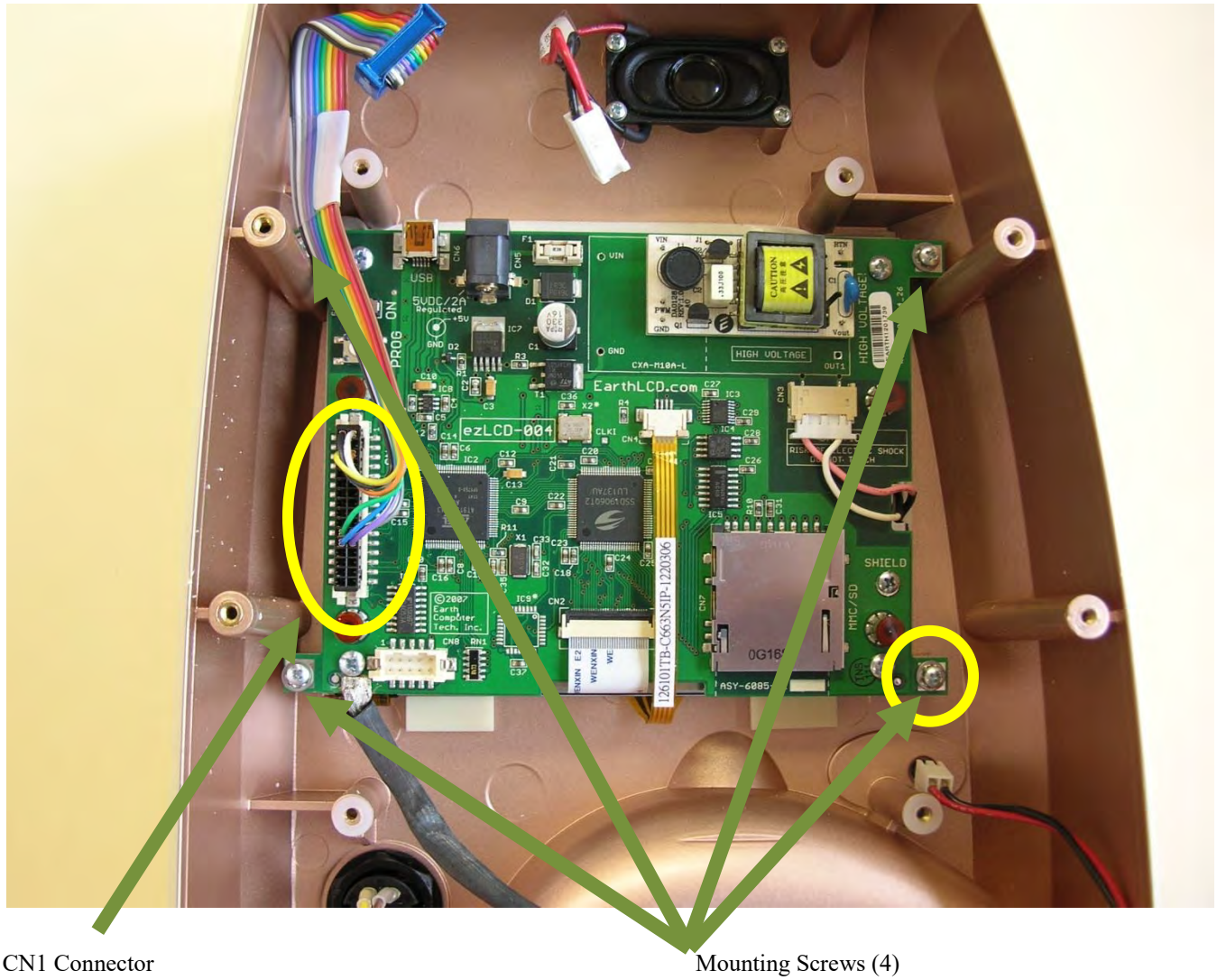


- Cut two (1) piece of foam adhesive (HA00559) approximately 3.5” long. Apply the cut piece of adhesive to position the Touchscreen (EP00201) in the front enclosure window. “Front of Screen” remove film, apply foam to all four sides assuring that black of display is showing all around.

Note: If the foam adhesive is placed too far into the touchscreen, the touchscreen will not respond to touch.

- Using the IPA Cleaner, prepare the inside of the front enclosure (MD00039) to receive the adhesive strips.

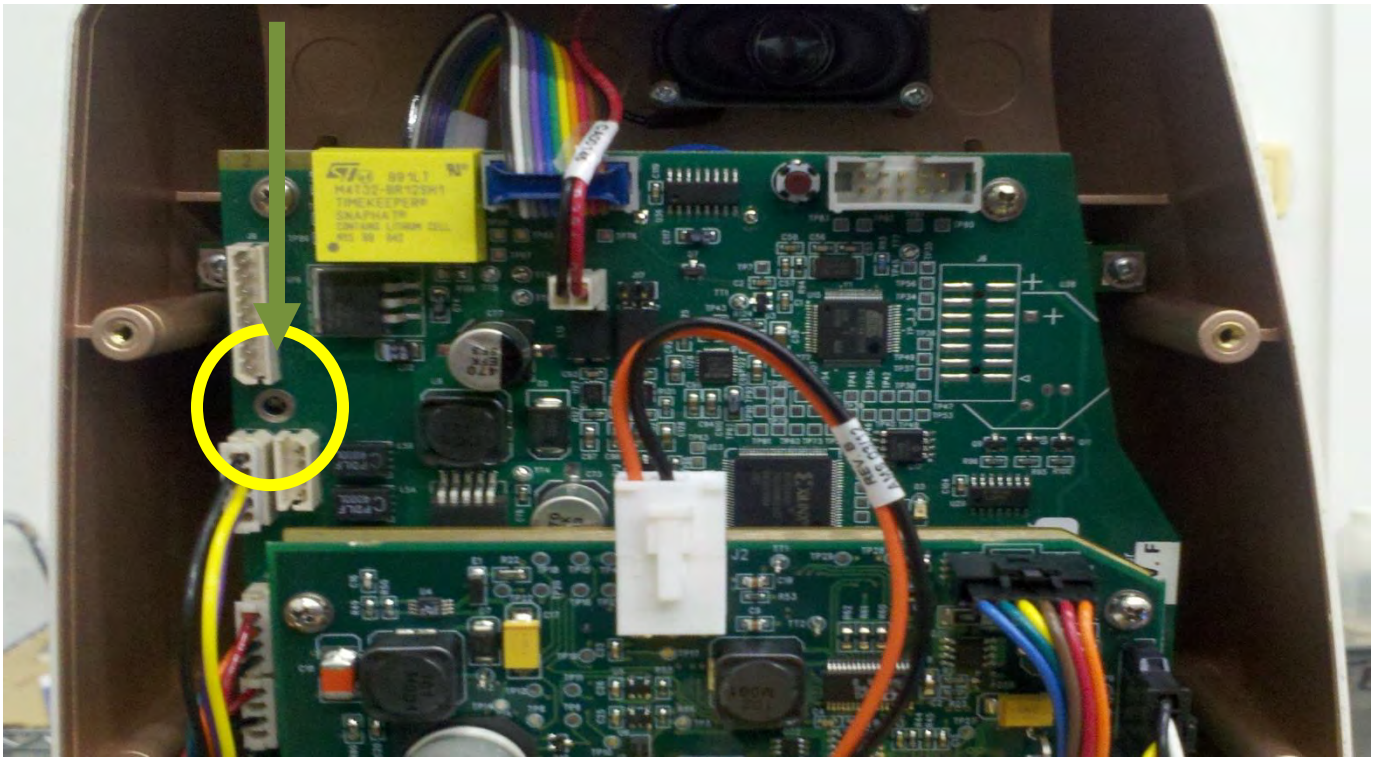
- Ensure that the switch SW1 on the back of the Touchscreen is set to the ON position.
- Orient the Touchscreen as shown in figure below with the connector CN1 on the left side. Using four each HiLo screws and internal tooth lock washers (HA00560 & HA00509), secure the Touchscreen to the front enclosure.
- Connect Touchscreen to Main PCB cable (CA00166) to the connector CN1.



TouchScreen Calibration

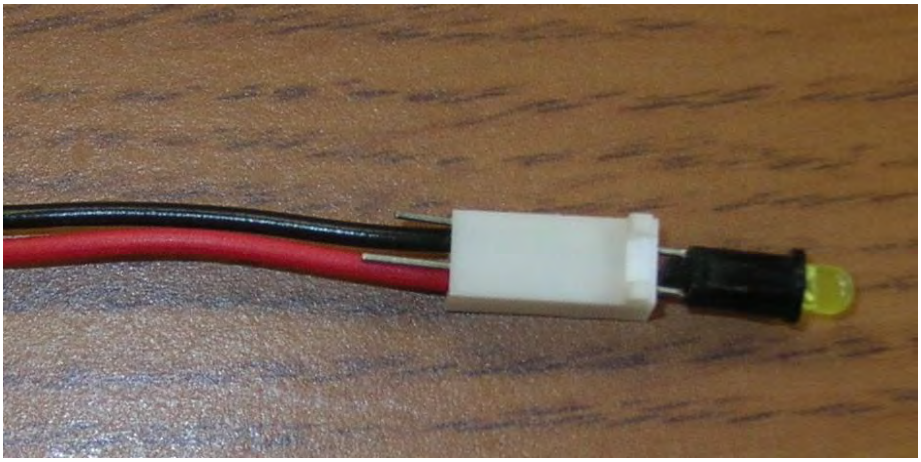
- Power cycle the RG console, and wait for the software to finish POST.
- Press the “PROG” button to enter the Touchscreen Calibration routine. The “PROG” button on the touchscreen can be accessed through the main PC bd by using a small tool and pushing the button directly behind the access hole.
- Following the onscreen instructions, use a stylus to touch the center of each target.
- When calibration is complete, the message “SAVED!” will be displayed.
- Power cycle the RG console.

Access Hole Touchsceen “PROG” Button



Battery LED Replacement

Insert the battery indicator LED (EP00209) through the front enclosure. Connect the long anode (+) lead of the LED to pin 1 (red wire) of the 2-pin connector on the LED-to-Main PCB cable (CA00168).



Battery Upgrade Procedure

These instructions detail the rework procedure to modify a RG Console to accept an Inspired Energy Battery (EP00212).

Tools Required: Philips head screw drivers
Nut drivers and latex gloves

Disassembly

- Remove the rear enclosure from the console.
- Remove the frame from the front enclosure.
- Separate the frame into its left and right sides. Remove all the components from the right side of the frame

Re-Assembly

Load Cell Setup and Installation: (figure 1)

Note: Gloves must be used whenever working with the load cell assemblies.

Install the infusion load cell in the left-most position. Label the connector J1 using the label maker, if not already labeled.

Install the urine load cell in the right-most position. Label the connector J2 using the label maker, if not already labeled.

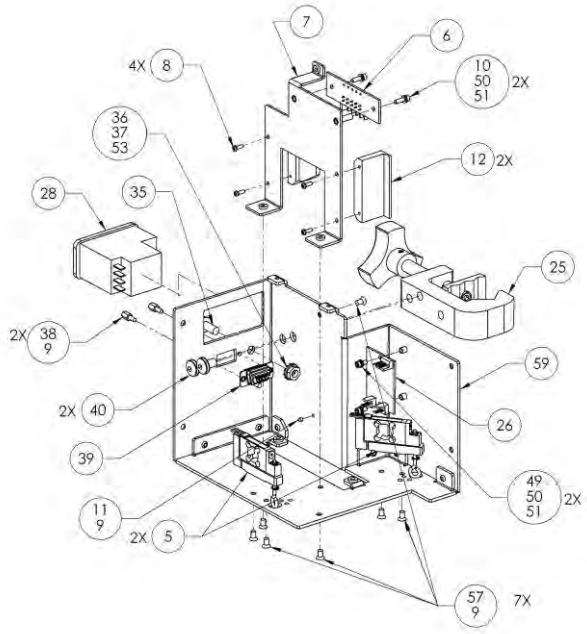
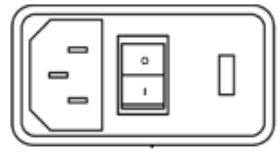


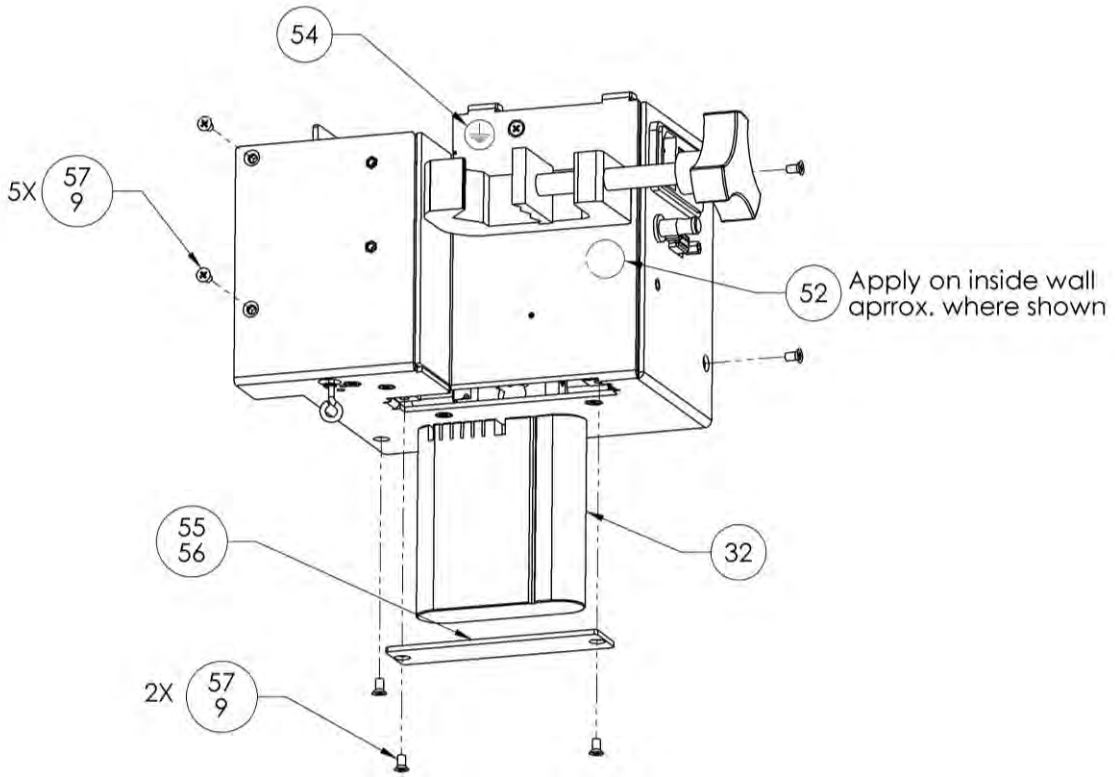
Figure 1

Bubble Detector PCB Installation: (figure 1)

- Using 2 each screws, lock washers, and nylon washers (items 49, 50 & 51) mount the bubble detector PCB (item 26) to the standoffs in the frame.
- Right/Rear Frame Setup: (figure 1) {Do not insert the power entry module at this time, see Step 7.5}
  - Install the equipotential ground stud, star washer, flat washer and nut (items 53, 37, 36 & 35), placing the large eye lug from the external ground cable (item 47) under the washer.
  - Connect the ring terminal from step 7.3.1 to the earth ground stud using a KEPS nut (item 41). Then connect the remaining eye lug from the external ground cable (item 47) to the earth ground stud using another KEPS nut (item 41). (This step not shown.)
  - Using 2 jack screws and Loctite 242 (items 38 & 9) install the RS-232 cable (item 39).
  - Using 2 self-locking screws (item 40) secure the pole clamp (item 25).
  - Using Loctite 242, insert the setscrew (items 11 & 9) into the indicated tapped hole from the outside. Insure that the head of the setscrew is flush with the exterior sheetmetal surface. The protruding portion of this setscrew functions as a battery orientation key.
- Battery Bracket Setup: (figure 1)
  - Using 2 Hi-Lo screws (item 8) secure the battery guide block (item 12) to the battery bracket (item 7). Repeat for second guide block.
    Note:Temporarily place the battery (item 32) between guides prior to tighten screws to assure proper fit.
  - Secure the Battery cable assembly PCB (item 6) to the Battery Bracket (item 7) using 2 screws with split lock and flat washers (items 10, 50 and 51).
  - Secure the Battery Bracket (item 7) to the frame (item 59) using 3 screws and Loctite 242 (items 57 & 9).
- Frame Closure (figure 2)
  - Secure the two assembled frame sections using five screws and Loctite 242 (items 57 & 9).
  - Install the power entry module (item 28) into the frame (Item 59). Insure that the power module switch is oriented as shown:
    - Re-attach the frame to the front enclosure of console.



Battery (item 32) Installation: (figure 2)

Apply the safety ground label (item 54) approximately as shown Apply the earth ground label (item 52) to the interior approximately as shown Cut a 3” long piece of adhesive-backed foam (item 56). Adhere the cut foam to the inside of the door. Insert the battery into the frame. Orient the battery such that the V-notch aligns with set screw in frame. Using two screws and Loctite 242 (items 57 & 9), secure the battery access door (item 55) to the frame. Re-attach the rear enclosure on to the console.	
	Figure 2

Connection for Event History Download

Hardware what is needed for the connection:

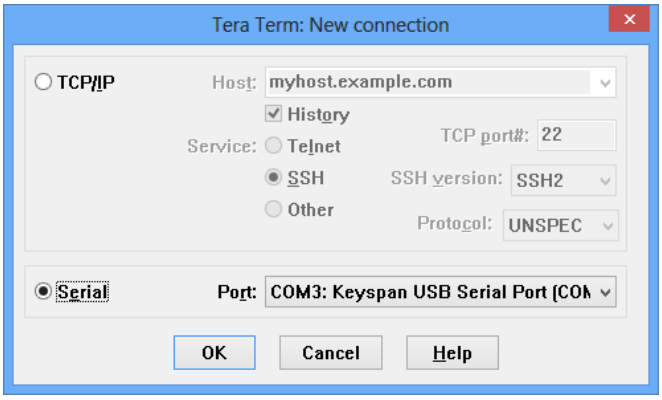
For PC with Serial Port:
One RS323 serial 9 pin sub D connector cable
One USB cable (normal plug A to plug Mini B Type)
Tera Term program installed (download from internet).
SAM-BA program for RenalGuard software loading (download from the internet).

For PC with USB Port only there is one part more that is needed:
One USB to Serial Adapter like Digitus DA-70156 USB serial Adapter USB 2.0
or DELOCK Adapter USB Serial 1x9 Pin St Chip FTDI

How to establish a RenalGuard to Notebook RS232 connection.
1st download the Tera Term software from the internet.
http://logmett.com/index.php?/download/tera-term-478-freeware.html
On your PC go to downloads and install the Tera Term Software to the PC

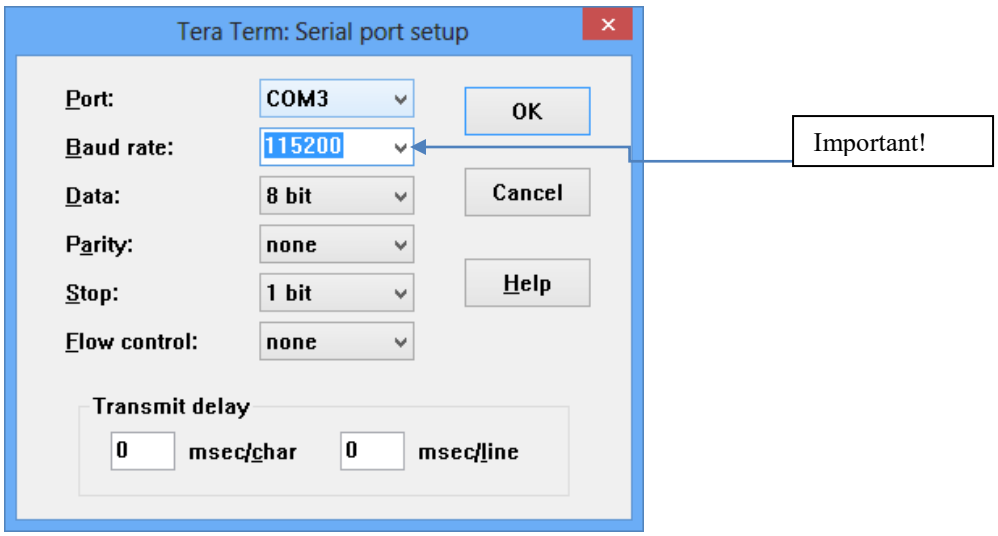
After installation of Tera Term connect the RG to the PC, see below. (here with USB-Serial adapter)

Switch on the console and start the program Tera Term.

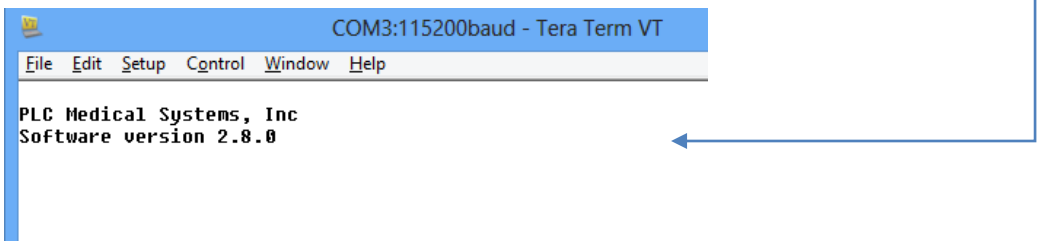


Click on the highlighted Serial button, the COM port should be assigned automatically, note down for future use. See on the left.

Go to serial port settings and alter all to the values below.



After clicking ok and switching the RG console off and on again you should read the data as shown below or equivalent. Now the RG is connected.

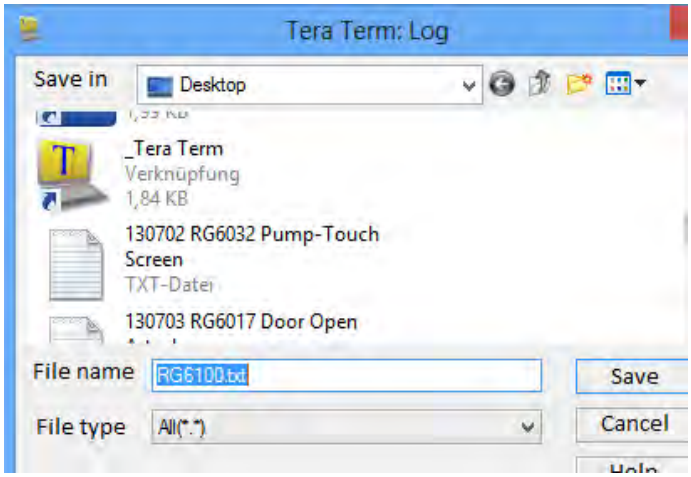


Follow the Event History download instruction below.

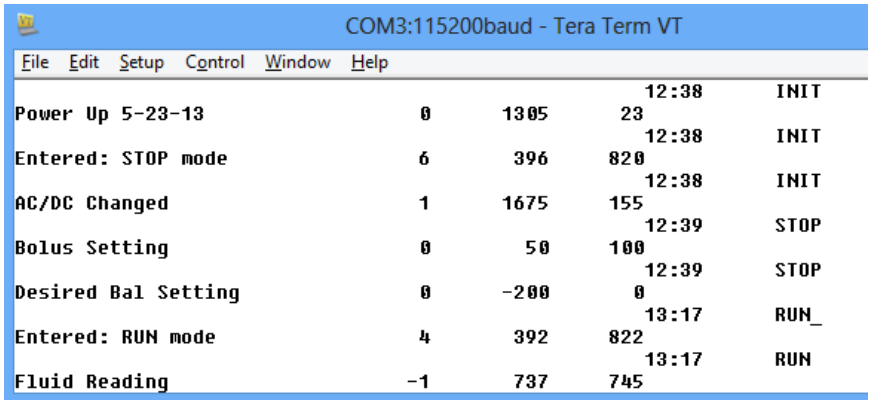
---- Debug Port Menu Options ----
X- display next data screen
N- display console serial number
L- print current event history
:- print recovered event history
R- erase event history (password required)

Storing the Event History:

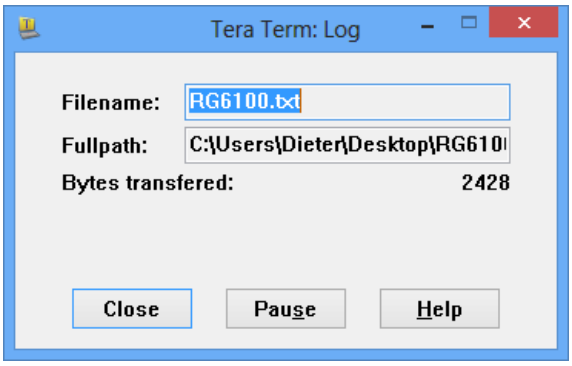
On Tera Term click **file** then **log** and insert a file name ending with a **.txt** (i.e. RG6100**.txt**)
Choose a folder where you want to store the file and click **save.** (i.e. desktop)



Then type **L** and see the data transfer.



Go to the 2nd window that Tera Term opened in the background. The number of bytes are displayed there and when the counter has stopped press **close**.



The log has been saved now and can be opened with Word or Word pad.

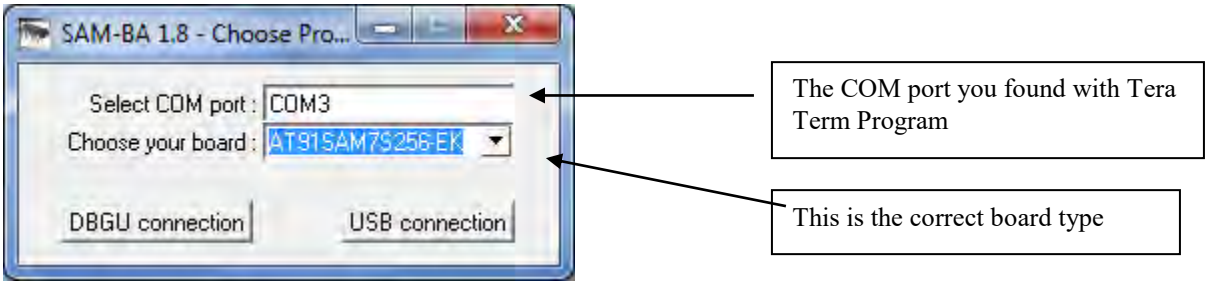
By E-Mail this file can be transferred to PLC for evaluation if needed.

RenalGuard Software upgrade using SAM-BA

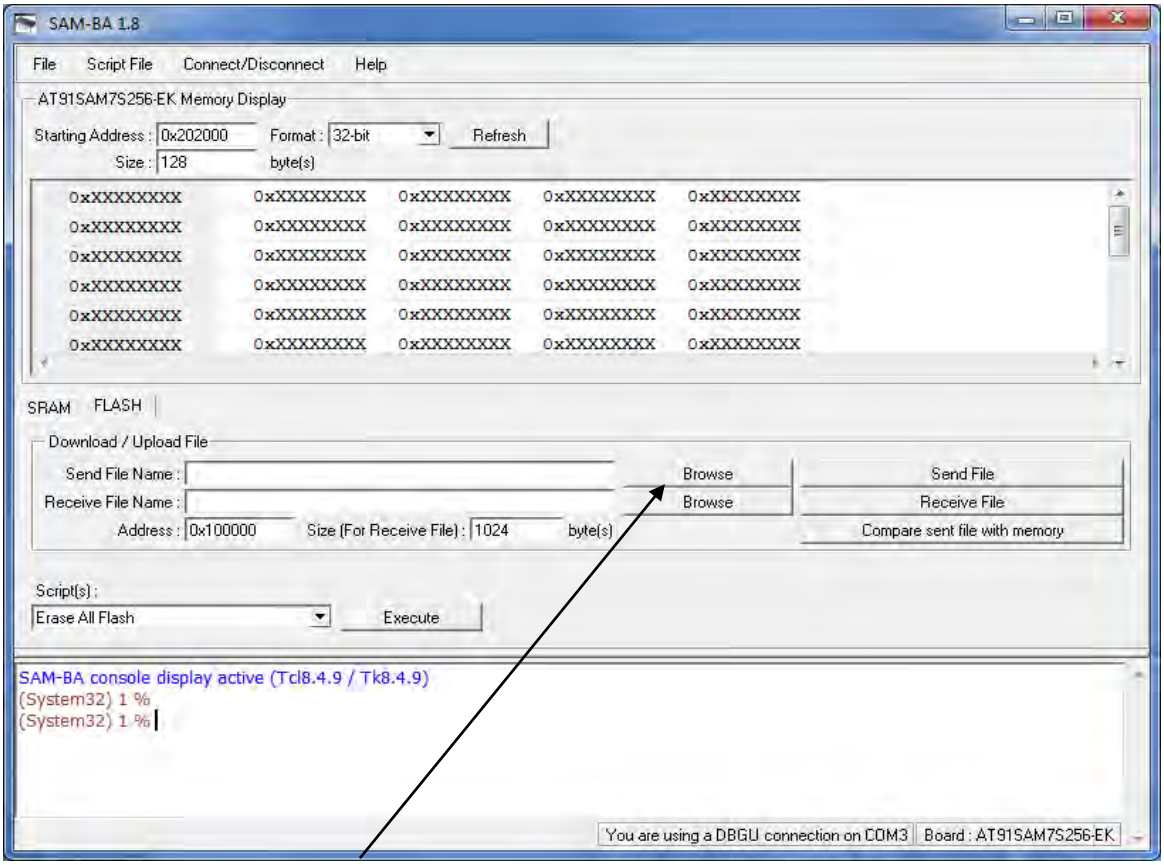
Before loading the RenalGuard Software to the console prepare the following:

- The samba software is installed on the PC / notebook.
  http://www.atmel.com/tools/ATMELSAM-BAIN-SYSTEMPROGRAMMER.aspx
- The SAM Memory of the console has been cleared.
- The PC / Notebook to RG the Serial connection is plugged in (or the adapter)
- The RG is switched on and no sound is coming from the console.

After the SAM-BA software is started the Com port must be correct (remember the Tera TERM setting). Then it is important to select the correct Board type.

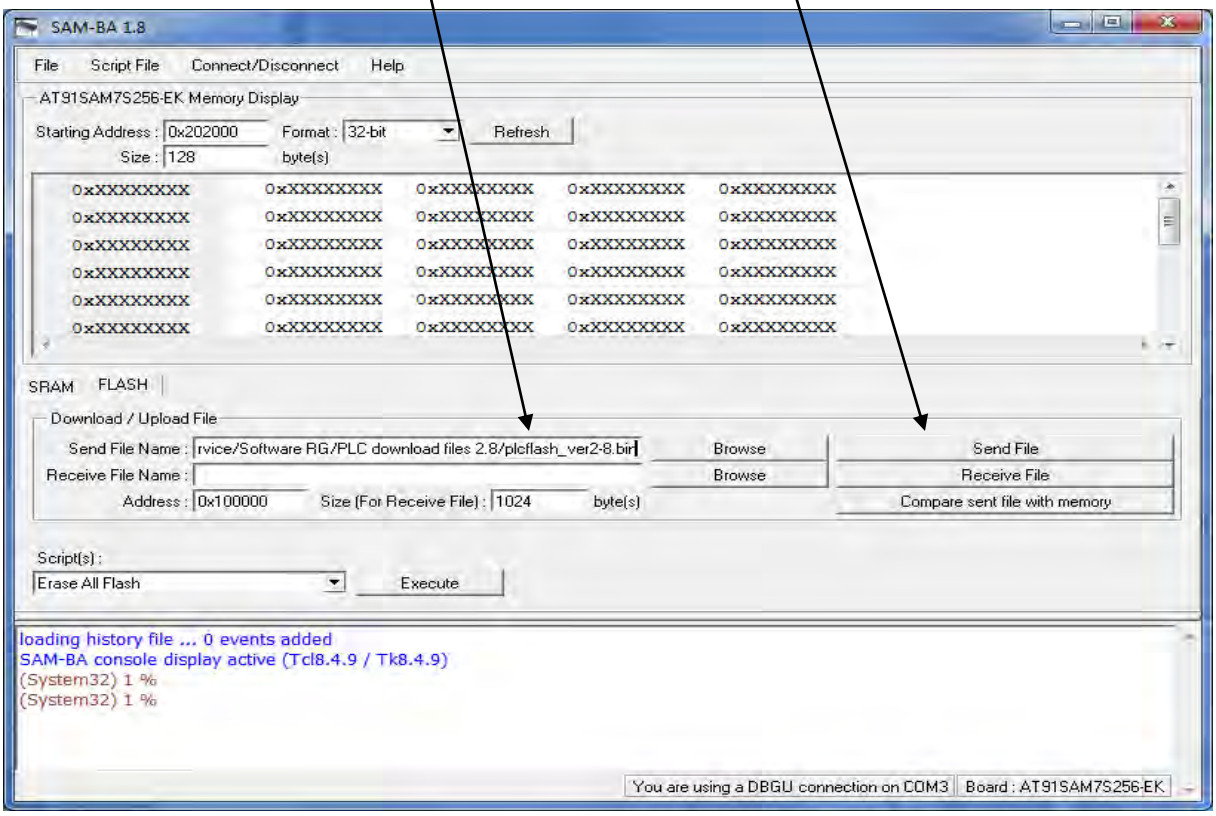


Click DBGU connection and follow the next steps



Browse to find the 2.8 software to find **plcflash_ver2-8.bin.**
It is on PC, flash or CD delivered by PLC .

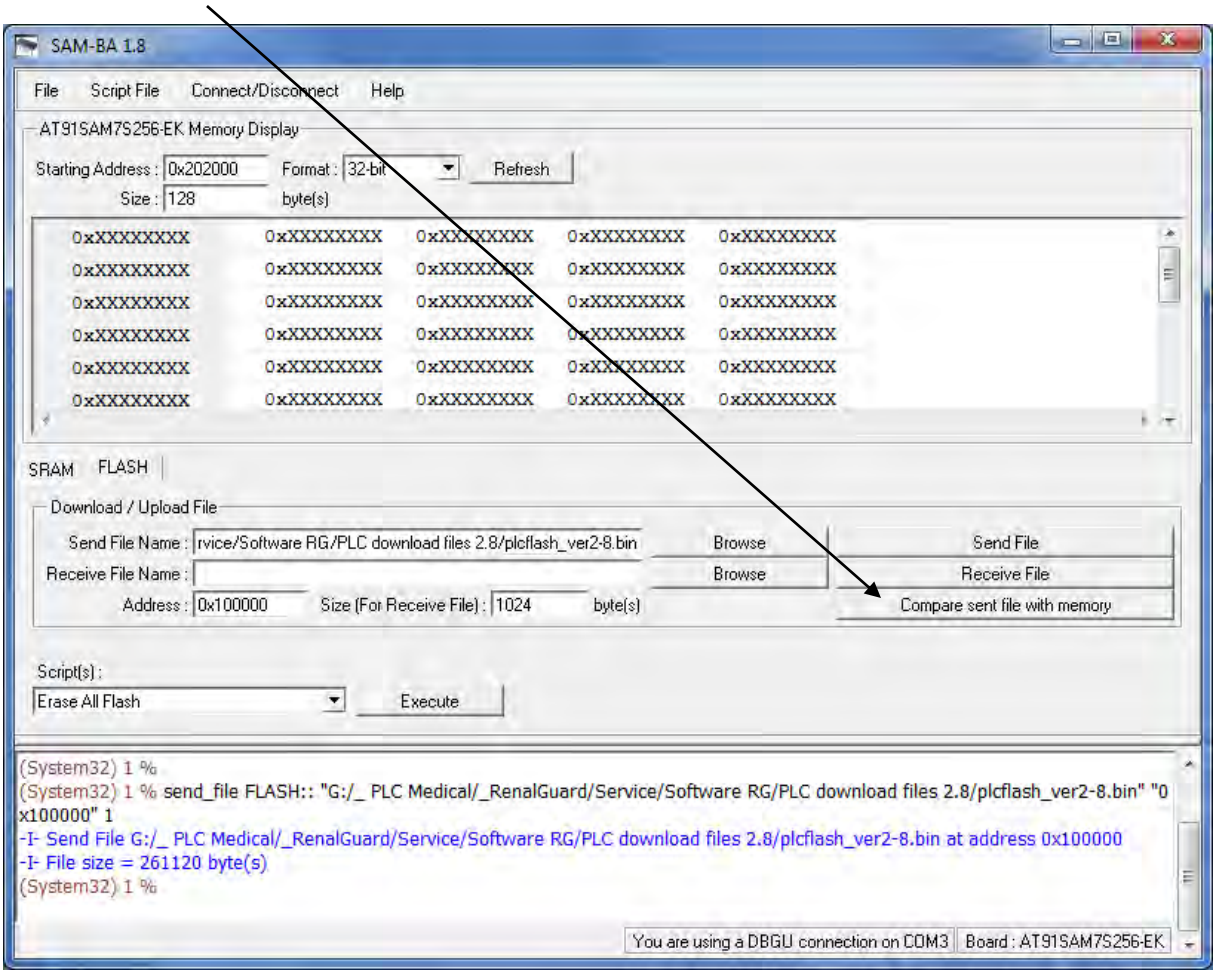
Open or double clicked on “plcflash_ver2-8.bin” and then type Send File.

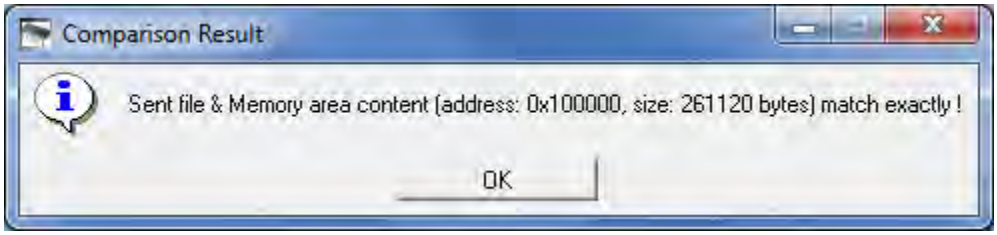


After a while in the next window you have to unlock and then it will last maybe 10min with the USB to serial adapter. The adapter LED is blinking fast during transfer.

After transfer you have to lock and the SW is loaded. Then you continue with Comparing file with Memory. See next page.

Click Compare sent file with memory. It will last a shorter time until next window sows up.





When you see the screen below you are done. Recycle power of the RG console.
The console will maybe come up with an error. The recycle the power again and continue with calibration check and testing.

RENALGUARD CONSOLE
Service Manual

LA00289

PART FOUR

PRODUCT CONFIGURATION AND SCHEMATICS

Schematics and Drawings

RG Console Configuration *

Serial Number Cut in	Load Cell (Fixed chain)EP00210	Split Two Piece Frame SM00146	Battery (Inspired energy)	Main PC BD SB90322	Battery Charger PC BD SB00325	Main PC BD SB90347	Powe r on /off switch cable CA00169	Battery indicator Cable CA00168
6005								
6057	X	X	X	X	X		X	X
6082	X	x	X	X	X	X	X	X

* as built" configuration
Contact Field Service for information about configuration changes made during system servicing.

System Diagrams

AC/ DC Wiring Diagram

Drawing #	*Rev*	*Description*	*Application*
WD00012		RG Wiring Diagram	Serial # 6005 to 6056
WD00013		RG Wiring Diagram	Serial # 6057 and higher

Load Cells

Serial Number Cut in	EP00189`Infusion EP00198 Urine Load Cells screw on	EP00210 Load Cell fixed Chain
6005	X	
6057		X

EP00189 and EP00198 are obsolete. If either load cell must be replaced you need to order EP00210 Load cell and the Long or Short chain.

Split Frame

Serial Number Cut in	*SM0147 Split frame right side	SM0160 Split frame right side
6005	X	
6057		X

*if console has beenupgraded to new style battery then use SM00160

Schematics and Drawings

Battery

Serial Number Cut in	*EP00193 Battery (House of Bateries)	EP00212 Battery (Inspired energy)
6005	X	
6057		X

EP00193 is obsolete. If this battery must be replaced you need to order SB00348 Battery Upgrade kit

Battery Charger PCB

Serial Number Cut in	*SB90310 Battery Charger PCB	SB90325 Battery Charger PCB
6005	X	
6057		X

SB90310 (limite d Qty). If this Battery Charger PCB must be replaced you need to order SB00325 Battery Charger PCB and CA00169 Power On-Off Switch Cable kit

SC00031 Schematic for SB90325 Battery Charger PC board

Power On-Off Switch Cable

Serial Number Cut in	*CA00158 Power On-Off Switch Cable	CA00169 Power On-Off Switch Cable
6005	X	
6057		X

CA00158 has a 4 pin connector and will only work with SB90310 Battery Charger PCB

CA00169 has a 5 pin connector and will only work with SB90347 Battery Charger PCB

Main PCB

Serial Number Cut in	*SB90309 Main PCB	**SB90322 Main PCB	SB90347 Main PCB
6005	X		
6057		X	
6082			X

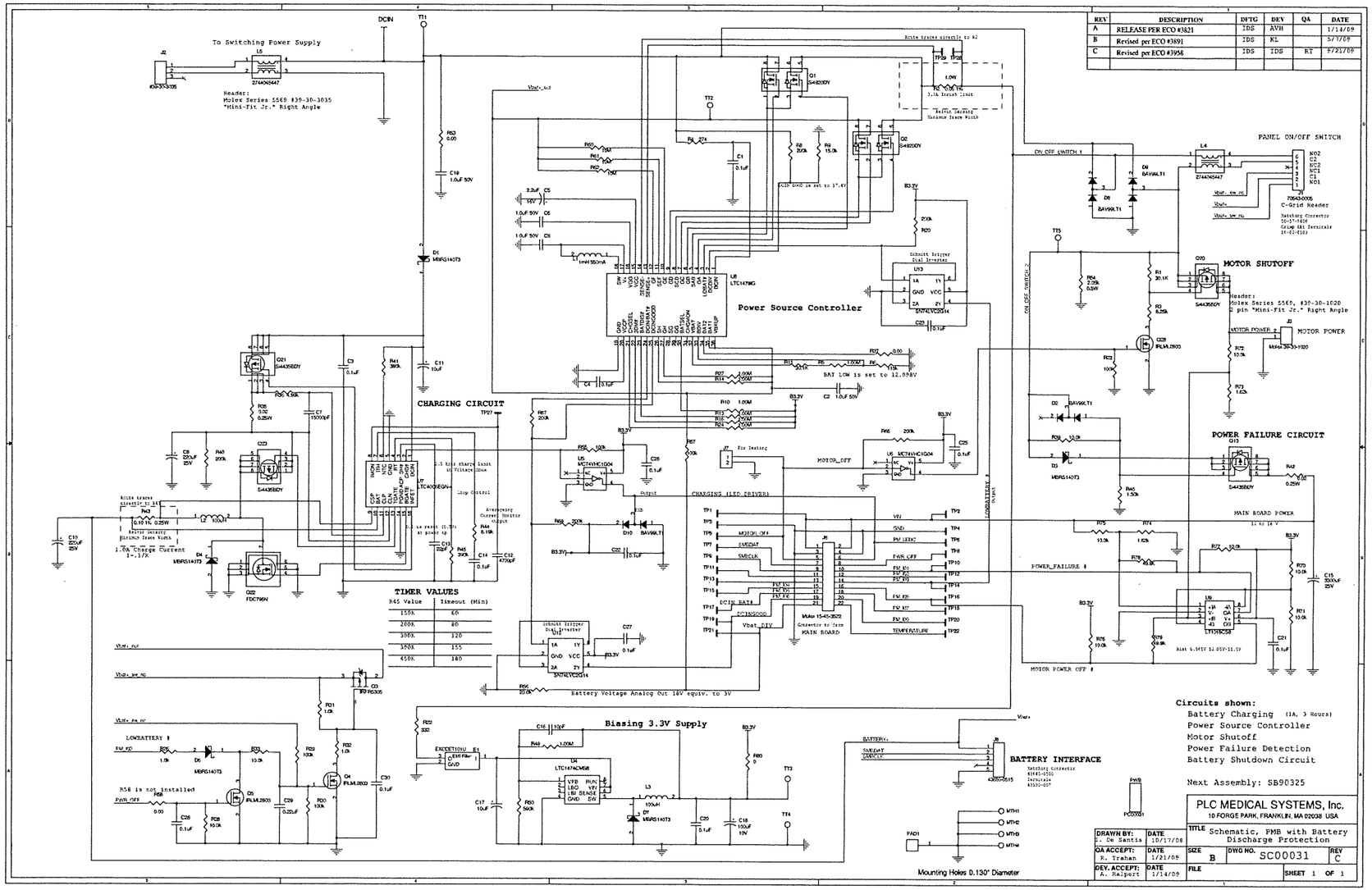
*SB90309 is obsolete. Order SB90347 and CA00168 Battery indicator LED Cable.
**SB90322 is obsolete. Order SB90347.which is direct replacement.

SC00036 Schematic for the SB90347 main PC Bd

Battery Indicator LED Cable

Serial Number Cut in	CA00165 Battery Indicator LED Cable	CA00168 Battery Indicator LED Cable
6005	X	
6057		X

REV	DESCRIPTION	DFTG	DEV	QA	DATE
A	RELEASE PER ECO #3821	IDS	AVH		1/13/09
B	Revised per ECO #3891	IDS	KL		5/7/09
C	Revised per ECO #3958	IDS	IDS	RT	9/21/09



COPY 09/23/09

REV	DESCRIPTION	DFTG	CHK	DATE
A	RELEASED PER ECO #	IDS		
B	REVISED PER CO4071	IDS		1/14/10

NOTE: R5 and R35 are used by software to sense presence of Load Cells

R5, R35 are EIA2512

R159 are EIA0805 and their mounting pe located inside the EIA2512 pads of R35 respectively.

R158, R159 are alternate parts to R5, R35.

AVCC Supply Current

Available (U11)	**50 mA**
U4,U8,U13 (3 x 1.3 mA)	3.9 mA
U1, U2,U12 (3 x .02 mA)	.06 mA
U10, U37 (2 x 2.0 mA)	4 mA
Load Cells (2 x 2.5 mA)	5 mA
Pressure Sensor	1.5 mA
Total Usage	**14.46 mA**

Analog 7 V

Load Cell Amplifiers
Load Cell Offset Calibration
Pressure Sensor Amplifier
18V step down to 7V switching PS
AVCC Voltage Source

NOTE: Signal ground and power ground planes are to be connected as specified.

R61 is not installed

PRESSURE
Vout= 0.91+ 0.0445 x (Pressure)
Vout= 1.80v @ 20 psi
Vout= 0.91v @ 0 psi
Voffset= 0.91
Vref=0.91v

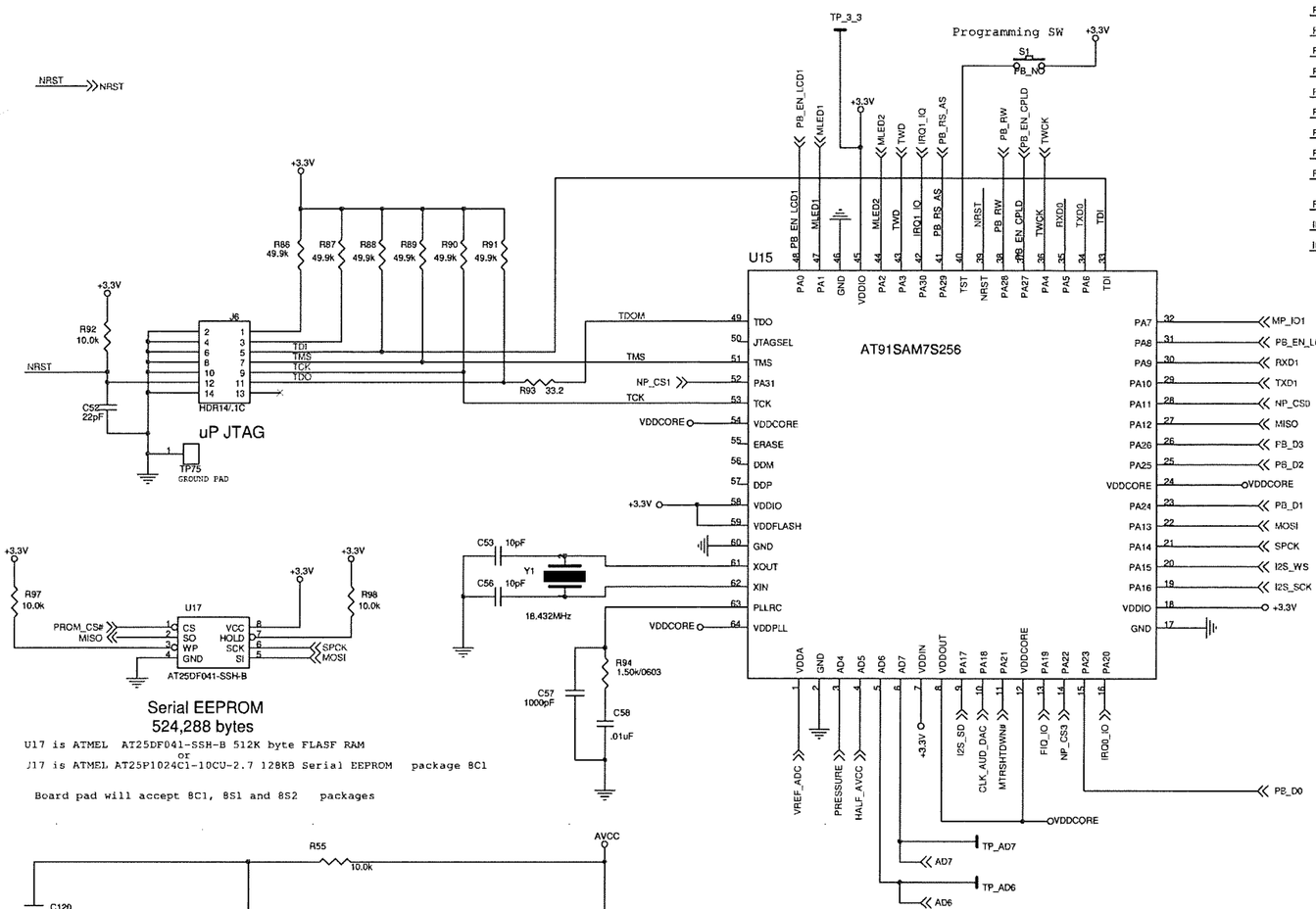
Current Compensation for Half Scale

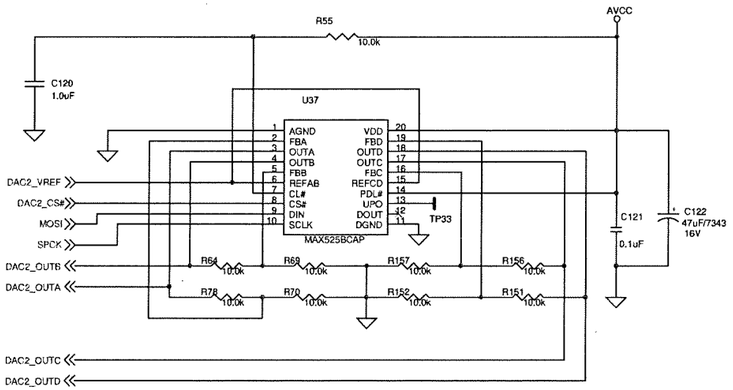
Half Scale 1.25 V

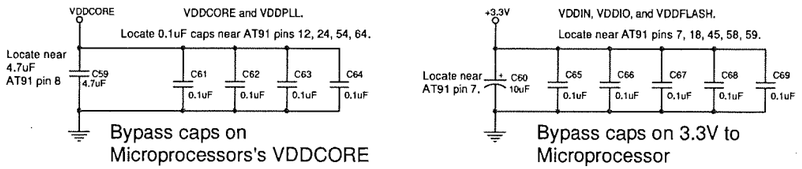
Next Assembly: SB90347

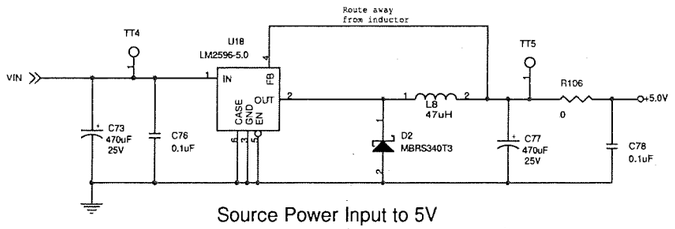
PCB PC00036

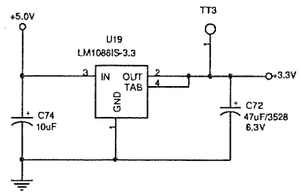
PLC MEDICAL SYSTEMS, Inc. 10 FORGE PARK, FRANKLIN, MA 02038 USA			
DRAWN BY: I. De Santis	DATE 10/19/09	TITLE Schematic, FMS Main PCB IV, RFID	
QA ACCEPT:	DATE	SIZE B	DWG NO. SC00036 REV B
DEV. ACCEPT:	DATE	FILE	SHEET 1 OF 4

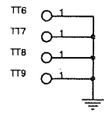












Microprocessor
plus Serial EEPROM
plus Power Input and
Voltage Regulators

plus SPI connectors

PLC MEDICAL SYSTEMS, Inc.
10 FORGE PARK, FRANKLIN, MA 02038 USA

DRAWN BY: I. De Santis	DATE 10/19/09	TITLE Schematic, FMS Main PCB, RFID		
QA ACCEPT:	DATE	SIZE B	DWG NO. SC00036	REV B
DEV. ACCEPT:	DATE	FILE	SHEET 2 OF 4	

U23

XC95144XL-TQFP100

CS#	CS3	CS1	CS0	CS ASSIGNMENT
0	0	0	0	CS for RTC_CS#
1	0	0	1	LCD/TOUCH_CS# (DATAKEY_CS1)
2	0	1	0	DATAKEY_CS2#
3	0	1	1	PROM_CS#
4	1	0	0	DAC2_CS#
5	1	0	1	DAC_CS#
6	1	1	0	ADC_CS#
7	1	1	1	Not Used

NOTE: CS2 is used by microprocessor

Wire OR'd Safety Shutdown

Connector to/from daughter Power Manager Board

Header Pins to CPLD

CPLD JTAG

Locate near the XC9572 pin 27

Locate near XC9572 pins 5,26,38,51,57,88 and 98

Locate near XC9572 pins 5,26,38,51,57,88 and 98 VCCINT and VCCIO

Locate near 10uF XC9572

CPLD bypass caps

PIEZO ALARM

Air Detector

Pump Door Switch

Motor Encoder

Level Translator 3.3V to 5.0V

RFID Connector

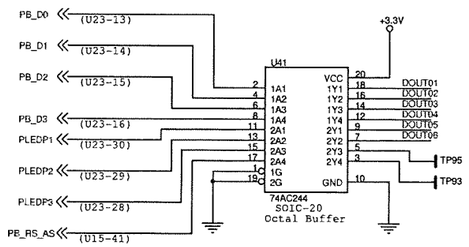
LCD/Touchscreen

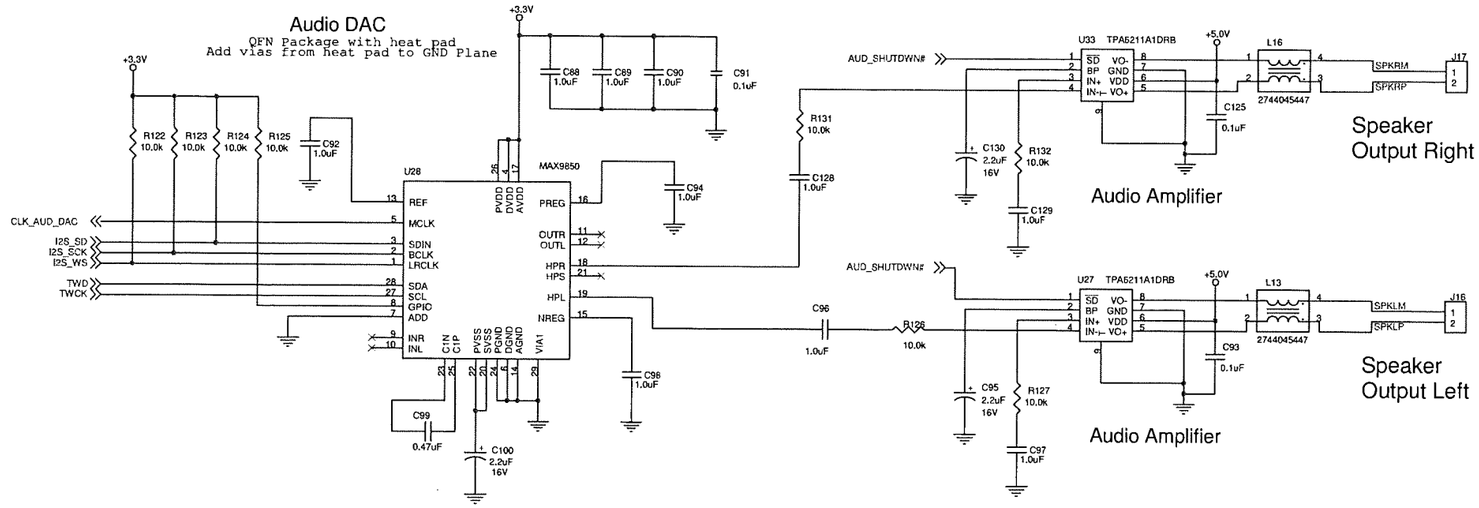
Locate near J19 and J20

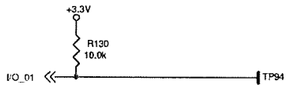
J20 is wired for type SR4210 DATA KEY

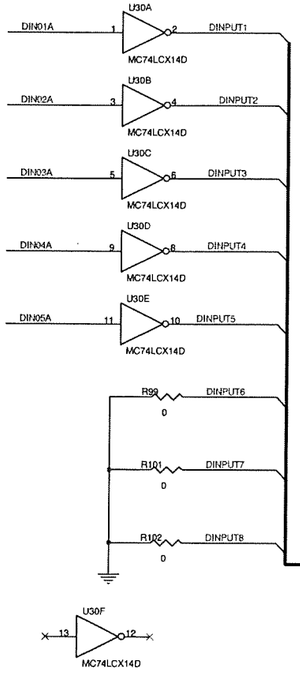
CPLD plus External Connections

PLC MEDICAL SYSTEMS, Inc. 10 FORGE PARK, FRANKLIN, MA 02038 USA			
DRAWN BY: I. De Santis	DATE 10/19/09	TITLE Schematic, FMS Main PCB, RFID	
QA ACCEPT:	DATE	SIZE B	DWG NO. SC00036 REV B
DEV. ACCEPT:	DATE	FILE	SHEET 3 OF 4



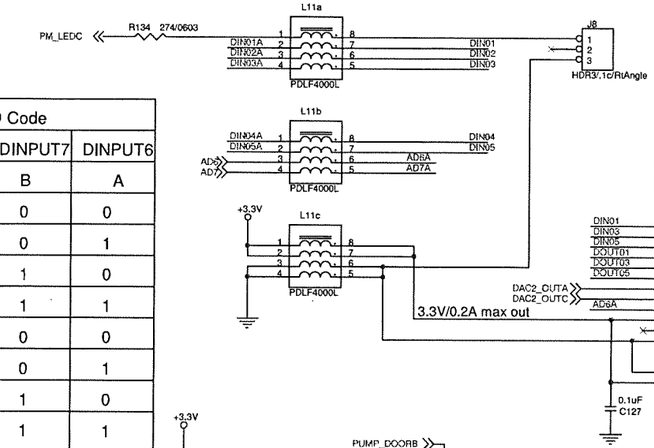


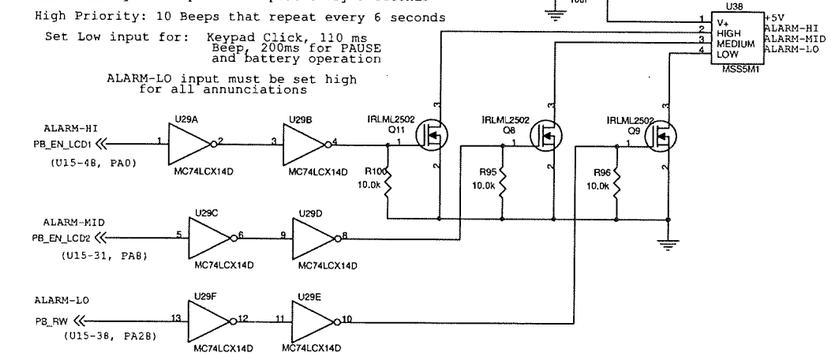




Board ID Code				
Board #		DINPUT8 C	DINPUT7 B	DINPUT6 A
Not Valid	0	0	0	0
***PC00036	1	0	0	1
	2	0	1	0
	3	0	1	1
	4	1	0	0
	5	1	0	1
	6	1	1	0
	7	1	1	1

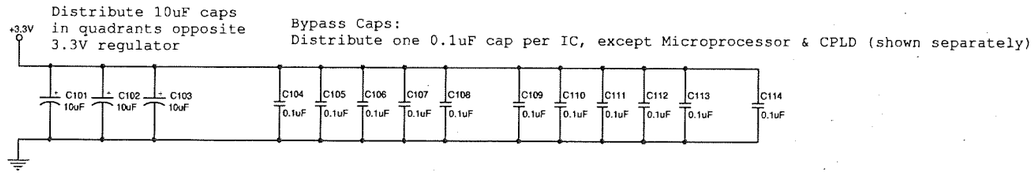
***NOTE: R99 is not installed for PC00036



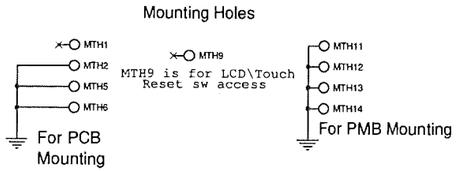


Rev B Notes:

Rev B removes connection (BC_LCD) from L11a.8 and J6.1 to U31.11. This connection should not be there as it loads the charge signal when the console is off, thus the charge LED is not on until the console is turned on.



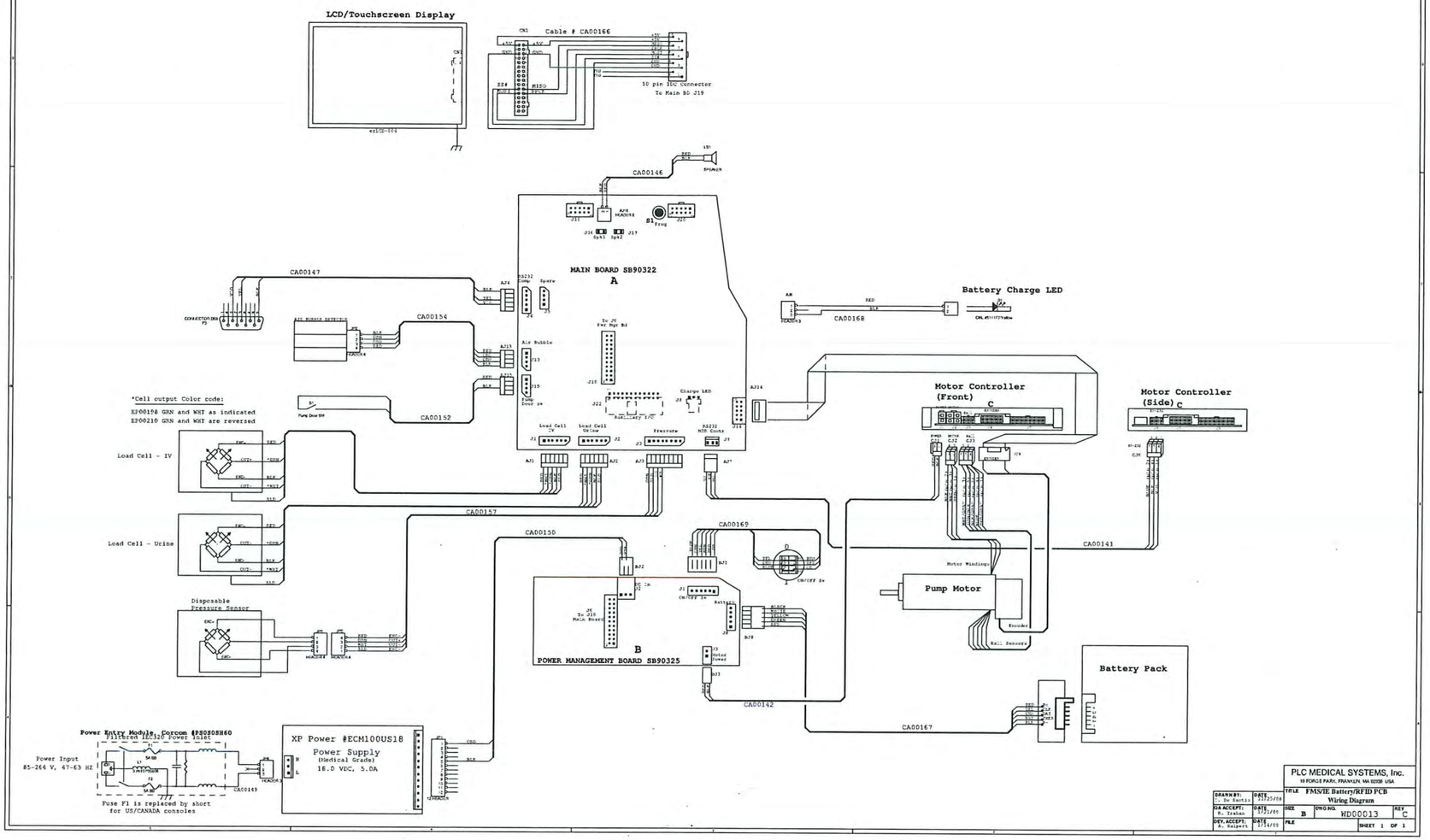
General distributed bypass caps for whole board



Audio and
I/O Connector Interface

PLC MEDICAL SYSTEMS, Inc. 10 FORGE PARK, FRANKLIN, MA 02038 USA			
DRAWN BY: I. De Santis	DATE 10/19/09	TITLE Schematic, FMS Main PCB, RFID	
QA ACCEPT:	DATE	SIZE B	DWG NO. SC00036 REV B
DEV. ACCEPT:	DATE	FILE	SHEET 4 OF 4

REV	DESCRIPTION	DFTG	DEV	QA	DATE
A	RELEASE PER ECO #3021	IGS	AVF	RT	7/14/09
B	Revised per CO #3054	IGS	IGS	RT	9/21/09
C	Revised per CO #4001	IGS	AVF	RT	11/20/09



COPY 11/24/09

REV	DESCRIPTION	DFTG	DEV	QA	DATE
A	RELEASE PER ECO # 3700	IDS	AVH	RT	1/21/08

LCD/Touchscreen Display

e2LCD-004

Cable # CA00166

10 pin IDC Connector
To Main BD J19

CA00146

SPEAKER

CA00147

CONNECTOR DB9 P3

CA00154

AIR BUBBLE DETECTOR

CA00152

Pump Door SW

MAIN BOARD SB90309 A

Air Dubble

Pump Door mr

Key Pad

CA00165

Battery Charge LED

Motor Controller (Front) C

Motor Controller (Side) C

Load Cell - IV

Load Cell - Urine

CA00157

Disposable Pressure Sensor

CA00150

CA00158

POWER MANAGEMENT BOARD SB90310 B

Motor Windings

Pump Motor

Encoder

Hall Sensors

CA00141

CA00142

Battery Pack

Power Entry Module, Corcom #P50S0SH60
Filtered IEC320 Power Inlet

Power Input
64 V, 47-63 HZ

CA00149

Fuse F1 is replaced by short
for US/CANADA consoles

XP Power #ECM100US18
Power Supply
(Medical Grade)
18.0 VDC, 5.0A

Copy 07/16/13

PLC MEDICAL SYSTEMS, Inc.
10 FORGE PARK, FRANKLIN, MA 02038 USA

DRAWN BY: T. De Santis	DATE 10/31/07	TITLE FMS Console with LCD/Touchscreen Wiring Diagram	
QA ACCEPT: A. Halpert	DATE 1/21/08	SIZE B	DWG NO. WD00012 REV A
DEV. ACCEPT: B. Stephan	DATE 1/21/08	FILE	SHEET 1 OF 1

RENALGUARD CONSOLE
Service Manual

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PART FIVE
TROUBLESHOOTING GUIDE

RenalGuard Troubleshooting & Repair Guide

Malfunction	Reason	Corrective Action
No alarm sound or intermittent no sound from speaker	Bad connection J16 on MB, speaker failure, Audio DAC / Amplifier on MB defective	Remove the bad connection Replace speaker Replace SB90347 MB
Infusion bag still full when "replace infusion bag" already alarm appears	Calibration out of tolerance or last calibration performed more than one year ago Connection problem J1 on MB Weight scale drift	Check 1st the infusion weight scale if calibration is far off. Check connection After calibration check for drift over time. If it is moving only to one side over time replace the EP00210 weight scale.
Infusion bag does not give "replace infusion bag" alarm and console stops with "air detect" alarm	Calibration out of tolerance or last calibration performed more than one year ago Connection problem J1 on MB Weight scale drift	Check 1st the infusion weight scale if calibration is far off. Check Connection After calibration check for drift over time. If it is moving only to one side over time replace the EP00210 weight scale.
LCD screen turns white during procedure, or show crazy characters	Grounding at the LCD screen missing or poor connection Defective LCD screen	Check the grounding, remove bad connections Replace the EP00201 LCD Display Touchscreen
LCD screen gets stuck, Touch screen not responding	White isolation foam around the edge extends into the sensitive surface of touchscreen Touchscreen fault	Remove the foam from the sensitive area; if this does not cure replace the touch screen.
Before calibration check out of tolerance more than 200gr within one year period	Calibration out of tolerance or last calibration performed more than one year ago, Connection problem J1 or J2 on MB, weight scale drift	Check weight scale how far calibration is off. After calibration check for drift over time. If it is moving only to one side over time replace the EP00210 weight scale.
Multiple pump mismatch errors	Software Rev lower than 2.8 Motor controller issue	Install latest Rev of RG software Replace Motor controller
Weak battery, duration of operation short when disconnected from power	On console up to 6056 is still the old battery installed, or the battery pack is close to its lifecycle end.	If old battery installed then install the SB00348 battery upgrade kit. Recalibrate Inspired Energy battery If Inspired battery is still weak replace the EP00212 battery

Malfunction	Reason	Corrective Action
Power switch in the back gets loose	The switch holder clamps of power entry module are broken.	Replace the EP00192 power entry module.
Power switch in the front intermittently will not turn on	Switch is sensitive to switch on speed, or switch is defect	Actuate the switch always quickly. In rare cases replace the CA00169 switch
Post error P010 after power on the console	Ext ADC fault, weight scales are adjusted during post, weight scales disconnected, or defective weight scale	Do not touch the hooks at power up, if it not than replace EP00210 weight scale
Constant bubble detector error	Tubing not inserted correctly, Loose connection, Defective bubble detector or bubble detector PCB	Check the tubing setup, Check the connectors, Replace the bubble detector (most likely) or if this does not cure the bubble detector PCB
Pressure Sensor Disconnected Errors	Pressure sensor cable disconnected from bd Connector mount has been over tightened	Connect cable, Loosen pressure sensor mount
Pressure Sensor error during setup	Pressure sensor cable (#4) not attached. Pressure sensor from new SUS is bad.	Connect white cable marked #4. Open and close pump head, go to service screen and look at pressure. It should be around zero +- 1. If not remove the connector and plug it reversed back into the socket. If these values are different the pressure transducer is bad. Use a new SUS.
Pressure Sensor error during normal operation at patient.	Pressure mismatch. This can be caused if one steps on the infusion line or if the patient pushed the line etc.	Open and close the pump door will release the pressure mismatch.
Pump door open errors steady or Intermittent	Missing or loose magnet at left side of pump door. Reed relay does not switch or does not switch correctly. Reed relay sensitivity lost	Check for magnet seating and tighten, Replace reed relay switch
Motor drive mismatch	Loose screws at motor driver shaft. Bad motor controller Bad motor module	Tighten the screws Replace motor controller Replace motor module
Continuous occlusion error	Bad pressure sensor calibration Pressure sensor defect Pressure transducer faulty	Check pressure calibration Replace pressure sensor Try with a new SUS

RENALGUARD CONSOLE
Service Manual

LA00289

PART SIX

PARTS LIST

PLC Medical Systems, Inc.
RG Console Spare Part Price List
2016 - 2017

Part #	Description	End User
7624	Ground Symbol Label	$5.00
CA00141	Main PCB to Motor Controller Cable	$15.00
CA00142	Power Management PCB to Motor Controller Cable	$15.00
CA00144	Cable Sheild to Ground	$7.50
CA00145	Speaker Cable	$45.00
CA00146	Cable Frame to Ground	$10.00
CA00147	Main PCB to RS232 Cable	$45.00
CA00149	Power Entry Module to Power supply Cable	$17.50
CA00150	Power Supply to P/M PCB Cable	$17.50
CA00152	Pump Head Safety Switch Cable	$30.00
CA00153	Linecord / USA	$25.00
CA00154	Bubble Sensor Input Cable	$20.00
CA00157	Ext Pressure Sensor Cable	$67.50
CA00159	Linecord /Europe	$43.75
CA00166	Main PCB to Touchscreen Cable	$95.00
CA00167	Battery Cable	$37.50
CA00168	Battery Indicator LED Cable	$12.50
CA00169	Power On-Off Switch Cable	$50.00
CA00174	Linecord / United Kingdom	$50.00
CA00179	Linecord / Australia / New Zealand	$45.00
CA00180	Linecord / Israel	$72.50
CA00181	Linecord / Brazil	$40.00
Co00032	FMS Packaging Box	$97.50
EH00206	EMI Finger	$7.50
EP00187	Bubble Detector Tube	$300.00
EP00188	Bubble Detector Sensor	$240.00
EP00192	Power Entry Module	$52.50
EP00201	LCD Display Touchscreen	$698.00
EP00205	Crystal Battery	$15.00
EP00209	Panel Mount LED	$2.50
EP00210	Load Cell/3.0kg/EyeHook/6-Pin Connector	$602.00
EP00212	Battery Pack (Inspired)	$210.00
Ha00509	Enclosure Screws (bag of 10)	$2.50
HA00527	Power Entry Gasket	$12.50
HA00530L	Urine Chain with Hook (Permenanetly attached)	$37.50
HA00530L	Long Chain Assembly (new style load cells)	$12.50
HA00530S	Infusion Chain with Hook (Permenanetly attached)	$37.50
HA00530S	Short Chain Assembly (new style load cell)	$10.00
HA00533	Magnet Disc	$7.50
HA00556	S-Hook	$2.50
HA00566	Split ring	$1.00
HA00579	Block, Guide Battery	$2.50
LA00184	Earth Ground label	$5.00
LA00226	Product ID Label	$12.50
LA00227	Label / Warning /Grounding Reliability / English & French	$20.00

PLC Medical Systems, Inc.
RG Console Spare Part Price List
2016 - 2017

Part #	Description	End User
LA00229	DFU, RenalGuard Single Use Set	$2.50
LA00234	Label / Pump Flow Direction / English	$12.50
LA00238	IV Set Loading label	$12.50
LA00245	Renal Guard Logo Label	$7.50
LA00248	RG Console Outer Box Label	$2.50
LA00252	Export Label	$2.50
LA00256	Label / Quick Start / English	$12.50
LA00259	Battery Charge Label	$20.00
LA00264	Manual / Operator / English	$30.00
LA00289	Manual / Servce / English	$150.00
LCR0227	Label / Warning Ground / Croatia	$42.50
LCR0234	Label / Pump Flow / Croatia	$47.50
LCR0256	Label / Quick Start / Croatia	$42.50
LFR0234	Label / Pump Flow / French	$15.00
LFR0256	Label / Quick Start / French	$15.00
LFR0264	Manual / Operator / French	$30.00
LGR0227	Label / Warning / GroundingReliability / German..	$15.00
LGR0234	Label / Pump Flow Direction / German..	$15.00
LGR0256	Label / Quick Start / German....	$15.00
LGR0264	Manual / Operator / German..	$30.00
LIT0227	Label / Warning / Ground Reliability / Italian	$32.50
LIT0234	Label / Pump Flow Direction / Italian..	$40.00
LIT0256	Label / Quick Start / Italian....	$32.50
LIT0264	Manual /Operator / Italian	$30.00
LNL0227	Label / Warning Ground / Netherlands	$42.50
LNL0234	Label / Pump Flow / Netherlands	$47.50
LNL0256	Label / Quick Start / Netherlands	$42.50
LNL0264	Manual /Operator / Dutch	$30.00
LPT0227	Label / Warning /Ground / Portuguese	$42.50
LPT0234	Label / Pump Flow / Portuguese	$47.50
LPT0256	Label / Quick Start / Portuguese	$42.50
LPT0264	Manual / Operator / Portuguese	$30.00
LRU0227	Label / Warning /Ground / Russian	$42.50
LRU0234	Label / Pump Flow / Russian	$47.50
LRU0256	Label / Quick Start / Russian	$42.50
LRU0264	Manual / Operator / Russian	$30.00
LSP0227	Label / Warning / Ground Reliability / Spanish	$35.00
LSP0234	Label / Pump Flow Direction / Spanish	$50.00
LSP0256	Label / Quick Start / Spanish	$32.50
LSP0264	Manaul /Operator / Spanish	$30.00
LTW0264	Manual / Operator / Tawain	$30.00
MA00258	Coupling, Motor	$67.50
MA00259	Plate, Motor Mounting	$45.00
MA00284	Clamp 1.5" Pole	$200.00
MA00290	LCD Stop Block	$27.50

PLC Medical Systems, Inc.
RG Console Spare Part Price List
2016 - 2017

Part #	Description	End User
SB00350	Front Enclosure with Coating	$210.00
SB00351	Rear Enclosure with Coating	$210.00
MT00006	Motor / Gearbox / Encoder / Brushes / 32mm / 80W	$900.00
MT00007	Motor Gear Box	$1,328.00
PW00029	Power Supply 18 DC	$177.50
SB00291	Urine Chain (Screw off) with hook RG S/N 6056 and lower	$62.50
SB00292	Infusion Chain (Screw off) with hook RG S/N 6056 and lower	$62.50
SB00305	Pump Head Assembly	$550.00
SB00308	Foot Assembly (bag of 4)	$25.00
SB00348	Upgrade Kit / Battery	$600.00
SB90325	Power Management PCB Assembly	$460.00
SB90347	Main Touchscree PCB Assembly	$1,350.00
SM00146	Frame (Front Left)	$122.50
SM00149	Access Door, Battery	$30.00
SM00159	Bracket Battery Housing	$50.00
SM00160	IE Battery Frame/Right	$175.00
SW00023	RG Software package	$225.00
WH00012	Cart ..	$1,040.00