

The touch screen uses intuitive color-coding: green indicates normal operation and red indicates an error, warning or that some intermediate step is needed. Blue indicates the user's menu selection and also indicates non-radioactive operation; the yellow radiation symbol indicates radioactive operation so the user knows when the unit is generating ionizing radiation.



When the unit is in radioactive operation, users should move away from the unit to a distance that allows them to avoid unnecessary exposure, in accordance with ALARA principles.

### 5.3 LOADING PRINTING LABELS

The system ships with one packet of labels for use with the RUBY Rubidium Elution System. Additional labels must be ordered from Jubilant DraxImage Inc.

To load the labels, open the printer access door on the back of the system (see Fig. 16, Printer Access Door). The label should face out when it is unfolded up toward the printer (see Fig. 17, Label Orientation). Thread the leading edge of the label up through the opening (see Fig. 18, Label Feed). Make sure the edges of the label are parallel to the edges of the print mechanism. The labels automatically feed into the printer. Close the printer access door before proceeding.



Figure 16, Printer Access Door



Figure 17, Label Orientation

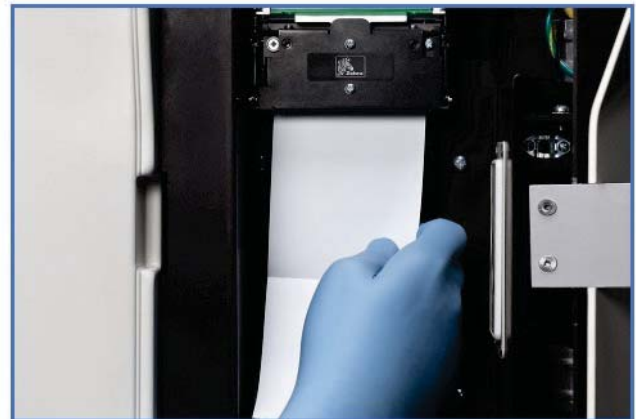


Figure 18, Label Feed

## 5.4 CONFIGURING THE SYSTEM

At installation, the system needs to be configured to the site's specification. The Jubilant DraxImage representative will configure the unit according to each site's needs by selecting Settings on the top row of the task bar. The admin level PIN may also access the Settings section that includes a choice of units, time zones, site-specific identification (name of clinic or hospital) and personal identification numbers (PINs) (see Fig. 19, Settings Control Panel Screen).

These five settings must be defined:

1. Manage PINs (The system's default PINs are User: 12345; Administrator: 11111)
2. Constancy Standard Setup
3. Site Setup
4. Elution Setup
5. USB Transfer File Setup (This should be performed prior to report transfer)

After the settings have been modified, press Save Changes, and return to the main software page by pressing Home at the bottom of the screen.

## 5.5 MANAGING PERSONAL IDENTIFICATION NUMBERS (PINs)

The RUBY Rubidium Elution System has two permission categories: administrator (admin) and user. The admin level has authority to select important site parameters determined by the medical staff. The user level allows the nuclear medicine technologist to perform normal set-up procedures and use the RUBY Rubidium Elution System. To modify a PIN, the administrator clicks on the appropriate permission level, then enters and confirms the new PIN. The administrator may reset the admin level PIN, or the PIN of the user (see Fig. 20, Managing PINs Screen).

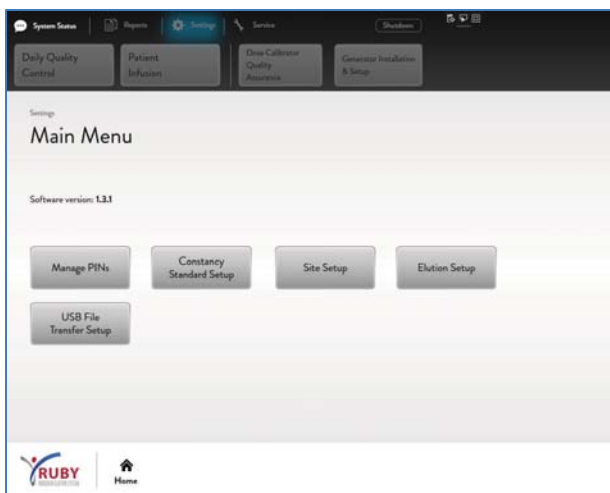


Figure 19, Settings Control Panel Screen

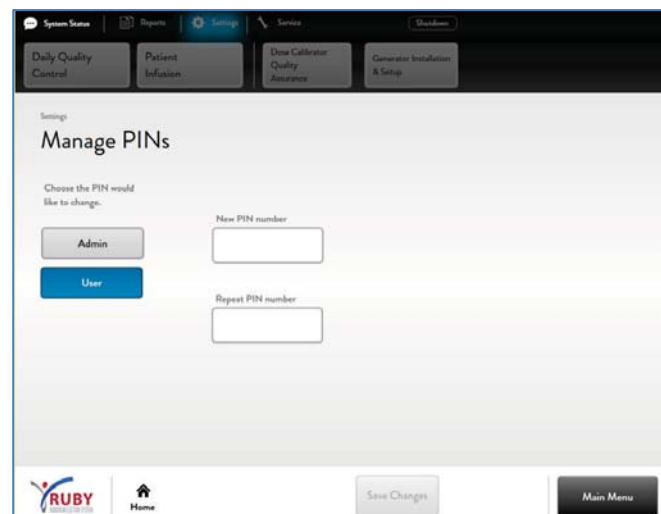


Figure 20, Managing PINs Screen



There is one admin PIN for all administrators and one user-specific PIN for all users. An admin level PIN must be entered to modify any setting.

## 5.6 CONSTANCY STANDARD SETUP

The RUBY Rubidium Elution System is equipped with an on-board dose calibrator. The daily quality assurance procedure recommended by the manufacturer and by regulatory bodies includes a daily constancy check of the dose calibrator. The check is performed by using a calibrated standard (for example, Cs-137) of long half-life and checking against it every day. The calibrated standard parameters must be entered in all the fields shown (see Fig. 21, Constancy Standard Setup Screen).

## 5.7 SITE SETUP

The RUBY Rubidium Elution System has a built-in report system. To customize reports and labels with site information, fill in all the fields on the screen (see Fig. 22, Site Setup Screen). The information entered here appears on all reports generated by the system (Daily Quality Control and Patient Infusion reports). The site setup information is also a part of a system setup.



Changing the system time, time zone and/or date could adversely affect future elutions. These parameters are set at initial installation. The Admin level PIN is required to adjust the system time for the daylight saving time period.



Press Save Changes to keep the changes. Then go to the Main Menu to select the next Settings screen or the Home screen. To restore default values, select Restore Defaults and Save Changes to reset the system to the factory assigned values.

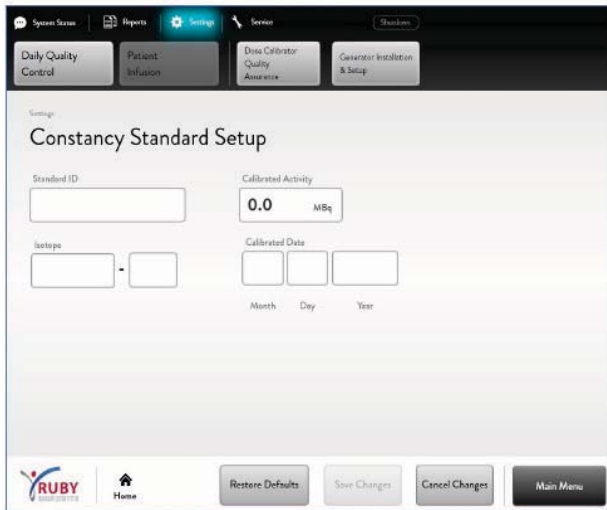


Figure 21, Constancy Standard Setup Screen

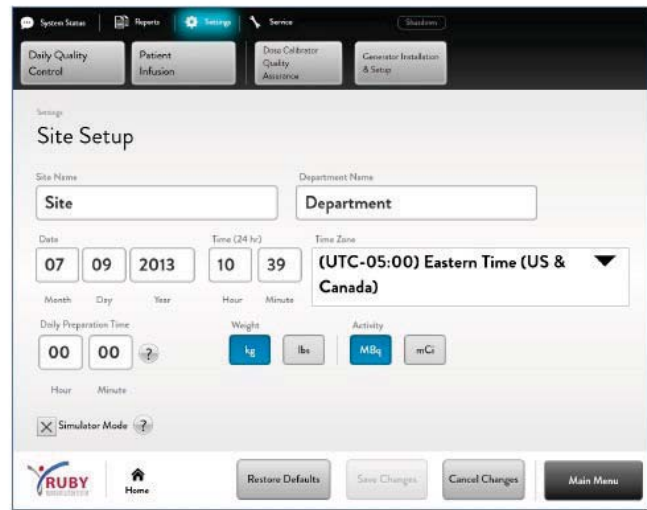


Figure 22, Site Setup Screen

## 5.8 ELUTION SETUP

The RUBY Rubidium Elution System has four configurable elution parameters: (see Fig. 23, Elution Setup Screen)

1. **Activity/Patient Weight Ratio** determines the amount of activity to inject per kilogram or pound. This ratio is multiplied by the weight of the patient to determine the total activity for the procedure.
2. **Extra Flush to Patient** sets the volume of saline that is injected after the total activity has reached the patient to lead the isotope to the heart. The default value is 5 mL. This volume is included in the 60 mL limit of total volume infused.
3. **Labels Printed per Elution** allows the user to determine how many copies of each label need to be printed after each daily QC and patient infusion. The default value is 1.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.