

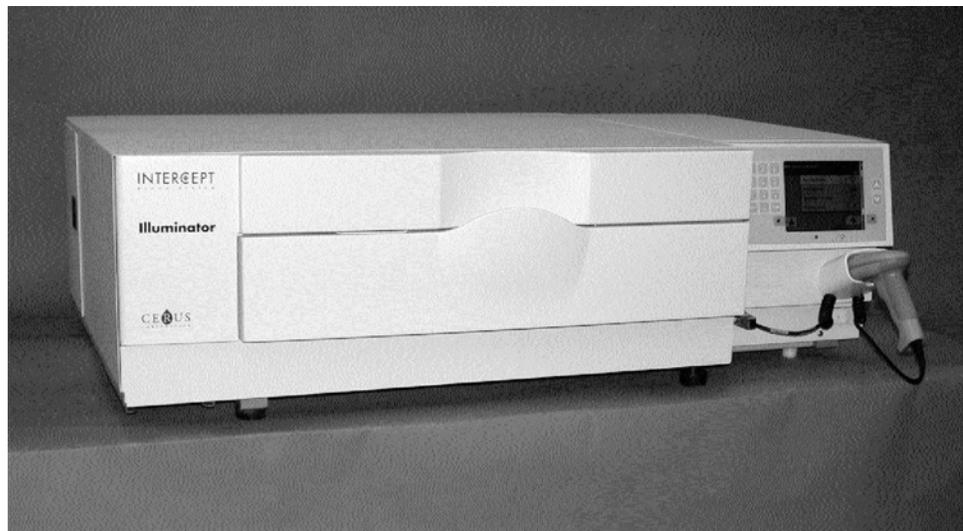


## Operator's Manual

# INTERCEPT ILLUMINATOR

## INT100

- INT100-50 for 50 Hz
- INT100-60 for 60 Hz





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Made in USA

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**CERUS**  
**Operator's Manual**

**INTERCEPT**  
**ILLUMINATOR**

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**INT100**

**Software Version 4.2**

Illuminator Serial Number \_\_\_\_\_

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## **Chapter 1.      What the Illuminator Does**

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## **Section 1.1      What the Illuminator Does**

The INTERCEPT Illuminator delivers a controlled dose of Ultraviolet A (UVA) light to blood products, as part of the process to inactivate pathogens. The illuminator is used in conjunction with platelets and plasma in an INTERCEPT Processing Set. The processing set allows blood products to be handled in a closed system. The illuminator maintains records of blood products, processes and transfers these records to a printer or computer.

Each blood product uses a specific processing set. It is important to use the correct processing set and use sets approved by your local regulatory authority.

A brief overview of the pathogen inactivation process is detailed below:

- The blood product is prepared from whole blood or by apheresis.
- The blood product is then mixed with amotosalen HCl.
- The amotosalen interacts with DNA or RNA in virus, bacteria, parasites or leukocytes if they are present in the blood product.
- When the blood product with amotosalen is exposed to UVA light, the amotosalen “crosslinks” the DNA or RNA. Pathogens can be prevented from replicating by this process.
- Residual amotosalen is reduced by adsorption prior to storage.

## **Section 1.2      Intended Use of the Illuminator**

The ‘illuminator’ refers to the INT100 INTERCEPT Illuminator. The INTERCEPT Illuminator is intended only for use in the pathogen inactivation process to deliver UVA light for the photochemical treatment of blood products. The illuminator should be used only by personnel trained to perform the INTERCEPT Blood System process.

## **Section 1.3      Indications for Use**

Platelets and plasma treated with the INTERCEPT Blood System process are indicated for support of patients requiring transfusions, according to clinical practice guidelines.

## **Section 1.4      Contraindications for Use**

Use of platelets and / or plasma treated with the INTERCEPT Blood System process is contraindicated in patients with a history of allergic response to amotosalen or psoralens.

## **Section 1.5**      **Notes to Transfusionists**

While laboratory studies of amotosalen processing with UVA light have shown a reduction in levels of certain viruses and bacteria, there is no pathogen inactivation process that has been shown to eliminate all pathogens.

INTERCEPT platelets or plasma components should not be prescribed to neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, and/or have a lower bound of the emission bandwidth <375 nm, due to the risk of erythema resulting from potential interaction between ultraviolet light (below 400 nm) and residual amotosalen.

## Section 1.6 Warnings

The warning messages below will alert you to potential hazards that may cause personal injury. This includes conditions that would compromise pathogen inactivation results.

Warning messages are listed according to the Section in which they appear.

### Chapter 3: ILLUMINATOR DESCRIPTION

-  **WARNING** **If the blood product leaks into the tray, tilting the drawer could cause the blood product to spill out. If the tray is above the operator's eye level, the operator should wear eye protection when tilting the drawer.**

Section 3.5 – *Illumination Door and Drawer*

-  **WARNING** **Amotosalen in contact with skin may result in photosensitization in the presence of ultraviolet light. If skin exposure occurs, flush exposed skin copiously with water.**

Section 3.5 – *Illumination Door and Drawer*

### Chapter 4: HOW TO USE THE ILLUMINATOR

-  **WARNING** **All materials containing platelets or plasma (including tubing) must be placed within the large compartment of the illuminator tray for adequate treatment to occur. The INTERCEPT Blood System is validated with unimpeded light transmission through the tray and the illumination container with the blood product. No labels or other material should be on this area. Labels should be placed on the illumination container flap only. The tray must be clean. The illumination container should not be folded.**

Section 4.3 - *Load Processing Set(s)*

-  **WARNING** **The tubing containing the blood product mixed with amotosalen must be held within the left-hand side of the chamber where illumination occurs. Platelet or plasma product in the tubing which is not entirely within the area receiving illumination will not be pathogen inactivated.**

Section 4.3 - *Load Processing Set(s)*

 **WARNING**      **Make sure the barcodes and chamber position of each container are correctly entered into the illuminator.**

Section 4.4 - *Scan Barcodes*

 **WARNING**      **Partial illumination has not been validated for pathogen inactivation. Do not attempt to re-treat a partially treated unit. Do not treat a blood product more than once. No claim of pathogen inactivation can be supported for partially illuminated units and they should be discarded.**

Section 4.7 - *Illumination Interruption*

Section 4.8 - *Unload the Processing Set(s)*

Chapter 6: MAINTENANCE, TRANSPORTATION AND STORAGE,  
WARRANTY AND SERVICE

 **WARNING**      **Lifting or carrying the illuminator should be done by a minimum of two people or by using a mechanical lifting device.**

Section 6.2 - *Selecting a Place for the Illuminator*

Section 6.4 - *Transportation and Storage*

 **WARNING**      **Do not stack illuminators more than two-high.**

Section 6.2 - *Selecting a Place for the Illuminator*

 **WARNING**      **Turn off the illuminator and disconnect the power source before performing any maintenance on your illuminator.**

Section 6.3 - *Cleaning the Illuminator*

 **WARNING**      **Blood products containing amotosalen should be treated like other blood products, that is, as biohazardous material. Follow the guidelines for use of protective equipment, cleaning and disposal, as laid out in your facility.**

Section 6.3 - *Cleaning the Illuminator*

 **WARNING**      **If the blood product leaks into the tray, tilting the drawer could cause the blood product to spill out. If the tray is above the operator's eye level, the operator should wear eye protection when tilting the drawer.**

Section 6.3 - *Cleaning the Illuminator*

Chapter 7: SPECIFICATIONS

-  **WARNING**      **The use of accessories and cables other than those specified in this manual, as replacement parts for internal components, may result in increased emissions or decreased immunity of the illuminators.**

*Section 7.2 - Illuminator Compliance with Standards*

-  **WARNING**      **The illuminators should not be used adjacent to or stacked with other manufacturer's equipment. If adjacent or stacked use is necessary, the illuminators should be observed to verify normal operation in the configuration in which it will be used.**

*Section 7.2 - Illuminator Compliance with Standards*

-  **WARNING**      **The pins of connectors identified with the ESD warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.**

**Precautionary procedures include:**

- **methods to prevent build-up of electrostatic charge (e.g. air conditioning, humidification, conductive floor coverings, non-synthetic clothing);**
- **discharging one's body to the frame of the EQUIPMENT or SYSTEM or to earth or a large metal object;**
- **bonding oneself by means of a wrist strap to the EQUIPMENT or SYSTEM or to earth.**

*Section 7.2 - Illuminator Compliance with Standards*

-  **WARNING**      **The illuminator must be attached to the mains and grounded to comply with appropriate standards.**

*Section 7.3 - Illuminator Requirements*

## Section 1.7 Cautions

The cautions below alert you to any conditions that could affect the blood product quality, damage the illuminator, or make the illuminator sound an alarm unnecessarily.

Cautions are listed according to the Section in which they appear.

### Chapter 3: ILLUMINATOR DESCRIPTION

- ! CAUTION** If any part of the illuminator tray is damaged (cracked, scratched or cloudy) contact your authorized service representative for a replacement. Do not use the illuminator if the tray is damaged.

Section 3.5 – *Illumination Door and Drawer*

- ! CAUTION** Do not change date or time while units are in the illuminator.

Section 3.6 – *Illuminator Settings*

- ! CAUTION** Illumination labels are not suitable for freezing and thawing.

Section 3.6 – *Illuminator Settings*

### Chapter 4: HOW TO USE THE ILLUMINATOR

- ! CAUTION** Make sure all tubings are in the tray before closing the cover and drawer.

Section 4.5 - *Repeat Set Loading for Container 2*

- ! CAUTION** Illumination should not be interrupted, unless it is absolutely essential. It will result in improperly treated blood product(s) that should be discarded.

Section 4.7 - *Illumination Interruption*

Chapter 6: MAINTENANCE, TRANSPORTATION AND STORAGE,  
WARRANTY AND SERVICE

- ! CAUTION** Do not use the illuminator if there is condensation on it. Humidity higher than 80% may shorten the life of instrument components.

Section 6.2 - *Selecting a Place for the Illuminator*

- ! CAUTION** Only use approved solutions to clean and disinfect the tray as non-approved solutions may cause damage.

Section 6.3 - *Cleaning the Illuminator*

- ! CAUTION** If any part of the illuminator tray is damaged (cracked, scratched or cloudy) contact your authorized service representative for a replacement. Do not use the illuminator if the tray is damaged.

Section 6.3 - *Cleaning the Illuminator*

Chapter 7: SPECIFICATIONS

- ! CAUTION** The illuminators need special precautions regarding electromagnetic compliance (EMC) and need to be installed and put into service according to the EMC information provided in the above tables.

Section 7.2 - *Illuminator Compliance with Standards*

- ! CAUTION** Portable and mobile radio frequency (RF) communications equipment can affect the illuminators by interfering with the electronics, causing the illumination to stop.

Section 7.2 - *Illuminator Compliance with Standards*

- ! CAUTION** If the fuse blows after bulb replacement, the illuminator should not be used. Contact your authorized service representative for assistance.

Section 7.3 - *Illuminator Requirements*

- ! CAUTION** If using Codabar (excluding Monarch 11 and UKBTS), the illuminator will not evaluate the integrity of the scanned data. Verify the data scanned matches the information displayed on the illuminator screen.

Section 7.4 – *Barcode Compatibility*

## **Chapter 2.      How to Use this Manual**

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## Section 2.1      **Getting Started**

This Section explains how to use the illuminator manual.

This manual gives detailed information about the use of the INTERCEPT Illuminator. It complements the package inserts that accompany the INTERCEPT Processing Sets. There are processing steps before and after illumination that are not described in this manual, but are described in the package insert for each processing set. Directions may be slightly different for each blood product, so it is important to consult the directions with the correct set.

The manual starts with a table of contents, which describes each chapter. The table of contents for each chapter has detailed sections. Each chapter is divided into sections that explain the illuminator function or procedure, with photographs and screen images. Some chapters have 'Questions and Answers' at the end. The manual contains these chapters:

- Chapter 1 What the Illuminator Does

This explains what functions the illuminator performs, the indications for use, contraindications, and summarizes all warnings and cautions that are used throughout the manual.

- Chapter 2 How to Use this Manual

This explains how to use the manual and the symbols that are used in the manual, on the illuminator and on the shipping carton.

- Chapter 3 Illuminator Description

This details the parts of the illuminator and the illuminator functions that may be set for your laboratory, such as date format and language.

- Chapter 4 How to Use the Illuminator

This details the day-to-day operation of the instrument, explaining how to perform illumination procedures.

- Chapter 5 Troubleshooting

This summarizes questions and answers found in each chapter and troubleshooting messages and operator interventions.

- Chapter 6 Maintenance, Transportation and Storage, Warranty and Service

This details cleaning and general maintenance and provides information on how to store and move the illuminator. It contains the warranty statement and service instructions.

- Chapter 7 Specifications

This provides the technical specifications for the illuminator.

- Chapter 8 Appendix

This appendix contains a glossary of terms and a summary of operator steps.

## Section 2.2 Symbols

### Symbols Used in This Manual

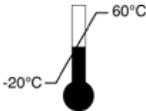
Throughout the manual the following symbols have been used. Each symbol and meaning is shown below:

Symbol	What the Symbol Means
	Warning
	Caution
	Note
	Q & A (Questions and Answers)

- Warnings will alert you to potential hazards that may cause personal injury.
- Cautions will alert you to conditions that could damage the illuminator, affect the illumination of the containers or make the illuminator sound an alarm unnecessarily.
- The notes give points of interest.
- The questions and answers address common queries.

**Symbols  
Used on the  
Illuminator  
Packaging**

The following symbols are used on the outer shipping carton of the illuminator:

Symbol	What the Symbol Means and Instructions
REF	“Catalogue number” (EN 980)
SN	“Serial number” (EN 980)
	“Date of manufacture” (EN 980)
	Attention, See instructions for use (EN 980)
	“Keep Dry” (The shipping carton and contents MUST be kept dry) (EN 20780)
	“Fragile, Handle With Care” (The shipping carton and contents have to be handled with care) (EN 20780)
	“This Way Up” (The package must be kept the right way up) (EN 20780)
	“Temperature limitations” (The shipping carton and contents must be kept within a certain temperature range when transported) (EN 20780)
	“Relative humidity” (The shipping carton and contents must be kept within a certain humidity range when transported) (ISO 7000)
CE	This marking reflects compliance with the Medical Devices Directive 93/42/EEC issued by the Council of the European Communities.
	“Manufacturer” (EN 980)
EC REP	“European Authorized Representative” (EN 980)

**Symbols  
Used on the  
Illuminator**

The following symbols are used on the illuminator:

Symbol	What the Symbol Means
	Tilt – this is the button that tilts the drawer.
	Sun - this side of the tray is exposed to light during the illumination process.
	Spanner or wrench - this shows the maintenance light. When this light is amber, the illuminator requires maintenance.
	Power switch - Power on.
	Power switch - Power off.
	Caution: High Voltage
	Attention, See instructions for use (EN 980)
	Ground
	Alternating current
1	RS-232 barcode scanner port (front of illuminator)
2	RJ-45 ethernet port (rear of illuminator)
3	RS-232 label printer port (rear of illuminator)
4	25-pin parallel printer port (rear of illuminator)
	Backspace, Delete or page back
	Advance or page forward

Chapter 2 – How to Use this Manual  
 Section 2.2 – Symbols

	<p>This marking reflects compliance with the Medical Devices Directive 93/42/EEC issued by the Council of the European Communities.</p>
	<p>Underwriters Laboratories symbol denoting compliance with specific safety guidelines as established by Underwriters Laboratories.</p>
	<p>“Serial number” (EN 980)</p>
	<p>“Date of manufacture” (EN 980)</p>
	<p>“Catalogue number” (EN 980)</p>
	<p>Container chamber 1 position indicator</p>
	<p>Container chamber 2 position indicator</p>
	<p>ESD Sensitive</p>
	<p>Requires separate electrical and electronic waste collection.</p>
	<p>CU US+Canada NRTL Certificate (cTÜVus Mark). This mark reflects compliance with UL 61010-1:2004 R10.08 and CAN/CSA-C22.2 No. 61010-1-04+GI1 (R2009).</p>

## Section 2.3      **Conventions Used in this Manual**

When messages from the illuminator screen are quoted in the manual, they will appear in bold type and quote marks, for example:

**'Select a function'** screen.

Some Chapters include a Q & A section at the end to provide answers to frequently asked questions.

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## Chapter 3. Illuminator Description

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## **Section 3.1      Light System**

The INTERCEPT Illuminator provides a controlled dose of Ultraviolet A (UVA) light for the INTERCEPT pathogen inactivation process. It contains fluorescent bulbs above and below a clear tray where blood products are placed.

The tray accommodates the blood product on the left-hand side and the attached set on the right-hand side. Two of the same set types may be illuminated at the same time. However, you can only illuminate one set type at a time. For example, you cannot illuminate a large volume and a small volume platelet set at the same time. There are four bulbs above each chamber and four bulbs below each chamber for every blood product, for a total of sixteen bulbs.

The correct wavelength of light is controlled by special bulbs and glass filters that screen out undesired wavelengths. The dose of light is measured by sensors called photodiodes. There is one sensor for each two bulbs, so four sensors for each blood product. These sensors are calibrated when each illuminator is installed and at prescribed periods after installation.

The illuminator adjusts the time of illumination so the correct light dose is administered. With use, the amount of light produced by fluorescent bulbs declines gradually. Illumination time will be the shortest with new bulbs. As bulbs age, illumination time will gradually lengthen. The UVA light dose administered to each blood product is controlled individually, even when two products are in the illuminator simultaneously.

Bulbs operate in pairs. If a bulb fails, the second bulb in the pair is automatically turned off as well. The sensor between the two bulbs measures that they are not on. If a bulb fails during treatment of a blood product, proper illumination has not occurred. This will be displayed on the screen and recorded on the treatment record. Partially illuminated blood products must be discarded. A blood product must not be illuminated a second time.

## **Section 3.2      Product Identification and Traceability**

The illuminator will recognize and is compatible with the following barcode formats:

1. Codabar (including Monarch 11 and UKBTS)
  - 10 numeric characters : 0 through 9
  - 6 control characters : minus (-), dollar sign (\$), period (.), plus (+), colon (:), forward slash (/)
  - 8 start / stop characters : a, b, c, d, t, n, \*, e (upper and lower case allowed)
2. Code 128 (including ISBT 128 and Eurocode)
  - All 128 ASCII characters

Refer to Chapter 7 of this manual for details.

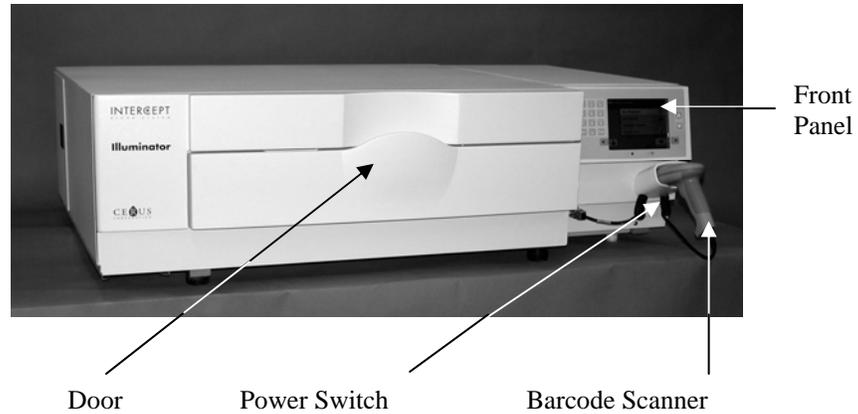
Each blood product is identified and traced by the combination of the donation number and blood product code. This identification is entered into the illuminator by scanning barcodes that are applied to the final storage container by your facility.

Upon completion of the illumination step, a record of each processed blood product is stored in the illuminator. Up to 3200 records may be stored, printed and/or transmitted to a computer. Upon completion of treatment number 3201, the number 1 treatment record is replaced.

## Section 3.3 Illuminator

The illuminator has two main areas of interest to the operator:

- the front panel, where the operator controls are located.
- the door and drawer, where blood products are placed for illumination.



Data ports and the outlet for the power cord are on the rear of the illuminator.

## Section 3.4 Front Panel Description

The front panel of the illuminator consists of separate parts as shown in the picture below. The buttons used to control operation are on either side of the screen.

Each of these parts is explained below.



### Color Screen

The screen is a liquid crystal display that gives instructions and other messages. It is not a touch screen. To move between screens or to select a function, use the buttons on the front panel, next to the screen.

Screens are organized by functions, with symbols in the upper left-hand corner to orient the operator to the functions. These functions and symbols are shown in the table below.

Screen Symbols	Function
	Main Menu
	Illumination
	Printing
	Illuminator settings

Messages appear in the middle of the screen. In addition to routine operating screens, there are three types of message screens. Shown in the table below are screen symbols and the corresponding message type.

Screen Symbols	Type of Message
	Alert
	Information
	Confirmation
	System Issue
	Barcode symbols

### Status Lights

The status lights refer to the small round lights on the front panel of the illuminator.



Power On Light      Service Light

- (Left hand light) This light is green when the power is on.
- (Right hand light) When the amber service light comes on, attention to the illuminator is needed.

### Barcode Scanner

At the front of the illuminator is a barcode scanner. Barcodes are scanned into the illuminator by pointing the scanner at the barcode and pressing the trigger.



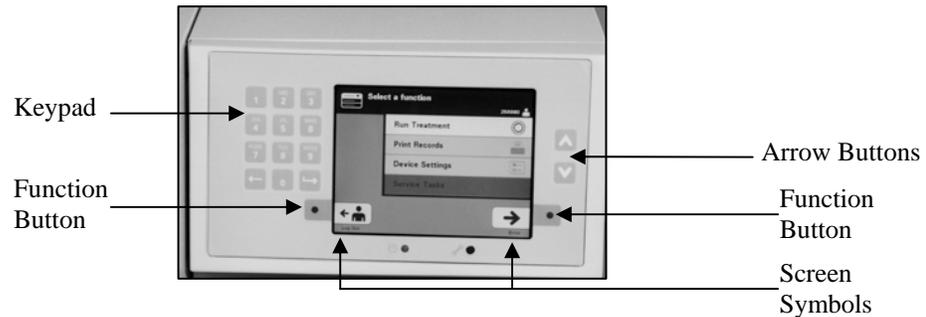
Barcodes are used to track blood products through the INTERCEPT Blood System process and can be found on the final storage container label of the INTERCEPT Processing Set.

If your laboratory uses a barcode for operator identification, you may use it to enter operator identification into the illuminator and records.

- ✉ **NOTE:** If the operator identification is in Codabar format, the start and stop characters will be deleted.

The system recognizes Codabar and Code 128 barcode formats.

### Buttons



There are three types of buttons on the front panel of the illuminator:

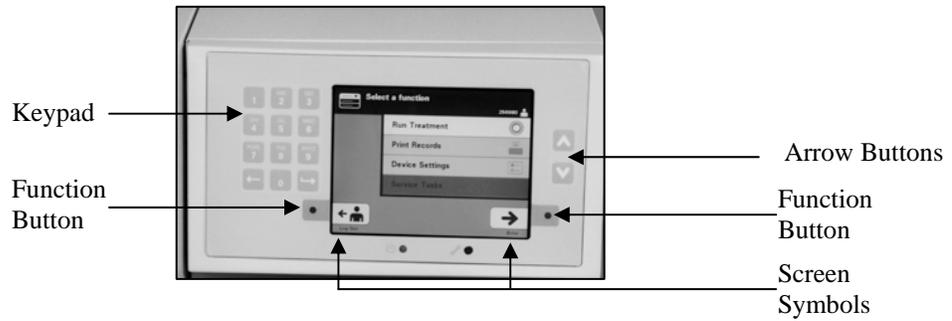
- Arrow buttons — up and down arrow buttons allow you to scroll through the screen choices.
- Function buttons — the meaning of these buttons change to guide you through the screen choices.
- Keypad — buttons with a number, letter and special character function.

The arrow buttons are to the right of the screen:

Buttons	Function
^	Up arrow allows you to scroll up through the menu
v	Down arrow allows you to scroll down through the menu

When a selection is chosen it has a light background.

**Function Buttons**



Function buttons have screen symbols and labels that change according to the step, to help you navigate through the screens.

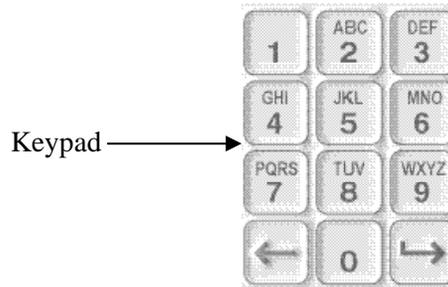
The screen symbols and labels below appear next to the function buttons.

✉ **NOTE:** Press the function buttons next to the screen symbols.

Chapter 3 – Illuminator Description  
 Section 3.4 – Front Panel Description

Screen Symbol	Labels and Use
	Back/Edit Use this button to return to the previous screen or to edit information.
	Cancel/Cancel treatment Use this button to: 1. Cancel the illuminator's current function. For example, to stop entering the barcode information and return to the previous screen. 2. Cancel out of the illumination process in an error.
	Enter/Continue/Login/Stop Agitator/Start Use this button to: 1. Enter information on the screen. 2. Continue to the next screen. 3. Stop the agitator after illumination.
	Log out Use this button to exit the current procedure.
	OK/Done Use this button to accept screen information.
	Stop Use this button to stop the illumination process.

**Keypad Buttons**



These buttons are on the left side of the screen. They may be used to enter information if a barcode cannot be scanned.

✉ **NOTE:** If desired, the keypad may be disabled to prevent manual treatment data entry. Contact your authorized service representative to disable the keypad.

✉ **NOTE:** Only capital letters can be entered via the keypad.

Symbol Needed	Number of Times to Press the Button
Number	Press once
First Letter	Press twice
Second Letter	Press three times
Third Letter	Press four times
Fourth Letter (on numbers 7 and 9) or to return to the number.	Press five times
Special Characters	Press '1' to select: '-', '+', '*', '\$', '.', '/', ':'

☒ **NOTE:** If you press the button for a long time, it will NOT continue to scroll through the number and letters.

There are also backspace (←) and advance (→) buttons on the keypad, as shown below in the previous figure:

- The backspace (←) button will delete the last number or letter only. To delete all the numbers and letters you need to push the button several times.
- The advance (→) button is used to let you enter the next number or letter using the same button as the previous number or letter. For example, to enter the number 2334+, you would do the following:

	<u>Result</u>
Press '2'	2
Press '3'	23
Press 'advance'	23_
Press '3'	233
Press '4'	2334
Press '1, 1, 1'	2334+

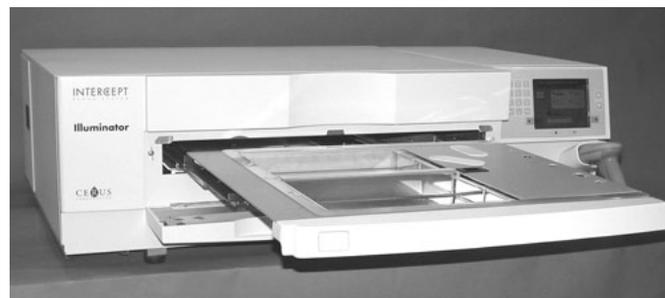
☒ **NOTE:** Entering information into the illuminator using the keypad is similar to entering information into a cellular phone using its keypad.

## Section 3.5      **Illumination Door and Drawer**

The door that extends across the front of the illuminator opens down.



Inside, a drawer pulls out. The clear tray where illumination is performed is held in the drawer. The drawer is on a flatbed agitator, so that blood products are agitated when they are in the illuminator. There are four compartments in the tray to hold blood products and the accompanying processing sets during illumination.



There is a cover for the two compartments on the right side, designed to keep the set and tubing from getting caught during agitation. The operator opens this cover to load the set and closes it before beginning illumination.



One blood product and processing set fits in the front chamber, chamber 1. The blood product in the illumination container goes on the left side of the chamber, with the rest of the set on the right side of the chamber.

A second blood product and set fits into the rear chamber, chamber 2. The illumination container goes on the left; the set goes on the right.

Under normal circumstances, if you are illuminating only one blood product, you must place it in the front chamber. If, however, the front chamber has malfunctioned and cannot be used, then you may illuminate one blood product in the rear chamber.

When you scan the INTERCEPT set codes on one of the final storage containers into the illuminator, the illuminator determines the dose of light to be given. The dosages and approximate treatment times are:

	Dosage	Treatment Time
• Large volume platelet set	3.5 – 4.3 J/cm <sup>2</sup>	4 - 6 minutes
• Small volume platelet set	3.2 – 4.0 J/cm <sup>2</sup>	4 - 6 minutes
• Plasma set	5.8 – 7.0 J/cm <sup>2</sup>	6 - 8 minutes

The treatment dosage may be reported with two decimal places.

If two different types of blood products are present, the illuminator will not begin treatment.

- ✉ **NOTE:** You can illuminate two containers at the same time, but they must contain the same type of set code. For example, you cannot illuminate a large volume and a small volume platelet set during the same illumination. You cannot illuminate one container of plasma and one container of platelets during the same illumination.

## Chapter 3 – Illuminator Description

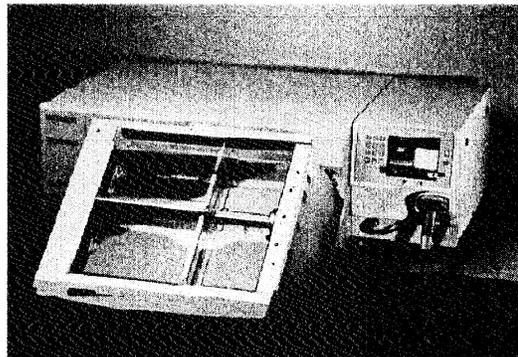
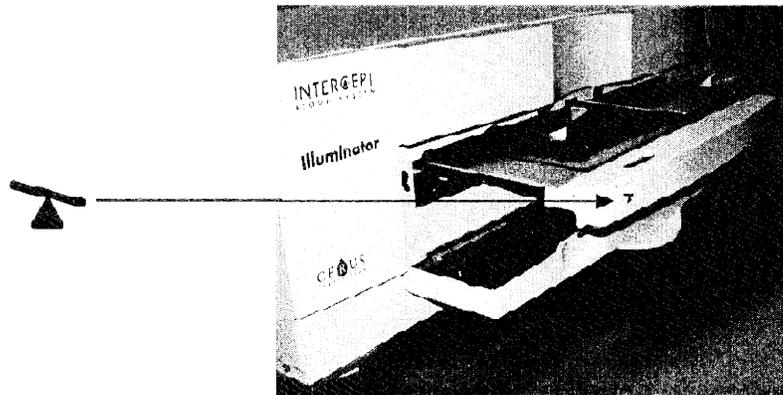
### Section 3.5 – Illumination Door and Drawer

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Illuminator trays may be tilted downward to make set loading and unloading and tray cleaning easier. Follow the instructions below:

1. Open the front door of the illuminator.
2. Pull out the drawer.
3. Open the drawer cover of the illuminator.
4. Press the white button with the fulcrum symbol to tilt the drawer downward.

☒ **NOTE:** The tray is designed to be able to hold the volume of a blood product in the event of a leak.



5. To close the drawer, tilt the drawer so it is flat. You will hear a ‘click’ sound.
6. When the drawer is horizontal, close the drawer cover.
7. Push the drawer back into the illuminator.
8. Close the door of the illuminator.

**!** **CAUTION** If any part of the illuminator tray is damaged (cracked, scratched or cloudy) contact your authorized service representative for a replacement. Do not use the illuminator if the tray is damaged.

**⚠** **WARNING** **If the blood product leaks into the tray, tilting the drawer could cause the blood product to spill out. If the tray is above the operator’s eye level, the operator should wear eye protection when tilting the drawer.**

**⚠** **WARNING** **Amotosalen in contact with skin may result in photosensitization in the presence of ultraviolet light. If skin exposure occurs, flush exposed skin copiously with water.**

## Section 3.6 Illuminator Settings

The settings that can be changed on the illuminator are: date/time, language, illuminator identification and configurations. The following describes these settings and how to change them.

Before you are able to select the setting, you must access the **'Select a setting'** screen. To access this screen, perform the following:

- After logging into the illuminator, the **'Select a function'** screen will appear.
- Use the arrow buttons at the right of the screen to choose the **'Illuminator Settings'** option.
- Press the **'Enter'** button. The **'Select a setting'** screen will appear.



Use these steps to access the illuminator settings option or press the **'Back'** button to get back to the previous screen or the **'Select a setting'** screen while you are changing your settings.

### Date and Time

The date/time setting allows you to change the date, time and the format of each.

**! CAUTION** Do not change date or time while units are in the illuminator.

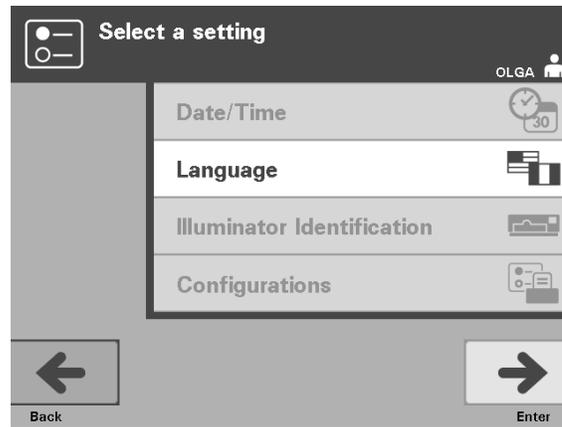
**✉ NOTE:** The illuminator does not automatically update for daylight savings time.

To change the date and time, perform the following:

- While in the **'Select a setting'** screen, use the arrow buttons at the right of the screen to choose **'Date/Time'**.

- Press the **'Enter'** button to select the option. The **'Select a date format'** screen will appear.
  - Use the arrow buttons at the right of the screen to choose the date format. Your choices are month/day/year, day/month/year or year/month/day.
  - Press the **'Enter'** button to select the format. The **'Enter date'** screen will appear.
  - Use the keypad (to the left of the screen) to enter the date manually. The illuminator will automatically take you to the next field (for example, month or year) when you have entered the numbers.
  - Press the **'Enter'** button when the date has been entered. The **'Select a time format'** screen will appear.
- ✉ **NOTE:** You must enter 2 numbers for the **'month'** and **'day'** fields and 4 numbers for the **'year'** field. (For example: 01/01/2002).
- Use the arrow buttons to choose the time format. Your choices are a 12 – hour clock or a 24 – hour clock.
- ✉ **NOTE:** If using the INTERCEPT Data Management System, select the 24-hour clock format.
- Press the **'Enter'** button to select the format. The **'Enter time'** screen will appear.
  - Use the keypad to enter the time manually.
  - Press the **'Enter'** button when the time has been entered.
- ✉ **NOTE:** You must enter 2 numbers for the **'hour'** and **'minute'** fields. (For example: 01:30).
- If you selected the 12 – hour clock, then the **'Select 12 hour period'** screen will appear. Use the arrow buttons at the right of the screen to choose whether the time is **'Morning: am'** or **'Evening: pm'**.
  - Press the **'Enter'** button to select the time period. A confirmation screen will appear.
  - If you selected the 24 – hour clock, the confirmation screen will appear.
  - If the date and time are incorrect, press the **'Edit'** button to return to the **'Select 12 hour period'** screen.
  - If this screen is incorrect, press the **'Back'** button to find the incorrect screen. Repeat the above steps to correct the information.

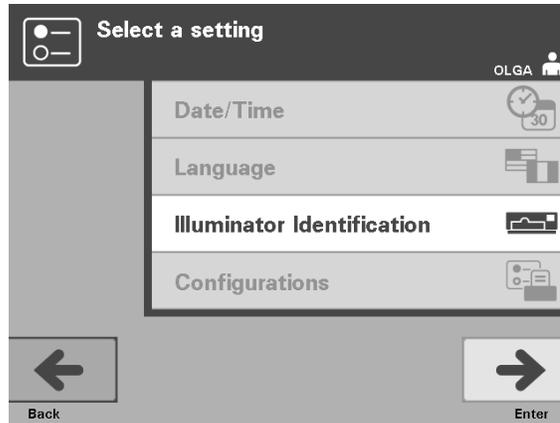
- Press the **'Enter'** button after every entry. A confirmation screen will appear once you have entered all the data for date and time.
- Press the **'OK'** button to confirm the date and time. The **'Select a setting'** screen will appear.



## Language

The language setting allows you to change the language displayed on the screen. To change the language, perform the following:

- From the **'Select a setting'** screen, use the arrow buttons to choose the **'Language'** option.
- Press the **'Enter'** button to select the option. The **'Select a language'** screen will appear.
- Use the arrow buttons to choose the desired language. If your language is not listed on the screen, press the advance (←→) button on the keypad to display the next page of languages. Then use the arrow buttons again to choose the desired language.
- Press the **'Enter'** button to select the language. A confirmation screen will appear.
- If the language is incorrect, press the **'Edit'** button to return to the **'Select a language'** screen.
- Use the arrow buttons to choose the correct language. Press the **'Enter'** button to select the language. A confirmation screen will appear.
- Press the **'OK'** button to confirm the language choice. The **'Select a setting'** screen will appear.



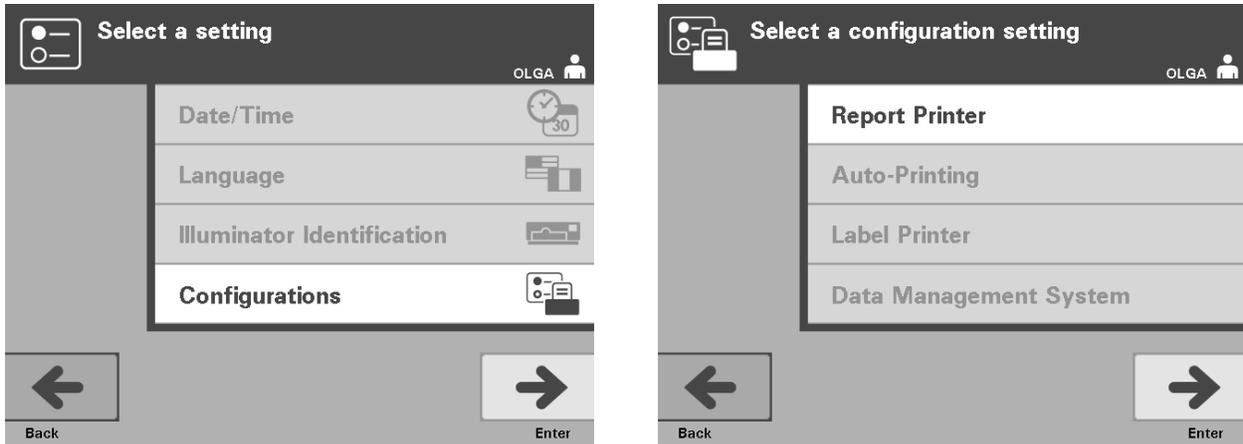
## Illuminator Identification

The illuminator identification setting allows you to enter an instrument identification number such as a serial number. To enter the identification number, perform the following:

- From the **'Select a setting'** screen, use the arrow buttons to choose the **'Illuminator Identification'** option.
- Press the **'Enter'** button to select the option. The **'Enter illuminator identification'** screen will appear.
- Use the keypad to enter the instrument 9-digit serial number manually. The serial number is located inside the front door of the illuminator.

✉ **NOTE:** If you are using the INTERCEPT Data Management System, use the keypad to enter both your facility's site code, and the instrument 9-digit serial number. The format for the illuminator identification should be site code, serial number. (For example NORTHBCV02000001).

- Press the **'Enter'** button when the number has been entered. A confirmation screen will appear.
- If the number is incorrect, press the **'Edit'** button to return to the **'Enter illuminator identification'** screen.
- Using the keypad, press the backspace (←) button to delete the numbers. Then, re-enter the correct number using the keypad.
- Press the **'Enter'** button when the number has been entered. A confirmation screen will appear.
- If the number is correct, press the **'OK'** button to confirm the number. The **'Select a setting'** screen will appear.

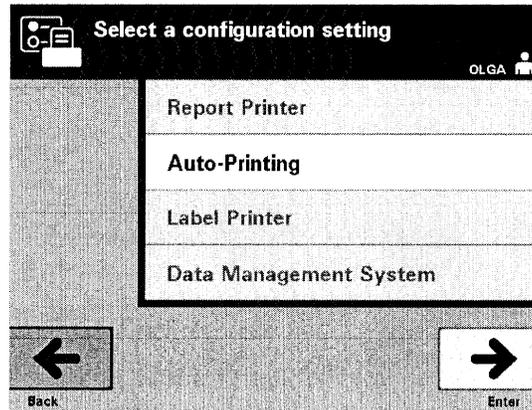


## Configurations

The Configurations setting allows you to set various printing options and enable a data management system. These printing options include report printing, auto-printing and label printing. The data management system option allows the illuminator to send information to another data management system, such as the INTERCEPT Data Management System. To set these various options, perform the following:

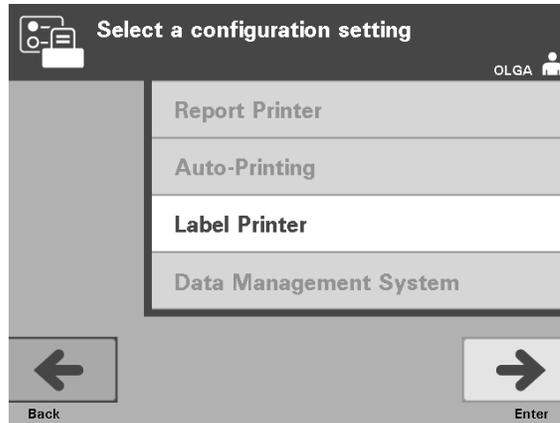
### Report Printer

- From the **'Select a setting'** screen, use the arrow buttons to choose the **'Configurations'** option.
- Press the **'Enter'** button to select the **'Configurations'** option. The **'Select a configuration setting'** screen will appear.
- Use the arrow buttons to choose the **'Report Printer'** option.
- Press the **'Enter'** button to select the **'Report Printer'** option. The **'Select a report printer option'** screen will appear.
- Use the arrow buttons to choose either **'On'** or **'Off'**. Selecting the **'On'** option will allow you to print the last treatment report, a specific treatment report or a shift report for a given day. If not using the optional printer, select the **'Off'** option. (Refer to Chapter 4 for printing directions.)
- Press the **'Enter'** button to select **'On'** or **'Off'**. A confirmation screen will appear.
- If the option is incorrect, press the **'Edit'** button to return to the **'Select a report printer option'** screen. Use the arrow buttons to select the correct option.
- If the selection is correct, press the **'OK'** button to confirm the selection. The **'Select a configuration setting'** screen will appear.



### Auto-Printing

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Auto-Printing'** option.
  - Press the **'Enter'** button to select the **'Auto-Printing'** option. The **'Select an auto-printing option'** screen will appear.
  - Use the arrow buttons to choose either **'On'** or **'Off'**. Selecting the **'On'** option will automatically print the last treatment record(s) during the container unloading. If not using Auto-Printing, select the **'Off'** option. (Refer to Chapter 4 for printing directions.)
  - Press the **'Enter'** button to select **'On'** or **'Off'**. A confirmation screen will appear.
  - If the option is incorrect, press the **'Edit'** button to return to the **'Select an auto-printing option'** screen. Use the arrow buttons to select the correct option.
  - If the selection is correct, press the **'OK'** button to confirm the selection. The **'Select a configuration setting'** screen will appear.
- ✉ **NOTE:** Report Printer must be on for Auto-Printing to print. See previous section for directions to turn Report Printer on.



### Label Printer

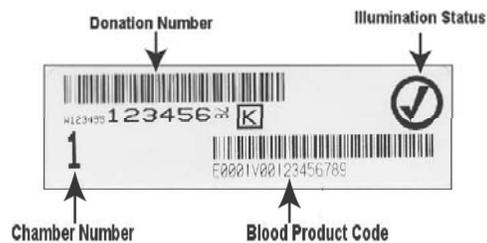
An illumination label will be printed after every treatment and must be applied to the illumination containers before they are removed from the illuminator.

✉ **NOTE:** If using the INTERCEPT Data Management System, the illumination label is not required for platelet treatment.

This label provides the following:

- Donation number.
- Blood product code
- Status of illumination.
- Illumination chamber number.

#### Platelet Label Example



#### Plasma Label Example



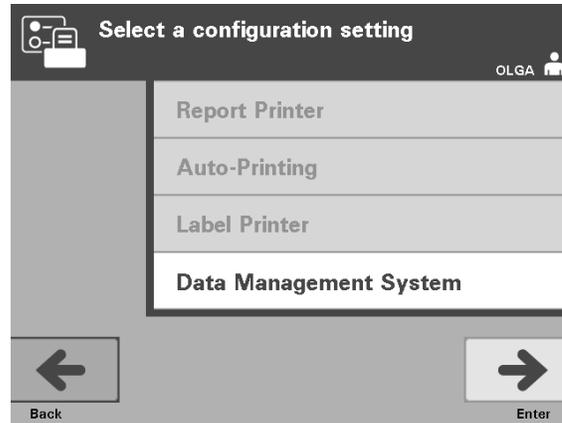
The information on the labels will be printed in the same format it was scanned, unless it was manually entered. If manually entered, no barcode will be printed.

A specific number of labels may be configured to be printed every time an illumination has finished. A maximum of 6 labels may be printed. Setting the value to '0' will turn the label printing feature off. Only turn the label printing off if the label printer is out of service / not functioning.

**!** **CAUTION** Illumination labels are not suitable for freezing and thawing.

To configure the number of labels to print, perform the following:

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Label Printer'** option.
- Press the **'Enter'** button to select the **'Label Printer'** option. The **'Select a blood component'** screen will appear.
- Use the arrow buttons to choose **'Platelets'**. Press the **'Enter'** button to select component. The **'Enter the number of platelet labels'** screen will appear.
- Use the keypad to enter the desired quantity (0 - 6) of labels to be printed.
- Press the **'Enter'** button to select the number of labels. A confirmation screen will appear.
- If the number of labels is incorrect, press the **'Edit'** button to return to the **'Enter the number of platelet labels'** screen. Use the backspace ( ) button on the keypad to delete the number and re-enter the correct number. Press the **'Enter'** button to select the number of labels. A confirmation screen will appear.
- If the number of labels is correct, press the **'OK'** button. The **'Select a blood component'** screen will appear.
- Repeat the process for the desired number of plasma labels to be printed.
- Press the **'Back'** button to return to the **'Select a configuration setting'** screen.



Do not connect the Illuminator to an open network. If using optional devices such as **'Data Management System'**, connect to a dedicated network.

### **Data Management System**

If your facility is using a data management system, set the configuration as described below. Your computer personnel may need to consult with your authorized service representative to set up a system.

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Data Management System'** option.
- Press the **'Enter'** button to select the **'Data Management System'** option. The **'Enter data management system TCP/IP address'** screen will appear.
- Use the keypad to enter the TCP/IP address of the data management system connected to the illuminator.
- Press the **'Enter'** button when the address has been entered. A confirmation screen will appear.
- If the address is incorrect, press the **'Edit'** button to return to the **'Enter data management system TCP/IP address'** screen.
- Using the keypad, press the backspace (  $\leftarrow$  ) button to delete the address. Then, re-enter the correct address using the keypad.

✉ **NOTE:** You must enter a 12 digit number for the TCP/IP address in this format, XXX . XXX . XXX . XXX .

- Press the **'Enter'** button when the address has been entered. A confirmation screen will appear.
- If the address is correct, press the **'OK'** button to confirm the address. The **'Enter illuminator TCP/IP address'** screen will appear.
- Use the keypad to enter the TCP/IP address of the illuminator.

- Press the **'Enter'** button when the address has been entered. A confirmation screen will appear.
- If the address is incorrect, press the **'Edit'** button to return to the **'Enter illuminator TCP/IP address'** screen.
- Using a keypad, press the backspace ( $\leftarrow$ ) button to delete the address. Then, re-enter the correct address using the keypad.

✉ **NOTE:** You must enter a 12-digit number for the TCP/IP address in this format, XXX . XXX . XXX . XXX .

- Press the **'Enter'** button when the address has been entered. A confirmation screen will appear.
- If the address is correct, press the **'OK'** button to confirm the address. The **'Select a configuration setting'** screen will appear.
- Press the **'Back'** button to return to the **'Select a setting'** screen.
- Press the **'Back'** button again to return to the **'Select a function'** screen.

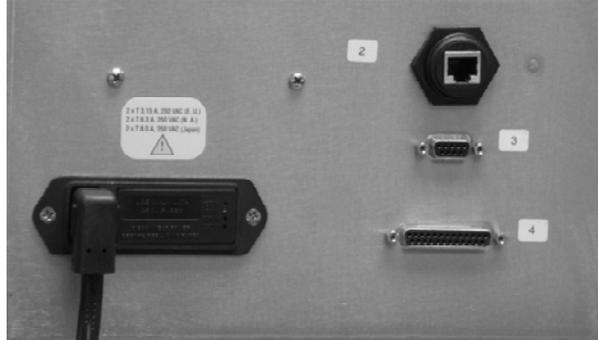
## **Section 3.7      Features for Safety and Function**

A microprocessor controls the illuminator. The illuminator also contains:

- Air flow sensor — to make sure that the fan is working.
- Air filter — to cover the fan vent and prevent dust from entering the illuminator.
- Container placement sensors — to ensure the containers are positioned correctly for illumination.
- Door lock — to lock the door during treatment.
- Door lock sensor — to ensure the door is locked during treatment.
- Magnetic door sensor — to ensure the door is closed.
- Interlock switch — to ensure the door is closed.
- Side access panel sensor — to ensure the side access panel is closed during illumination.
- Agitator sensor — to ensure the agitator is moving.
- Drawer sensor — to ensure the drawer is closed.

## Section 3.8 Computer Connections

There are three connectors on the rear of the illuminator. Refer to Section 7.3 for details.



- ✉ **NOTE:** There are panels on each side of the illuminator that have no customer serviceable parts. Opening either panel of the illuminator requires special tools and should only be opened by an authorized service representative.



## Section 3.9 Questions and Answers

**? Q & A:** *Whom should you contact if the illuminator is damaged?*

- If you notice the illuminator is damaged, contact your authorized service representative. Please refer to the front of this manual for contact details.

**? Q & A:** *How do you know that the containers receive the correct amount of light?*

- Each illuminator chamber has 4 photodiode sensors, 2 at the top and 2 at the bottom. These sensors measure the amount of light through the blood product with every treatment cycle and the illuminator adjusts the time of the cycle to provide the correct light dose.
- As a secondary check, the illuminator software checks the treatment time to make sure that it is within the appropriate range set by the authorized service representative.
- The bulbs will need changing if the time approaches the limit for adequate illumination. The light system is automatically checked during power on or every 24 hours, and during power failure recovery.
- The sensors are calibrated by your authorized service representative when the illuminator is installed and during preventive maintenance.

**? Q & A:** *What should you do if the barcode scanner does not work?*

- Occasionally, the barcode scanner will not scan the barcodes on the containers. If this happens, enter the numbers of the barcode into the illuminator manually via the keypad if this is permitted by your facility's procedures. Refer to Sections 3.4 and 4.4 for instructions.
- If the problem seems to be with the scanner, not the barcode label, contact your authorized service representative for assistance.

**? Q & A:** *What should you do if the treatment times in your illuminator are consistently at the upper end of the range in Section 3.5?*

- The correct dose of light is being administered to the blood product, so pathogen inactivation is being appropriately achieved. The treatment time automatically increases as the bulbs gradually become dimmer, so that the correct dose is administered.
- If the treatment time exceeds the appropriate range as set by the authorized service representative, a message will be displayed to change the bulbs.

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## Chapter 4.      **How to Use the Illuminator**

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4.9      Optional Printing Treatment Reports and Additional Labels	4-17
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## Section 4.1      Introduction

This chapter will guide you through a complete treatment cycle with the illuminator. A summary of operator steps is given in the Appendix.

Illumination is one step in the INTERCEPT Blood System process. Refer to the Directions for Use included with the INTERCEPT Processing Set, and follow the instructions for the preparation of blood products that must be completed before and after illumination.

- ☒ **NOTE:** Only use approved INTERCEPT Processing Sets cleared by the appropriate regulatory agencies in your country.

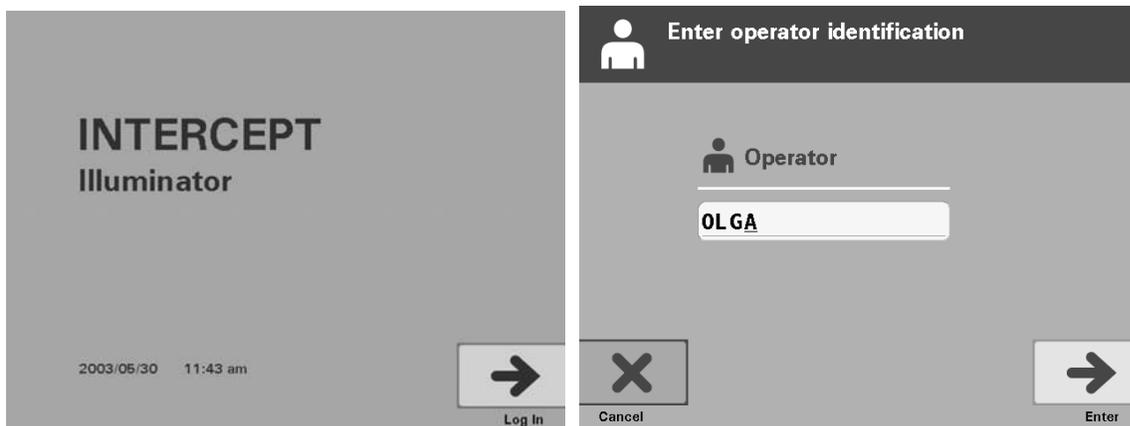
## Section 4.2 Turn On the Illuminator and Log In

1. Press the power switch, under the screen, to turn the illuminator on.

The illuminator will run several self-tests.

When the self-tests are complete, the **'Log In'** function button will appear.

2. Press the **'Log In'** button. The **'Enter operator identification'** screen will appear.



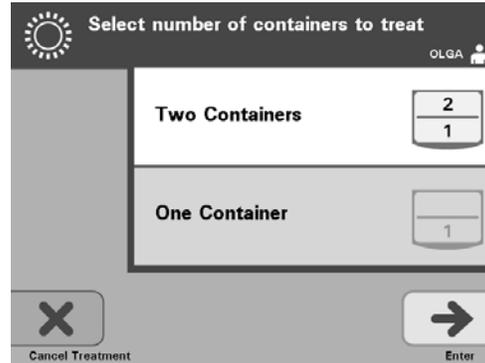
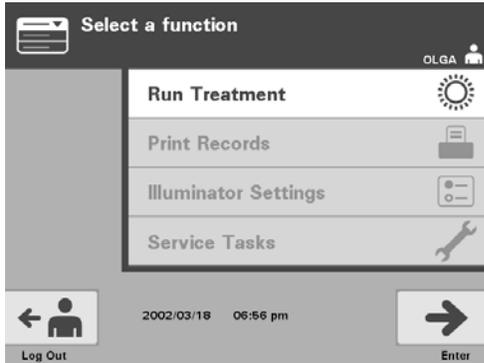
3. If you have a barcode for identification, scan it. After scanning, the **'Select a function'** screen will appear. If a barcode is not available, enter the identification manually.

✉ **NOTE:** The maximum number of characters that may be entered is 17.

4. To enter your identification manually, perform the following:
  - Use the keypad to enter your identification name or number.
  - If the identification is incorrect, press the backspace (←) button on the keypad to delete the wrong identification. Then, re-enter the correct identification using the keypad.
  - If the identification is correct, press the **'Enter'** button. The **'Select a function'** screen will appear.

## Section 4.3 Load Processing Set(s)

1. Use the arrow buttons to select the **'Run Treatment'** option.
2. Press the **'Enter'** button. The **'Select number of containers to treat'** screen will appear.



✉ **NOTE:** At any time, when entering information into the illuminator, you may press the **'Cancel Treatment'** button. This will remove any information that you have entered and you will go back to the **'Select a function'** screen.

3. Use the arrow buttons to select the number of containers to illuminate.
4. Press the **'Enter'** button.

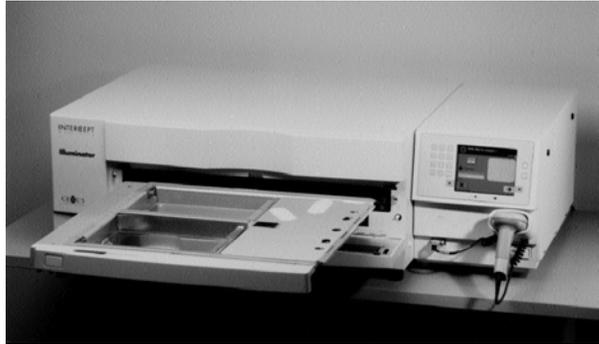
✉ **NOTE:** The illuminator default is set for you to illuminate two containers using both chambers 1 (front chamber) and 2 (back chamber). Under normal circumstances, if you wish to illuminate just one container, then you must use chamber 1. If, however, the front chamber has malfunctioned and cannot be used, then you may use chamber 2 to illuminate one platelet or one plasma product.

5. Open the front door of the illuminator.



✉ **NOTE:** If the door is not opened, then an information screen will appear to remind you to open the door.

6. Pull out the drawer.



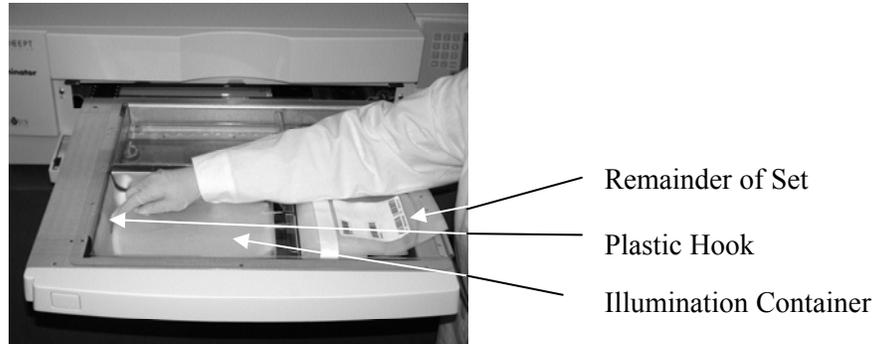
7. Open the cover of the tray by sliding the black latch to the right.  
(The cover will open to the right.)



**⚠ WARNING** All materials containing platelets or plasma (including tubing) must be placed within the large compartment of the illuminator tray for adequate treatment to occur. The INTERCEPT Blood System is validated with unimpeded light transmission through the tray and the illumination container with the blood component. No labels or other material should be on this area. Labels should be placed on the illumination container flap only. The tray must be clean. The illumination container should not be folded.

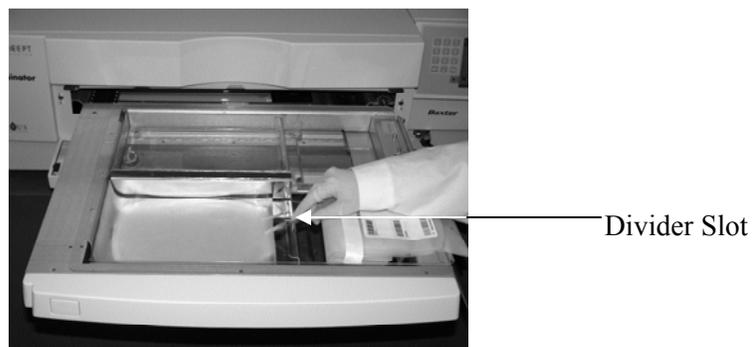
**✉ NOTE:** Chamber locations are embossed on the tray. Chamber 1 is the front compartment. Chamber 2 is the rear compartment. The left-hand side of each chamber is the illumination side, marked by a sun symbol.

- Place the illumination container, marked with the number 1, into the front illumination chamber 1, in the left-hand side of the tray.
- Secure the container flap onto the plastic hook in the tray.



- Put the tubing from the illumination container in the slot of the divider. Make sure that the sealed tubing containing blood product is within the left-hand side of the chamber.

**WARNING** The tubing containing the blood product mixed with amotosalen must be held within the left-hand side of the chamber where illumination occurs. Platelet or plasma product in the tubing which is not entirely within the area receiving illumination will not be pathogen inactivated.



Chapter 4 – How to Use the Illuminator  
Section 4.3 – Load Processing Set(s)

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11. Place the other containers into the right-hand side of the front chamber 1 so that the final storage container label is facing up.

☒ **NOTE:** Ensure that the containers in the right-hand side of the chamber remain secure.

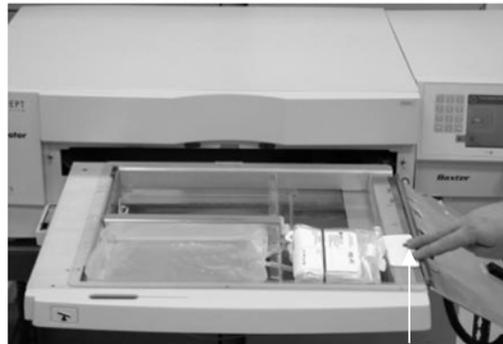
12. Secure the set to the drawer by putting the alignment holes over the pegs.

Platelet Product



Alignment  
Holes

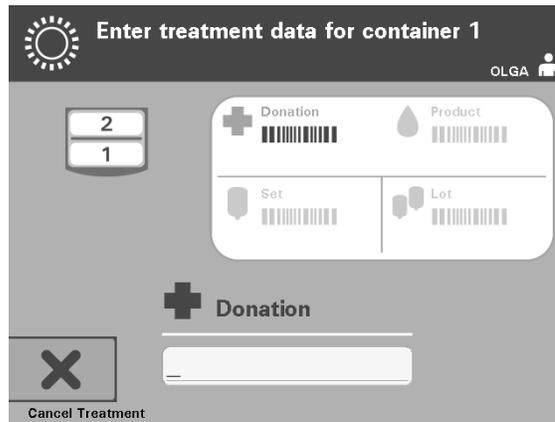
Plasma Product



Alignment  
Holes

☒ **NOTE:** If you are treating two blood products, you may load the second processing set into the rear chamber 2 at this time or after scanning the barcodes for the first set. Refer to Section 4.5, “**Repeat Set Loading for Container 2**” for loading container 2.

## Section 4.4 Scan Barcodes



The **'Enter treatment data for container 1'** screen will appear.

1. Scan the barcodes from the final storage container in the following order:

Symbol		Description
	Barcode 1	Donation number (applied by your facility)
	Barcode 2	Blood product code (applied by your facility)
	Barcode 3	INTERCEPT set code (product)
	Barcode 4	INTERCEPT manufacturing lot number

The barcode symbol on the screen is dark before the barcode has been entered. After the barcode has been entered the symbol will change to gray with a check mark across it.

- ✉ **NOTE:** Data entry methods (barcode scanned or manually entered) for treatment data must be the same between the illuminator and the data management system.
- ✉ **NOTE:** The maximum number of characters in a barcode that may be entered is 17.
- ✉ **NOTE:** At any time, when entering information into the illuminator, you may press the **'Cancel Treatment'** button. This will remove any information that you may have entered and you will go back to the **'Select a function'** screen.

- If the barcode cannot be scanned, you may enter the information manually by performing the following:

	<ul style="list-style-type: none"><li>• Use the keypad to enter the human-readable barcode. Special characters may be entered by pressing the '1' button. Refer to Section 3.4 for the special characters.</li><li>• Press the <b>'Enter'</b> button. The <b>'Confirm Barcode'</b> screen will appear.</li><li>• If the barcode is incorrect, press the <b>'Edit'</b> button. The <b>'Enter treatment data for container 1'</b> screen will appear.</li><li>• Using the keypad, press the backspace (←) button to delete the wrong barcode. Then, re-enter the correct barcode using the keypad.</li><li>• Press the <b>'Enter'</b> button. The <b>'Confirm Barcode'</b> screen will appear.</li><li>• If the barcode is correct, press the <b>'OK'</b> button to confirm the barcode. The <b>'Enter treatment data for container 1'</b> screen will appear.</li><li>• Repeat the above steps until all the barcodes have been entered.</li></ul>
--	---

✉ **NOTE:** Each barcode symbology has a specific data input format. Refer to Section 7.4 for guidelines of manual entry for specific barcode formats.

When all the barcodes have been scanned for container one, a **'Done'** button will appear at the bottom of the screen.

⚠ **WARNING** **Make sure the barcodes and chamber position of each container are correctly entered into the illuminator.**

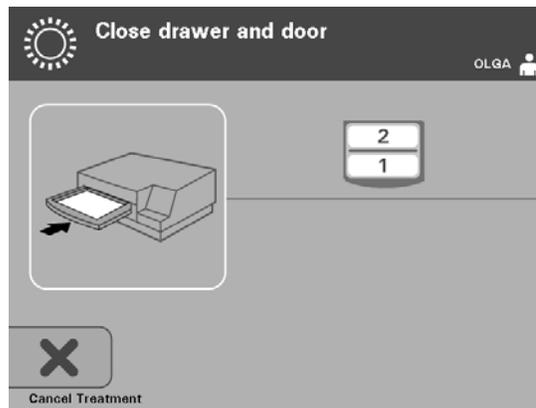
- Press the **'Done'** button.

## Section 4.5 Repeat Set Loading for Container 2

If two containers have been selected for treatment, the **'Enter treatment data for container 2'** screen will appear.

Follow previous steps in Sections 4.3 and 4.4 to load the second set into the illuminator tray and scan barcodes, placing second container in the rear chamber 2.

The **'Close drawer and door'** screen will appear.



Platelet Product



Plasma Product

**! CAUTION** Make sure all tubings are in the tray before closing the cover and drawer.

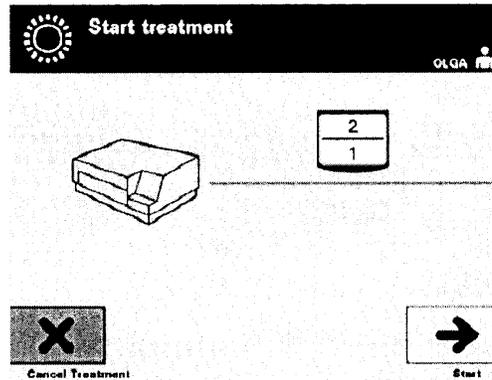
1. Close the tray cover and ensure that it is secured by the black latch.
2. Push the drawer into the illuminator until it clicks in place.
3. Close the door.

**✉ NOTE:** The door will lock and the agitator will start automatically when the door is closed.

## Section 4.6      **Begin Illumination Process**

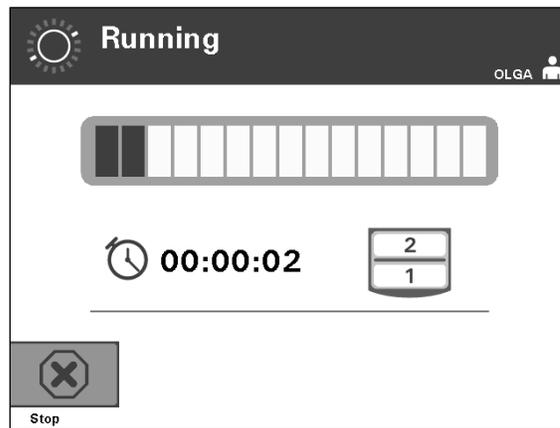
The **'Start treatment'** screen will appear.

The **'Start treatment'** screen will appear.



✉ **NOTE:** Pressing the **'Start'** button is not required for treating plasma products but is required when treating platelet products.

1. Press the **'Start'** button. The **'Running'** screen will appear.



✉ **NOTE:** The blue bar moves to the right as the illumination progresses and is based on the target dose. The numbers beside the clock show how much time has elapsed since illumination began.

## Section 4.7 Illumination Interruption

**!** **CAUTION** Illumination should not be interrupted, unless it is absolutely essential. It will result in improperly treated blood product(s) that should be discarded.

1. To stop illumination at any time, press the **'Stop'** button. The **'Are you sure you want to stop treatment?'** screen will appear.
2. Press the **'No'** button to resume the treatment or press the **'Yes'** button to end the treatment. Treatment continues until you press the **'Yes'** button. If you press the **'Yes'** button you cannot resume or begin treatment again.

**✉ NOTE:** If the treatment has stopped, the record for any blood product in the illuminator will be marked as Incomplete.

**⚠ WARNING** **Partial illumination has not been validated for pathogen inactivation. Do not attempt to re-treat a partially treated unit. Do not treat a blood product more than once. No claim of pathogen inactivation can be supported for partially illuminated units and they should be discarded.**

### **Other Illumination Interruption**

The following can cause interruption in illumination:

- Power failure
- Opening the side access panel
- Error messages related to a sensor failure

If a single interruption or the accumulation of several interruptions exceeds 10 minutes, the record for any blood product in the illuminator will be marked as Incomplete.

## Section 4.8 Unload the Processing Set(s)

When the illumination of the blood product(s) has finished, the **‘Complete’** screen, which has an orange background, will appear.



- The illuminator will make a pair of triple beep sounds (i.e., beep-beep-beep, pause, beep-beep-beep).

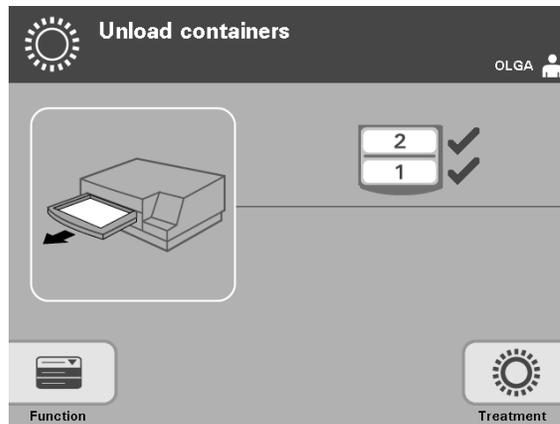
If the illumination treatment was properly completed, a “√” mark will appear next to the chamber icon on the screen. If there was a problem, an “X” will appear next to the chamber icon.

Symbol	Status
√	Complete
X	Incomplete

**⚠ WARNING** **Partial illumination has not been validated for pathogen inactivation. Do not attempt to re-treat a partially treated unit. Do not treat a blood product more than once. No claim of pathogen inactivation can be supported for partially illuminated units and they should be discarded.**

- ✉ **NOTE:** The platelet product(s) should be removed from the illuminator within 30 minutes of completion. After that, the treatment record(s) for platelet product(s) will be recorded as Incomplete.
- ✉ **NOTE:** The plasma product(s) should be removed from the illuminator according to your facility’s procedure for freezing plasma after completion of illumination. After 8 hours, the treatment record(s) for the plasma product(s) will be recorded as Incomplete.

- The screen will start counting the elapsed number of minutes, after the illumination has been completed.
  - The agitator will continue shaking the containers for platelet products but stop for plasma products.
  - Approximately every 2 minutes the illuminator will make a beep sound to remind you that the containers need to be removed from the illuminator.
1. Press the **'Unlock Door'** button and an information screen will appear to confirm that label printing is occurring.
  2. When the labels have printed, the door will unlock. The **'Unload containers'** screen will appear.



3. Open the front door of the illuminator.
  4. Pull out the drawer and open the cover.
  5. Check the screen for the treatment status symbol. Follow your facility's procedures for handling product(s) recorded as Incomplete.
  6. When the label has printed, place the appropriate label on each illumination container and remove the container(s) from the tray.
- ✉ **NOTE:** When placing the label on the illumination container, the label can be matched to the correct product by the donation number and by the chamber number located on the lower left corner of the label.

**This completes the illumination process.**

- ✉ **NOTE:** If the status of the treatment is unknown, review the treatment report to verify the status. Refer to Section 4.10 for printing treatment reports.

Refer to the Instructions for Use in the INTERCEPT Processing Set for the next steps in the process.

**Process  
Additional  
Blood  
Products**

1. Press the **'Treatment'** button. The **'Select number of containers to treat'** screen will appear.
2. Repeat the steps described earlier, beginning with Section 4.3, "Load Processing Set(s)."

## Section 4.9 Labels

## Optional Printing Treatment Reports and Additional

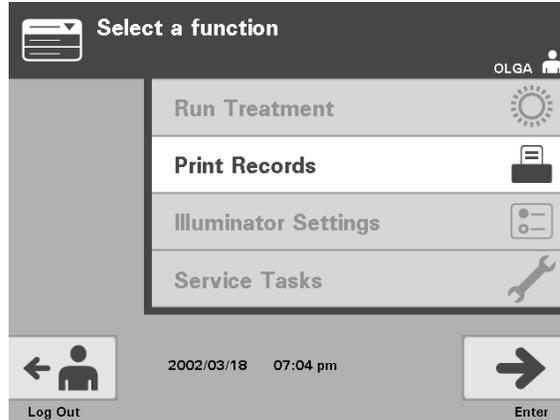
## Additional

When the illuminator is configured to print reports (refer to Section 3.6, Illuminator Settings, for details), four options are available. They are printing the last treatment manually, printing a specific treatment, printing a shift report, or printing labels. The following will describe how to create these reports once the printer is connected and the illuminator is configured.

When the auto-printing option is chosen, the last treatment report(s) will automatically be printed when the procedure is complete during the container unloading. No further operator intervention is required.

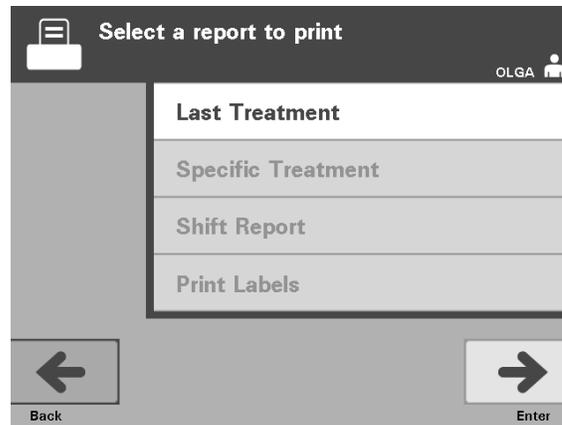
All of the following printing options are accessible from the **'Select a report to print'** screen. To access this screen, perform the following:

1. After logging into the illuminator, the **'Select a function'** screen will appear. If the **'Unload containers'** screen is present, press the **'Function'** button to return to the **'Select a function'** screen.
2. Use the arrow buttons to choose the **'Print Records'** option. The **'Select a report to print'** screen will appear.



Use these steps to access the report printing options or press the **'Back'** button to get back to the previous screen or the **'Select a report to print'** screen while you are printing reports.

- ✉ **NOTE:** If the status of the treatment is unknown, review the treatment report to verify the status.

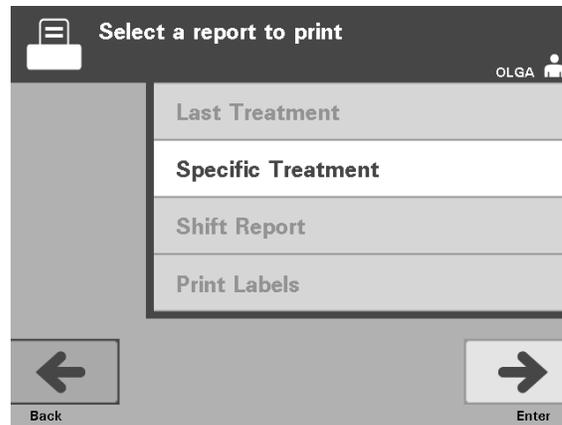


### Last Treatment

The Last Treatment option refers to the last procedure performed on the illuminator. To print this report, perform the following:

1. While in the **'Select a report to print'** screen, use the arrow buttons to choose **'Last Treatment'** option.
2. Press the **'Enter'** button to select the option. The **'Print the last treatment report'** screen will appear.
3. If this screen is incorrect, press the **'Back'** button. The **'Select a report to print'** screen will appear. Use the arrow buttons to choose the **'Specific Treatment'** option. (Refer to the Specific Treatment Section below.)
4. If the **'Print the last treatment report'** screen is correct, press the **'Print'** button. The **'Printing Last Treatment Report'** information screen will appear to confirm that printing is occurring.
5. When the report has been printed, the **'Select a report to print'** screen will appear.

✉ **NOTE:** The treatment report will contain information specific to the treatment selected. This will include, illuminator identification (ID), donation number, blood product code, operator ID, treatment start date / time and treatment status.



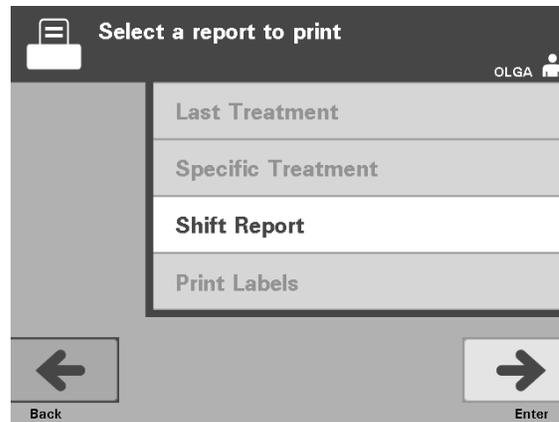
### **Specific Treatment**

The Specific Treatment option refers to a selected product treated by the illuminator. To print this report, perform the following:

1. While in the **'Select a report to print'** screen, use the arrow buttons to choose **'Specific Treatment'** option.
2. Press the **'Enter'** button to select the option. The **'Select a treatment to print'** screen will appear.
3. Use the arrow buttons to choose the desired treatment. If the treatment is not listed on the screen, press the advance ( **↩** ) or backspace ( **↪** ) buttons on the keypad to display the next pages of treatments. Continue to use these buttons until you find the correct page with the desired treatment listed. Then use the arrow buttons to choose the desired treatment.

✉ **NOTE:** The treatments will be listed by date, time and donation number in chronological order.

4. Press the **'Enter'** button to select the desired treatment. The **'Print the displayed treatment report'** screen will appear.
5. If the report is incorrect, press the **'Back'** button to return to the **'Select a treatment to print'** screen. Repeat the steps to choose the desired treatment to print.
6. If the report is correct, press the **'Print'** button. The **'Printing Selected Treatment Report'** information screen will appear to confirm that printing is occurring.
7. When the report has been printed, the **'Select a report to print'** screen will appear.



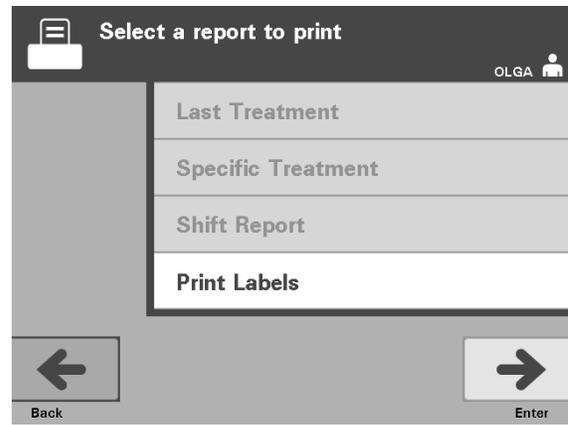
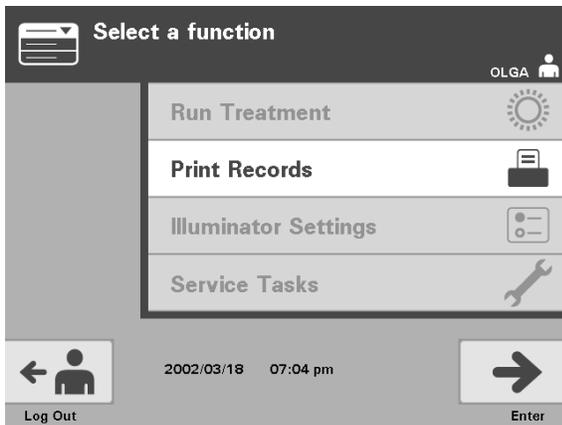
### **Shift Report**

The Shift Report option refers to a specific 24-hour day in which treatments were performed on the illuminator. To print this report, perform the following:

1. While in the **'Select a report to print'** screen, use the arrow buttons to choose the **'Shift Report'** option.
2. Press the **'Enter'** button to select the option. The **'Select a shift report to print'** screen will appear.
3. Use the arrow buttons to choose the desired date. If the date is not listed on the screen, press the advance (↩→) or backspace (←↪) buttons on the keypad to display the next page(s) of dates. Continue to use these buttons until you find the correct page with the desired date listed. Then use the arrow buttons to choose the desired date.

✉ **NOTE:** The shifts will be listed by date and number of treatments in reverse chronological order.

4. Press the **'Print'** button to select the desired date. The **'Printing shift report'** screen will appear.
5. When the report has been printed, the **'Select a report to print'** screen will appear.



## Print Additional Labels

To print additional labels, perform the following:

1. Return to the **'Select a function'** screen by selecting the **'Function'** button on the **'Unload containers'** screen.
2. Use the arrow buttons to choose the **'Print Records'** option.
3. Press the **'Enter'** button. The **'Select a report to print'** screen will appear.
4. Use the arrow buttons to choose the **'Print Labels'** option.
5. Press the **'Enter'** button to select this option. The **'Select a treatment to print'** screen will appear.
6. Use the arrow buttons to choose the desired treatment. If the treatment is not listed on the screen, press the advance (↩→) or backspace (←↪) buttons on the keypad to display the next pages of treatments. Continue to use these buttons until you find the correct page with the desired treatment listed. Then use the arrow buttons to choose the desired treatment.

✉ **NOTE:** The treatments will be listed by date, time and donation number in chronological order.

7. Press the **'Enter'** button to select the desired treatment. The **'Print the selected treatment labels'** screen will appear. A confirmation screen will appear.
8. Press the **'Print'** button to select this option.

✉ **NOTE:** The number of labels that print will be determined by the label printer configuration setting.

9. When the labels have been printed, the **'Select a report to print'** screen will appear.

## **Section 4.10      Change Users Before the Next Illumination Cycle**

If a different operator is performing the treatment process, perform the following:

1. Press the **'Function'** button on the **'Unload containers'** screen. The **'Select a function'** screen will appear.
2. Press the **'Log out'** button on the **'Select a function'** screen. The **'Log In'** screen will appear.
3. Repeat the steps to log in, found in Section 4.2, "Turn On the Illuminator and Log In."

## **Section 4.11      Turn Off the Illuminator**

If you want to turn off the illuminator:

1. Press the **'Function'** button on the **'Unload containers'** screen.  
The **'Select a function'** screen will appear.
2. Press the **'Log out'** button. The **'Log In'** screen will appear.
3. Press the power switch.
4. The illuminator will transition to a battery back-up power supply to enable software to shut down successfully.
5. Once this has been completed, the illuminator power will turn off.

## Section 4.12 Questions and Answers

? **Q & A:** *What will happen if the self-tests are not successful?*

- If the self-tests are not successful, an error message will appear on the screen with additional instructions. However, if these additional instructions are not helpful, turn the illuminator off, wait until the screen darkens, then turn it back on. If this does not resolve the issue, contact your authorized service representative for assistance.

? **Q & A:** *What should you do if your operator badge will not scan into the illuminator?*

- If your operator badge will not scan into the illuminator, manually enter your identification number into the illuminator using the keypad.

? **Q & A:** *How will you know if only one of the drawer chambers is working and can be used?*

- When only one chamber is working and can be used, the illuminator will display which chamber is available in the last option of the menu on the **'Number of containers'** screen. There will be a blue **'X'** on the screen across the chamber that is not working and cannot be used. This is shown in the examples below. Therefore, if chamber 1 is not working, you can use chamber 2 to perform the illumination process. As you will not be able to select two containers, the arrow buttons will not work at this stage.



? **Q & A:** *What should you do if one of the chambers cannot be used?*

- When one of the chambers cannot be used, you may use the other chamber, if the **'Run Treatment'** choice is offered. This screen will show a number for the chamber that can be used and an **'X'** for the chamber that cannot be used. Some problems are such that no treatment may be performed, so the **'Run Treatment'** choice is not offered. Call your authorized service representative for assistance.

? **Q & A:** *What if the containers are not removed from the illuminator within the required amount of time?*

- The treatment record will be marked as incomplete. Follow your center guidelines or contact the medical director, to determine if the product is acceptable.

**? Q & A:** *What should you do if you are unable to locate a treatment record?*

- To locate a treatment record in the illuminator, refer to Section 4.9, Optional Printing Treatment Reports and Additional Labels. See Specific Record for details on how to find a treatment record. If you cannot locate a record for a given product, follow your center's guidelines, or contact the medical director. The status of a blood product cannot be determined without a treatment record, and should be regarded as Incomplete.

**? Q & A:** *What should you do if a treatment record is marked as Incomplete?*

- Follow your center's guidelines or contact the medical director, since the pathogen inactivation process has not been validated for products recorded as Incomplete.

**? Q & A:** *Why would a label be placed on the illumination container after treatment?*

- If there are multiple illuminators at a blood center or a single illuminator for treating plasma, means must be employed to protect against release of a double illuminated blood product.
- The label applied to the illumination container after treatment, provides visual evidence that the unit received partial or complete treatment in the illuminator, and should not be re-illuminated.
- Use of the INTERCEPT Data Management System is another means of protecting against release of a double illuminated blood product.

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## Chapter 5.      **Troubleshooting**

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
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5.2      Summary of Questions and Answers	5-4
5.3      Error Messages	5-8
5.4      System Issue Messages	5-25
5.5      Confirmation Messages	5-26
5.6      Information Messages	5-27

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## Section 5.1 Introduction

During an INTERCEPT procedure, a “pop-up” message may describe events ranging from errors to general procedure information.

These are the types of messages that can occur during a procedure:

Symbol	What the Symbol Means
	<p>Error            The error messages will be indicated by a red bordered pop-up screen and have an exclamation point in a yellow diamond.</p>
	<p>System issue            The system issue message will be indicated by a red screen with white lettering. These screens are used to alert the operator of critical issues with the illuminator.</p>
	<p>Confirmation            The confirmation messages will be indicated by a blue bordered pop-up screen containing a checkmark in a box. These screens are used to confirm that the entered data is correct.</p>
	<p>Informational            The information messages will be indicated by a blue bordered pop-up screen with a lowercase ‘i’ in a circle. These screens indicate what is currently occurring.</p>

Each message screen will contain information related to the operation of the illuminator or an intervention the operator should perform. Follow the directions on the screen to resolve issues or confirm information. If error messages continue to occur, contact your authorized service representative for assistance.

## Section 5.2 Summary of Questions and Answers

The following is a list of the Questions and Answers used in the Operator's Manual.

### Chapter 3: ILLUMINATOR DESCRIPTION

**? Q & A:** *Whom should you contact if the illuminator is damaged?*

- If you notice the illuminator is damaged, contact your authorized service representative. Please refer to the front of this manual for contact details.

**? Q & A:** *How do you know that the containers receive the correct amount of light?*

- Each illuminator chamber has 4 photodiode sensors, 2 at the top and 2 at the bottom. These sensors measure the amount of light through the blood product with every treatment cycle and the illuminator adjusts the time of the cycle to provide the correct light dose.
- As a secondary check, the illuminator software checks the treatment time to make sure that it is within the appropriate range set by the authorized service representative.
- The bulbs will need changing if the time approaches the limit for adequate illumination. The light system is automatically checked during power on or every 24 hours, and during power failure recovery.
- The sensors are calibrated by your authorized service representative when the illuminator is installed and during preventive maintenance.

**? Q & A:** *What should you do if the barcode scanner does not work?*

- Occasionally, the barcode scanner will not scan the barcodes on the containers. If this happens, enter the numbers of the barcode into the illuminator manually via the keypad. Refer to Sections 3.4 and 4.4 for instructions.
- If the problem seems to be with the scanner, not the barcode label, contact your authorized service representative for assistance.

**? Q & A:** *What should you do if the treatment time on the printed report begins to consistently exceed the approximate time range?*

- Occasionally, the treatment time on the printed report will exceed the approximate time range. This is an indication the bulbs are becoming dimmer. If the treatment time exceeds the appropriate range as set by the authorized service representative, a message will display to change the bulbs.

- If the treatment time is consistently exceeding the approximate range but no message has occurred, the illuminator is delivering the appropriate dosage for the blood product. The bulbs may be changed before the message appears.
- Contact your authorized service representative to change the bulbs.

#### Chapter 4: HOW TO USE THE ILLUMINATOR

? **Q & A:** *What will happen if the self-tests are not successful?*

- If the self-tests are not successful, an error message will appear on the screen with additional instructions. However, if these additional instructions are not helpful, turn the illuminator off, wait until the screen darkens, then turn it back on. If this does not resolve the issue, contact your authorized service representative for assistance.

? **Q & A:** *What should you do if your operator badge will not scan into the illuminator?*

- If your operator badge will not scan into the illuminator, manually enter your identification number into the illuminator using the keypad.

? **Q & A:** *How will you know if only one of the drawer chambers is working and can be used?*

- When only one chamber is working and can be used, the illuminator will display which chamber is available in the last option of the menu on the **'Number of containers'** screen. There will be a blue **'X'** on the screen across the chamber that is not working and cannot be used. This is shown in the examples below. Therefore, if chamber 1 is not working, you can use chamber 2 to perform the illumination process. As you will not be able to select two containers, the arrow buttons will not work at this stage.



? **Q & A:** *What should you do if one of the chambers cannot be used?*

- When one of the chambers cannot be used, you may use the other chamber, if the **'Run Treatment'** choice is offered. This screen will show a number for the chamber that can be used and an **'X'** for the chamber that cannot be used. Some problems are such that no treatment may be performed, so the **'Run Treatment'** choice is not offered. Call your authorized service representative for assistance.

**? Q & A:** *What if the containers are not removed from the illuminator within the required amount of time?*

- The treatment record will be marked as Incomplete. Follow your center guidelines or contact the medical director, to determine if the product is acceptable.

**? Q & A:** *What should you do if you are unable to locate a treatment record?*

- To locate a treatment record in the illuminator, refer to Section 4.9, Optional Printing Treatment Reports and Additional Labels. See Specific Record for details on how to find a treatment record. If you cannot locate a record for a given product, follow your center's guidelines, or contact the medical director. The status of a blood product cannot be determined without a treatment record, and should be regarded as Incomplete.

**? Q & A:** *What should you do if a treatment record is marked as Incomplete?*

- Follow your center's guidelines or contact the medical director, since the pathogen inactivation process has not been validated for products recorded as Incomplete.

**? Q & A:** *Why would a label be placed on the illumination container after treatment?*

- If there are multiple illuminators at a blood center or a single illuminator for treating plasma, means must be employed to protect against release of a double illuminated blood product.
- The label applied to the illumination container after treatment, provides visual evidence that the unit received partial or complete treatment in the illuminator, and should not be re-illuminated.
- Use of the INTERCEPT Data Management System is another means of protecting against release of a double illuminated blood product.

#### Chapter 5: TROUBLESHOOTING

**? Q & A:** *What should you do if the system issue screen appears?*

- The system issue message is used to alert the operator of critical issues with the illuminator. Turn the illuminator OFF, wait 10 seconds, then turn it back on. Should the system issue screen continue to occur, contact your authorized service representative for assistance.

**? Q & A:** *What should you do if an error occurs?*

- On most error screens, there are two buttons: an **'OK'** button and a **'Cancel'** button. If an error occurs, follow the instructions on the screen to resolve the issue and select the **'OK'** button. If you have tried to resolve the issue and cannot, select the **'Cancel'** button. This button should only be selected if there is a problem and it cannot be resolved as it disables the **'Run Treatment'** option. If this issue cannot be resolved, contact your authorized service representative for assistance.

**? Q & A:** *What should you do if the service light comes on?*

- The service light indicates that the illuminator needs servicing. The illuminator will display a message indicating the reason for the issue when the service light turns on. For example, the service light may be turned on when an accessory printer or data management system is not responding, or when there is a problem with one of the illuminator's sensors. Refer to the message to determine the cause of the light.

## Section 5.3 Error Messages



The error messages will be indicated by a red-bordered pop-up screen and will have an icon with an exclamation point in a yellow diamond.



The error messages, or alarm messages, account for the largest portion of the possible pop-up messages in this Section. Therefore, error messages will be divided into subcategories. These subcategories will make it easier to rapidly locate pertinent information. The subcategories are:

- Agitator
- Bulbs
- Data Entry
- Drawer
- Fan
- Front Door
- Integrity Check Issues (Self-tests)
- Processing Sets and Treatment
- Hardware Accessories
- Side Access Panel

The pop-up text message will dictate in which section the information will be found. For example, if the text message displayed in the error pop-up is **‘Treatment stopped by operator. Check treatment status.’** the information for this message would be found in the Processing Sets and Treatment Section.

**Agitator**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
There is an issue with the agitator. Treatment must be canceled. Contact service for assistance.	The agitator is stopped or is moving slowly. Contact your authorized service representative for assistance.	On after <b>'Cancel'</b> is selected
Hold time exceeded.	The <b>'Unlock Door'</b> button is not pressed and the product is not removed within the required time after illumination. Follow your facility's guidelines for products marked Incomplete.	Off

**Bulbs**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
The bulbs are not working properly in chamber(s) (1, 2 or both). Treatment has been stopped in chamber(s) (1, 2 or both).	Bulbs need to be replaced. Contact your authorized service representative for assistance.	On after <b>‘Continue’</b> is selected
The illumination sensors are not working properly. Treatment must be canceled.	There are issues with the illumination sensors. Contact your authorized service representative for assistance.	On after <b>‘Cancel’</b> is selected
There is an issue with the illumination sensors. Treatment must be canceled. Contact service for assistance.	There are issues with the illumination sensors. Contact your authorized service representative for assistance.	On after <b>‘Cancel’</b> is selected
A Treatment Issue has occurred (T1004). Replace bulbs ‘X’ and ‘Y’. Refer to the Operator’s Manual for assistance.	The listed bulbs need to be replaced. Contact your authorized service representative for assistance.	Off
An Integrity Check Issue has occurred (C0011). Contact service for assistance.	There are issues with the illumination sensors. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred. (C0012). Contact service for assistance.	There are issues with the illumination sensors. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0013). Replace bulbs ‘X’ and ‘Y’. Refer to the Operator’s Manual for assistance.	The listed bulbs need to be replaced. Contact your authorized service representative for assistance.	On

**Data Entry**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
The alphanumeric string is too long to fit in the data field. It will be truncated for display purposes.	There are too many characters in an entry field. The entry field is limited to 17 characters.	Off
The Set ID does not match a required set code. Touch Edit to re-enter the Set ID.	The illuminator was not configured to use the selected processing set. Ensure the barcode data has been entered in the correct order. If this message continues to occur, contact your authorized service representative.	Off
The valid range for labels is 0 – 6. Touch Edit to re-enter the number of labels to print.	The number entered for labels to be printed was greater than 6.	Off
The entered date is invalid. Touch Edit to re-enter the date.	The date was not entered in the correct format. You must enter 2 numbers each for the month and day fields and 4 numbers for the year field. See Section 3.6 for details.	Off
The entered time is invalid. Touch Edit to re-enter the time.	The time was not entered in the correct format. You must enter 2 numbers each for the hour and minute fields. See Section 3.6 for details.	Off
The entered TCP/IP address is invalid. Touch Edit to re-enter the address.	The TCP/IP address was not entered in the correct format. You must enter 12 characters for the address. See Section 3.6 for details.	Off

**Data Entry**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
<p>Format Error.            The data does not match the selected format for this field. Please press Cancel to re-enter the data.</p>	<p>The data entered into a field does not match the selected format. Upon canceling the pop-up message, re-enter the data in the correct format or press Cancel to quit the treatment.</p>	Off
<p>Checksum Error.            The data entered cannot be verified. Please press Cancel to re-enter the data.</p>	<p>The selected format for the data field includes a checksum and the checksum does not match the calculation made in the software. Upon canceling the pop-up message, re-enter the data or press Cancel to quit the treatment.</p>	Off
<p>Symbology Error.            The barcode symbology scanned is not allowed for this field. Please press Cancel to re-enter the data.</p>	<p>The barcode scanner sends a symbology code that is not allowed for the field being read. Upon canceling the pop-up message, re-enter the data or press Cancel to quit the treatment.</p>	Off

**Drawer**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
Open the door and drawer and complete entry of treatment data. Touch OK to continue or Cancel to quit.	The drawer is closed before the treatment data has been entered. Open the drawer and enter the treatment data.	On after <b>'Cancel'</b> is selected
Open the door and drawer. Make sure there are no sets in the illuminator. Close the drawer and door when finished. Touch OK to continue or Cancel to quit.	Processing set(s) are in the illuminator and should not be. Remove the processing set(s) and continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected
Close the drawer. Touch OK to continue or Cancel to quit.	The drawer is open and it should be closed. Close the drawer and continue. If this message continues to occur, contact your authorized service representative.	Off
Open the door, and push the drawer into the latched position. Close the door. Touch OK to continue or Cancel to quit.	The drawer is unlatched and it should be latched. Close the drawer and continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected

**Fan**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
The fan is not working properly. Check that the fan's air intake is not blocked and that the air filter is clean. Touch OK to continue or Cancel to quit.	The fan is not working properly, or the air filter is blocked or missing. Ensure the air filter is clean and present. See Section 6.3 for cleaning instructions. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected

**Front Door**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
Close the door and drawer. Touch OK to continue or Cancel to quit.	The door and/or drawer are open and should be closed. Close the drawer and door to continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected
The door is unlocked. Open and close the door. Touch OK to continue or Cancel to quit.	The door is unlocked and should be locked. Open and close the door to continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected
Open the door and drawer and complete entry of treatment data. Touch OK to continue or Cancel to quit.	The drawer is closed before the treatment data has been entered. Open the drawer and enter the treatment data.	On after <b>'Cancel'</b> is selected
Open the door and drawer. Make sure there are no sets in the illuminator. Close the drawer and door when finished. Touch OK to continue or Cancel to quit.	Processing set(s) are in the illuminator and should not be. Remove the processing set(s) and continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected
The door did not lock. Open and close the door. Touch OK to continue or Cancel to quit.	The door is unlocked and should be locked. Open and close the door to continue. If this message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected

Chapter 5 – Troubleshooting  
 Section 5.3 – Error Messages

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
<p>The door is open. Open and close the door. Touch OK to continue or Cancel to quit.</p>	<p>The door is open and should be closed. Close the drawer and door to continue. If this message continues to occur, contact your authorized service representative for assistance.</p>	<p>On after <b>'Cancel'</b> is selected</p>
<p>The door is locked and should not be. Touch Cancel to quit. Contact service for assistance.</p>	<p>The door is locked and should be unlocked. Try gently pushing on the door to release the lock. If that does not work and there are processing sets in the illuminator, turn the illuminator off to release the lock. If this message continues to occur, contact your authorized service representative for assistance.</p>	<p>On</p>

**Integrity  
Check Issues  
(Self-tests)**

These are the self tests that the illuminator runs each time the power is turned on or every 24 hours. These tests ensure that the device is working properly.

Message	This occurs if:	Service Light
An Integrity Check Issue has occurred (C0002). Contact service for assistance.	A problem is detected during the self-tests. Contact your authorized service representative for assistance.	Off
An Integrity Check Issue has occurred (C0003). Contact service for assistance.	A problem is detected during the self-tests. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0004). Contact service for assistance.	A problem is detected during the self-tests. Ensure the side access panel is closed. Turn the illuminator off, wait until the screen darkens, then turn on to restart the illuminator. If this message continues to occur, contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0005). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator and open the door. Open and close the drawer. Close the door and turn on the illuminator. If this message continues to occur, contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0006). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator. Open and close the door, then turn on the illuminator. If this message continues to occur, contact your authorized service representative for assistance.	On

Chapter 5 – Troubleshooting  
 Section 5.3 – Error Messages

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
An Integrity Check Issue has occurred (C0007). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator. Ensure no processing sets are in the drawer. Close the drawer and door, then turn on the illuminator. If this message continues to occur, contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0008). Contact service for assistance.	A problem is detected during the self-tests. Ensure the air filter is clean and present. See Section 6.3 for cleaning instructions. If this message continues to occur, contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0009). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator. Open and close the door, then turn on the illuminator. If this message continues to occur, contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0010). Contact service for assistance.	A problem is detected during the self-tests. The agitator is stopped or is moving slowly. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0011). Contact service for assistance.	A problem is detected during the self-tests. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0012). Contact service for assistance.	A problem is detected during the self-tests. Contact your authorized service representative for assistance.	On

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
An Integrity Check Issue has occurred (C0013). Replace bulbs 'X' and 'Y'.	A problem is detected during the self-tests. The listed bulbs need to be replaced. Contact your authorized service representative for assistance.	On
An Integrity Check Issue has occurred (C0014). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator. Ensure the tray is clean and present then turn on the illuminator. If this message continues to occur, contact your authorized service representative.	On
An Integrity Check Issue has occurred (C0016). Contact service for assistance.	A problem is detected during the self-tests. Turn off the illuminator. Check the cable connection from the barcode scanner to port 1 on the illuminator. Then, turn on the illuminator. If this message continues, data may be entered manually. If this message continues to occur, contact your authorized service representative.	On

**Processing Sets and Treatment**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
At least one of the sets has not received sufficient energy.	One or both processing sets did not receive enough UVA light. Refer to the <b>‘Complete’</b> screen for treatment status.	On
At least one of the sets has received an overdose of energy.	One or both processing sets has received too much UVA light. Refer to the <b>‘Complete’</b> screen for treatment status.	Off
Container(s) are not in the appropriate chamber(s). Treatment must be canceled.	The processing sets are in the wrong chambers or there is an issue with the placement sensors. Ensure the processing sets are correctly positioned. If this message continues to occur, contact your authorized service representative.	Off
The set(s) have not been properly placed in the illuminator. Treatment must be canceled.	The processing sets are in the wrong chambers or there is an issue with the placement sensor. Ensure the processing sets are correctly positioned. If this message continues to occur, contact your authorized service representative.	Off
The illumination time is longer than the maximum allowable illumination time.	The illumination time was too long. The bulbs may need to be changed. If this message continues to occur, contact your authorized service representative.	Off
The treatment time was shorter than the minimum required treatment time.	The treatment time was too short. Contact your authorized service representative for assistance.	Off
This container has already been treated. Treatment must be canceled.	The donation number and blood product code have been entered previously. Press the <b>‘Cancel’</b> button to cancel the treatment. Then, start the illumination process with a different blood product.	Off

Message	This occurs if:	Service Light
Treatment halted because of power failure. Containers are not in appropriate chambers. Treatment must be canceled.	There is a power failure during treatment and the processing sets have been removed from the illuminator. If processing sets are removed, the sets cannot be re-illuminated when the power returns. The treatment must be canceled.	Off
Treatment halted because of power failure. Touch Continue to finish or Stop to cancel treatment.	There is a power failure during a treatment. If less than 10 minutes have elapsed since the power failure and the processing sets are in place, press the <b>‘Continue’</b> button to resume the treatment.	Off
Treatment halted because of power failure for more than 10 minutes. Treatment is Incomplete.	The power to the illuminator was off for more than 10 minutes. The treatment must be canceled.  Or The treatment has been interrupted several times for an accumulated time over 10 minutes. The treatment must be canceled.	Off
A Treatment Issue has occurred (T1004). Replace bulbs ‘X’ and ‘Y’.	The bulbs listed need to be replaced. Contact your authorized service representative for assistance.	On
Hold time exceeded.	The <b>‘Unlock Door’</b> button is not pressed and the blood product is not removed within the required time after illumination. Follow your facility’s guidelines for products marked Incomplete.	Off
Treatment stopped by operator. Check treatment status.	The operator pressed the <b>‘Stop’</b> button during the illumination process.	Off
Blood component parameters do not match. Treatment must be canceled.	Two different kinds of set codes were loaded into the illuminator for treatment. For example, a large volume set and small volume platelet set cannot be illuminated together. Press the <b>‘Cancel Treatment’</b> button and start the process with identical kinds of set codes.	Off

**Hardware  
 Accessories**

Message	This occurs if:	Service Light
<p>The label printer is not working. Check that the label printer is connected to the illuminator, and it has adequate supplies. Touch OK to retry the label printer or Cancel to quit.</p>	<p>There is an issue with the label printer. Turn off the illuminator after treatment. Check the cable connection to port 3. Check the label printer for adequate paper and supplies. Turn on the illuminator and try to reprint labels. If this message continues to occur, contact your authorized service representative.</p>	<p>Off</p>
<p>The printer is not working. Check that the printer is connected to the illuminator, and that the printer has adequate paper and toner supplies. Touch OK to retry the printer or Cancel to quit.</p>	<p>There is an issue with the treatment printer. Turn off the illuminator after treatment. Check the cable connection to port 4. Check the printer for adequate paper and supplies. Turn on the illuminator and try to reprint the report. If this message continues to occur, contact your authorized service representative.</p>	<p>Off</p>
<p>The valid range for labels is 0 – 6. Touch Edit to re-enter the number of labels to print.</p>	<p>The number entered for labels to be printed is greater than 6.</p>	<p>Off</p>
<p>The entered TCP/IP address is invalid. Touch Edit to re-enter the address.</p>	<p>The TCP/IP address was not entered in the correct format. You must enter 12 characters for the TCP/IP address. See Section 3.6 for details.</p>	<p>Off</p>

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
<p>A Data Management issue has occurred (C0015).</p>	<p>The connection between the illuminator and the data management system has been interrupted. Check the TCP/IP address for accuracy. See Section 3.6 for details.</p> <p>After treatment, turn off the illuminator and check the cable connection to port 2. Then turn on the illuminator. If this message continues to occur, contact your System Administrator and/or your authorized service representative.</p>	<p>Off</p>
<p>The TCP/IP addresses define a subnet of greater than 1023 nodes. Both TCP/IP addresses must be re-entered. Touch Cancel to continue.</p>	<p>The TCP/IP addresses entered are invalid. Re-enter the data management TCP/IP address and the illuminator TCP/IP address. If this message continues to occur, contact your System Administrator and/or your authorized service representative.</p>	<p>Off</p>

**Side Access  
Panel**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
Close the side access panel. Touch OK to continue or Cancel to quit.	The side access panel is open and should be closed. Close the panel to continue. If the message continues to occur, contact your authorized service representative.	On after <b>'Cancel'</b> is selected

## Section 5.4 System Issue Messages

The system issues screens are full screens and will be in the following format:

A Safety Issue has occurred (S1XXX).

Contact service for assistance.

The systems issue alarms typically prevent continued use of the illuminator and may require intervention by a service representative. If a System Issue appears, the illuminator power must be turned off, wait until the screen darkens, and then you may turn on the device again. Note the S1XXX number for troubleshooting the issue, using the table below.

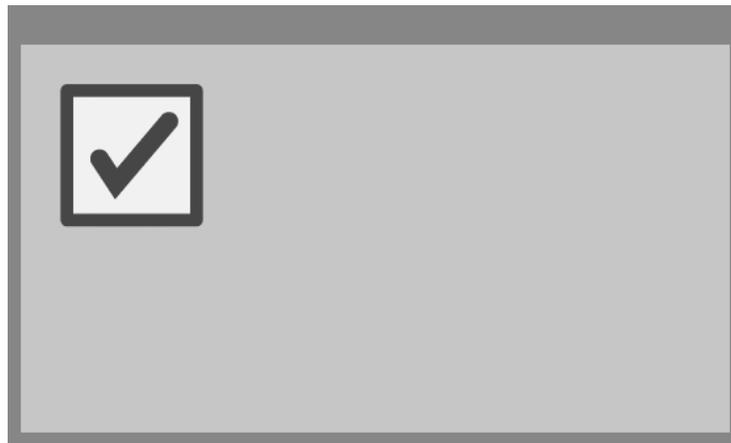
Message	This occurs if:	Service Light
A Safety Issue has occurred (S1007). Contact service for assistance.	The bulbs are on when they should be off. Contact your authorized service representative for assistance.	On
A Safety Issue has occurred (S1010). Contact service for assistance.	The agitator is moving slowly or moving when it should not be. Contact your authorized service representative for assistance.	On
A Safety Issue has occurred (S1012). Contact service for assistance.	There are issues with the software. Contact your authorized service representative for assistance.	On
A Safety Issue has occurred (S1013). Contact service for assistance.	There are issues with the software. Contact your authorized service representative for assistance.	On
A Safety Issue has occurred (S1014). Contact service for assistance.	A problem is detected. Contact your authorized service representative for assistance.	On

## Section 5.5 Confirmation Messages



This Section deals with non-alarm pop-up screens. The confirmation messages will be indicated by a blue-bordered pop-up screen containing an icon with a check mark in a box. These text messages will typically be displayed to provide general operator information. They will contain data entry information that should be confirmed to ensure accuracy of data.

In general these screens will contain **'Edit'** and **'OK'** function buttons. If the information is incorrect, press the **'Edit'** button to change the data. If the information is correct, press the **'OK'** button to proceed.



An exception to the Confirmation Message convention is when the **'Stop'** button is pressed during treatment. The following describes that message in detail. Refer to Section 4.7 for Illumination Interruption details.

Message	This occurs if:	Service Light
Are you sure you want to stop treatment?	The <b>'Stop'</b> button is pressed during a treatment. Press the <b>'No'</b> button to continue illuminating or the <b>'Yes'</b> button to quit.	Off

## Section 5.6 Information Messages



The information messages will be indicated by a blue-bordered pop-up screen with an icon of a lowercase ‘i’ in a circle. In general, these screens will provide operational status. For example, when printing labels, an information screen will appear stating labels are printing.



Exceptions to the Information Message standard are the messages listed below.

Message	This occurs if:	Service Light
Open the door and drawer to process treated set(s).	The door and drawer are not opened after treatment. Open the door and drawer to continue.	Off
Open the door and drawer. Place the container(s) to be treated into the illuminator’s tray and then scan or manually enter the required data.	The door and drawer are not opened before entering the data from the container(s).	Off
Illumination time was longer than normal. Replace the bulbs to improve throughput. Refer to the Operator’s Manual for assistance.	The treatment time is longer than expected. The bulbs should be replaced. Contact your authorized service representative for assistance.	Off

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## **Chapter 6. Maintenance, Transportation and Storage, Warranty and Service**

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
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6.2 Selecting a Place for the Illuminator	6-4
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## Section 6.1      **Installation: What to Expect When the Illuminator Arrives**

The illuminator will be unpacked and installed by your authorized service representative. The shipping container will include:

- (1) Illuminator (INT100)
- (1) Tray
- (2) Glass filter plates
- (1) Barcode scanner with operating instructions and cable

✉ **NOTE:** If you keep the original packaging from the illuminator, it may be reused in case the illuminator needs to be shipped.

## Section 6.2      **Selecting a Place for the Illuminator**

The illuminator should be:

- Placed on a solid and level surface capable of supporting the illuminator(s) and any optionally connected devices. See Chapter 7 for details.
- At least 8 cm (3 inches) away from anything that will block the air filter on the bottom left-hand side of the illuminator.

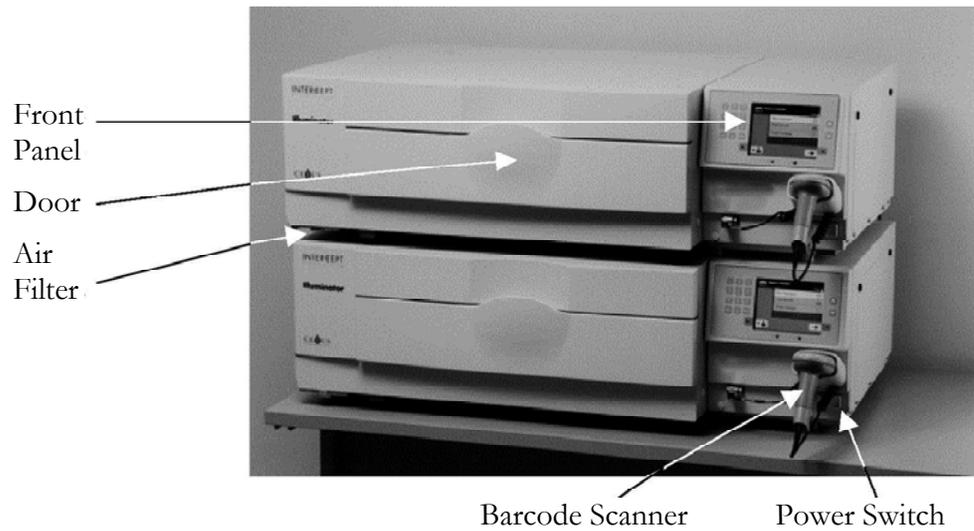
✉ **NOTE:** Place the illuminator so that there is enough space to open the left side access panel.

- Used in an environment that is maintained between +18° C and +30° C.

! **CAUTION** Do not use the illuminator if there is condensation on it. Humidity higher than 80% may shorten the life of instrument components.

⚠ **WARNING** **Lifting or carrying the illuminator should be done by a minimum of two people or by using a mechanical lifting device.**

The illuminators may be stacked two-high as shown below.



**⚠ WARNING**

**Do not stack illuminators more than two-high.**

**⚠ WARNING**

**If the blood product leaks into the tray, tilting the drawer could cause the blood product to spill out. If the tray is above the operator's eye level, the operator should wear eye protection when tilting the drawer.**

## Section 6.3      **Cleaning the Illuminator**

This Section gives information on procedures that should be used by trained personnel. Wear appropriate personal protective equipment when cleaning or disinfecting the instrument.

There are several parts of the illuminator that will need cleaning and / or disinfecting when they get dirty or contaminated with blood, including the outer cover, the tray and the air filter. This section contains information on how to clean or disinfect parts of the illuminator.

-  **WARNING**      **Turn off the illuminator and disconnect the power source before performing any maintenance on the illuminator.**
  
-  **WARNING**      **Blood products containing amotosalen should be treated like all other blood products, that is, as biohazardous material. Follow the guidelines for use of protective equipment, cleaning and disposal, as laid out in your facility.**

The following tables describe the cleaning and disinfectant solutions that may be used on the illuminator, including the maximum concentrations, if applicable. Use a soft cloth and the solutions recommended in each section, as applicable, for cleaning or disinfecting specific parts. Remove solutions using a soft cloth dampened with water. All other preparation/application parameters should be per the solution manufacturer's instructions.

For general cleaning:

<b>Solution</b>	<b>Tray</b>	<b>Reflective Divider in Tray</b>	<b>Screen and Keypad</b>	<b>External Surface</b>
Mild soap (2%)	YES	YES	YES	YES
Alcohol (70%)	NO	YES	YES	YES

For disinfecting:

<b>Solution</b>	<b>Tray</b>	<b>Reflective Divider in Tray</b>	<b>Screen and Keypad</b>	<b>External Surface</b>
Freshly Prepared Bleach (10%) (Sodium hypochlorite)	YES	NO	YES	YES
Iodine based disinfectant	YES	YES	NO	YES
LpH se disinfectant	NO	YES	YES	YES
Bacillol AF (ready to use) (Bode, Germany)	NO	YES	YES	YES
CaviCide (ready to use) (Metrex, USA)	YES	YES	YES	YES
DAX 70+ (ready to use) (OpusHealth Care, Sweden)	YES	YES	YES	YES
Gigasept FF New (5%) (Schulke & Meyr, Germany)	YES	YES	YES	YES
Incidin Plus (2%) (Ecolab, Germany)	YES	YES	YES	YES
Kohrsolin Extra (0.5%) (Bode, germany)	YES	YES	YES	YES
Mikrobac Tissues (ready to use) (Bode, Germany)	YES	YES	YES	YES
Mikrozid Sensitive Liquid (ready to use) (Schulke & Meyr, Germany)	YES	YES	YES	YES
M-Ytdes (ready to use) (Kemetyl, Sweden)	YES	YES	YES	YES
Terralin Protect (2%) (Schulke & Meyr, Germany)	YES	YES	YES	YES

**Cleaning the  
Outer Cover**

1. If the outer cover of the illuminator needs cleaning or disinfecting, wipe the outer cover of the illuminator with a soft cloth dampened with the applicable solution.
2. Use a soft cloth dampened with water to remove the solution.

**Cleaning the  
Tray**



**CAUTION**

Only use approved solutions to clean/disinfect the tray; otherwise, damage may occur.

The tray should be inspected at least monthly for cleanliness or damage. If it is dirty or there is a blood spill, clean following the directions below:

1. Open the front door of the illuminator.
2. Pull out the drawer.
3. Open the tray cover.
4. Clean the plastic container tray including the corners, gently but thoroughly, with an approved solution using a soft cloth. You may lift the tray out of the illuminator drawer (optional).
5. Use a soft cloth dampened with water to remove the solution.
6. Dry the surface of the tray and make sure no streaks can be seen.
7. Put the tray back into the drawer if removed.
8. Close the drawer cover.
9. Push the drawer back into the illuminator.
10. Close the door of the illuminator.



**WARNING**

**If the blood product leaks into the tray, tilting the drawer could cause the blood product to spill out. If the tray is above the operator's eye level, the operator should wear eye protection when tilting the drawer.**



**CAUTION**

If any part of the illuminator tray is damaged (cracked, scratched or cloudy) contact your authorized service representative for a replacement. Do not use the illuminator if the tray is damaged.

### **Cleaning the Air Filter**

The air filter should be inspected monthly for cleanliness. If found dirty, clean following the directions below. Cleaning agents that may be used include a mild detergent solution.

The air filter can be found under the bottom left hand corner of the illuminator.

1. Pull the ring towards you and slide out the air filter.



2. Wash the air filter in a mild detergent solution, rinse in water and allow to air dry.
3. Align the air filter into its rails (metal grid side up) as shown in the photographs and slide back under the illuminator until it is in line with the front of the instrument.



## Section 6.4 Transportation and Storage

### Transportation

If relocating the illuminator to a nearby site, then the illuminator can be moved on a trolley or cart.



#### **WARNING**

**Lifting or carrying the illuminator should be done by a minimum of two people or by using a mechanical lifting device.**

If the illuminator needs to be shipped, contact your authorized service representative to remove the glass plates and pack the illuminator in an appropriate shipping container.

### Storage

For long-term storage, the illuminator should be covered to prevent accumulation of dust. Storage conditions are shown below.

Temperature	- 20° C to + 60° C
Humidity	10 - 90% non-condensing

## Section 6.5      **Warranty and Service**

This Section details the warranty and service instructions for your illuminator.

### **Warranty Statement**

Ask your authorized service representative for a copy of the specific written warranty information applicable to your region.

A list of authorized service representatives is available at the front of this manual.

### **Service Instructions**

Contact your authorized service representative for service and repair information.

- ✉ **NOTE:**      There is a panel on either side of the illuminator that has no customer serviceable parts. Opening either panel requires special tools and should only be opened by an authorized service representative.

## **Section 6.6 Illuminator Calibration and Preventive Maintenance**

### **Calibration and Verification**

The INT100 INTERCEPT illuminator is calibrated and verified at the time of illuminator manufacture, at the time of installation at the customer site, and at six-month intervals thereafter. Qualified service personnel perform calibration and verification activities.

Calibration and verification are performed using an external radiometer (ER) that was specifically designed for use with the INTERCEPT illuminator. Each ER is indirectly calibrated against an NIST traceable standard at six-month intervals. The ER has the same dimensions as an illumination container, and is placed in the same location within the tray as an illumination container.

The ER contains eight (8) photodiodes with UVA filters on both top and bottom surfaces, that are dispersed over the surface such that the external radiometers samples the same light field seen by the illumination container. During use, the external radiometer is placed in each illumination tray and connected by a cable to the computer of the INTERCEPT illuminator.

During the calibration process, the ER collects energy readings from the INTERCEPT illuminator UVA bulbs at 3.0, 4.0, 5.0, 6.0, and 7.0 J/cm<sup>2</sup>. The instrument software uses these energy readings to recalculate the calibration constants of the photodiode sensors inside the illuminator. Calibration is followed by verification, in which a different ER is placed in the illumination tray and connected to the illuminator. As with the calibration procedure, energy readings are collected from the radiometer at 1 J/cm<sup>2</sup> increments from 3.0 to 7.0 J/cm<sup>2</sup>. If the energy readings seen by the illuminator using the new calibration constants at each of the above dose points are within 10% of the energy readings seen by the verification radiometer, then the new calibration constants become permanent until the next calibration procedure.

### **Preventive Maintenance**

Preventive maintenance (PM) is performed every 6 months after successful INTERCEPT Illuminator installation, and is characterized as either major PM or minor PM. The first scheduled PM is minor PM 6 months after installation. After installation, major PM will be performed annually and minor PM will be performed 6 months after each major PM.

Major PM consists of tests and verifications of the illuminator systems and settings, and implementation of any updates or corrections as required. In addition, all UVA bulbs are replaced, key illuminator components are inspected for damage and cleaned or replaced as necessary, and calibration and verification is performed.

Minor PM consists of verification of system settings, and implementation of any updates or corrections as required. The product illumination tray and glass plates are inspected for damage and cleaned or replaced as necessary, and calibration and verification is performed.

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## Chapter 7. Specifications

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
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## Section 7.1 Illuminator Dimensions



Illuminator height (approximate)	37 cm (14.5 inches)
Illuminator width (approximate)	115 cm (45 inches)
Illuminator depth (approximate)	74 cm (29 inches)
Power cord length	Europe: 3 m North America: 9 feet 10 inches
Weight (approximate)	69 kg (152 lbs)

## **Section 7.2      Illuminator Compliance with Standards**

The illuminator complies with the following Directives and Standards:

- Low Voltage Directive (LVD) 2006/95/EC
- Medical Devices Directive (MDD) 93/42/EEC.
- Directive 2002/96/EC (WEEE)
- EN 980
- EN 1041
- EN 50419
- EN 55011
- EN 61000-3-2, EN 61000-3-3
- EN 61000-4-1, EN 61000-4-2, EN 61000-4-3, EN 61000-4-4, EN 61000-4-5,  
EN 61000-4-6, EN 61000-4-8, EN 61000-4-11
- EN 61010-1
- EN 61326-1
- EN ISO 13485
- EN ISO 14155
- EN ISO 14971
- EN ISO 15225
- ISO 7000
- ISO 7064
- ISO 9001
- ASTM D880-92
- ASTM D4003-98
- ASTM D4169-09
- ASTM D4332-01
- ASTM D4728-06
- ASTM D5276-98
- ASTM D5487-98
- CAN/CSA-C22.2 No. 61010-1-04+G11 (R2009)
- UL 61010-1:2004 R10.08

### **Guidance and Manufacturer’s Declaration – Electromagnetic Immunity**

The INT100 illuminator has been tested and found to comply with the limits of the standard for control, measurement, and laboratory equipment IEC 61326-1. The unit also complies with the requirements of the 61326-1 standard, providing the presumption of compliance to the European Union’s EMC Directive 200/95/EC. The limits are designed to provide reasonable protection against harmful interference in a typical installation. This equipment generates, uses, and can radiate radio frequency energy, and, if not installed and used in accordance with the manufacturer’s instructions may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference with other devices, which may be determined by turning the equipment off and on, the user is encouraged to try and correct the interference by one or more of the following measures:

- Reorient or relocate the device receiving the interference.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field technical service representative for help.

**!** **CAUTION** Portable and mobile radio frequency (RF) communications equipment can affect the illuminators by interfering with the electronics.

**⚠** **WARNING** **The use of accessories and cables other than those specified in this manual, as replacement parts for internal components, may result in increased emissions or decreased immunity of the illuminators.**

**⚠** **WARNING** **The illuminators should not be used adjacent to or stacked with other manufacturer’s equipment. If adjacent or stacked use is necessary, the illuminators should be observed to verify normal operation in the configuration in which it will be used.**

## Section 7.3 Illuminator Requirements

### **Power Requirements**

There are two illuminator models: INT100-50 and INT100-60. The appropriate model must be selected based on the AC-line frequency and voltage, as determined by a Cerus-trained technical service representative.

Each illuminator requires 330 Watts during treatments (50 Watts when idle). Therefore, each illuminator needs its own power supply (a single socket). Two illuminators must not be plugged into a single socket (using an adaptor) but may be plugged into a double socket. For safety purposes, the INT100 illuminator should be connected to a reliable earth ground.

### **Energy (BTU) Output**

The instrument produces a nominal 1126 BTU/hour (1187 KJ/hour) with the lights and the shaker on. The instrument produces a nominal 171 BTU/hour (180 KJ/hour) with the lights and shaker off.

### **Power Cord**

Power cords are provided by the technical service representative as part of the installation kit for the INT100 illuminator.

### **Battery Requirements**

Each illuminator contains two 6-V lead acid batteries. These batteries will be replaced as necessary by your technical service representative.

When the useful life of the lead batteries has expired, the batteries should be removed by service personnel and disposed of in accordance with all national and local codes. Contact your local environmental control or disposal agency for further details.

### **Fuses**

Fuses are provided by authorized technical service personnel as part of the installation kit for the illuminator. Fuses must be installed and replaced by trained technical service personnel only.

**! CAUTION** If the fuse blows after bulb replacement, the illuminator should not be used. Contact your authorized technical service representative for assistance.

### **Bulb Replacement**

Contact your authorized technical service representative for replacement of bulbs.

**Computer  
Ports**

The following table provides a description of the ports on the illuminator. There is a fifth port located inside the front door of the illuminator for service personnel only.

<b>Port Label</b>	<b>Type</b>	<b>Location</b>	<b>Function</b>
1	RS - 232	Front	Barcode Scanner
2	RJ – 45	Rear	Data Management
3	RS – 232	Rear	Label Printer
4	25 Pin Parallel	Rear	Treatment Printer

## Section 7.4 Barcode Compatibility

The illuminator will recognize and is compatible with the following barcode formats:

1. Codabar (including Monarch 11 and UKBTS)

- 10 numeric characters: 0 through 9
- 6 control characters: minus (-), dollar sign (\$), period (.), plus (+), colon (:), forward slash (/)
- 8 start / stop characters: a, b, c, d, t, n, \*, e (upper and lower case)

<u>Codabar</u>	<u>Traditional Codabar</u>	
<u>Start/Stop</u>	<u>Start</u>	<u>Stop</u>
A	a	t
B	b	n
C	c	*
D	d	e

2. Code 128 (includes ISBT 128 and Eurocode)

- All 128 ASCII characters

✉ **NOTE:** When manually entering data, only upper-case letters can be selected from the keypad. If the human-readable portion of the barcode contains lower-case letters, manually enter the data using upper-case letters.

During illuminator installation, assist the authorized service representative in configuring the barcode data fields of donation number and blood product code. The authorized service representative will configure the set code and lot number. Follow the guidelines below for barcode configuration.

### Donation Number

One of the following formats can be selected for donation number: Code 128, Codabar, Monarch 11, ISBT 128 or Eurocode.

1. Code 128

- Code 128 Scanned Data Input

All Code 128 characters are accepted, stored and printed both in human-readable and in barcode format on the printed label if label printing is selected.

- Codabar Scanned Data Input not allowed.
- Manually Entered Data Input

All keypad characters accepted. The manually entered characters are printed only in a human-readable form on the printed label, if label printing is selected.

2. Codabar

- Code 128 Scanned Data Input not allowed.
- Codabar Scanned Data Input

All legal Codabar characters accepted. If asterisks and alpha stop and start characters are encountered, they are not printed in human-readable form on the printed label if label printing is selected.

- Manually Entered Data Input

All legal Codabar numeric and control characters accepted. The manually entered characters are printed only in human-readable form on the printed label if label printing is selected.

**! CAUTION** If using Codabar (excluding Monarch 11 and UKBTS), the illuminator will not evaluate the integrity of the scanned data. Verify the data scanned matches the information displayed on the illuminator screen.

3. Monarch 11

- Code 128 Scanned Data Input not allowed.
- Codabar Scanned Data

Must be in the following format

a	Start Code [a or A]
xx	2 digit Blood Bank ID [0 – 9]
yy	2 digit last two digits of current year [0 – 9]
pppppp	6 digit Donation Number [0 – 9]
k	If the check digit is equal to ten, it is represented in the barcode portion of the label by a “-” [0 – 9 or minus]
a	Stop Code [a or A]

- Manually Entered Data

Must be in the following format

xx	2 digit Blood Bank ID
yy	2 digit last two digits of current year
pppppp	6 digit Donation Number
k	If the check digit is equal to ten, it is represented in the barcode portion of the label by a “-”

4. ISBT 128

- Code 128 Scanned Data

Must be in the following format

=	Primary Data Identifier [=]
a	1 character secondary data identifier and part of the Country Collection Facility Code [A – N, P – Z, 1 – 9]
pppp	4 digits of the Country Collection Facility Code [0 – 9]
yy	2 digit year of collection [0 – 9]
nnnnnn	6 digit Donation Number [0 – 9]
ff	Two non-data character flag digits used for either process control or for a data transmission check (checksum). Optionally displayed in the human-readable portion if they are not a checksum. When displayed in human-readable form, these two characters are rotated ninety degrees [0 – 9].

- Codabar Scanned Data not allowed.

- Manually Entered Data

Must be in the following format

a	1 character secondary data identifier and part of the Country Collection Facility Code
pppp	4 digits of the Country Collection Facility Code
yy	2 digit year of collection
nnnnnn	6 digit Donation Number
ff	Two optional non-data character flag digits used for either process control or for a data transmission check (checksum). Optionally displayed in the human-readable portion if they are not a checksum. When displayed human-readable, these two characters are rotated ninety degrees.
k	This character is printed enclosed in a box and it is used to support accurate manual data entry.

5. Eurocode

- Code 128 Scanned Data

Must be in the following format

!	Primary Data Identifier [!]
ccc	3 digit Country ID [0 – 9]
iii	3 digit Blood Bank ID [0 – 9]
nnnnnnnnnnnn	6 to 12 digit Donation Number [0 – 9]

- Codabar Scanned Data not allowed.
- Manually Entered Data

Must be in the following format

ccc	3 digit Country ID
iii	3 digit Blood Bank ID
nnnnnnnnnnnn	6 to 12 digit Donation Number

**Blood Product Code**

One of the following formats can be selected for Product Code: Code 128, Codabar, UKBTS Codabar, ISBT 128 or Eurocode.

1. Code 128

- Code128 Scanned Data Input

All Code 128 characters are accepted, stored and printed both in human-readable form and in barcode format on the printed label if label printing is selected.

- Codabar Scanned Data Input not allowed.
- Manually Entered Data Input

All keypad characters accepted. The manually entered characters are printed only in human-readable form on the printed label if label printing is selected.

2. Codabar

- Code128 Scanned Data Input not allowed.
- Codabar Scanned Data Input

All legal Codabar numeric and control characters accepted. If stop and start characters are encountered, they are not printed in human-readable form on the printed label if label printing is selected.

- Manually Entered Data Input

All legal Codabar characters accepted. The manually entered characters are printed only in human-readable form on the printed label if label printing is selected.

**! CAUTION**

If using Codabar (excluding Monarch 11 and UKBTS), the illuminator will not evaluate the integrity of the scanned data. Verify the data scanned matches the information displayed on the illuminator screen.

3. UKBTS Codabar

- Code128 Scanned Data Input not allowed.
- Codabar Scanned Data Input

Must be in the following format:

a	Start Code [A or a]
x	Split number [0 – 9]
nnnnn	Component code [0 – 9]
3b	Stop Code [3B or 3b]

- Manually Entered Data

Must be in the following format:

CT	The prefix assigned to Product Codes by UKBTS
nnnn	Label ID Number
m	Version Number

4. ISBT 128

- Code128 Scanned Data

Must be in the following format:

=<	Data Identifier [=<]
a	One alphanumeric character used to describe the blood product [E – Z]
oooo	Four characters used to describe the blood product [0 – 9]
t	Alphanumeric designating the type of donation or intended use [A – Z, a – z, 0 – 9]
d	Character that provides information about divisions of the blood product [A – Z or 0]
s	Character that provides information about divisions of the blood product [a – z or 0]

- Codabar Scanned Data not allowed.
- Manually Entered Data

Must be in the following format:

a	One alphanumeric character used to describe the blood product
oooo	Four characters used to describe the blood product
t	Alphanumeric designating the type of donation or intended use
d	Character that provides information about divisions of the blood product
s	Character that provides information about divisions of the blood product

5. Eurocode

- Code128 Scanned Data

Must be in the following format:

!	Primary Data Identifier [!]
a	Secondary Data Identifier [P or Q]
nnnnnn	6 digits numeric [0 – 9]

- Codabar Scanned Data not allowed.
- Manually Entered Data

Must be in the following format:

a	Secondary Data Identifier
nnnnnn	6 digit numeric

## Section 7.5 Connecting External Devices

The illuminator is designed to function with certain external devices. The peripheral devices include a label printer, a printer for treatment records and a data management system. The following sections describe the requirements for the attached devices.

### Printers

Two printers may be connected to the illuminator, a printer for making labels and a printer for treatment records. The table below describes the printers compatible with the illuminator.

Label Printer	Treatment Printer
Zebra printer, model T402	Any Hewlett Packard laser printer
Zebra printer, model GK420T	
Zebra printer, model TLP 2844-Z	

If using the label printer, 4" x 1" (102 mm x 25 mm) labels (Zebra part number 83340) should be used. If label printing is required, because plasma is being processed or no data management system is present, every illuminator must have its own label printer.

### Data Management System

The illuminator may be connected to an optional data management system. The illuminator will send treatment information to the data management system to add to the process record. Refer to your data management system for the TCP/IP addresses and site code to configure the illuminator.

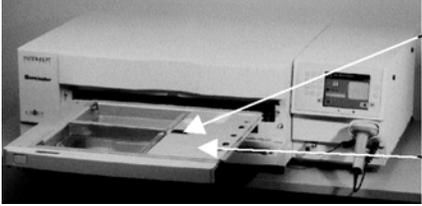
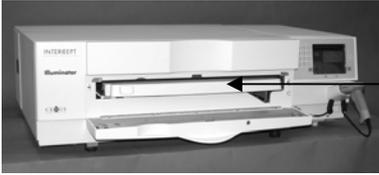
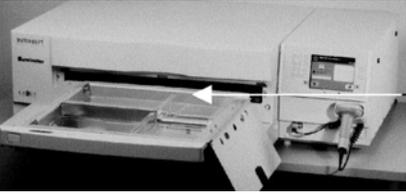
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## **Chapter 8. Appendix**

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
8.1 Glossary	8-3
8.2 Summary of Operator Steps	8-4

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**Section 8.1**      **Glossary**

Amotosalen HCl	The compound used in the INTERCEPT Blood System with UVA light to crosslink genetic material. The first time amotosalen is mentioned in the text, it is referred to as ‘amotosalen HCl’, and in subsequent references ‘amotosalen’ is used.
CAD	Compound Adsorption Device - This component of the processing set reduces levels of residual amotosalen as a step in the INTERCEPT Blood System.
Cover	 <p>Latch Cover</p>
Crosslink	To form a permanent link.
Donation Number	The donation number from a blood product or the number identifying a platelet pool.
Drawer	 <p>Drawer</p>
Illumination	The process of exposing a blood product to UVA light.
INTERCEPT Data Management System	A data management system that may be linked to the illuminator.
NIST	National Institute for Standards and Technology.
Set ID (REF)	INTERCEPT Product Code (REF).
Tray	 <p>Tray</p>
Treatment Cycle	The process of loading a processing set, acquiring data from that set and initiating and terminating the illumination step.

## Section 8.2      Summary of Operator Steps

This is a simplified list of the steps taken by the operator to perform an illumination treatment. No notes, warnings or cautions are included. Refer to Chapter 4 for detailed instructions including notes, warnings and cautions.

Perform the following to treat blood products in the illuminator.

### Turn On the Illuminator And Log In

Step	Action
1.	Press power switch, under screen, to turn illuminator on. When the self-tests are complete, 'Log In' function button will appear.
2.	Press <b>'Log In'</b> button. <b>'Enter operator identification'</b> screen will appear.
3.	If you have a barcode for identification, scan it. After scanning, the <b>'Select a function'</b> screen will appear. If a barcode is not available, enter the identification manually.
4.	To enter your identification manually, perform the following: <ul style="list-style-type: none"><li>• Use keypad to enter your identification name or number.</li><li>• If identification is correct, press <b>'Enter'</b> button. <b>'Select a function'</b> screen will appear.</li><li>• If identification is incorrect, press backspace ( ← ) button on keypad to delete wrong identification. Then re-enter correct identification using keypad.</li><li>• If identification is correct, press <b>'Enter'</b> button. <b>'Select a function'</b> screen will appear.</li></ul>

**Load  
 Processing  
 Set(s)**

<b>Step</b>	<b>Action</b>
1.	Use arrow buttons to select <b>'Run Treatment'</b> option.
2.	Press <b>'Enter'</b> button. <b>'Select number of containers to treat'</b> screen will appear.
3.	Use arrow buttons to select the number of containers to illuminate.
4.	Press <b>'Enter'</b> button.
5.	Open front door of illuminator.
6.	Pull out drawer.
7.	Open cover of tray by sliding black latch to right. (The cover will open to the right.)
8.	Place illumination container, marked with number 1, into front illumination chamber 1, in left-hand side of tray.
9.	Secure container flap onto plastic hook in tray.
10.	Put tubing from illumination container in slot of divider. Make sure that sealed tubing containing platelets is within left-hand side of the chamber.
11.	Place other containers into right-hand side of front chamber 1 so that final storage container label is facing up.
12.	Secure set to drawer by putting alignment holes over pegs.

**Scan  
 Barcodes**

Step	Action								
1.	<p><b>‘Enter treatment data for container 1’</b> screen will appear. Scan barcodes from final storage container in following order:</p> <table border="0" data-bbox="618 373 1096 646"> <tr> <td data-bbox="618 373 743 407">Barcode 1</td> <td data-bbox="834 373 1040 407">Donation number</td> </tr> <tr> <td data-bbox="618 453 743 487">Barcode 2</td> <td data-bbox="834 453 1065 487">Blood product code</td> </tr> <tr> <td data-bbox="618 533 743 567">Barcode 3</td> <td data-bbox="834 533 1094 567">INTERCEPT set code</td> </tr> <tr> <td data-bbox="618 613 743 646">Barcode 4</td> <td data-bbox="834 613 1308 646">INTERCEPT manufacturing lot number</td> </tr> </table>	Barcode 1	Donation number	Barcode 2	Blood product code	Barcode 3	INTERCEPT set code	Barcode 4	INTERCEPT manufacturing lot number
Barcode 1	Donation number								
Barcode 2	Blood product code								
Barcode 3	INTERCEPT set code								
Barcode 4	INTERCEPT manufacturing lot number								
2.	<p>If barcode cannot be scanned, you may enter information manually by performing the following:</p> <ul style="list-style-type: none"> <li>• Use the keypad to enter the barcode.</li> <li>• Press <b>‘Enter’</b> button. <b>‘Confirm Barcode’</b> screen will appear.</li> <li>• If barcode is incorrect, press <b>‘Edit’</b> button. <b>‘Enter treatment data for container 1’</b> screen will appear.</li> <li>• Using keypad, press backspace (←) button to delete wrong barcode. Then re-enter correct barcode using keypad.</li> <li>• Press <b>‘Enter’</b> button. <b>‘Confirm Barcode’</b> screen will appear.</li> <li>• If barcode is correct, press <b>‘OK’</b> button to confirm barcode. <b>‘Enter treatment data for container 1’</b> screen will appear.</li> <li>• Repeat above steps until all barcodes have been entered.</li> </ul>								
3.	Press <b>‘Done’</b> button.								

**Repeat Set  
Loading for  
Container 2**

If two containers have been selected for treatment, the **'Enter treatment data for container 2'** screen will appear.

Follow previous steps to load the second set into the illuminator tray and scan the barcodes, placing the second container in the rear chamber 2.

The **'Close drawer and door'** screen will appear.

Step	Action
1.	Make sure that all tubings are in tray and containers are flat.
2.	Close tray cover and ensure that it is secured by black latch.
3.	Push drawer into illuminator until it clicks in place.
4.	Close door.

The **'Start treatment'** screen will appear.

**Begin  
Illumination  
Process**

Step	Action
1.	Press <b>'Start'</b> button. <b>'Running'</b> screen will appear.

 **NOTE:** Pressing the **'Start'** button is not required for treating plasma products but is required when treating platelet products.

**Illumination  
 Interruption**

Step	Action
1.	To stop treatment at any time, press <b>'Stop'</b> button. <b>'Are you sure you want to stop treatment?'</b> screen will appear.
2.	Press <b>'No'</b> button to resume treatment, or press <b>'Yes'</b> button to end treatment.

**Unload  
 Processing  
 Set(s)**

Step	Action
1.	Press <b>'Unlock Door'</b> button and the door will unlock.
2.	An information screen will appear to confirm that label printing is occurring.
3.	The <b>'Unload containers'</b> screen will appear. Open front door of illuminator.
4.	Pull out drawer and open cover.
5.	Check screen for treatment status symbol. Follow your facility's procedures for handling product recorded as Incomplete.
6.	When the label has printed, place the label on the illumination container and remove the containers from the tray.

**This completes illumination process.**

**Process  
 Additional  
 Blood Products**

Step	Action
1.	Press <b>'Treatment'</b> button. <b>'Select number of containers to treat'</b> screen will appear.
2.	Repeat steps described earlier, beginning with Load Processing Sets.