

# INTERCEPT Blood System™

## Pathogen Inactivation Process

### ILLUMINATOR

# Operator Manual

Software Version 5.1





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**CERUS**



**INTERCEPT  
ILLUMINATOR**

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**INT100**

**Operator Manual**

**Software Version 5.1**

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.

✉ **NOTE:**      The operator is protected from the UVA source during normal illuminator operation per EN 61010-1.

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 in accordance with approved specifications for processing with INTERCEPT. Refer to the Instructions for Use provided with the processing sets for treatment specifications.
- 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.

- ☒ **NOTE:** Only INTERCEPT Blood System disposable processing sets can be used with the INT100 INTERCEPT Illuminator.

## **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 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.**


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 the illuminator.**

Section 6.3 - *Cleaning 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.**

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 6.2 - *Selecting a Place for the Illuminator*

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*

- ! CAUTION** Once an account has been disabled, it cannot be reactivated. Furthermore, the username cannot be reused.

### 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** Use only approved solutions to clean and disinfect the tray; otherwise, damage may occur.

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






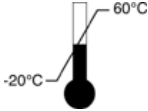
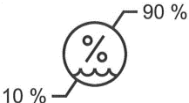




Throughout the manual the following symbols have been used. Each symbol and meaning is shown below:

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”
SN	“Serial number”
	“Date of manufacture”
	Consult Instructions for Use
	“Keep Dry” (The shipping carton and contents MUST be kept dry)
	“Fragile, Handle With Care” (The shipping carton and contents have to be handled with care)
	“This Way Up” (The package must be kept the right way up)
	“Temperature limitations” (The shipping carton and contents must be kept within a certain temperature range when transported)
	“Relative humidity” (The shipping carton and contents must be kept within a certain humidity range when transported)
	This marking reflects compliance with the Medical Devices Directive 93/42/EEC issued by the Council of the European Communities.
	“Manufacturer” (EN 980)
	“European Authorized Representative” (EN 980)
	Requires separate electrical and electronic waste collection.











	<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>
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**Symbols  
Used on the  
Illuminator**

The following symbols are used on the illuminator:

Symbol	What the Symbol Means
	Caution
	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
	Consult Instructions for Use
	Ground
	Alternating current
<p>1</p>	RS-232 barcode scanner port (front of illuminator)
<p>2</p>	RJ-45 ethernet port (rear of illuminator)
<p>3</p>	RS-232 label printer port (rear of illuminator)

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

4	25-pin parallel printer port (rear of illuminator)
	Backspace, Delete or page back
	Advance or page forward
	This marking reflects compliance with the Medical Devices Directive 93/42/EEC issued by the Council of the European Communities.
SN	“Serial number”
	“Date of manufacture”
REF	“Catalogue number”
	Container chamber 1 position indicator
	Container chamber 2 position indicator
	ESD Sensitive
	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).

## 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.

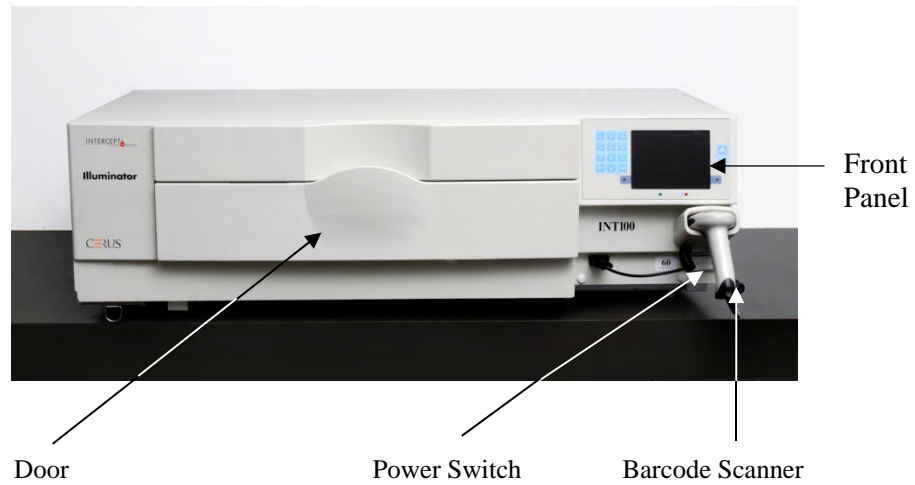
Upon completion of the illumination step, a record of each processed blood product is stored in the illuminator. Up to 3200 records may be stored, printed and/or transmitted to a computer. Upon completion of treatment number 3201, the number 1 treatment record is replaced.



## 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
	Function
	Illumination
	Printing
	Illuminator settings
	Enter Username/Enter Password
	Date/Time
	Illuminator Identification

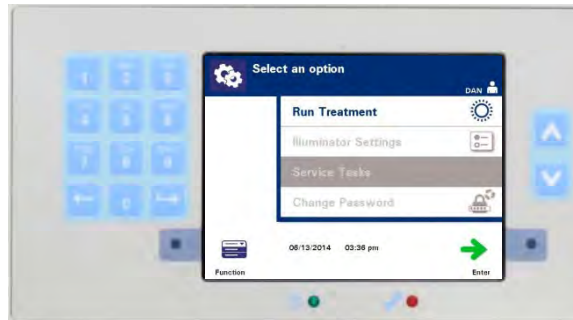
Screen Symbols	Function
	Exporting Service Data
	Exporting Treatment Records
	Configurations
	Service Tasks
	Exporting
	Languages

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

Screen Symbols	Type of Message
	Error
	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.



Barcode Scanner

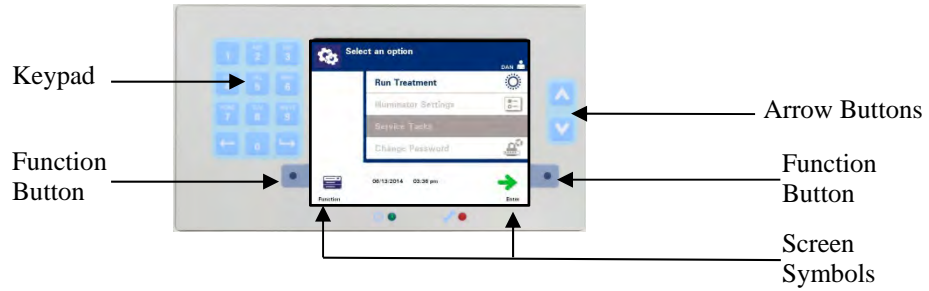
Barcodes are used to track blood products through the INTERCEPT Blood System process and can be found on the final storage container label of the INTERCEPT Processing Set.

The barcode scanner may be used 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. See Section 3.2 for additional details.

**Buttons**



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

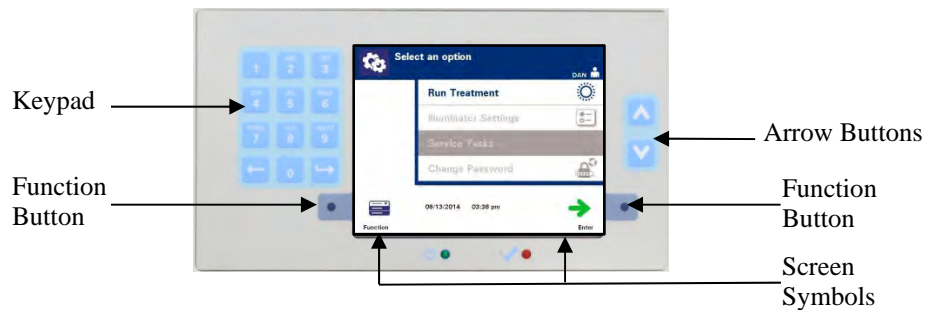
- **Arrow buttons** — up and down arrow buttons allow you to scroll through the screen choices.
- **Function buttons** — the meaning of these buttons change to guide you through the screen choices.
- **Keypad** — buttons with a number, letter and special character function.

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**



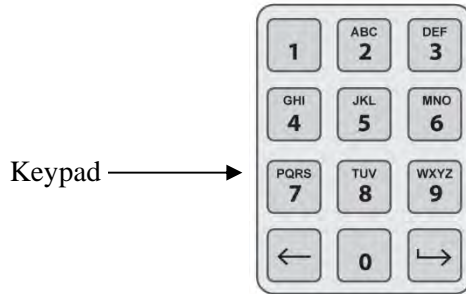
Function buttons have screen symbols and labels that change according to the step, to help you navigate through the screens.

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

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

Screen Symbol	Labels and Use
	<p><b>Back/Edit</b>            Use this button to return to the previous screen or to edit information.</p>
	<p><b>Cancel/Cancel treatment</b>            Use this button to:</p> <ol style="list-style-type: none"> <li>1. Cancel the illuminator's current function.              For example, to stop entering the barcode information and return to the previous screen.</li> <li>2. Cancel out of the illumination process in an error.</li> </ol>
	<p><b>Enter/Continue/Login/Stop Agitator/Start</b>            Use this button to:</p> <ol style="list-style-type: none"> <li>1. Enter information on the screen.</li> <li>2. Continue to the next screen.</li> <li>3. Stop the agitator after illumination.</li> </ol>
	<p><b>OK/Done</b>            Use this button to accept screen information.</p>
	<p><b>Stop</b>            Use this button to stop the illumination process.</p>
	<p><b>Export</b>            Use this button to export the confirmed data.</p>
	<p><b>Print</b>            Use this button to print the confirmed data.</p>
	<p><b>Function</b>            Use this button to directly access the 'Select a function' screen.</p>
	<p><b>Treatment</b>            Use this button to directly access the 'Select number of containers to treat' screen.</p>

**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.

**Backspace  
and Advance**

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

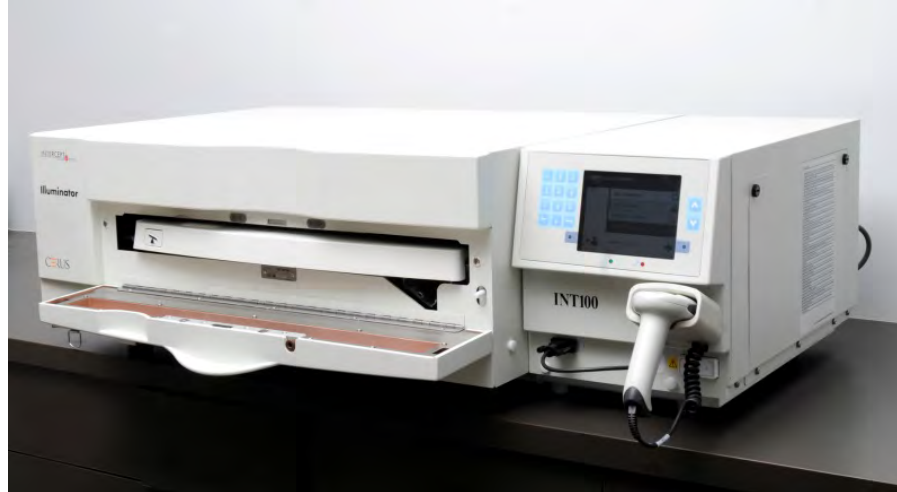
- The backspace (←) button will delete the last number or letter only. To delete all the numbers and letters you need to push the button several times.
- The advance (→) button is used to let you enter the next number or letter using the same button as the previous number or letter. For example, to enter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

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



## Section 3.5 Illumination Door and Drawer

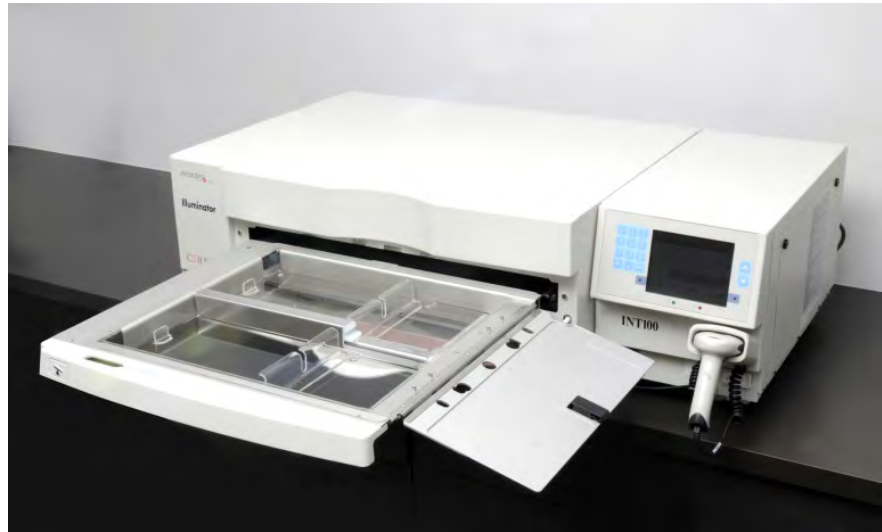
The door that extends across the front of the illuminator opens down.



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.

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. 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.



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

**!** **CAUTION** Since the INTERCEPT Process is dependent on the UVA light reaching the product from both above and below, it is extremely important that the tray remains clear, clean, and undamaged.

Do not attempt to service the UVA light sources or open areas of the illuminator which are not described in this operating manual. Contact a Cerus-authorized service company or representative for assistance.

**⚠** **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 User Access Levels

The illuminator is designed with three user access levels: Operator, Administrator, and Service. The Service features are accessible only by a Cerus authorized field service engineer. The table below contains a summary of the functionality available within each access level.

All access levels require a username and password. Usernames must be unique (i.e. two people cannot have the same username) and cannot be re-used once disabled in the system.

Upon installation, the Cerus authorized field service engineer will work with your center’s designated representative to establish the first Administrator account in each illuminator. This Administrator can then set up operator accounts and additional administrator accounts as needed. The number of authorized administrators should be defined by your internal policies and procedures.

Function	Operator	Administrator	Service <sup>a</sup>
<b>Treatments</b>			
Run illumination treatments	X	X	X
<b>Printing</b>			
Print treatment reports	X	X	X
Print treatment labels	X	X	X
<b>User Account Management</b>			
Change password (for self)	X <sup>b</sup>	X	X
Add or disable user account	---	X (Operator & Administrator accounts)	X (All account types)
Reset password for another user’s account (e.g., in the case of a forgotten password)	---	X (Operator & Administrator accounts)	X (All account types)

Chapter 3 – Illuminator Description  
 Section 3.6 – User Access Levels

Function	Operator	Administrator	Service <sup>a</sup>
<b>Illuminator Settings</b>			
Set date and time (including format)	---	X	X
Input illuminator serial number	---	X	X
Select print options (e.g. automatic printing of reports and labels; choice of number of labels to print).	---	X	X
Select password expiration policy (options are “disable”, 30 days, 60 days, 90 days)	---	X	X
Connect and configure a data management system	---	X	X
<b>Electronic Data Export</b>			
Export treatment and service data	---	X	X
<b>Service Tasks</b>			
Program valid INTERCEPT set codes	---	---	X
Assign barcode formats	---	---	X
Calibrate device	---	---	X
Establish first administrator account	---	---	X

<sup>a</sup>. Accessible only by Cerus authorized field service engineer.

<sup>b</sup>. Applicable if operator function is required to use a password.

X = Access allowed

--- = Access not allowed

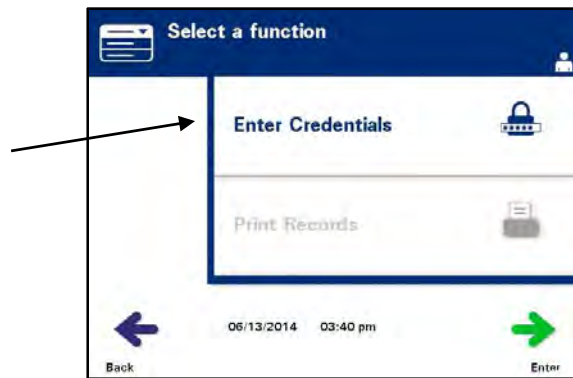
## Section 3.7 Illuminator Settings

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.

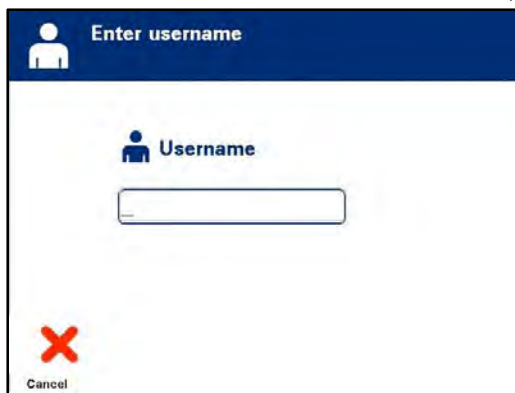
- ✉ **NOTE:** Only ‘Administrator’ and “Service” accounts have the ability to access the ‘Illuminator Settings’ screen. Your authorized Cerus Service representative will assist you to set up the first Administrator account.

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

- Turn on the device and press the ‘Enter’ button once it appears.
- The ‘Select a function’ screen will appear. Select the ‘Enter Credentials’ option and press the ‘Enter’ button.



- The ‘Enter username’ screen will appear. Use the keypad to enter your username and press the ‘Enter’ button. A confirmation screen will appear. If the username is correct, press the ‘OK’ button.

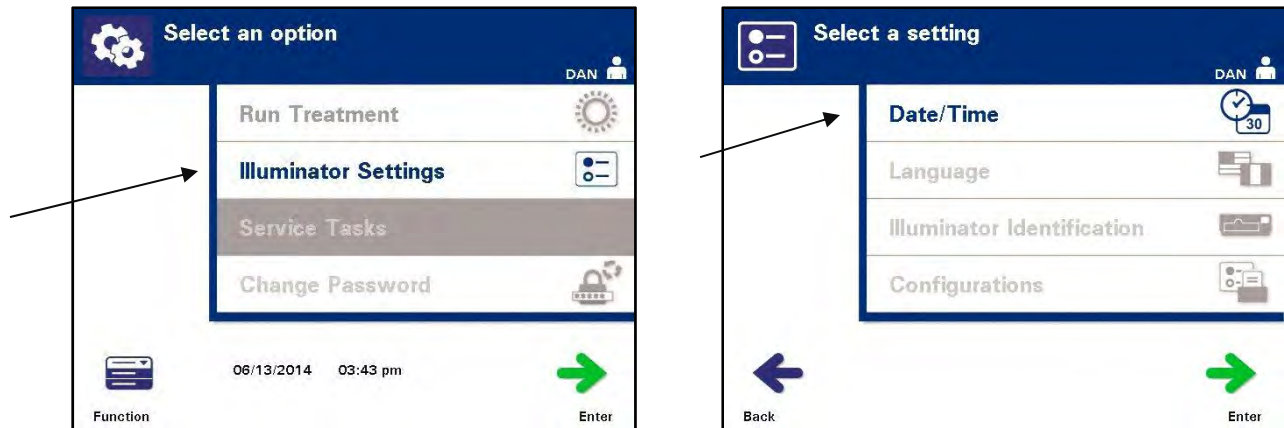


- Alternatively, you may scan your username via the barcode scanner. If the barcode scanner is used, you will not need to press ‘Enter’ and there will not be a confirmation screen.

- The **'Enter password'** screen will appear. Use the keypad to enter your password and press the **'Enter'** button. A confirmation screen will appear. If the password is correct, press the **'OK'** button. Alternatively, if allowed by your institution, you may scan your password. If the barcode scanner is used, you will not need to press **'Enter'** and there will not be a confirmation screen.



- The **'Select an option'** screen will appear. Select the **'Illuminator Settings'** option and press the **'Enter'** button. The **'Select a setting'** screen will appear.



Use the following steps to access the desired illuminator settings option or press the **'Back'** button to get back to the previous screen.

### **Date and Time**

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

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

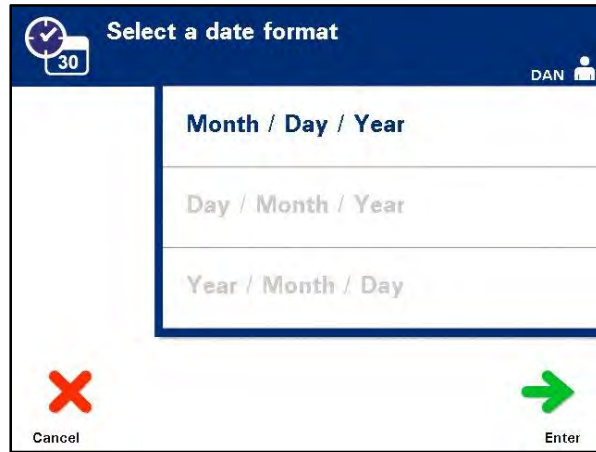
**✉** **NOTE:** The illuminator does not automatically update for daylight savings time.

To change the date and time, perform the following steps:

- 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.

✉ **NOTE:** You must enter 2 numbers for the **'month'** and **'day'** fields and 4 numbers for the **'year'** field. (For example: 01/01/2002).

- Press the **'Enter'** button when the date has been entered. The **'Select a time format'** screen will appear.
- Use the arrow buttons to choose the time format. Your choices are a 12 – hour clock or a 24 – hour clock.

✉ **NOTE:** If using a data management system, select the 24-hour clock format.

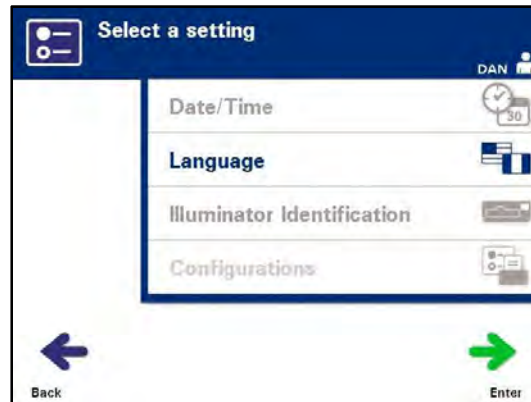
- Press the **'Enter'** button to select the format. The **'Enter time'** screen will appear.
- Use the keypad to enter the time manually.
- Press the **'Enter'** button when the time has been entered.

- ✉ **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.

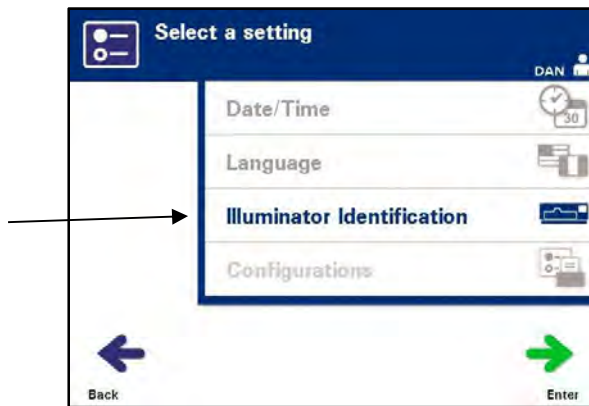


- Press the **'Enter'** button to select the option. The **'Select a language'** screen will appear.
- Use the arrow buttons to choose the desired language. If your language is not listed on the screen, press the advance (←→) button on the keypad to display the next page of languages. Then use the arrow 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 a File Transfer Protocol, 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.

✉ **NOTE:** The **'Enter'** button will only appear if the serial number is in the correct format.

- 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

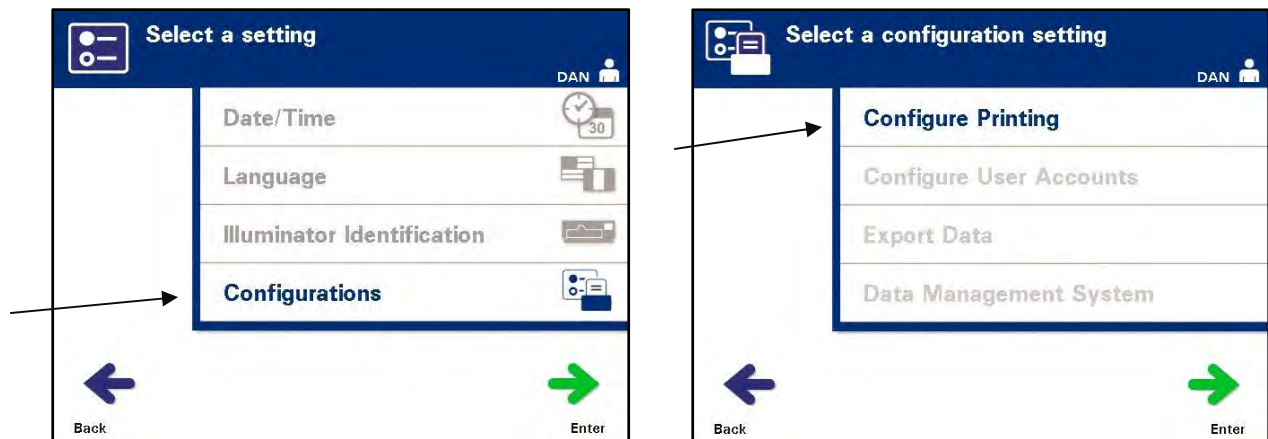
The Configurations setting allows you to:

- Set printing options: report printing, auto printing, and label printing
- Configure user accounts: add accounts, disable accounts, reset passwords, and set password expiration interval
- Export data: export all treatments, treatments in a date range, all service data, and service data in a date range
- Enable a data management system: send information to a data management system

To set these various options, perform the following:

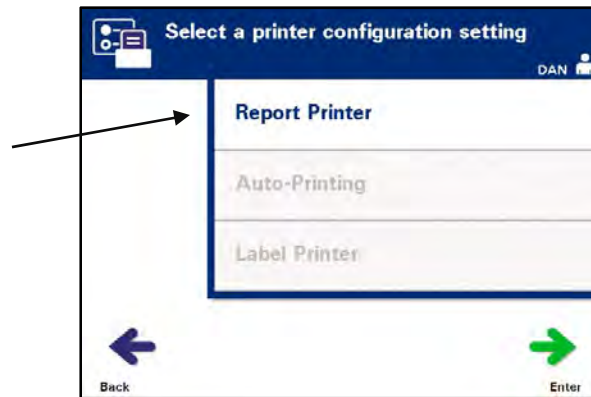
### Report Printer

- From the **'Select a setting'** screen, use the arrow buttons to choose the **'Configurations'** option.

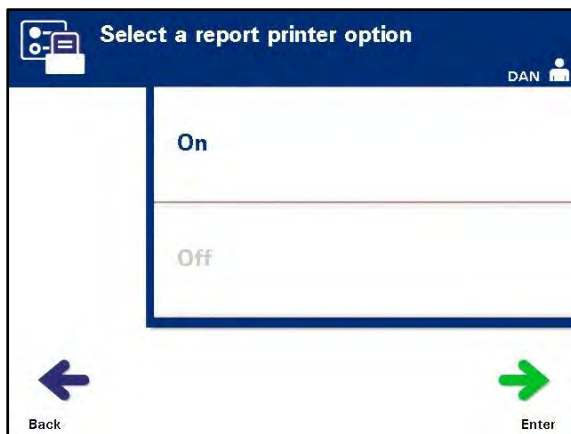


- Press the **'Enter'** button to select the **'Configurations'** option. The **'Select a configuration setting'** screen will appear.
- Use the arrow buttons to choose the **'Configure Printing'** option.
- Press the **'Enter'** button to select the **'Configure Printing'** option.

- The **'Select a printer configuration setting'** screen will appear.



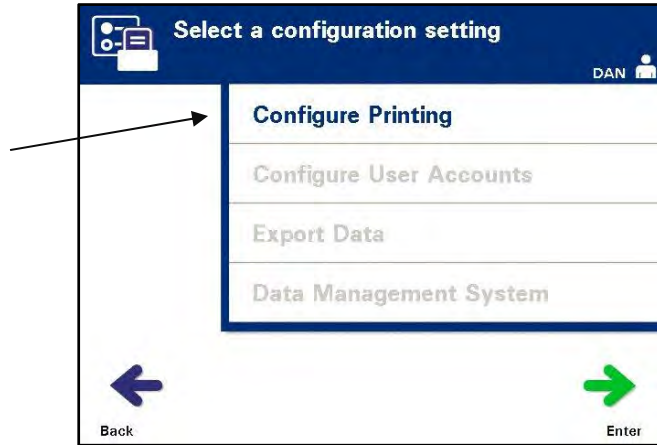
- Use the arrow buttons to choose the **'Report Printer'** option.
- Press the **'Enter'** button to select the **'Report Printer'** option. The **'Select a report printer option'** screen will appear.
- Use the arrow buttons to choose either **'On'** or **'Off'**. Selecting the **'On'** option will allow you to print the last treatment report, a specific treatment report, a shift report for a given day, or all treatment reports in a date range. 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.



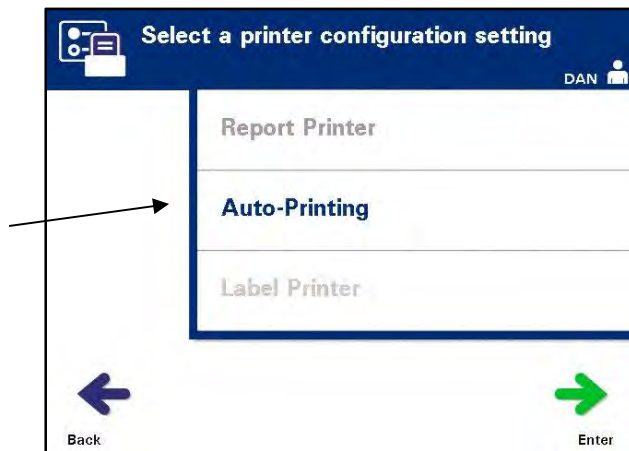
- If the option is incorrect, press the **'Edit'** button to return to the **'Select a report printer option'** screen. Use the arrow buttons to select the correct option.
- If the selection is correct, press the **'OK'** button to confirm the selection. The **'Select a printer configuration setting'** screen will appear.

**Auto-Printing**

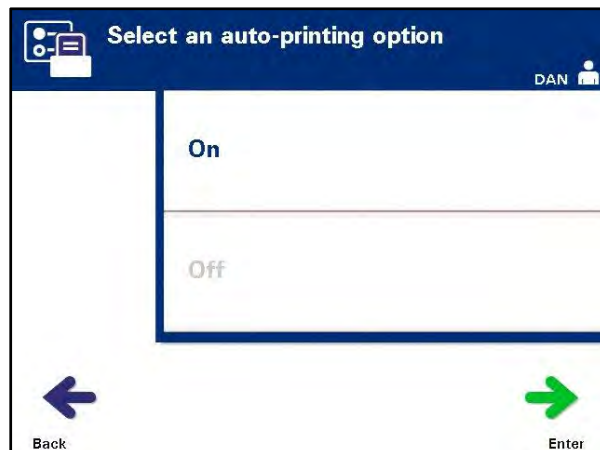
From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure Printing'** option.



- Press the **'Enter'** button to select the **'Configure Printing'** option.
- The **'Select a printer configuration setting'** screen will appear. 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 printer configuration setting'** screen will appear.

✉ **NOTE:** Report Printer must be on for Auto-Printing to print. See the Report Printer section for directions to turn the Report Printer on.

✉ **NOTE:** When a large number of files are selected, there may be a delay while the illuminator prepares the files.



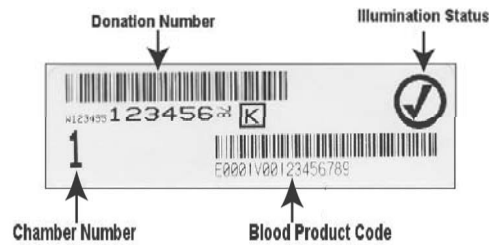
**Label Printer**

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

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.

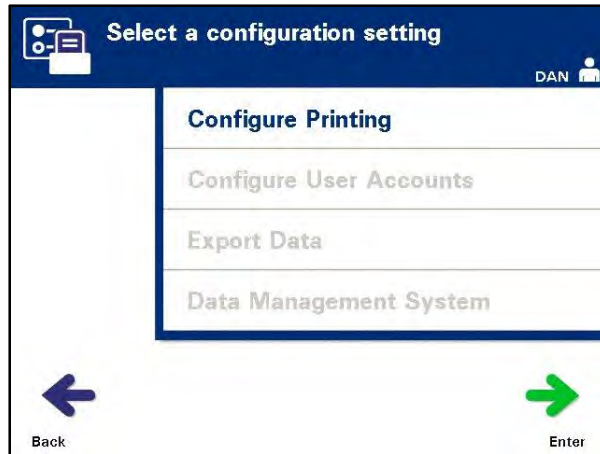
A specific number of labels may be configured to be printed every time an illumination has finished. **A maximum of 6 labels may be printed.** Setting the value to '0' will turn the label printing feature off. Only turn the label printing off if the label printer is out of service / not functioning.

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

**✉ NOTE:** When a large number of files are selected, there may be a delay while the illuminator prepares the files.

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

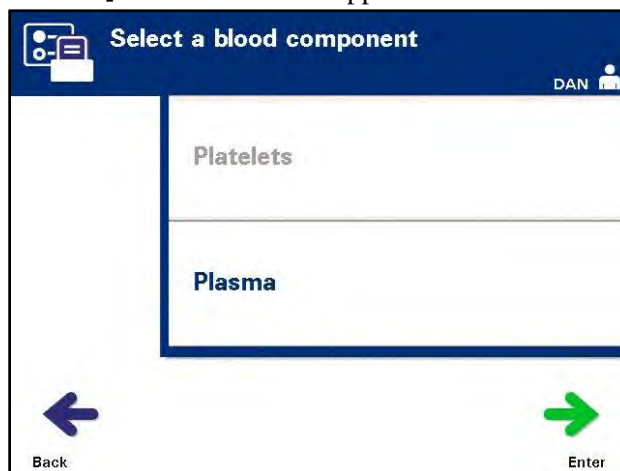
- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure Printing'** option.



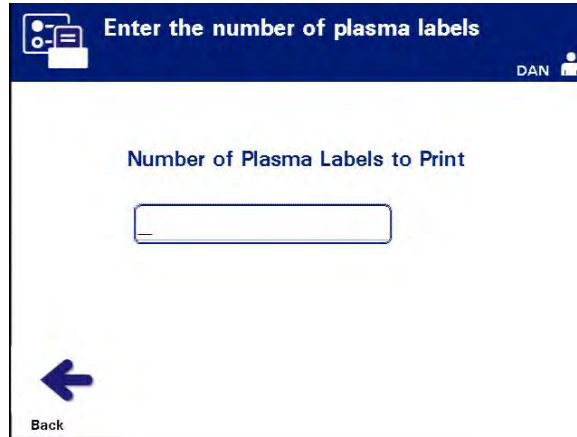
- Press the **'Enter'** button to select the **'Configure Printing'** option. The **'Select a printer configuration setting'** screen will appear.



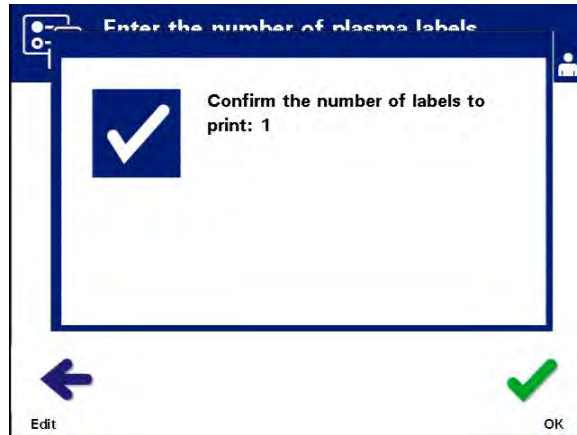
- Use the arrow buttons to choose the **'Label Printer'** option.
- Press the **'Enter'** button to select the **'Label Printer'** option. The **'Select a blood component'** screen will appear.



- Use the arrow buttons to choose **'Platelets'** or **'Plasma.'** Press the **'Enter'** button to select component. The **'Enter the number of platelets/plasma 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.

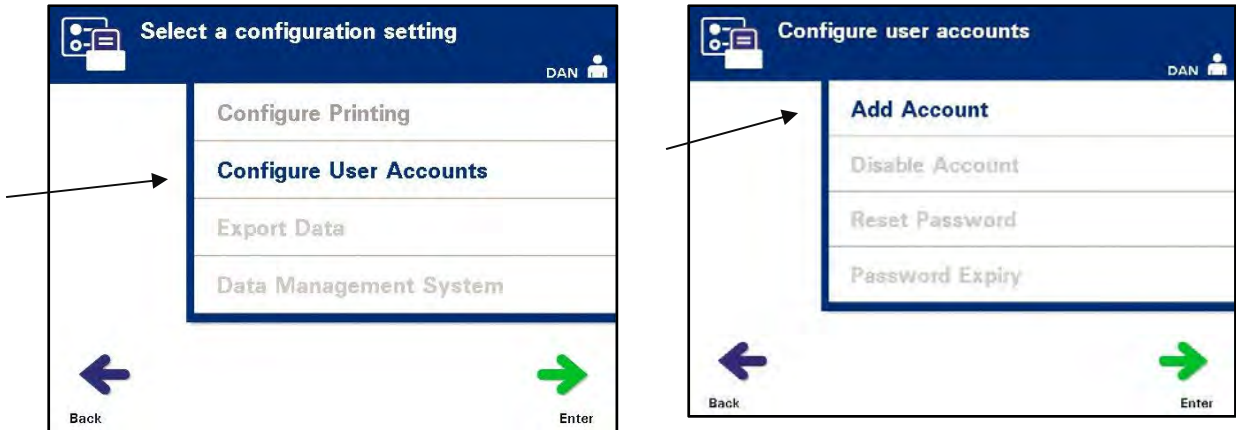


- If the number of labels is incorrect, press the **'Edit'** button to return to the **'Enter the number of platelet/plasma labels'** screen. Use the backspace (  $\leftarrow$  ) button on the keypad to delete the number and re-enter the correct number. Press the **'Enter'** button to select the number 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 platelet/plasma labels to be printed.
- Press the **'Back'** button to return to the **'Select a configuration setting'** screen.

## Configure User Accounts

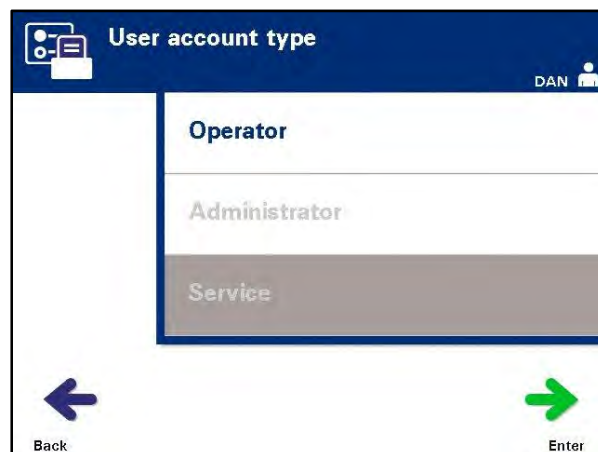
**Add Account** Use to add User accounts to the Illuminator.

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure User Accounts'** option.



- Press the **'Enter'** button to select the **'Configure User Accounts'** option. The **'Configure user accounts'** screen will appear.
- Use the arrow buttons to choose the **'Add Account'** option. Press the **'Enter'** button to select the **'Add Account'** option.
- The **'User account type'** screen will appear and provide a choice of user account to add, either Operator or Administrator.

☒ **NOTE:** The Service account option is accessible only by a Cerus-authorized field service engineer. This option is disabled for Administrators.



- Use the arrow buttons to select the account type, Operator or Administrator. Press the **'Enter'** button.

The **'Add account'** screen will appear. Enter the username for the account, either by scanning a barcode or by entering the username manually with the keypad. (Refer to Section 4.2.) Press the **'Enter'** button if the username is manually entered.

**NOTE:** The **'Enter'** button only appears when an acceptable username is entered.



- ✉ **NOTE:** Valid usernames are 2 to 17 characters in length and are limited to alphabetic characters, digits, and the special characters “-“, “+“, “\*“, “\$“, “.”, “/“, and “:”. Usernames are NOT case sensitive, must be unique, and cannot be reused once disabled.
- The **'Confirm username'** pop-up window will appear if the username was manually entered. If the manually-entered username is incorrect, press the **'Edit'** button and correct it.



- If the manually-entered username is correct, press the **'OK'** button. The **'Enter password'** screen will appear.

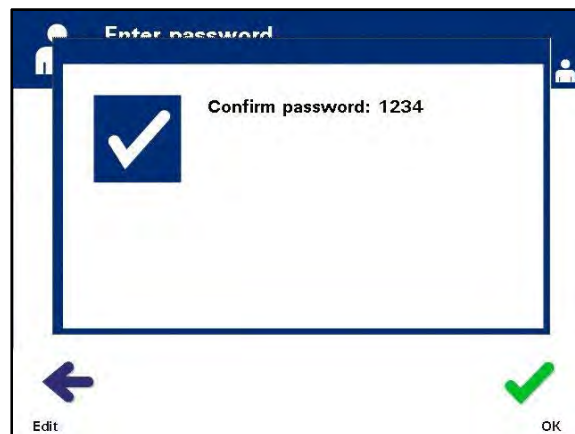
- Enter the password for the account, either by scanning a barcode or by entering the password manually with the keypad. (Refer to Section 4.2.) Press the **'Enter'** button if the password is manually entered.

✉ **NOTE:** The 'Enter' button only appears when an acceptable password is entered.

✉ **NOTE:** Valid passwords are 3 to 17 characters in length and are limited to alphabetic characters, digits, and the special characters “-“, “+“, “\*“, “\$“, “.”, “/”, and “:”. Passwords are NOT case sensitive.



- The **'Confirm password'** pop-up window will appear if the password was manually entered. If the manually-entered password is incorrect, press the **'Edit'** button and correct it.

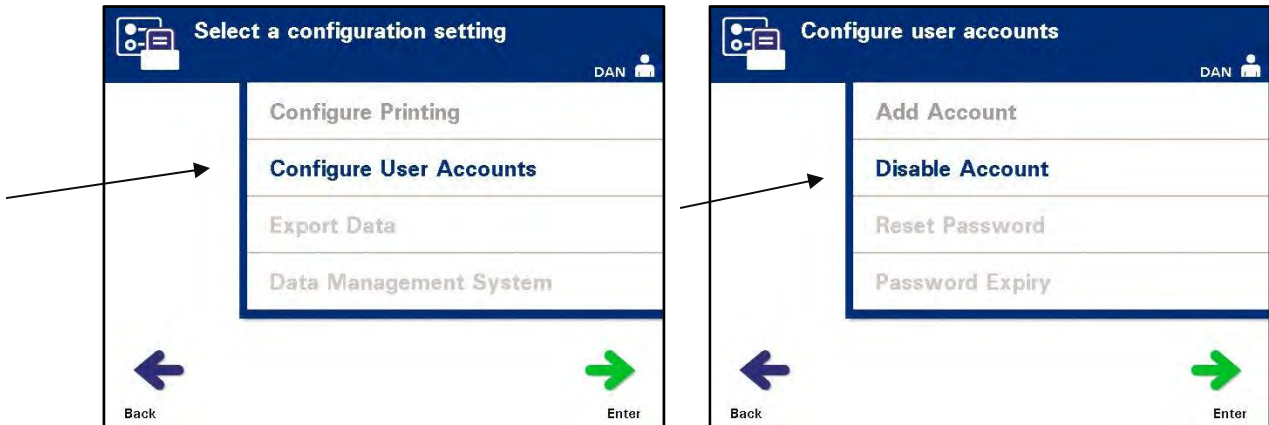


- If the manually-entered password is correct, press the **'OK'** button.

**Disable Account** Use to disable an account so that it is no longer a valid username.

**! CAUTION** Once an account has been disabled, it cannot be reactivated. Furthermore, the username cannot be reused.

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure User Accounts'** option.



- Press the **'Enter'** button to select the **'Configure User Accounts'** option. The **'Configure user accounts'** screen will appear.
- Use the arrow buttons to select the **'Disable Account'** option. Press the **'Enter'** button to choose the **'Disable Account'** option.
- The **'Disable account'** screen will appear. Enter the username of the account to be disabled, either by scanning a barcode or by entering the username manually with the keypad . (Refer to Section 4.2.) Press the **'Enter'** button if the username is manually entered.



- The **'Confirm username'** pop-up window will appear if the username was manually entered. If the manually-entered username is incorrect, press the **'Edit'** button and correct it.

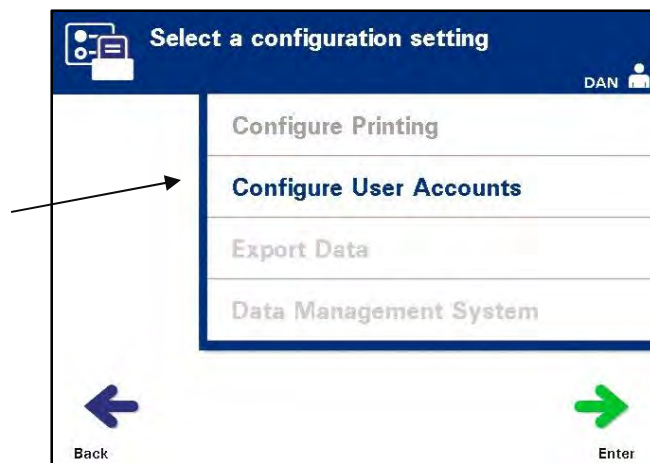


- If the manually-entered username is correct, press the **'OK'** button.

## Reset Password

An Administrator can reset the password for an Operator or another Administrator. (Use this feature if a password is forgotten.)

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure User Accounts'** option.



- Press the **'Enter'** button to select the **'Configure User Accounts'** option. The **'Configure user accounts'** screen will appear.





- Use the arrow buttons to choose the **'Reset Password'** option. Press the **'Enter'** button to select the **'Reset Password'** option.
- The **'Enter username'** screen will appear. Enter the username of the account whose password is to be reset either by scanning a barcode or by entering the username manually with the keypad. (Refer to Section 4.2.) Press the **'Enter'** button if the username is manually entered.
- If the username is valid, the **'Enter password'** screen will appear.

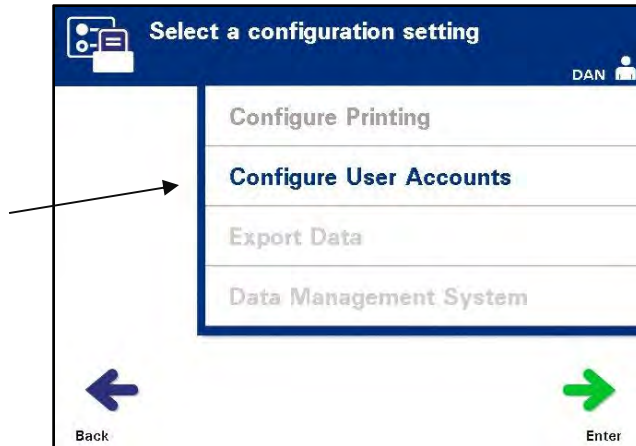


- Enter the **new** password for the account, either by scanning a barcode or by entering the username manually with the keypad. (Refer to Section 4.2.) Press the **'Enter'** button if the password is manually entered. The **'Confirm Password'** popup window will appear if the password was manually entered. If the manually-entered password is incorrect, press the **'Edit'** button and correct. If the manually-entered password is correct, press the **'OK'** button.
- ✉ • **NOTE:** The new password must be different than the current password.
- Upon successful completion, the **'Select an option'** screen will appear.

## Password Expiry

Use to set the number of days that a user's password is valid. Options are disabled (no expiration), 30 days, 90 days, or 180 days.

- From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Configure User Accounts'** option.



- Press the **'Enter'** button to select the **'Configure User Accounts'** option. The **'Configure user accounts'** screen will appear.



- Use the arrow buttons to choose the **'Password Expiry'** option. Press the **'Enter'** button to select the **'Password Expiry'** option.

- The **'Configure password expiry time'** screen will appear.



- Use the arrow buttons to choose **'Disable', '30 days', '90 days', or '180 days'**. Press the **'Enter'** button to choose one of the options.
- The **'Confirm password expiry time'** pop-up window will appear. If the expiry time is incorrect, press the **'Edit'** button and correct it.
- If the expiry time is correct, press the **'OK'** button to confirm the expiry time.

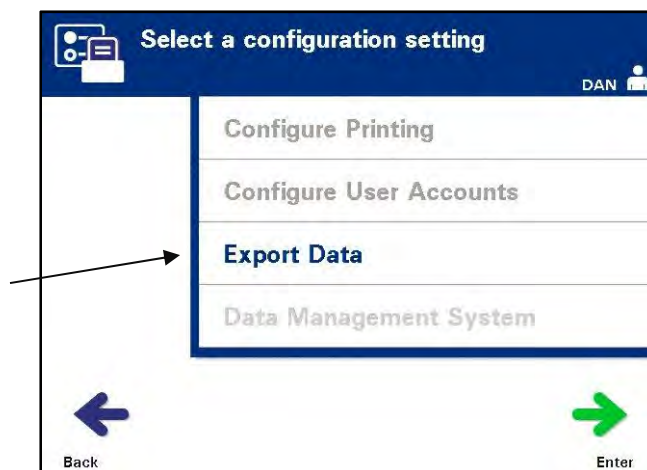
## Export Data

Use to export treatment and service data to a host computer.

Export Data options are:

- Export All Treatments
- Export Treatments in Date Range
- Export All Service Data
- Export Service Data in Date Range

From the **'Select a configuration setting'** screen, use the arrow buttons to choose the **'Export Data'** option.



- Press the **'Enter'** button to select the **'Export Data'** option. The **'Select Data To Export'** screen will appear. The following sections detail each of the export data options.

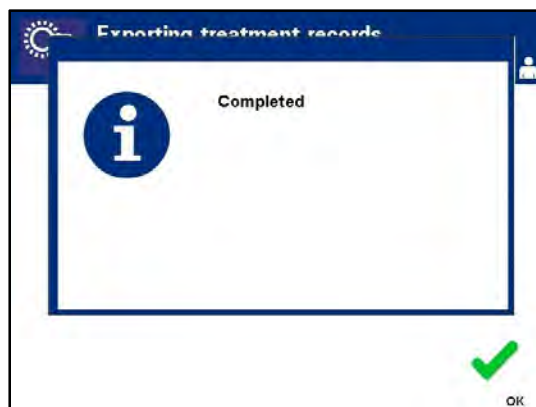


- ☒ **NOTE:** When a large number of files are selected, there may be a delay while the illuminator prepares the files.

**Export All Treatments** Use **'Export All Treatments'** to export all treatment records in the system memory to a host computer.

- From the **'Select Data To Export'** screen, use the arrow buttons to choose the **'Export All Treatments'** option. Press the **'Enter'** button to select the **'Export All Treatments'** option.

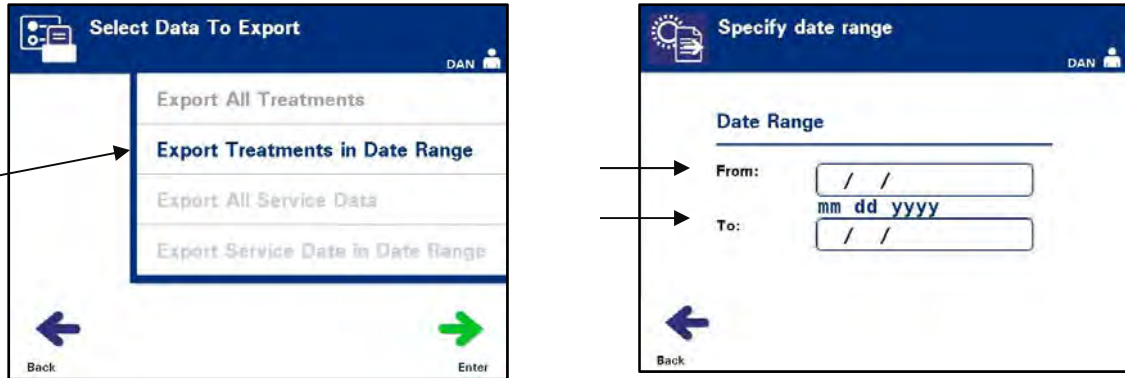
- ☒ **NOTE:** After **'Enter'** is pressed, there may be a delay while the illuminator prepares the files. **DO NOT** re-press **'Enter.'**
- The **'Export all treatment records'** screen will appear. To cancel *before* the export operation begins, press the **'Cancel'** button.
- To start exporting **all treatment records**, press the **'Export'** button. The **'Exporting treatment records'** screen will appear. Alternatively, if the **'Export'** button is NOT pressed, the **'Exporting treatment records'** screen will appear automatically after a short delay.
- ☒ **NOTE:** To stop exporting at any time during the export process, press the **'Cancel'** button. The **'Export will be canceled'** pop-up window will appear. Press the **'OK'** button to cancel the export operation.
- When the export operation is finished, the **'Completed'** pop-up window will appear. Press the **'OK'** button.



### Export Treatments in Date Range

Use to export treatment records within a specified date range to a host computer.

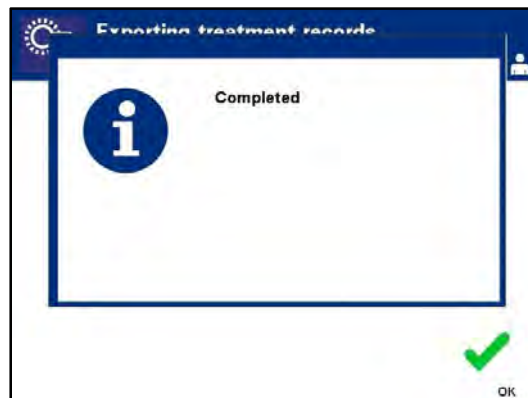
- From the **'Select Data To Export'** Screen, use the arrow buttons to choose the **'Export Treatments in Date Range'** option. Press the **'Enter'** button to select the **'Export Treatments in Date Range'** option.
- The **'Specify date range'** screen will appear. Use the keypad to enter the **'From'** date.



- Use the arrow buttons to advance to the **'To'** date. Use the keypad to enter the **'To'** date.
- Press the **'Enter'** button. The **'Confirm date range for export'** screen will appear.

✉ **NOTE:** After **'Enter'** is pressed, there may be a delay while the illuminator prepares the files. **DO NOT** re-press **'Enter.'**

- If the data entered is incorrect, press the **'Edit'** button. The **'Specify date range'** screen will appear. Use the arrow buttons and the keypad to edit the date range and correct it.
- If the data entered is correct, press the **'Export'** button to begin exporting data. The **'Exporting treatment records'** screen will appear. Alternatively, if the **'Export'** button is NOT pressed, the **'Exporting treatment records'** screen will appear automatically after a short delay.
- When the export operation is finished, the **'Completed'** pop-up window will appear. Press the **'OK'** button.



## Export All Service Data

Use **'Export All Service Data'** to export all service data to a host computer.

- From the 'Select Data To Export' screen, use the arrow buttons to choose the **'Export All Service Data'** option. Press the **'Enter'** button to select the **'Export All Service Data'** option.

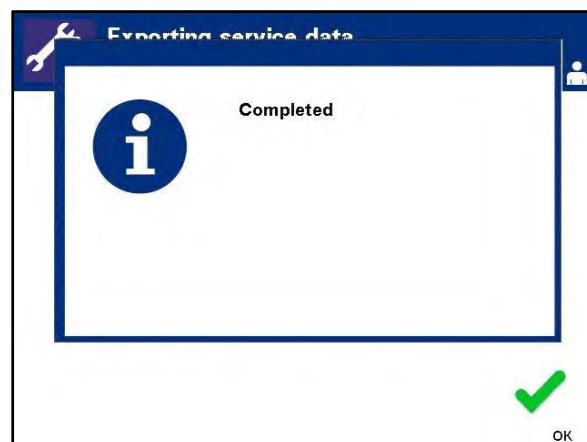
✉ **NOTE:** After **'Enter'** is pressed, there may be a delay while the illuminator prepares the files. **DO NOT** re-press **'Enter.'**



- The **'Export all service data'** screen will appear. To cancel before the export operation begins, press the **'Cancel'** button.
- To start exporting all service data, press the **'Export'** button. The **'Exporting service data'** screen will appear. Alternatively, if the **'Export'** button is NOT pressed, the **'Exporting service data'** screen will appear automatically after a short delay.

✉ **NOTE:** To stop exporting at any time during the export process, press the **'Cancel'** button. The **'Export will be canceled'** pop-up window will appear. Press the **'OK'** button to cancel the export operation.

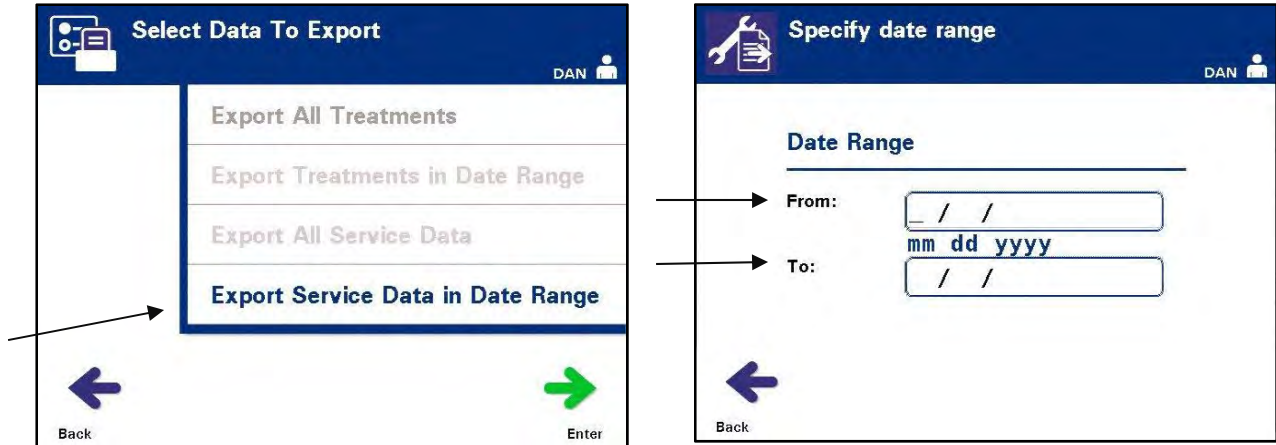
- When the export operation is finished, **'Completed'** pop-up window will appear. Press the **'OK'** button.



## Export Service Data in Date Range

Use **'Export Service Data in Date Range'** to export service data within a specified date range to a host computer.

- From the **'Select Data to Export'** screen, use the arrow buttons to choose the **'Export Service Data in Date Range'** option. Press the **'Enter'** button to select the **'Export Service Data in Date Range'** option.



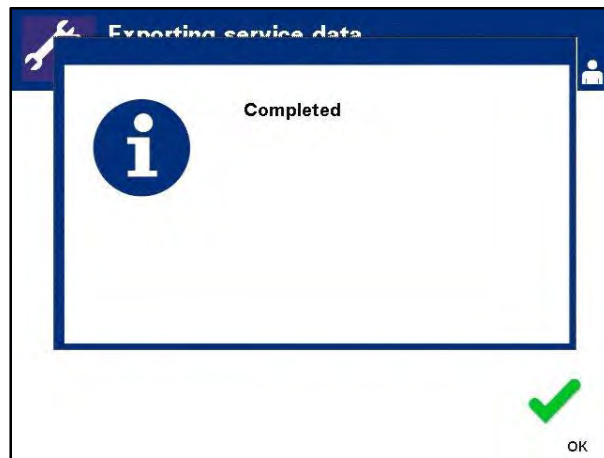
- The **'Specify date range'** screen will appear. Use the keypad to enter the **'From'** date.
- Use the arrow buttons to advance to the **'To'** date. Use the keypad to enter the **'To'** date.
- Press the **'Enter'** button.

☒ **NOTE:** After **'Enter'** is pressed, there may be a delay while the illuminator prepares the files. **DO NOT** re-press **'Enter.'**

- The **'Confirm date range for export'** screen will appear.



- If the data entered is incorrect, press the **'Edit'** button. The **'Specify date range'** screen will appear. Use the arrow buttons and the keypad to edit the date range and correct it.
- If the data entered is correct, press the **'Export'** button to begin exporting service data. The **'Exporting service data'** screen will appear. Alternatively, if the **'Export'** button is NOT pressed, the **'Exporting service data'** screen will appear automatically after a short delay.
- When the export operation is finished, the **'Completed'** pop-up window will appear. Press the **'OK'** button.



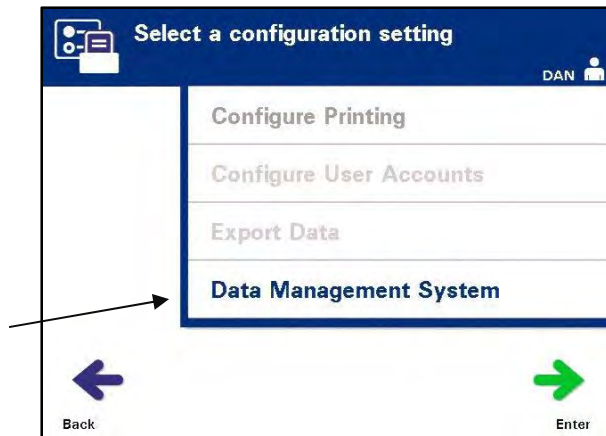


## Data Management System

Do not connect the Illuminator to an open network. If using optional devices, such as **'Data Management System.'** Only connect the illuminator to a firewall-protected network.

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 (←) button to delete the address. Then, re-enter the correct address using the keypad.

✉ **NOTE:** You must enter a unique 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 (←) 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 .

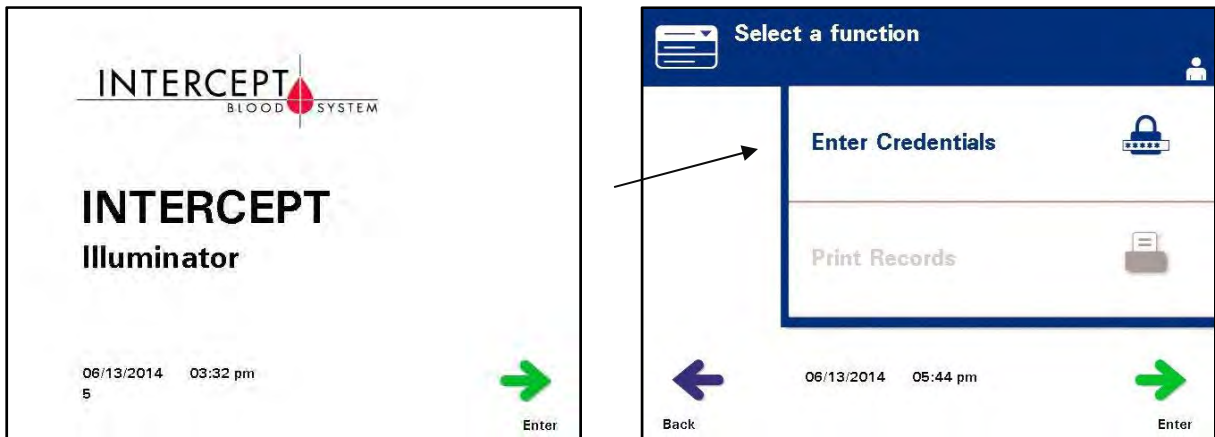
- Press the **'Enter'** button when the address has been entered. A confirmation screen will appear.
- If the address is correct, press the **'OK'** button to confirm the address. The **'Select a configuration setting'** screen will appear.
- Press the **'Back'** button to return to the **'Select a setting'**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

## Section 3.8 Change Password

Any user can change their own account password after providing the appropriate credentials. The new password must be different from the current password. Valid passwords are 3 to 17 characters in length and are limited to alphabetic characters, digits, and the special characters “-”, “+”, “\*”, “\$”, “.”, “/”, and “:”. Passwords are NOT case sensitive.

If the system is configured for password expiration, the system will prompt the user to change the password once a day for 7 days prior to password expiry for the account. If a user’s password has expired, the user will be required to change it prior to gaining access to any password-protected functions.

To change the account password, perform the following steps:

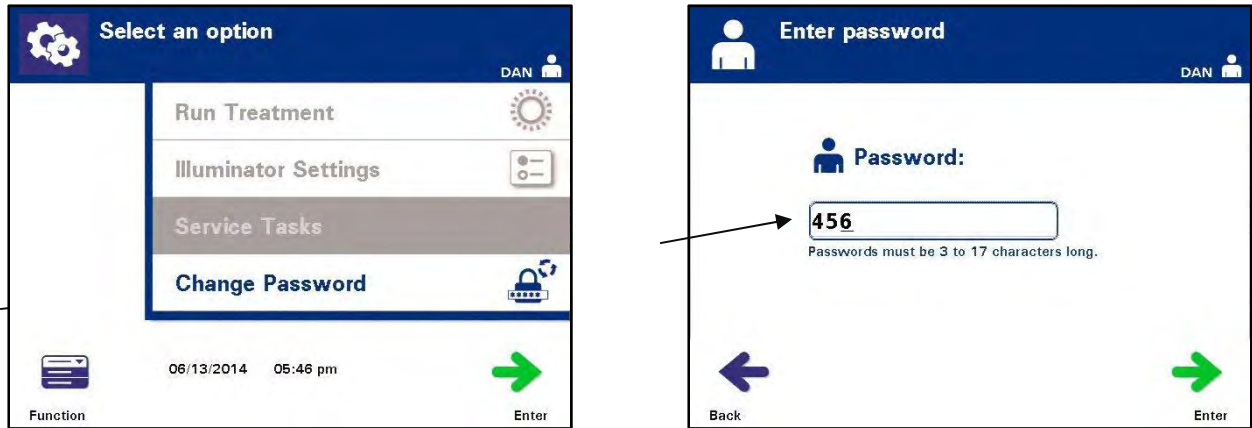


- Turn on the device and press the **‘Enter’** button once it appears.
- The **‘Select a function’** screen will appear. Select the **‘Enter Credentials’** option and press the **‘Enter’** button.
- The **‘Enter username’** screen will appear. Enter your username and press the **‘Enter’** button.
- The **‘Enter password’** screen will appear. Enter your password and press the **‘Enter’** button.

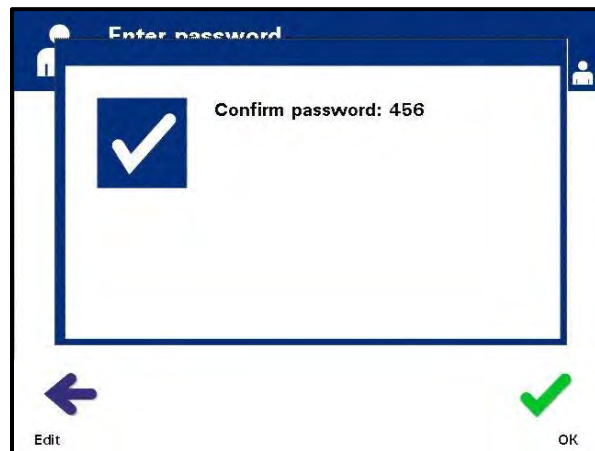


Chapter 3 – Illuminator Description  
Section 3.8 – Change Password

- The **'Select an option'** screen will appear. Select the **'Change Password'** option and press the **'Enter'** button. The **'Enter password'** screen will appear.
- Enter the **new** password either by scanning a barcode or by entering the password manually with the keypad. (Refer to Section 4.2.) Press the **'Enter'** button if the password is manually entered.



- The **'Confirm password'** pop-up window will appear if the password was manually entered. If the manually-entered password is incorrect, press the **'Edit'** button and correct it.



- If the manually-entered password is correct, press the **'OK'** button.

## **Section 3.9      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 3.10 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 3.11 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**

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
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4.2      Turn On the Illuminator and Enter Credentials	4-4
4.3      Load Processing Set(s)	4-6
4.4      Scan Barcodes	4-10
4.5      Repeat Set Loading for Container 2	4-12
4.6      Begin Illumination Process	4-13
4.7      Illumination Interruption	4-14
4.8      Unload the Processing Set(s)	4-15
4.9      Optional Printing Treatment Reports and Additional Labels	4-18
4.10     Change Users Before the Next Illumination Cycle	4-27
4.11     Turn Off the Illuminator	4-28
4.12     Questions and Answers	4-29

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## Section 4.1      Introduction

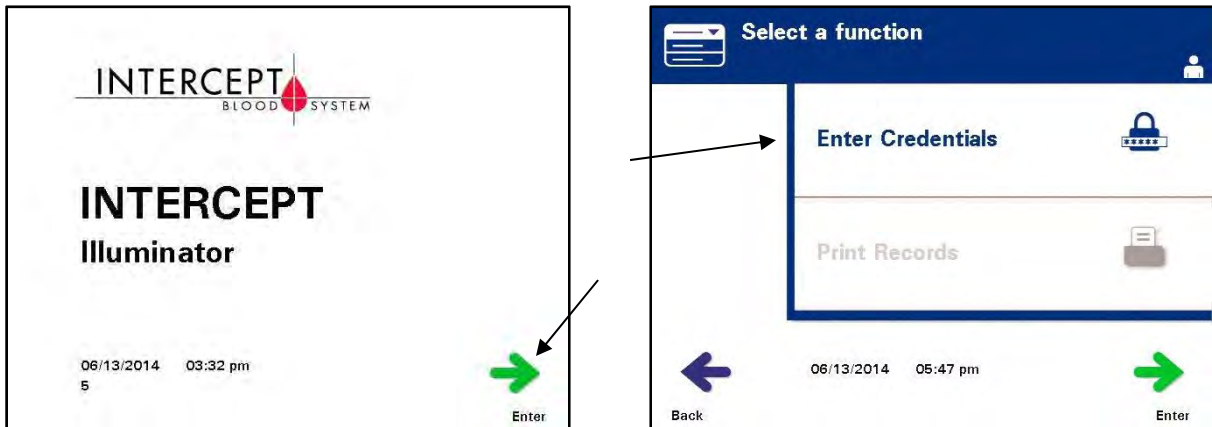
This chapter will guide you through a complete treatment cycle with the illuminator. A summary of operator steps is given in the Appendix.

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.

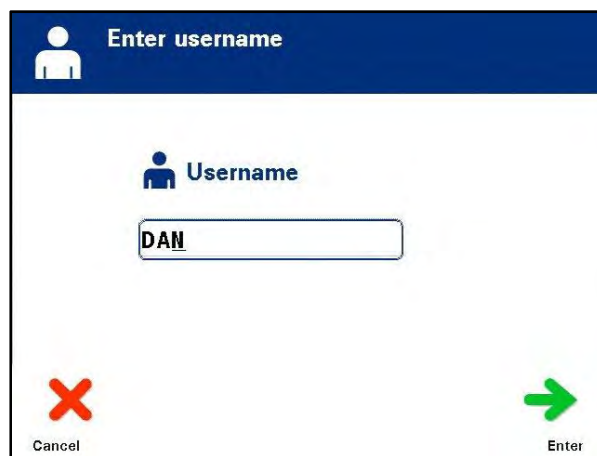
- ☒ **NOTE:** Only use approved INTERCEPT Processing Sets cleared by the appropriate regulatory agencies in your country.

## Section 4.2 Turn On the Illuminator and Enter Credentials

1. Press the power switch, under the screen, to turn on the illuminator on.
  - The illuminator will run several self-tests. When the self-tests are complete, the **'Enter'** function button will appear.
2. Press the **'Enter'** button. The **'Select a Function'** screen will appear.



3. While the **'Select a function'** screen is displayed, use the arrow buttons to select the **'Enter Credentials'** option.
4. Press the **'Enter'** button to choose the **'Enter Credentials'** option. The **'Enter username'** screen will appear.



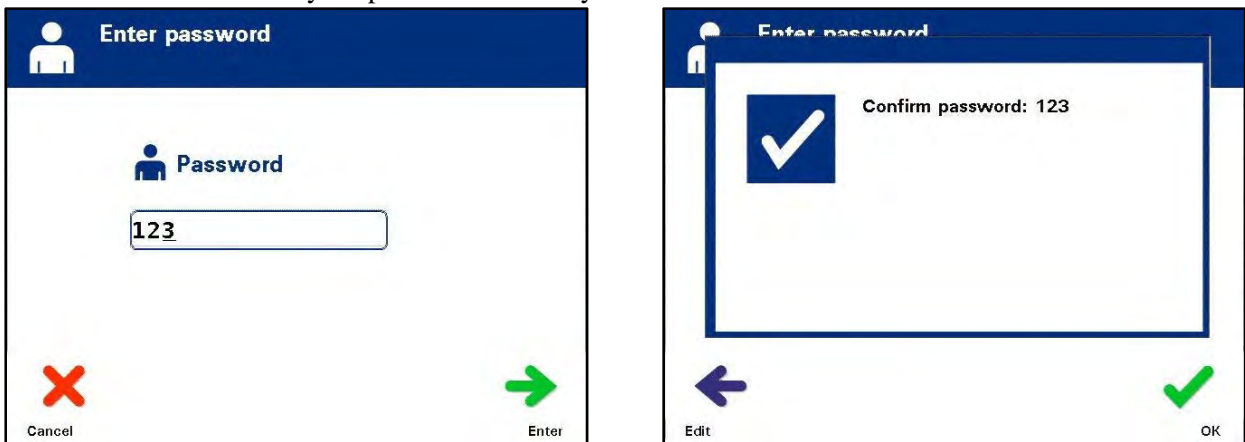
5. If you have a barcode for username identification, scan it. If a barcode is not available, enter the identification manually.

To enter your username manually, perform the following steps:

- Use the keypad to enter your username name or number.
- If the username is incorrect, press the backspace ( ← ) button on the keypad to delete the wrong username. Then, re-enter the correct username using the keypad.
- If the identification is correct, press the **'Enter'** button. A confirmation screen will appear. Press **'OK'** to confirm.

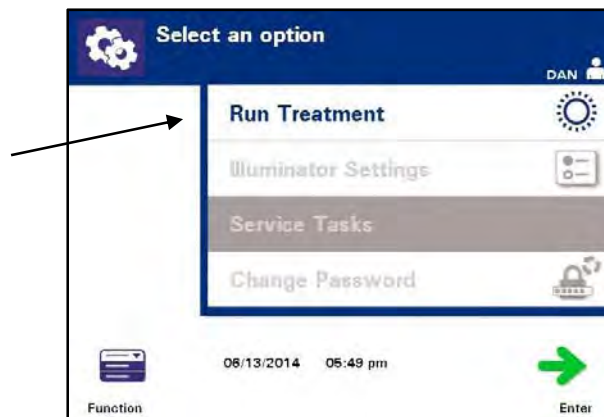
✉ **NOTE:** The illuminator installation configuration may not require password entry after operator credential entry.

6. If you have a barcode password, scan it. If a barcode is not available, enter your password manually.



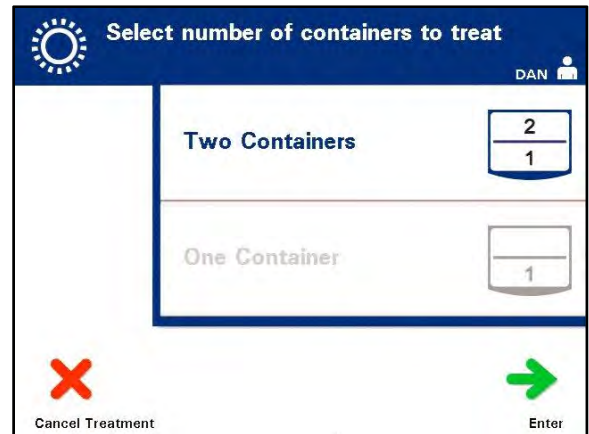
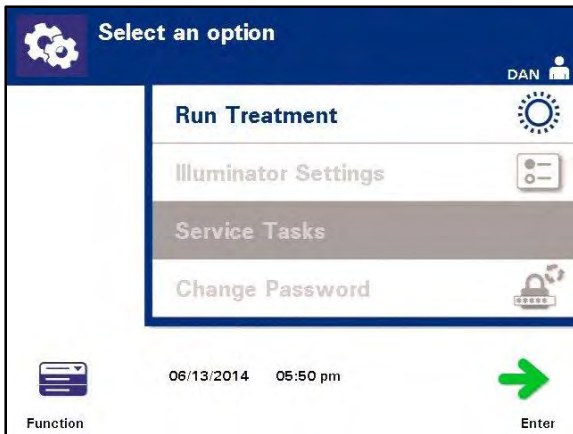
7. If the manually-entered password is correct, press the **'Enter'** button. A confirmation screen will appear. Press **'OK'** to confirm.

8. The **'Select an option'** screen will appear.



## Section 4.3 Load Processing Set(s)

1. Access the **'Select an Option'** screen (refer to Section 4.2), then 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.

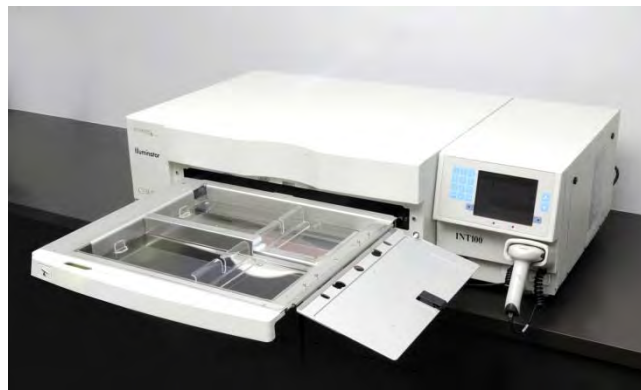


✉ **NOTE:** If the door is not opened, then an information screen will appear to remind you to open the door.

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.**

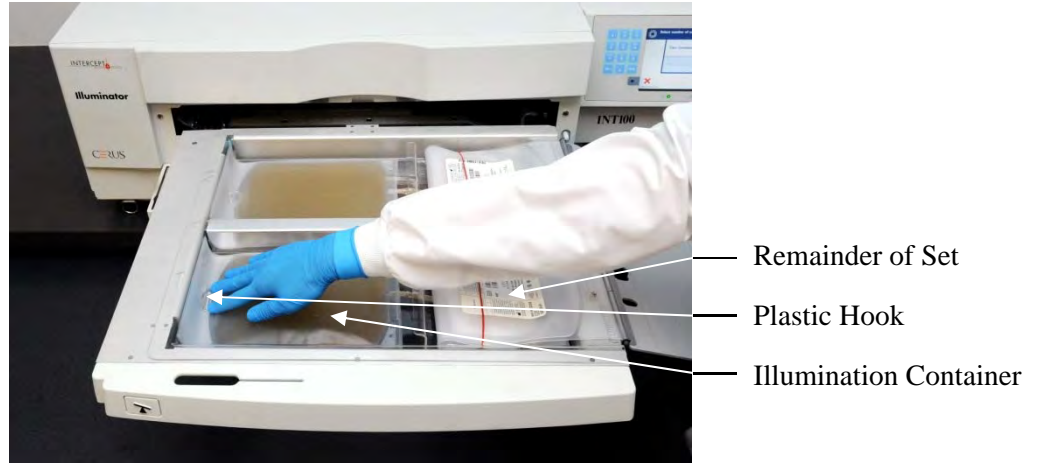
**✉ NOTE:**

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.

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

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- 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.

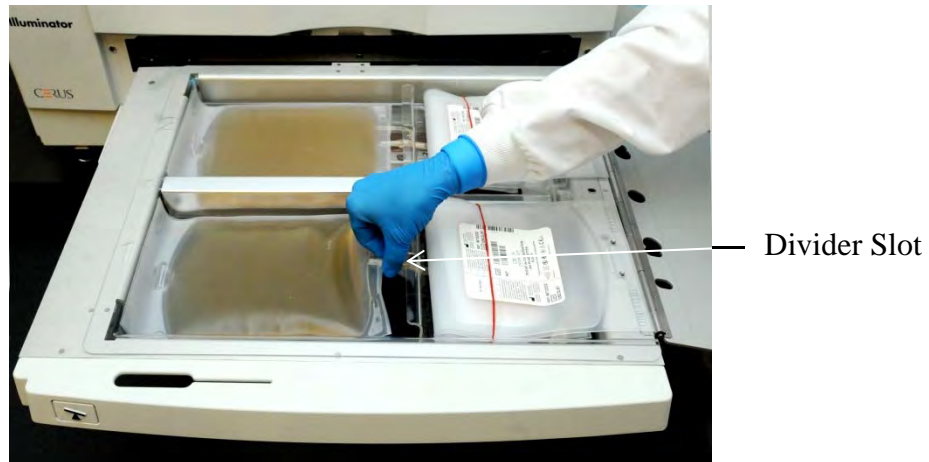


- Put the tubing from the illumination container in the slot of the divider. Make sure that the sealed tubing containing blood product is within the left-hand side of the chamber.



**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.**



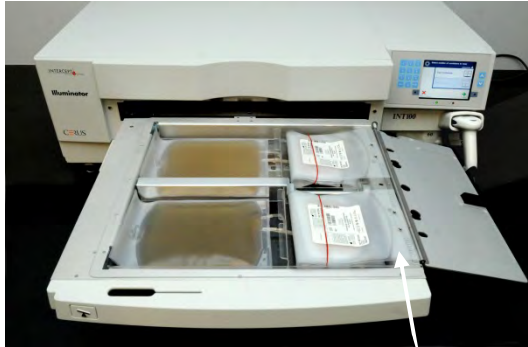


11. Place the other containers into the right-hand side of the front chamber 1 so that the final storage container label is facing up.

✉ **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

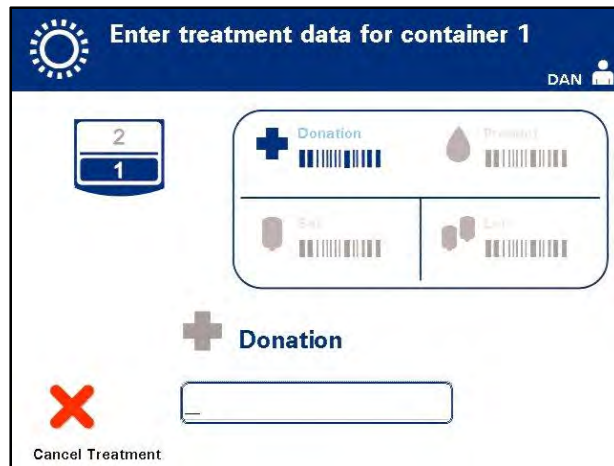


Alignment Holes



✉ **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 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.

### Platelet Product



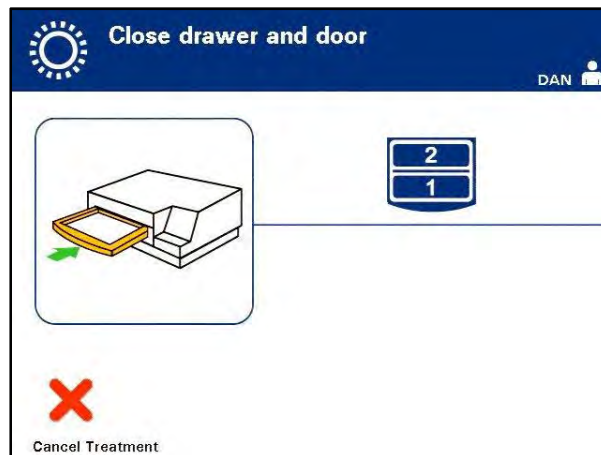
### Plasma Product



**! 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.

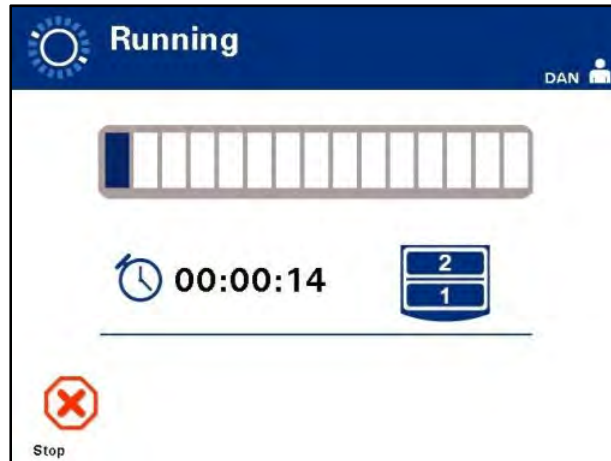
The **‘Close drawer and door’** screen will appear.



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

## Section 4.6      **Begin Illumination Process**

The **Running** screen will automatically 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. If you press the **'Yes'** button, a popup screen will alert you that the treatment has been stopped by the operator. Press **'OK.'**

**✉** **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**

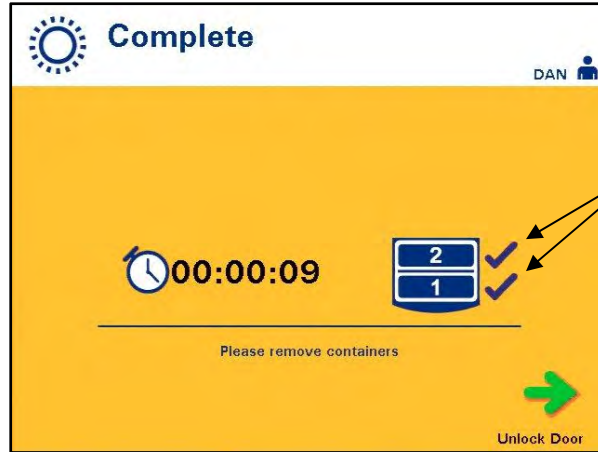
The following can cause interruption in illumination:

- 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. Illuminator restart may be required.

## 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.



“✓” Indicates Treatment is Complete

- 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
✗	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 **'Enter username'** screen will appear.
2. Repeat the steps described earlier, beginning with Section 4.2.5, to enter username and password (optional).

✉ **NOTE:** To go directly to the **'Select a function'** screen from the **'Unload containers'** screen, press the **'Function'** button.


## Section 4.9      **Optional Printing Treatment Reports and Additional Labels**

When the illuminator is configured to print reports (refer to Section 3.6, Illuminator Settings, for details), the following options are available:

- Print the last treatment manually
- Print a specific treatment
- Print a shift report
- Print treatments in a date range
- Print labels

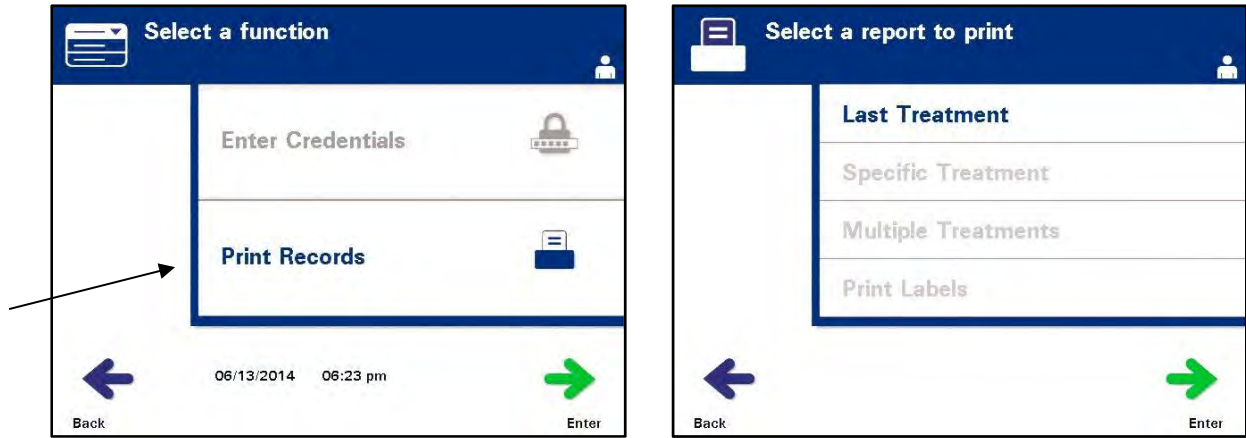
The following paragraphs describe how to create these reports once the printer is connected and the illuminator is configured. (Refer to Chapter 3.6 for illuminator configuration and to Chapter 7.5 for connecting external devices.)

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.

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

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

1. Turn on the Illuminator and press the **'Enter'** button once it is displayed. The **'Select a function'** screen will appear.
2. Use the arrow buttons to choose the **'Print Records'** option and press **'Enter.'** The **'Select a report to print'** screen will appear.



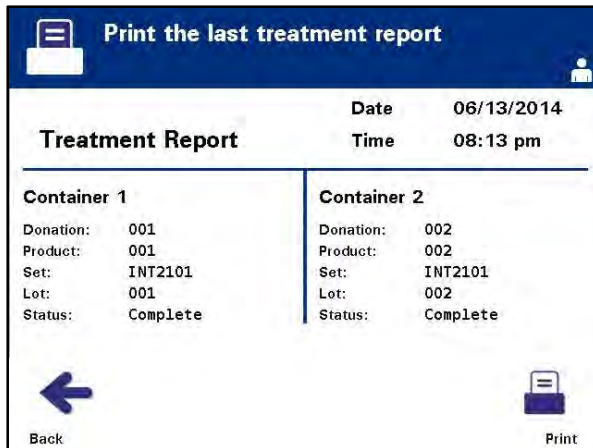
Use these steps to access the report printing options or press the **'Back'** button to get back to the previous screen or the **'Select a report to print'** screen while you are printing reports.

✉ **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.



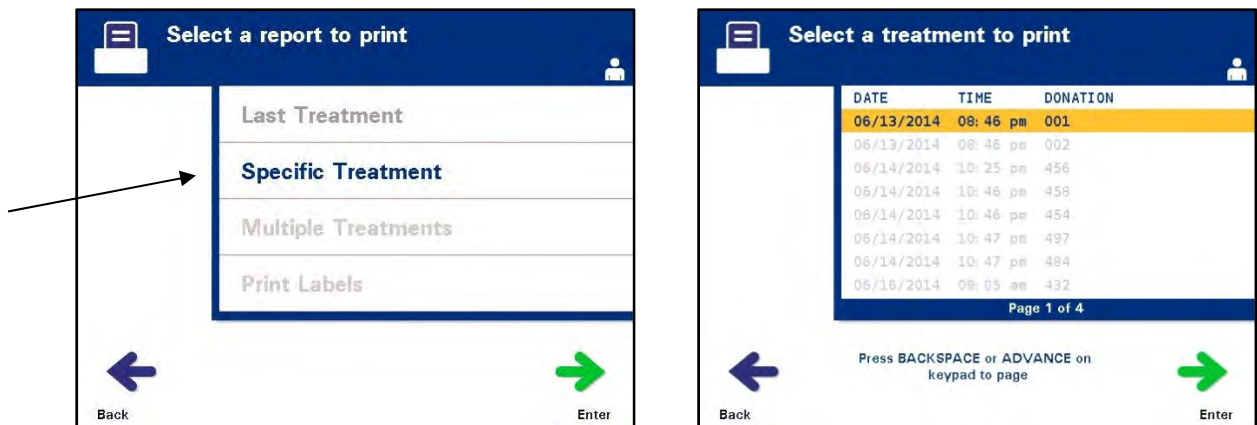
3. If this screen is incorrect, press the **'Back'** button. The **'Select a report to print'** screen will appear. Use the arrow buttons to choose the **'Specific Treatment'** option. (Refer to the Specific Treatment Section below.)
4. If the **'Print the last treatment report'** screen is correct, 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 (oldest to newest) 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.



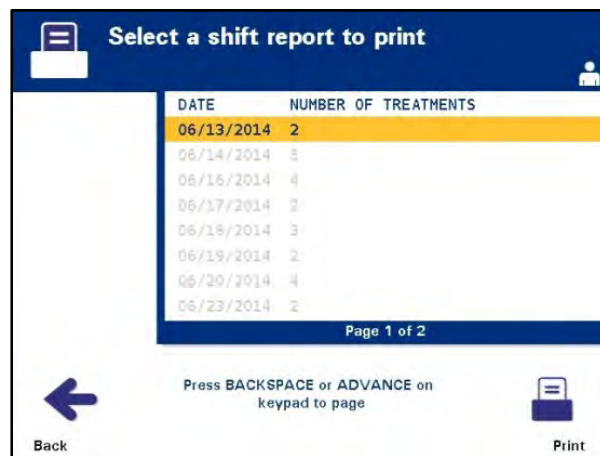
**Shift Report**

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 **'Multiple Treatments'** option.
2. Press the **'Enter'** button to select the option. The **'Select treatments'** screen will appear.



3. Use the arrow buttons to choose the **'Shift Report'** option.
4. Press the **'Enter'** button to select the option. The **'Select a shift report to print'** screen will appear.



5. 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 chronological (oldest to newest) order.

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

### Treatments in Date Range

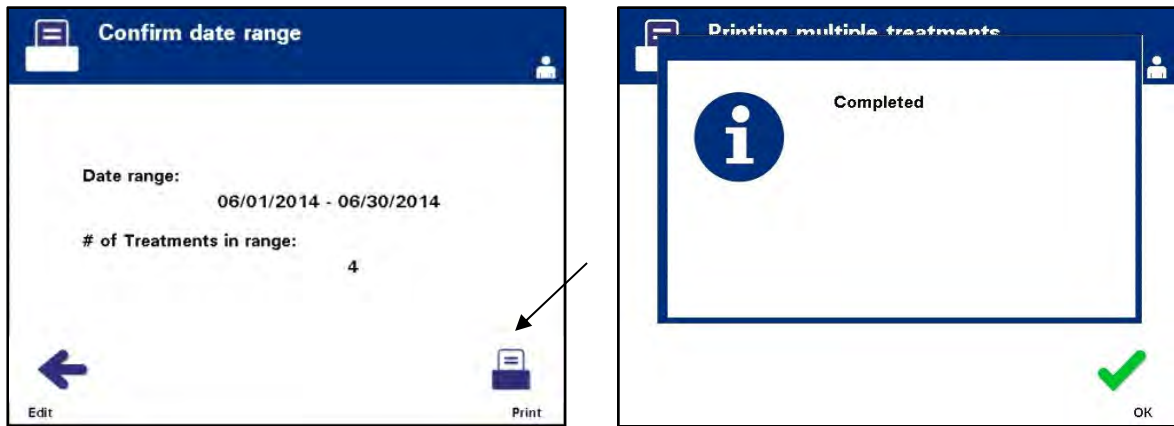
The Treatments in Date Range option refers to a user designated set of dates in which treatments were performed on the illuminator. To print this report:

1. While in the **'Select a report to print'** screen, use the arrow buttons to select the **'Multiple Treatments'** option.
2. Press the **'Enter'** button to choose the option. The **'Select treatments'** screen will appear.
3. Use the arrow buttons to select the **'Treatments in Date Range'** option.
4. Press the **'Enter'** button to choose the option. The **'Specify date range'** screen will appear.

The screenshot shows a screen titled "Specify date range". At the top, there is a blue header bar with a menu icon on the left and a user icon on the right. Below the header, the text "Date Range" is displayed above a horizontal line. There are two input fields: "From:" and "To:". The "From:" field contains the date format " / /". The "To:" field contains the date format "mm dd yyyy". A blue arrow points to the left at the bottom left, with the word "Back" below it. Two arrows from the left point to the "From:" and "To:" labels.

5. Use the keypad to enter the **'From'** date. Then, use the arrow buttons to advance to the **'To'** date. Use the keypad to enter the **'To'** date.

6. Press the **'Enter'** button to confirm the desired date range. The **'Confirm date range'** screen will appear.



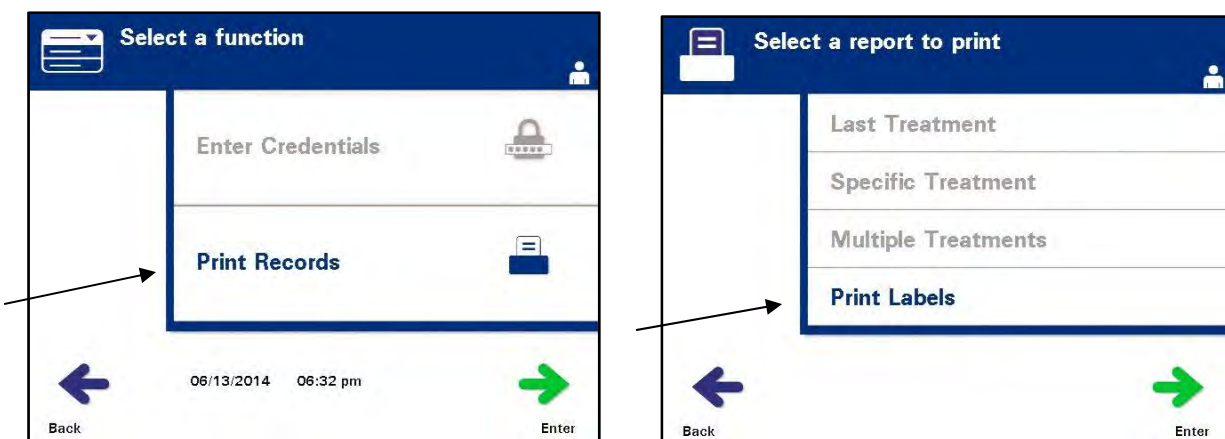
7. When the reports have been printed, the **'Completed'** screen will appear. Press **'OK.'**
8. The **'Select treatments'** screen will appear.



**Print  
 Additional  
 Labels**

To print additional labels, perform the following:

1. From the 'Select a function' screen, use the arrow buttons to choose the **'Print Records'** option.



2. Press the **'Enter'** button. The **'Select a report to print'** screen will appear.
3. Use the arrow buttons to choose the **'Print Labels'** option.
4. Press the **'Enter'** button to select this option. The **'Select a treatment to print'** screen will appear.



5. 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 (oldest to newest) order.

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

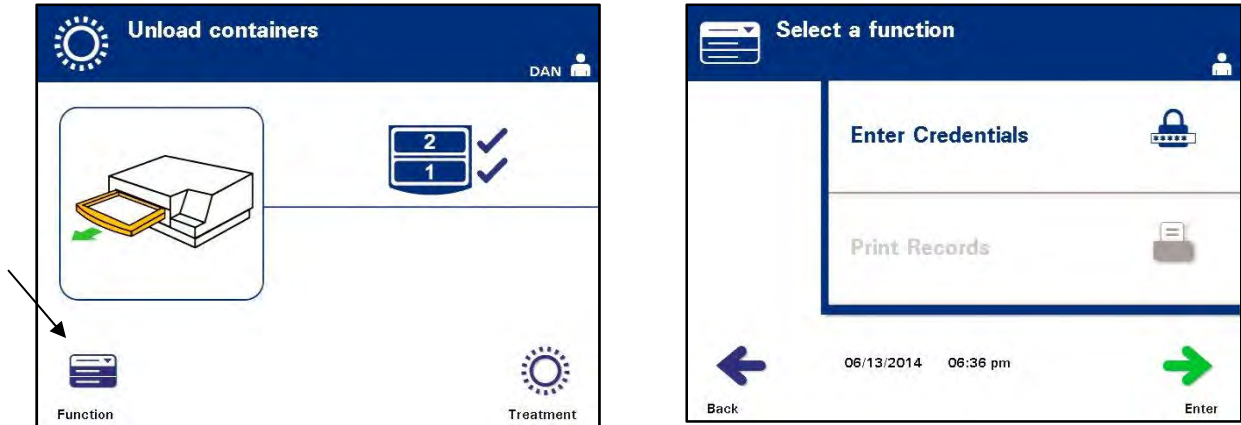
☒ **NOTE:** The number of labels that print will be determined by the label printer configuration setting.

8. 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.



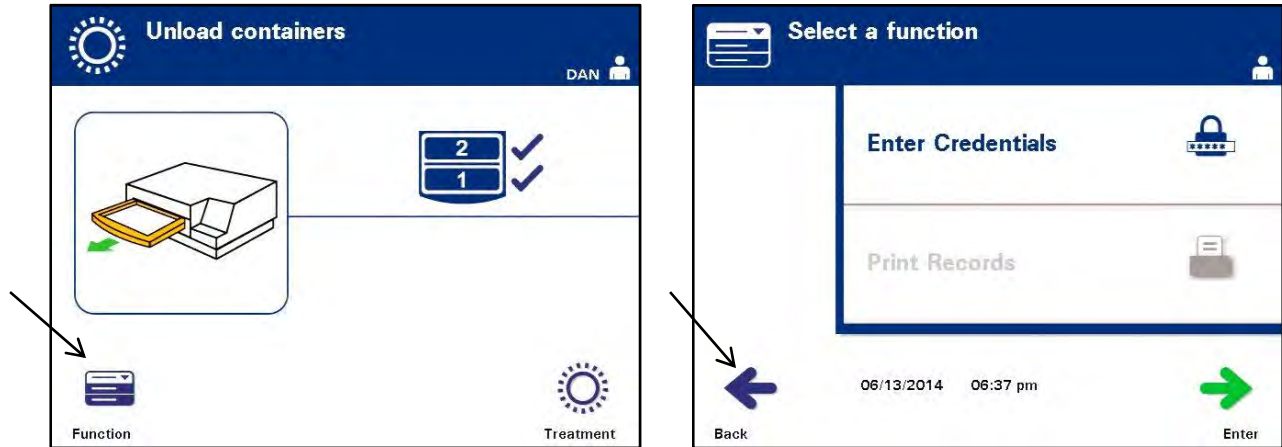
2. To enter credentials, repeat the steps in Section 4.2 to enter credentials.

✉ **NOTE:** When the **'Unload containers'** screen is initially displayed, there are no softkeys. After the door and drawer have been opened, the Unload containers screen has two softkeys: Function on the left and Treatment on the right.

## 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 **'Back'** button. The **'Power On'** 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, use the keypad to manually enter your operator username into the illuminator.

? **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.

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## Chapter 5. Troubleshooting

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5.2 Summary of Questions and Answers	5-4
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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:

Screen Symbols	What the Symbol Means
	<p><b>Error</b> The error messages will be indicated by a red bordered pop-up screen and have an exclamation point in a yellow diamond.</p>
	<p><b>Confirmation</b> 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><b>Information</b> 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>
	<p><b>System issue</b> 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>

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, 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.

#### 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 operator username 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.

#### 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 on the Treatment Complete screen 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. Additional characters will not be displayed.	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 <b>'Edit'</b> 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 Set ID is obsolete. Touch <b>'Edit'</b> to re-enter the Set ID.	The Set ID entered has been disabled and is no longer intended for use.	Off
The valid range for labels is 0 – 6. Touch <b>'Edit'</b> 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 <b>'Edit'</b> 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 <b>'Edit'</b> 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 <b>'Edit'</b> 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

<b>Data Entry</b>	<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 <b>'Cancel'</b> 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>	<p>Off</p>
	<p>Checksum Error.            The data entered cannot be verified. Please press <b>'Cancel'</b> 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>	<p>Off</p>
	<p>Symbology Error.            The barcode symbology scanned is not allowed for this field. Please press <b>'Cancel'</b> 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>	<p>Off</p>
	<p>The current user has been auto-logged out due to inactivity. Touch <b>'OK'</b> to continue.</p>	<p>The user was idle (no button presses or barcode scans) for five minutes.</p>	<p>Off</p>
	<p>Make sure the start date is not later than the end date and both dates are within the full date range.</p>	<p>The entered start date is earlier than the entered end date or either date is not within the full date range.</p>	<p>Off</p>

**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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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

Chapter 5 – Troubleshooting  
Section 5.3 – Error Messages

**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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'OK'</b> to continue or <b>'Cancel'</b> 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

**Front Door**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
<p>The door is open. Open and close the door. Touch <b>'OK'</b> to continue or <b>'Cancel'</b> 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 <b>'Cancel'</b> 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.

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
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

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

<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



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

<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.	Off
At least one of the sets has received an overdose of energy.	One or both processing sets have 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.	On
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

**Processing  
Sets and  
Treatment**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
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 <b>'Continue'</b> to finish or <b>'Stop'</b> 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 on the Treatment complete screen 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**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
The label printer is not working. Check that the label printer is connected to the illuminator, and it has adequate supplies. Touch <b>'OK'</b> to retry the label printer or <b>'Cancel'</b> to quit.	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.	Off
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 <b>'OK'</b> to retry the printer or <b>'Cancel'</b> to quit.	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.	Off
The valid range for labels is 0 – 6. Touch <b>'Edit'</b> to re-enter the number of labels to print.	The number entered for labels to be printed is greater than 6.	Off
The entered TCP/IP address is invalid. Touch <b>'Edit'</b> to re-enter the address.	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.	Off
The TCP/IP addresses define a subnet of greater than 1023 nodes. Both TCP/IP addresses must be re-entered. Touch <b>'Cancel'</b> to continue.	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.	Off

**Side Access  
Panel**

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
Close the side access panel. Touch <b>'OK'</b> to continue or <b>'Cancel'</b> 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.

<b>Message</b>	<b>This occurs if:</b>	<b>Service Light</b>
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



Message	This occurs if:	Service Light
<p>Invalid username.  Usernames must be 2 to 17 characters long and only contain letters, digits, or the special characters -\$.:/:+. Touch <b>'Edit'</b> to enter a new username.</p>	<p>The username scanned is too short, too long, or contains invalid characters.</p>	<p>Off</p>
<p>Invalid password.  Passwords must be 3 to 17 characters long and only contain letters, digits, or the special characters -\$.:/:+. Touch <b>'Edit'</b> to enter a new password.</p>	<p>The password scanned is too short, too long, or contains invalid characters.</p>	<p>Off</p>
<p>Invalid username. Touch <b>'Edit'</b> to enter a new username.</p>	<p>The username entered does not correspond to an existing account.  <b>OR</b>  The username is already in use and cannot be used to create a new account.</p>	<p>Off</p>
<p>Invalid password. Touch <b>'Edit'</b> to enter a new password.</p>	<p>The password entered does not correspond to the current account.  <b>OR</b>  The new password is already the same as the old password.</p>	<p>Off</p>
<p>The username entered is for the current account. An active account cannot disable itself. Touch <b>'Edit'</b> to enter a new username.</p>	<p>A user account cannot disable itself. Log in using different identification to disable the account.</p>	<p>Off</p>

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

<b><u>SECTIONS</u></b>	<b><u>PAGE</u></b>
6.1 Installation: What to Expect When the Illuminator Arrives	6-3
6.2 Selecting a Place for the Illuminator	6-4
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6.6 Illuminator Calibration and Preventive Maintenance	6-12

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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.

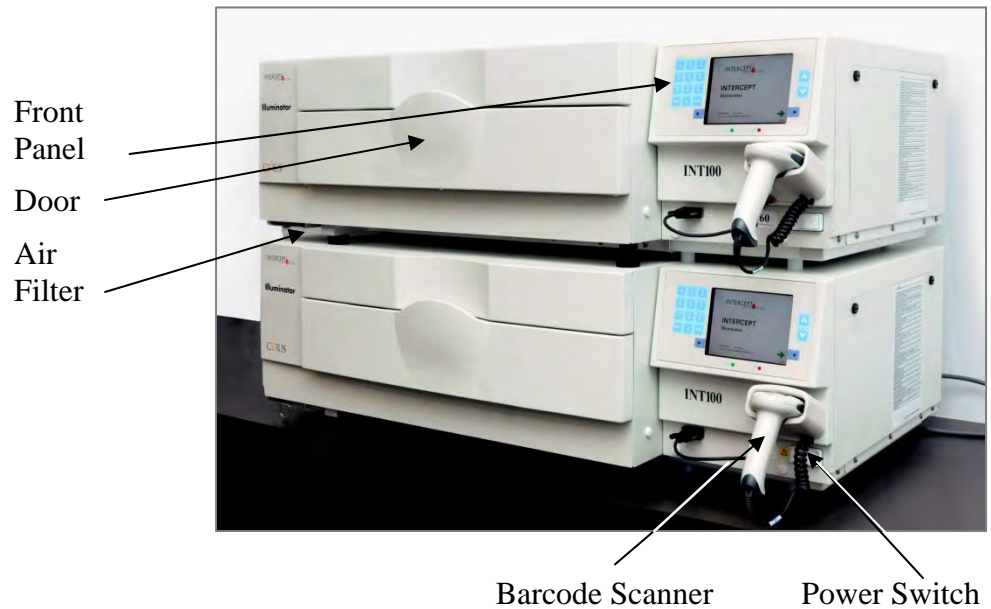
 **NOTE:** Place the illuminator so that there is enough space to open the left side access panel.

- Use 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.



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.



Air Filter

## 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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7.2 Illuminator Compliance with Standards	7-4
7.3 Illuminator Requirements	7-6
7.4 Barcode Compatibility	7-8
7.5 Connecting External Devices	7-15

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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 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
- IEC 60601-1
- ISO 7000
- ISO 7064
- ISO 9001
- ISO 15223-1
- 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+GII (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** The illuminators need special precautions regarding electromagnetic compliance (EMC) and need to be installed and put into service according to the EMC information provided above.

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

**⚠** **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.**

**⚠** **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 7.3 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.



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

### 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.



**NOTE:** Electrical creepage distances and air clearances are designed and approved to an altitude of 2000 M.

**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

**Network  
Connections**

Only connect the illuminator to firewall-protected networks.

## 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]

Chapter 7 – Specifications  
 Section 7.4 – Barcode Compatibility

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- 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"×1" (102 mm × 25 mm) labels (Zebra part number 83340) should be used. 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.

### Network Connections

Only connect the illuminator to firewall-protected networks.

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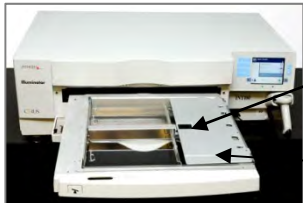

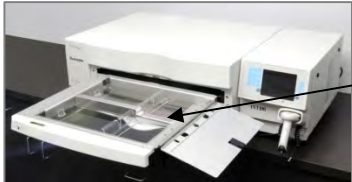
## **Chapter 8. Appendix**

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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	
Crosslink	To form a permanent link.
Donation Number	The donation number from a blood product or the number identifying a platelet pool.
Drawer	
Illumination	The process of exposing a blood product to UVA light.
NIST	National Institute for Standards and Technology.
Set ID (REF)	INTERCEPT Product Code (REF).
Tray	
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

(Refer to Section 4.2 for details.)

Step	Action
1.	Press power switch, under the screen, to turn the illuminator on. When the self-tests are complete, the <b>'Enter'</b> function button will appear.
2.	Press the <b>'Enter'</b> button. The <b>'Select a function'</b> screen will appear.
3.	Use the keypad to select <b>'Enter Credentials'</b> and press the <b>'Enter'</b> button. The <b>'Enter username'</b> screen will appear.

### Enter Credentials

(Refer to Section 4.2 for details.)

Step	Action
1	If you have a barcode for username, scan it. If a barcode is not available, enter the username manually.
2	To enter your username manually, perform the following: <ul style="list-style-type: none"> <li>• Use keypad to enter your username.</li> <li>• If username is correct, press <b>'Enter'</b> button.</li> <li>• If username is incorrect, press the backspace ( ← ) button on the keypad to delete the wrong username. Re-enter the correct username using the keypad.</li> <li>• If username is correct, press the <b>'Enter'</b> button.</li> </ul>
3	The <b>'Enter password'</b> screen will appear. If you have a barcode for password, scan it. If a barcode is not available, enter the password manually and press the <b>'Enter'</b> button.
4	The <b>'Select an option'</b> screen will appear.

✉ **NOTE:** The illuminator installation configuration may not require password entry after operator credential entry.

**Begin a Treatment**

Step	Action
1.	Use the arrow buttons to select the <b>'Run Treatment'</b> option.
2.	Press the <b>'Enter'</b> button. The <b>'Select number of containers to treat'</b> screen will appear.

**Load Processing Set(s)**

(Refer to Section 4.3 for details.)

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

<b>Scan Barcodes</b>	<b>Step</b>	<b>Action</b>								
(Refer to Section 4.4 for details.)	1.	<p>The <b>'Enter treatment data for container 1'</b> screen will appear. Scan barcodes from the final storage container in following order:</p> <table border="0" data-bbox="618 369 1424 621"> <tr> <td data-bbox="618 369 743 401">Barcode 1</td> <td data-bbox="834 369 1187 401">Donation number (<b>'Donation'</b>)</td> </tr> <tr> <td data-bbox="618 443 743 474">Barcode 2</td> <td data-bbox="834 443 1198 474">Blood product code (<b>'Product'</b>)</td> </tr> <tr> <td data-bbox="618 516 743 548">Barcode 3</td> <td data-bbox="834 516 1170 548">INTERCEPT set code (<b>'Set'</b>)</td> </tr> <tr> <td data-bbox="618 590 743 621">Barcode 4</td> <td data-bbox="834 590 1386 621">INTERCEPT manufacturing lot number (<b>'Lot'</b>)</td> </tr> </table>	Barcode 1	Donation number ( <b>'Donation'</b> )	Barcode 2	Blood product code ( <b>'Product'</b> )	Barcode 3	INTERCEPT set code ( <b>'Set'</b> )	Barcode 4	INTERCEPT manufacturing lot number ( <b>'Lot'</b> )
	Barcode 1	Donation number ( <b>'Donation'</b> )								
	Barcode 2	Blood product code ( <b>'Product'</b> )								
Barcode 3	INTERCEPT set code ( <b>'Set'</b> )									
Barcode 4	INTERCEPT manufacturing lot number ( <b>'Lot'</b> )									
2.	<p>If the 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 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. 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 barcodes have been entered.</li> </ul>									
3.	Press the <b>'Done'</b> button.									

**Repeat Set  
Loading for  
Container 2**

(Refer to  
Section 4.5  
for details.)

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.

<b>Step</b>	<b>Action</b>
1.	Make sure that all tubings are in the tray and the containers are flat.
2.	Close the tray cover and ensure that it is secured by the black latch.
3.	Push the drawer into the illuminator until it clicks in place.
4.	Close the door.
5.	The <b>'Running'</b> screen will appear.

**Illumination Interruption**

(Refer to Section 4.5 for details.)

Step	Action
1.	To stop treatment at any time, press the <b>'Stop'</b> button. The <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)**

(Refer to Section 4.8 for details.)

Step	Action
1.	Press the <b>'Unlock Door'</b> button.
2.	An information screen will appear to confirm that label printing is occurring.
3.	The <b>'Unload containers'</b> screen will appear. 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 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 the illumination process.**

**Process Additional Blood Products**

(Refer to Section 4.9 for details.)

Step	Action
1.	Press the <b>'Treatment'</b> button. The <b>'Enter username'</b> screen will appear.
2.	Repeat the Enter Credentials steps.
3.	Repeat the Load Processing Set(s) steps.

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