



INTERCEPT™ Blood System

INTERCEPT Illuminator

Model INT200

User Manual





Cerus Corporation

1220 Concord Avenue
Concord, CA 94520
USA

Made in USA



Cerus Europe B.V.

Stationstraat 79-D
3811 MH Amersfoort
The Netherlands



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Preface

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About this manual

This manual gives detailed information about the use of the INTERCEPT™ Illuminator. It complements the Instructions for Use that accompany the INTERCEPT Blood System processing sets. The Instructions for Use for each processing set describes the processing steps to use before and after illumination. It is important to follow the specific directions for each blood product.

Section contents

Preface	The product description, its indications for use, safety information, and typographic conventions. Also includes all warnings and cautions that are used with this product manual.
Chapter 1: Product Overview	The Illuminator hardware and software in detail.
Chapter 2: Settings	The user management and configuration settings of the Illuminator.
Chapter 3: Performing Treatments	How to use the Illuminator with processing sets.
Chapter 4: Viewing Data and Generating Reports	How to perform searches and generate reports.
Appendix A: Treatment Confirmation and Calibration	Detailed treatment and calibration information.
Appendix B: System Messages	Error messages and notifications that can be seen in the product.
Appendix C: System Icons	Describes the icons used in the product.
Appendix D: Cybersecurity	Describes various details on cybersecurity.
Appendix E: Care & Maintenance	How to change the air filter and clean the Illuminator.

Illuminator role in pathogen inactivation process

The INTERCEPT Illuminator delivers a controlled dose of ultraviolet A (UVA) light to blood products as part of a process to reduce pathogens. The Illuminator is used with INTERCEPT Processing Sets. The processing set allows blood products to be handled in a closed system. The blood product is mixed with amotosalen (a psoralen) and transferred to an illumination container, then it is treated with the Illuminator. The Illuminator can print the treatment results and transfer the data to a network file location. The data is also stored in the Illuminator up to the memory limit for future review.

The following is an overview of the pathogen inactivation process:

1. Amotosalen addition
2. Illumination
3. Agitation with Compound Adsorption Device
4. Transfer to Storage Containers

Refer to the Instructions for Use provided with the processing sets for more information on the process and processing specifications.

- ☒ **NOTE:** While laboratory studies of amotosalen processing with UVA light have shown a reduction in levels of certain pathogens, there is no pathogen inactivation process that has been shown to eliminate all pathogens.

Intended purpose of the Illuminator

The INTERCEPT Illuminator is intended only for use in the INTERCEPT Blood System pathogen inactivation process to deliver UVA light for the photochemical treatment of blood products.

Intended user

The Illuminator is intended for use by blood component laboratory/manufacturing staff. Users should be trained on blood component manufacturing in accordance with the local institution procedures and receive training on the use of the INTERCEPT Illuminator by a qualified trainer.

Intended patient population

Platelets or Plasma prepared and stored using the INTERCEPT Blood System (INTERCEPT Processing Sets and INTERCEPT Illuminator) are intended for transfusion in all patients of all ages requiring platelet or plasma transfusions according to local, national or regional clinical practice guidelines.

Indications for use

The INTERCEPT Illuminator is indicated for use with the INTERCEPT Blood System for platelets and plasma to inactivate broad spectrum of viruses, bacteria, and parasites as well as contaminating donor leukocytes in platelets or plasma components. Platelet concentrates or plasma components treated with the INTERCEPT Blood System are indicated for transfusion support of patients requiring transfusions, according to clinical practice guidelines.

Please refer to Technical Data Sheets PRD-TDS 00674 and PRD-TDS 00675 for additional pathogen inactivation, clinical, and safety information.

Contraindications

The INTERCEPT Illuminator INT200 has no contraindications.

Safety information

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Operating and storage temperatures	Operating temperature: 18 to 30°C with relative humidity 10 to 80% (non-condensing). Transportation and storage temperature: -20 to 60°C with relative humidity 10 to 90% (non-condensing).
Condensation	Condensation may damage the device. If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before use. Do not operate the device outside of the operating temperature range specified in this manual.
Environment for use	For indoor use only
Processing sets	Only use INTERCEPT processing sets with this device. Ensure that all consumables are used prior to their expiration date.
Power cord	Route the power cord to the outlet in a way that prevents the cord from being tripped over. Use only power cords supplied by Cerus for this device. Use of power cords not supplied by Cerus may cause overheating or damage to the device. Do not use extension cords with this device.
Air Filters	Properly installed, undamaged filters are required to prevent particles, such as dust, from entering the system and to ensure adequate air flow to keep the blood product cool during treatment.
Preventive maintenance	Preventive Maintenance is carried out by Cerus Technical Services or authorized representatives periodically.



Care and maintenance	<p>Periodically inspect electrical cords for signs of wear or damage.</p> <p>Periodically clean or change the air filter and clean or disinfect the device. See Appendix E: Care & Maintenance for details.</p> <p>Repairs and adjustments must be performed by Cerus Technical Service or authorized representative.</p>
Improperly functioning device	If you notice any unexplained changes in the performance of the device, or if the tray is cracked, discontinue use and contact your Cerus Technical Service or authorized representative.
EMC	Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed according to EMC information. Contact Cerus if there are questions regarding EMC installation information.
Device placement	Do not place the device in or on any surface that can collect or hold water. Do not place the device directly onto carpet, fabric, or other flammable materials.
Equipment ratings	<p>Applicable to MET certified illuminators</p> <p>120 VAC ~ 60Hz</p> <p>230 VAC ~ 50Hz</p> <p>800 VA is the maximum input current for this device</p> <hr/> <p>Applicable to SGS certified illuminators</p> <p>100 - 240 VAC~</p> <p>50 – 60 Hz</p> <p>1200 VA is the maximum power rating for this device</p>
Fuse ratings	Slow-Blow 12 A, 250 V
Voltage	Overvoltage category II
Pollution	This device is considered a pollution degree 2, meaning that normally only non-conductive pollution occurs. Temporary conductivity caused by condensation is to be expected.
Disposal	Contact Cerus or follow facility guidelines for proper disposal.








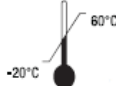





Symbols

The symbols in this section are used in product labeling of the Illuminator.

Shipping carton label symbols




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

Symbol	What the Symbol Means and Instructions
	Catalogue number
	Model number



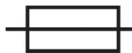










Symbol	What the Symbol Means and Instructions
	Serial number
	European Authorized Representative and Importer
	Date of manufacture
	Consult Instructions for Use
	Keep Dry The shipping carton and contents MUST be kept dry.
	Fragile, Handle with Care The shipping carton and contents must be handled with care.
	This Way Up The package must be kept the right way up.
	Storage temperature range 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.
	Manufacturer
	Requires separate electrical and electronic waste collection.
	Medical device
	CE Mark



Product labeling symbols

The following symbols appear on the instrument:

Symbol	Meaning
	Power standby button
	On. Must be on to use the Illuminator and for the internal fans to operate.
	Off. Cuts all power to the device. Equivalent to disconnecting the power cord.

The following symbols are used on the label on the Illuminator:



Symbol	Meaning
	Manufacturer
	Input
	Fuses
	European Authorized Representative and Importer
	Unique Device Identifier
	Serial number
	Model number
	Made in USA and Date of Manufacture
	Product Safety Certification reflecting compliance with electrical safety standards.
	
	Caution
	Requires separate electrical and electronic waste collection.
	Consult Instructions for Use

Symbol	Meaning
	Medical device
	CE Mark

Messages

Message conventions




Throughout the manual the following messages are used.

Message	Description
 WARNING	Alerts you to potential hazards that may cause personal injury.
! CAUTION	Alerts you to conditions that could damage the Illuminator, affect the illumination of the containers, make the Illuminator sound an alarm unnecessarily or affect the blood product quality.
 NOTE	Provides additional information to support the successful use of the Illuminator.
TIP	Indicates practical, but non-essential information, such as alternate methods.

Warnings

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

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

Chapter	Section	Message
Chapter 1: Product Overview	Device description - General	 WARNING: The side access panel should only be opened by a Cerus Technical Service or authorized representative. There are no user-serviceable parts accessible by the side access panel.
		 WARNING Illuminators should not be stacked on each other or on top of other manufacturer's equipment.
	Product information	 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 Illuminator.

Chapter	Section	Message
		⊗ WARNING: The pins of connectors identified with the Electrostatic Discharge (ESD) warning symbol should not be touched and connections should not be made to these connectors unless ESD precautionary procedures are used.
Chapter 3: Performing Treatments		⊗ WARNING: The user should always wear appropriate protective equipment and use care when handling blood products.
		⊗ 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 determined by your facility.
		⊗ 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.
		⊗ WARNING: Partial illumination has not been validated for pathogen reduction. Do not attempt to re-treat a partially treated unit. Do not treat a blood product more than once. No claim of pathogen reduction can be supported for partially illuminated units and they should be discarded.
	How to Load the Tray	⊗ WARNING: The tubing containing the blood product mixed with amotosalen must be loaded in the large compartment of the tray and the other parts of the processing set are loaded in the tray bucket at the front. Blood product in the tubing which is not entirely within the area receiving illumination will not be pathogen reduced.
		⊗ WARNING: 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.

Cautions

The following cautions alert you to any conditions that could damage the Illuminator, affect the illumination of the containers, make the Illuminator sound an alarm unnecessarily or affect the blood product quality.

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

Chapter	Section	Message
Chapter 1: Product Overview	Device description - Front	! CAUTION: If any part of an Illuminator tray is damaged (cracked, scratched, or cloudy) contact your Cerus Technical Service or authorized representative for a replacement. Do not use that drawer if the tray is damaged.

Chapter	Section	Message
		! CAUTION: The air filter must be replaced periodically to ensure adequate air flow to keep the blood product cool during treatment.
	Device description - General	! CAUTION: Use care not to block the air vents of the Illuminator during operation.
		! CAUTION: Do not use the Illuminator if there is condensation on it. Humidity higher than 80% may shorten the life of instrument components.
	Product information	! 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.
		! CAUTION: Portable and mobile radio frequency (RF) communications equipment can affect the Illuminators by interfering with the electronics, causing the illumination to stop.
	Peripherals	! CAUTION: Illumination labels are not suitable for freezing and thawing.
Chapter 3: Performing Treatments	How to Load the Tray	! CAUTION: Make sure all tubing is in the tray before closing the drawer.
		! CAUTION: After containers are placed in the tray, make sure empty containers are not pushed into the Illumination area during drawer closure.
		! CAUTION: Do not terminate the treatment unless it is an emergency, as this will result in incompletely treated blood products. The treatment will be noted as unsuccessful with the symbol ☒ on the report and label.
Appendix E: Care & Maintenance	Cleaning and Disinfecting	! CAUTION: Use only approved solutions to clean and disinfect the internal drawer surfaces and operator touch areas.
	Clean or change air filter	! CAUTION: The air filter must be cleaned or replaced periodically to ensure adequate air flow to keep the blood product cool during treatment.

Chapter 1: Product Overview

Quick links

- [Light system](#)
- [Device description - Front](#)
- [Device description - Back](#)
- [Device description - General](#)
- [Computer connections](#)
- [Product information](#)
- [Network connections](#)
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Light system

The INTERCEPT Illuminator provides a controlled dose of Ultraviolet A (UVA) light for the INTERCEPT pathogen inactivation process. The Illuminator contains two independent illumination chambers. Each chamber can process a single blood component at a time. UVA light is delivered by internal light-emitting diode (LED) sources and is regulated by microprocessors and internal light sensors during the illumination process. Each blood component rests on a UVA-transparent illumination tray that undergoes horizontal agitation during the illumination process. UVA light is delivered by two opposing arrays of LEDs, which are mounted above and below the illumination tray in each chamber.

The Illuminator can process any two processing set configurations at the same time. Each processing set configuration has a pre-programmed instrument setting to administer treatment per the appropriate illumination process parameters. The treatment time for platelet sets is approximately five minutes, depending on the set type. The treatment time for plasma sets is approximately ten minutes.

Product identification and traceability

The Illuminator recognizes and is compatible with the following barcode formats:

- Codabar (including Monarch 11)
- Code 128 (including ISBT 128 and Eurocode)
- Code 39

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

Upon completion of the illumination step, a record of each processed blood product is stored in the Illuminator. Also, if configured, one to three labels can be printed with the donation identification number (DIN) and blood product code. These labels can be placed on the container, the printed treatment report, or both.

Device description - Front

Front power standby button



Controls standby power.

- **On:** Starts the Illuminator when main power switch is ON.
- **Off:** Turns off functions and enters a state of low power consumption.

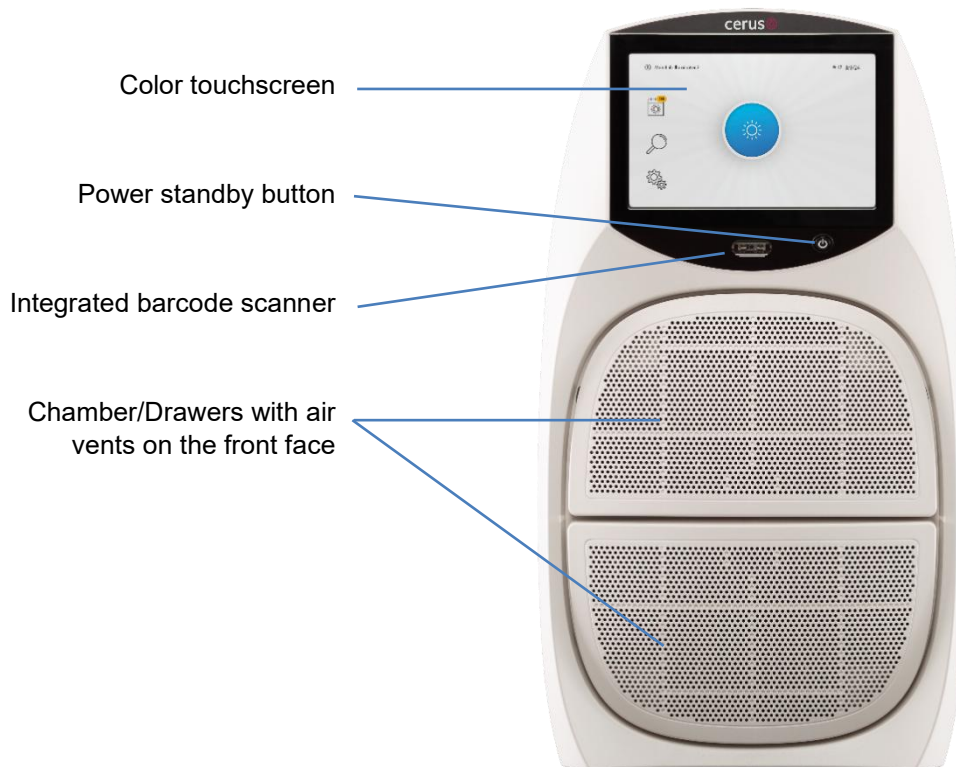


Figure 1: Front of device

Color touchscreen display and Home Screen

The display on the instrument serves as the mechanism for interfacing with the software. It is a touchscreen that works whether or not the user is wearing gloves. The user can tap buttons to navigate through the software and can enter information manually with an on-screen keyboard when needed.

The home screen appears after the unit is powered on or taken out of standby mode and certain self-checks are performed. This usually takes approximately 90 seconds.

In the upper-left corner, there is an information button. When the user taps this button, information is displayed including the instrument serial number, the version of software for the user interface and versions of software operating in other components in the device. Cerus may ask for this information if there is a service issue.

Next to the information button, the custom name of this Illuminator is displayed. On the left side there are buttons for **Today's Treatments**, **Search** and **Settings**. The date and time are displayed in the upper right corner. In the center of the screen, there is the large **Begin Treatment button**. These functions will be described later in this manual.



Figure 2: Home Screen

Integrated barcode scanner

The user can enter data embedded in bar codes by presenting them in front of this scanner. See Entering data later in this chapter.

Drawers

The two drawers can be opened independently of each other. Once a drawer is opened by the software, the user can pull it out further to load the tray. When ready, the user pushes the drawer all the way closed and then it is locked during the treatment process.

- ☒ **NOTE:** The drawer can only be opened using the software. There are no handles to pull. In the event of a software issue, see [Manual drawer opening](#) later in this chapter for information on manual opening.

If a drawer is unavailable, that drawer will be shown in grey on the user interface.

- ! **CAUTION:** If any part of an Illuminator tray is damaged (cracked, scratched, or cloudy) contact your Cerus Technical Service or authorized representative for a replacement. Do not use that drawer if the tray is damaged.

While the drawer is open, the user can also remove the tray for cleaning or access the air filters. See [Appendix E: Care & Maintenance](#) .

- ! **CAUTION:** The air filter must be replaced periodically to ensure adequate air flow to keep the blood product cool during treatment.

Device description - Back

Back power switch

There is a Main Power switch on the back of the device.

- On Must be on to use the Illuminator and for the internal fans to operate.
- Off Cuts all power to the device. This is equivalent to disconnecting the power cord.

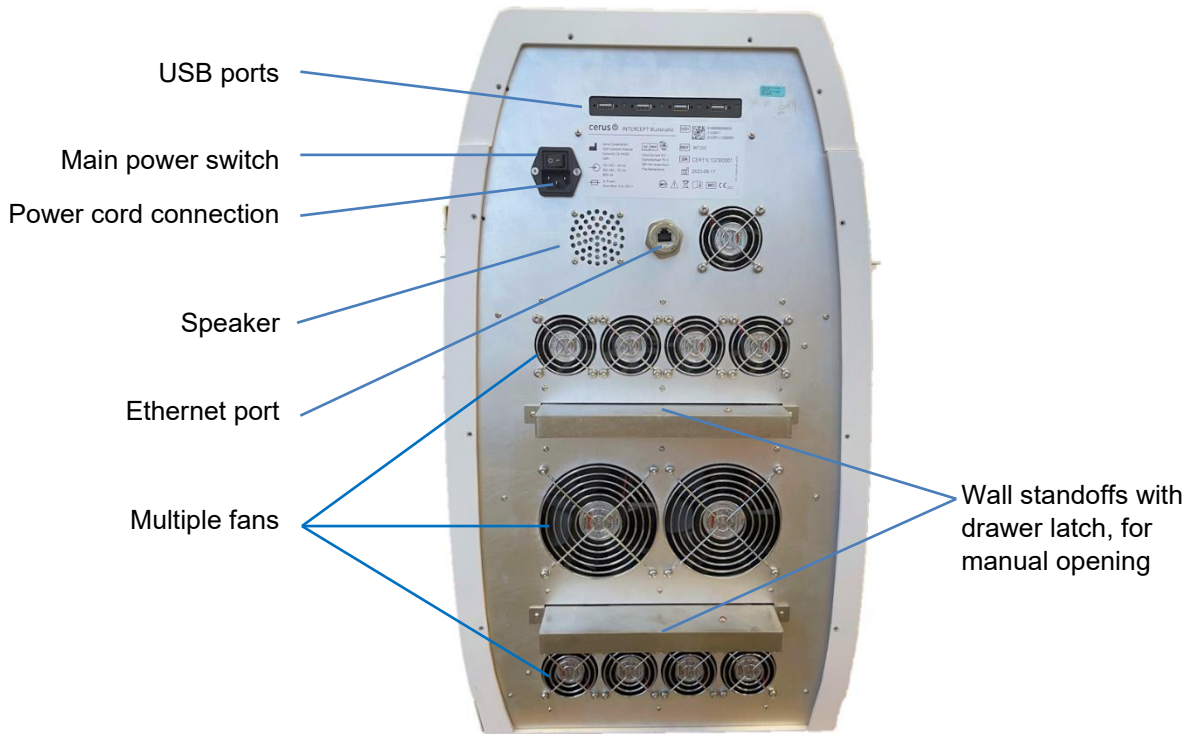
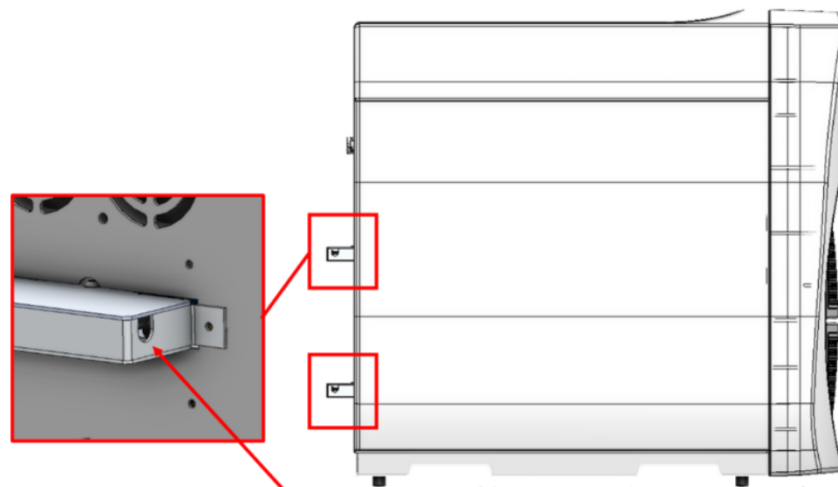


Figure 3: Back of device

Manual drawer opening

You can manually open each drawer.

With the instrument powered off, engage the drawer release mechanism at the back of the instrument located on the side of the corresponding wall standoff, as shown in the following figure:



Insert a long, thin object, such as a pencil (eraser end), into the hole on the side of the wall standoff and press against the release mechanism.

Figure 4: Release mechanisms to manually open drawers

Device description - General

- ⊗ **WARNING** The side access panel should only be opened by a Cerus Technical Service or authorized representative. There are no user-serviceable parts accessible by the side access panel.
- ⊗ **WARNING:** Illuminators should not be stacked on each other or on top of other manufacturer's equipment.
- ! **CAUTION:** Use care not to block the air vents of the Illuminator during operation.
- ! **CAUTION:** Do not use the Illuminator if there is condensation on it. Humidity higher than 80% may shorten the life of instrument components.
- ☒ **NOTE:** In the event of a single temporary power loss, a treatment can be resumed provided that power is restored within ten minutes. If the power loss has been greater than ten minutes, an error message will be displayed and the treatment will be marked as unsuccessful.

Computer connections

The INTERCEPT Illuminator has 4 USB type A ports and 1 Ethernet port on the back of the device.



Product information

Illuminator specifications

The following table lists the dimensions of the INTERCEPT Illuminator.

Illuminator height	70 cm
Illuminator width	40 cm
Illuminator depth	77 cm
Weight	66 kg
Power requirements	Applicable to MET certified illuminators Max power rating: 800 VA Equipment rating: 120 VAC ~ 60Hz 230 VAC ~ 50Hz

Max power consumption: 1390 W, not including peripherals

Applicable to SGS certified illuminators

Max power rating: 1200 VA

Equipment rating: 100 - 240 VAC~
50 - 60 Hz

Max power consumption: 1390 W, not including peripherals

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Illuminator has been tested and found to comply with the limits of the standard for control, measurement, and laboratory equipment IEC 61326-1, 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 devices are connected.
 - Consult the manufacturer or Cerus Technical Service or authorized representative for help.
- ⊗ **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 Illuminator.
- ⊗ **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 (such as, 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

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

Data

After treatment, a record of each processed blood product is saved. Up to 25,000 records can be stored. When the memory is full, new records will overwrite the earliest records in memory. Data can be exported to a network file location where it can be archived, as described in the next section.

Network connections

A network connection can be established to:

- export data in CSV format to a location designated by the Administrator.
- print using a shared printer connected to the network.

This is uni-directional communication, as the Illuminator blocks or ignores incoming data and commands. Connecting the Illuminator to firewall-protected networks is recommended.

The Illuminator sends data in CSV (comma-separated values) file format using the Secure File Transfer Protocol (SFTP). The data management system requires a SFTP server to receive data files from the Illuminator. The Illuminator must be configured with the IP (Internet Protocol) address, network port and credentials of the SFTP server on the data management system to export files. See [Data export](#) in Chapter 4 and [Appendix D: Cybersecurity](#) for more information.

Peripherals

The Illuminator can be directly connected to peripherals using the ports in the back. The peripherals include a printer for reports, a label printer, and a handheld bar code scanner.

Report printer

Each Illuminator can be directly connected to a printer. Alternatively, each Illuminator can be connected to a compatible shared printer through a network connection, as described in the previous section. The site can also elect not to print and only export data or do both.

Printers manufactured by Hewlett-Packard (HP) or Brother with the following specifications are recommended:

- Connection: Ethernet 10/100/1000BASE-T or USB 2.0 compatible
- Driver: PCL 6 or later

Printers not meeting these specifications are not supported by Cerus.

Label printer

At the completion of a treatment, up to three identical labels per drawer can be generated. Each label includes the following information:

- Donation ID
- Blood product code
- Drawer used
- Whether treatment was successful or not

These labels can be placed on the Illuminator container to remind the user that the unit has been treated. They can also be placed on the treatment report or used in some other way determined by your institution.

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

The label printer is connected with a USB 2.0 compatible connection.

☒ **NOTE:** Each Illuminator can be connected to one dedicated label printer.

Handheld bar code scanner

The handheld scanner is optional. It can be used with or as an alternative to the integrated bar code scanner. It connects to the instrument with a USB 2.0 compatible connection.

Cerus will inform you of the make and model of compatible handheld scanners.

Entering data

The following table describes how the colors and icons guide you through the data entry process, whether entering the data manually or by scanning.

Gray line	Not ready for information
Blue line	Ready for information
Green line	Valid value entered
Red line	Invalid value entered

Barcode scanning

The integrated scanner and an optional handheld scanner can be used to acquire information on various screens.

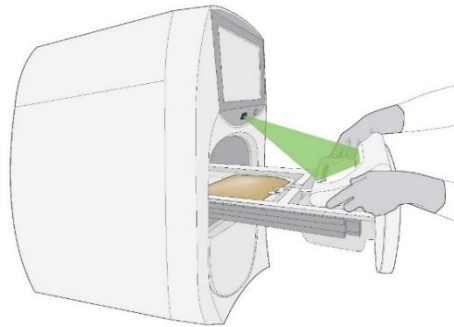
When entering information on the Load Screen, the barcodes on the container label can be scanned in any order. The Illuminator automatically assigns each barcode to its respective field. There will be confirmatory audible sounds once scanned items are successfully populated on the Load Screen.

If there is human readable text that accompanies a given bar code, the information displayed on the Illuminator screen after the scan matches.

Integrated Scanner

To acquire the information, hold barcodes in front of the scanner approximately the length of your hand away from the instrument. The optimal distance can vary based on the size of the bar code.

A green aiming light projects out of the scanner to guide you where to place the barcode. The barcode does not have to line up exactly with the green light.



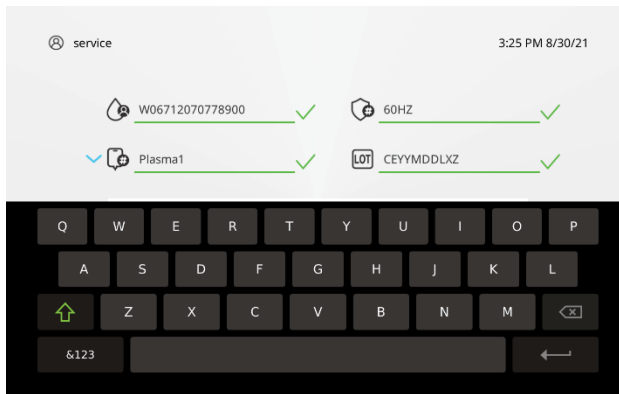
Barcode scanning with Optional handheld scanner

To acquire the information, hold the barcode in front of the scanner approximately the length of your hand away from the handheld scanner. The optimal distance can vary based on the size of the bar code.

Engage the trigger to scan the information in each barcode.

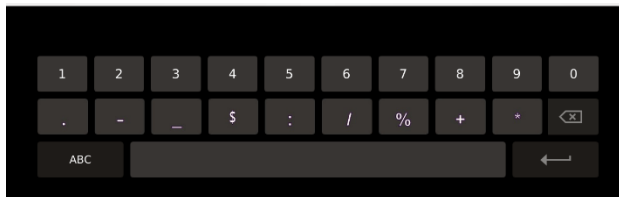
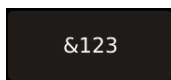
Manual entry

Tap on a data-entry field. An on-screen keyboard will appear on the bottom portion of the display.



Enter information using this on-screen keyboard, up to 25 characters.

☒ **NOTE:** Numbers and additional keys can be accessed by tapping on the button with numbers on the bottom-left of the keyboard.



If there is additional information to enter in another field, tap on the relevant field and continue to use the on-screen keyboard.

When completed, the user should always check to ensure the data entered are correct. Tap anywhere on the top portion of the display to exit the on-screen keyboard.

Chapter 2: Settings

Users with administrator or service permissions can perform certain configuration activities for the INTERCEPT Illuminator described in this chapter.


Quick links

[User management](#)

[Configuration settings](#)

User management

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 Technical Service or authorized representative. Service accounts are denoted by this symbol, . The service symbol is grayed out for operator and administrator users.

After installation, the Cerus Technical Service or authorized representative establishes the first administrator account for the designated person at your facility. That administrator account is used to set up operator accounts and additional administrator accounts as needed.

- ☒ **NOTE:** It is recommended that at least two Administrator accounts are created, with password expiration set at different times. This way, one Administrator account can change the password for the other Administrator account.

The following table summarizes the functionality available for each access level.

Function	Operator	Administrator	Service
Perform illumination treatments	●	●	●
Review completed treatment and event history information	●	●	●
Access drawers for periodic cleaning and filter changes	●	●	●
Manage user accounts	—	● (Operator and Administrator accounts)	● (All account types)
Configure most Illuminator settings	—	●	●
Configure specialized Illuminator settings and perform Service tasks	—	—	●

- ☒ **NOTE:** The following additional configuration activities are described in the *INTERCEPT Illuminator Technical Service Manual* and are performed by a Cerus Technical Service or authorized representative only: entering Set Codes, entering Blood Product Codes, defining barcode formats, assigning a serial number to the instrument.

User account configuration

Using the following procedures, you can add, edit, or deactivate user accounts on your system. You can also print out a list of all user accounts. This functionality is only available to administrator and service users.

All access levels require a unique username. The requirement of a password to perform a treatment is configurable. A password is required for configuration activities. Accounts can be deactivated and reactivated in the system.

Quick links

[Add users](#)

[Edit users, including changing passwords](#)

[Print user account report](#)

Add users

1. Tap **Settings**.



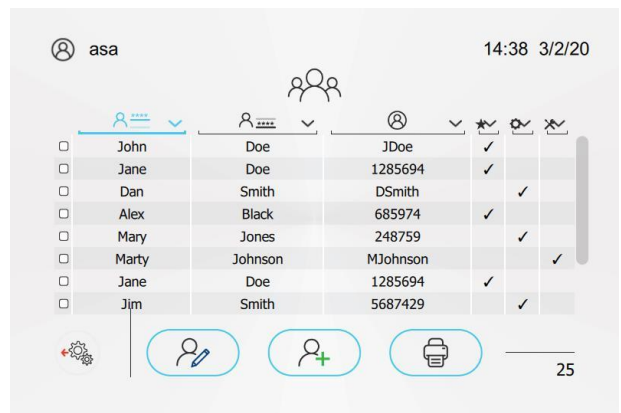
2. Enter your credentials. Once the credentials are verified, the Main Settings Navigation screen displays.

TIP: You can use a barcode scanner or the on-screen keyboard to enter your credentials

3. Tap **User Management**.



The User Management screen displays.







4. Tap **Add User**.







The Add User screen displays.

5. Select the user permission type.

-  Operator user
-  Administrator user
-  Inactive user
-  Service user
(Option only available to Service users)

6. Enter the first and last name, username, and password of the user. Acceptable characters are alphanumeric characters and the following special characters: , . - _ \$: / % + *.

-  First name
-  Last name
-  Username
-  Password

7. Tap **Save**.



Edit users, including changing passwords

1. Tap **Settings**.



2. Enter your credentials.

Once the credentials are verified, the Main Settings Navigation screen displays.

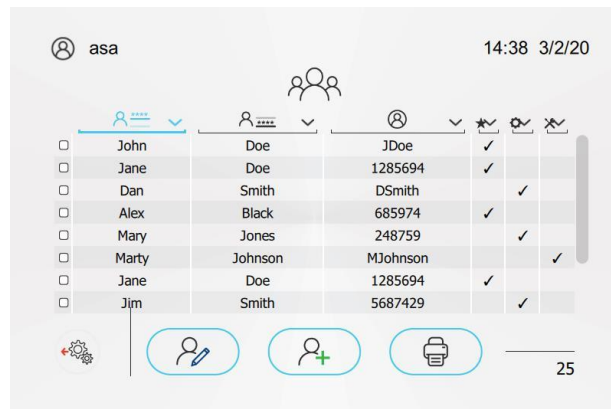
TIP: You can use a barcode scanner or the on-screen keyboard to enter your credentials

3. Tap User Management.



The User Management screen displays.

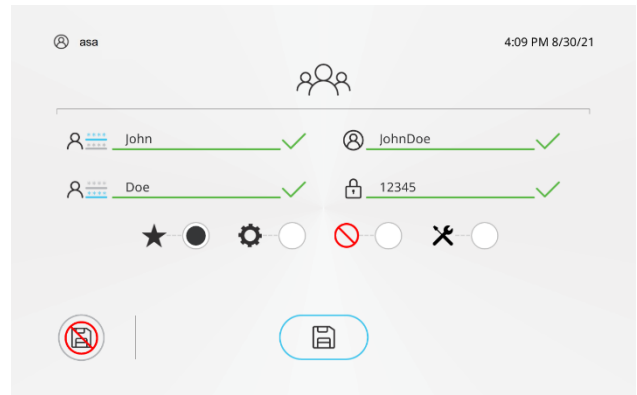
TIP: Click on the column headers to sort by first name, last name, username, and permissions.




4. Select user and tap **Edit User**.



The Edit User screen displays.



5. You can edit the information and the user type.

TIP: Select  to inactivate a user account. A user can be changed back to another user type later.



Operator user



Administrator user



Inactive user



Service user
(Option only available to Service users)

6. Tap **Save**.



Print user account report

The report includes the first name, last name, username and a 2D barcode for each user. This barcode can be used by a Cerus Technical Service or authorized representative to transfer user information to another Illuminator.

1. Tap **Settings**.



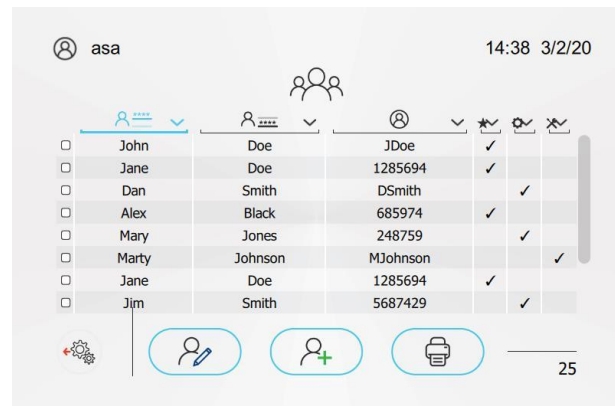
2. Enter your credentials.

Once the credentials are verified, the Main Settings Navigation screen displays.

3. Tap **User Management**.



The User Management screen displays.



4. Tap **Print**.



5. To return to the Settings screen, tap button.



Configuration settings

The following configuration settings are available to administrator and service users.

In addition to these, during Illuminator installation, the administrator should assist the Cerus Technical Service or authorized representative to configure how the Illuminator should recognize the donation IDs used by the site (barcode symbology and number of digits). They should also work together to load the blood product codes used at the site into the Illuminator.

1. Tap **Settings**.



2. Enter your credentials.

Once the credentials are verified, the Main Settings Navigation screen displays.

TIP: You can use a barcode scanner or the on-screen keyboard to enter your credentials.

3. Tap **Configuration**.



The Configuration screen displays.

4. Tap desired setting button.

Choices are:



[Change date and time settings](#)



[Configure data transfer settings](#)



[Configure Treatment Report printing settings](#)



[Configure Label printing settings](#)



[Change language setting](#)



[Set Illuminator information](#)



[Configure password settings](#)









5. To return to the Settings screen, tap **Settings**.



Change date and time settings




NOTE: Manually adjust time settings for regions participating in daylight saving time.

1. Toggle between MM/DD/YY or DD/MM/YY date format
2. Toggle between a 24-hour clock and 12-hour clock.
3. Tap  to open the calendar and select the date.
4. Tap the hour number and click  or  to change it.
5. Tap the minute number and click  or  to change it.
6. If the 12-hour clock is selected, you can also choose AM or PM. Click  or  to change it.
7. Tap 

TIP: Check the date and time in the upper right corner of the screen to confirm your updates have been made.


Configure data transfer settings



1. Toggle between exporting or not exporting treatment data after each treatment.
2. Enter the network port, the IP address for the network file location, username, and password.
3. Tap 


Configure Treatment Report printing settings



1. Select to print two per page (both drawers on one printout), one per page, or no printing.
2. If using a network printer, enter the printer IP address and select the printer.
3. Tap 


Configure Label printing settings



1. Select to print one, two, or three labels, or not to print.
2. Tap 


Change language setting



1. Choose language from the list. You may need to scroll down to find the desired language. Most of the software is icon based, but language is used for on-screen error messages and printed reports. Also, the on-screen keyboard will use language-specific characters.
2. Tap 


Set Illuminator information



1. Enter a custom name for the Illuminator. The name is displayed on the Home Page and on printed reports.
NOTE: The Illuminator's serial number can only be entered by a service user.
2. Tap 

Configure password settings



1. Toggle between password entry required for performing treatments or not required.
2. Select length of time before requiring a password reset:
 - 30 days
 - 60 days
 - 90 days
 - 180 days
 - Never (default setting)
The Administrator should consider whether this is the desired setting.
3. Tap 

Chapter 3: Performing Treatments

Quick links

[How to load the tray](#)

[Treat only one set](#)

[Treat two sets](#)

Illumination is one part of the INTERCEPT Blood System process. Refer to the Instructions for Use provided with the processing set, and always follow the instructions for the preparation of blood products that must be completed before and after illumination.

- ⊗ **WARNING:** The user should always wear appropriate protective equipment and use care when handling blood products.
- ⊗ **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 determined by your facility.
- ⊗ **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.
- ⊗ **WARNING:** Partial illumination has not been validated for pathogen reduction. Do not attempt to re-treat a partially treated unit.¹ Do not treat a blood product more than once. No claim of pathogen reduction can be supported for partially illuminated units and they should be discarded.
- ☒ **NOTE:** The user is protected from the UVA light source during normal Illuminator operation per EN 61010-1.

¹ If there is a power outage that lasts less than 10 minutes, the instrument attempts to complete the treatment.

How to load the tray

The following images represent how to correctly load the processing sets into the Illuminator tray and which practices would be incorrect.

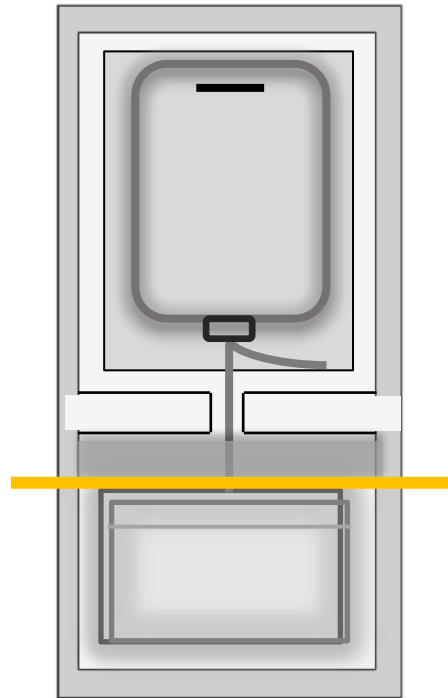


Correct

Tray is clean.

Illumination container with blood product has minimal air and no labels cover either side of the fluid containing region. The container is placed completely within the large area of the tray. This includes the tubing stub that was sealed off prior to illumination.

Other parts of the processing set are placed in the smaller area of the tray. They should be behind the illustrative yellow line on the diagram. For Platelet processing sets, fold the flaps of the empty bags. Place the bundle in the deepest part of the tray.

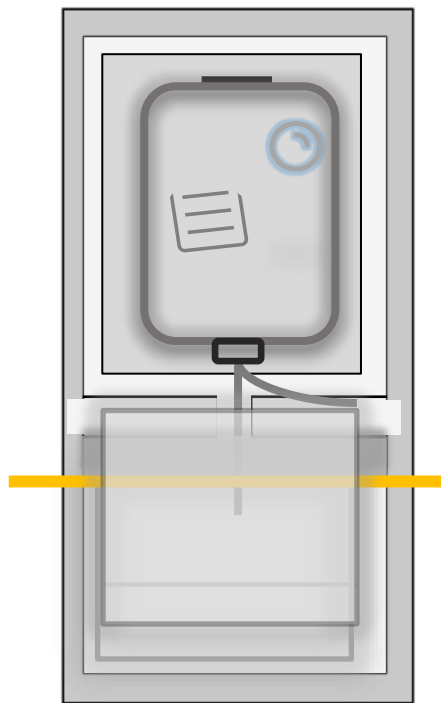


✘ Incorrect

Tray is not clean.

Illumination container has significant amount of air remaining and a label covers the fluid containing region. The tubing stub that was sealed off prior to illumination is outside the large area of the tray and may not receive UV light.

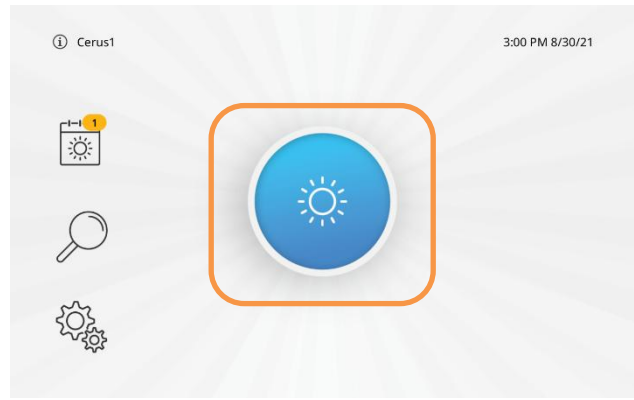
Other parts of the processing set are too far forward, beyond the illustrative yellow line. They are not placed in the deepest part of the tray.



- ⊗ **WARNING:** The tubing containing the blood product mixed with amotosalen must be loaded in the tray and the other parts of the processing set are loaded in the tray bucket at the front. Blood product in the tubing which is not entirely within the area receiving illumination will not be pathogen reduced.
- ⊗ **WARNING:** 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.
- ! **CAUTION:** Make sure all tubing and containers are in the tray before closing the drawer.
- ! **CAUTION:** After containers are placed in the tray, make sure empty containers are not pushed into the Illumination area during drawer closure.

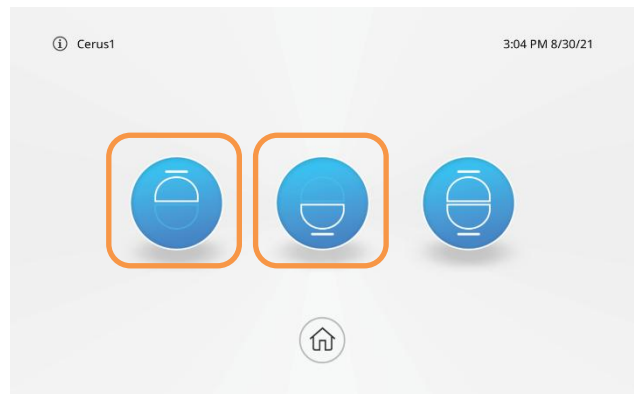
Treat only one set

1. Tap **Begin Treatment** to initiate the treatment process.



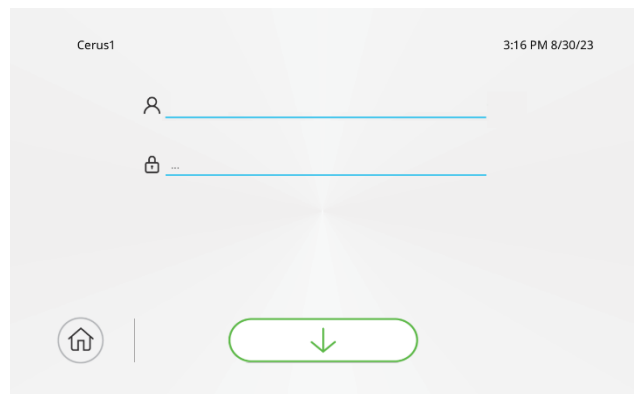
2. Tap **Top drawer** or **Bottom drawer**, whichever you prefer.

NOTE: If a drawer is unavailable, it will be grayed out.

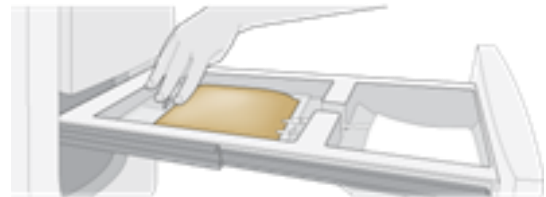


3. Enter your credentials. Depending on system configuration, a password may or may not be required. The login may automatically advance. If not, tap the Continue button.


TIP: You can use a barcode scanner or the on-screen keyboard to enter your credentials.

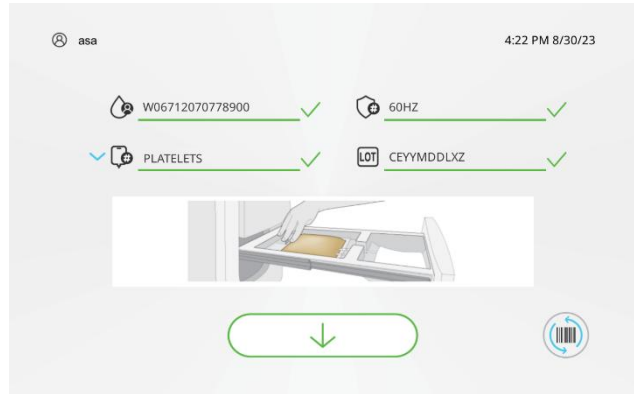


The selected drawer opens. Avoid contact between the processing set and the rails.








For most users, the preferred workflow is to place the illumination container on the tab in the tray and then lift the final storage container to scan the barcodes. However, after the drawer is open, you can scan the barcodes prior to placement on the tray. The process you use should be determined by your facility.

4. Scan the barcodes on the set or manually enter the information. You can scan the barcodes in any order. Option: tap  next to Blood product code to select these manually. For details on scanning, see [Entering data](#). When completed, the user should always check to ensure the data entered is correct.



LEGEND

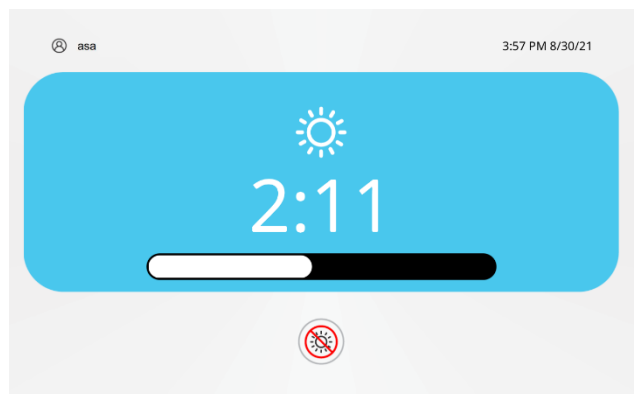
-  Donor ID
-  Blood product code
-  Processing set code
-  Lot number

TIP: To clear values, tap 


TIP: To cancel the load process, you can close an empty drawer and return to the home screen.

5. Place the processing set fully in the tray. See [How to load the tray](#) for proper placement instructions.
6. After placing the set and scanning the barcodes, close the drawer. The treatment begins automatically.

A blue counter displays the time elapsed during the illumination and a progress bar advances.



✉ **NOTE:** If you must stop a treatment, tap  to terminate the process.

! **CAUTION:** Do not terminate the treatment unless it is an emergency as this will result in an incompletely treated blood product. The result will be noted as unsuccessful with the symbol  on the report and label.

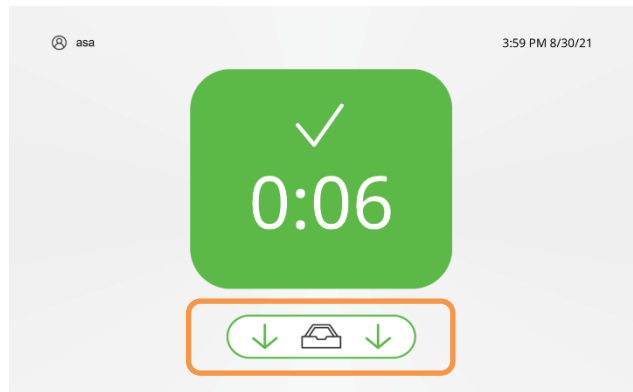
After the treatment completes, a counter displays.

You must begin to remove the set before the counter **reaches 30 minutes**.

- ☒ **NOTE:** As the timer approaches 30 minutes, the system will beep with increasing frequency². When the hold time reaches 25 minutes, the display flashes between a green and yellow background every second.

7. Tap **Open Drawer**.

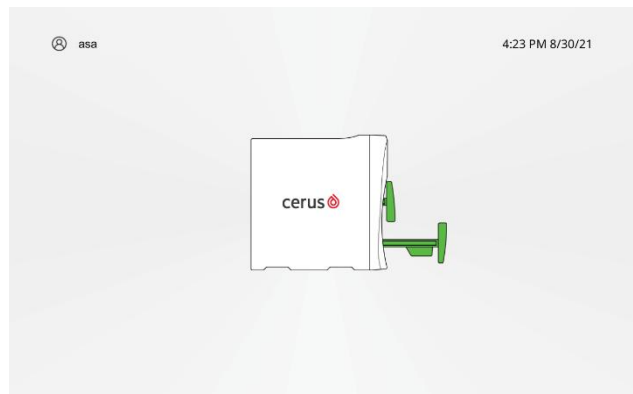
The drawer opens.



If configured to print labels, one or more labels will print on the label printer. Apply the label to the illumination container before removing it from the Illuminator. The treatment report will also automatically print when the procedure is complete.

8. Remove processing set and close drawer.

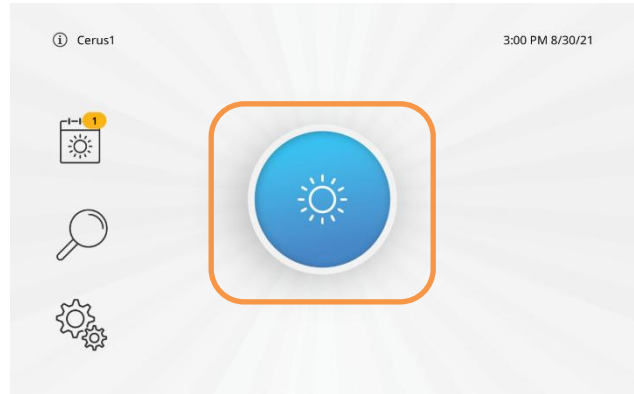
The Home screen displays.



² Once the complete screen displays, an audible reminder occurs periodically. The beep occurs more frequently as the time since treatment approaches thirty minutes.

Treat two sets

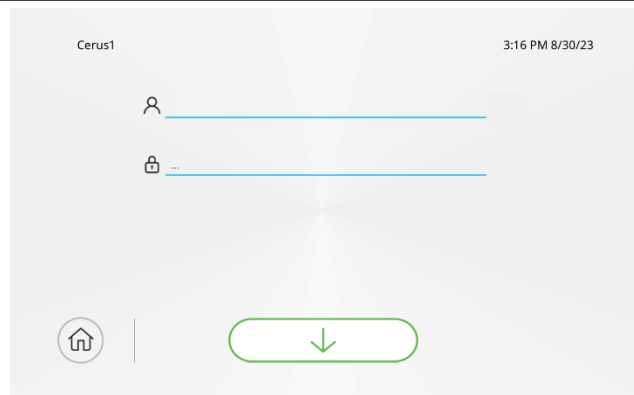
1. Tap **Begin Treatment** to initiate the treatment process.



2. Tap **Both drawers**.



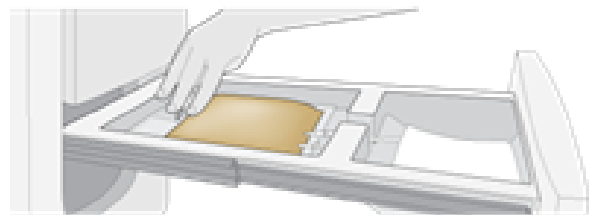
3. Enter credentials. Depending on system configuration, a password may or may not be required. The login may automatically advance. If not, tap the Continue button.



TIP: You can use a barcode scanner or the on-screen keyboard to enter your credentials.


The top drawer opens. Avoid contact between the processing set and the rails.

For most users, the preferred workflow is to place the illumination container on the tab in the tray and then lift the final storage container to scan the barcodes. However, after the drawer is open,

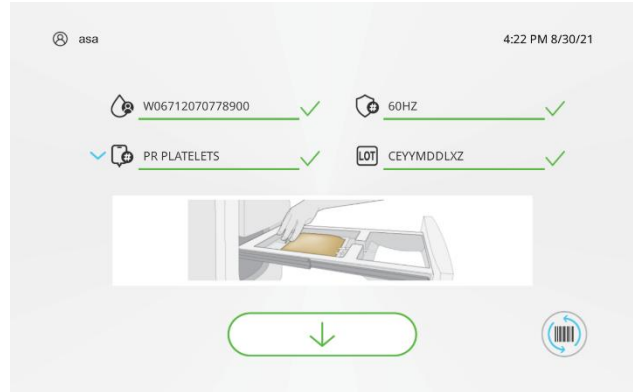


you can scan the barcodes prior to placement on the tray. The process you use should be determined by your facility.


4. Scan the barcodes on the set or manually enter the information. You can scan the barcodes in any order.

Tap  next to Blood product code to select these manually.





For details on scanning, see [Entering data](#).



When completed, the user should always check to ensure the data entered is correct.

TIP: To clear values, tap 

LEGEND

	Donor ID
	Blood product code
	Processing set code
	Lot number

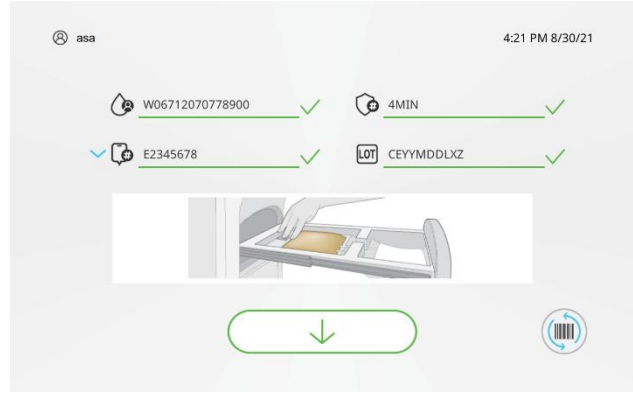
5. Place the processing set fully in the tray. See [How to load the tray](#) earlier in this chapter for proper placement instructions.

NOTE: The top drawer begins to agitate. The treatment has not started.

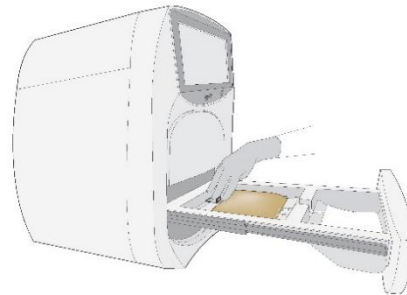
6. After placing the set and scanning the barcodes, close the drawer. The bottom drawer opens.

TIP: If you change your mind and only want to treat one set, you can close the empty bottom drawer. An on-screen message will appear asking you to confirm this is what you want to do. The treatment for the top drawer will then begin.

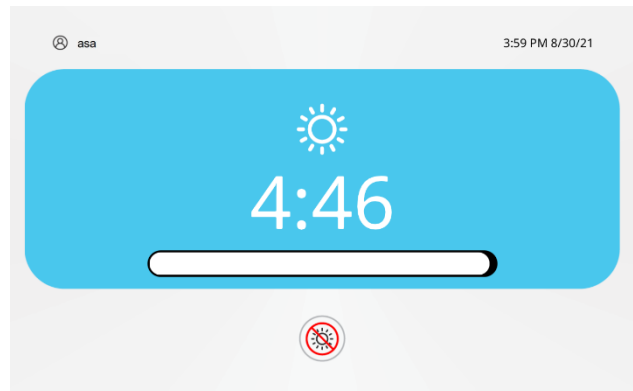
7. Bring the next processing set to the bottom tray.
8. Scan the barcodes.




9. Place the processing set fully in the tray. See [How to load the tray](#) earlier in this chapter for proper placement instructions.
10. Close the drawer. The treatment begins in both drawers.

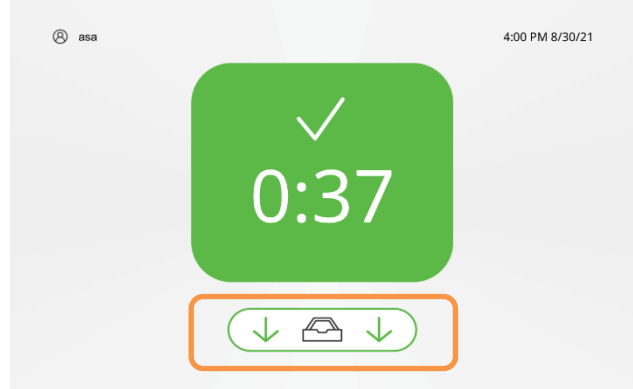


A blue counter displays the time elapsed during the illumination and a progress bar advances.



- ☒ **NOTE:** When both drawers are used, the treatment in one drawer may finish before the other and will stop receiving UVA light. Both drawers will remain closed and the trays agitating, while the counter continues until the treatment in the other drawer is finished.
- ☒ **NOTE:** If you must stop a treatment, tap  to terminate the process.
- ! **CAUTION:** Do not terminate the treatment unless it is an emergency as this will result in incompletely treated blood products. The treatment will be designated as unsuccessful.
- ☒ **NOTE:** After the treatment completes, a counter displays. It may or may not start at zero. The counter reflects the time since the first treatment was completed. You must begin the removal process before the counter reaches 30 minutes.

- ☒ **NOTE:** As the timer approaches 30 minutes, the system will beep with increasing frequency³. When the hold time reaches 25 minutes, the display flashes between a green and yellow background every second.



11. Tap **Open Drawer**.

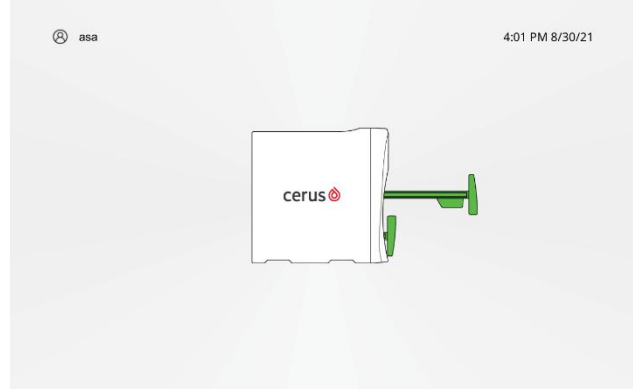
The top drawer opens.

If configured to print labels, one or more labels will print on the label printer. Apply the label to the illumination container before removing it from the Illuminator.

12. Remove the processing set from top drawer and then close drawer.

The bottom drawer opens.

If configured to print labels, one or more labels will print on the label printer. Apply the label to the illumination container before removing it from the Illuminator.



13. Remove the processing set from bottom drawer and then close drawer.

The treatment report will also automatically print when the procedure is complete.

- ☒ **NOTE:** Depending on the configuration for printing the treatment report, there will either be one page with treatment information for the set in each drawer or two separate pages for each set.

The Home screen displays.

³ Once the complete screen displays, an audible reminder occurs periodically. The beep occurs more frequently as the time since treatment approaches thirty minutes.

Chapter 4: Viewing Data and Generating Reports

This chapter describes the search features and reporting. The following reports are available:

- Today's treatments
- Search of all treatments
- Search of event history

☒ **NOTE:** No sign in is required to review this information.

Quick links

[Accessing treatment records from today](#)

[Search records](#)

[Treatment](#)

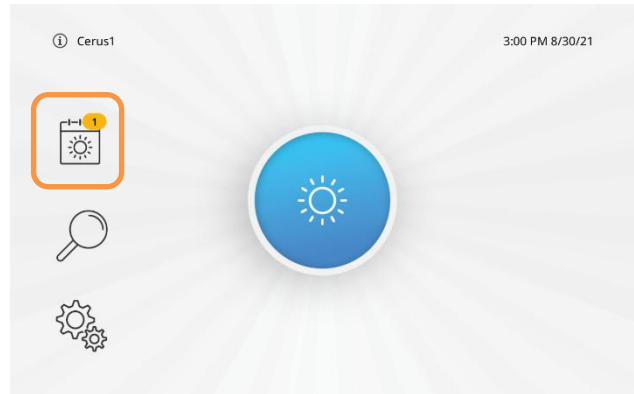
[Data export](#)

Accessing treatment records from today only

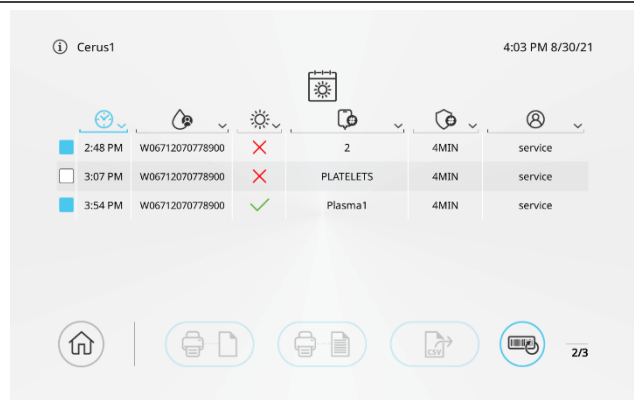
Use the following directions to view all the treatment records for the current 24-hour period, starting at midnight.

1. Tap **Today's Treatments**.

The number of treatments performed today are shown in the orange bubble on the icon.



The treatment results from midnight to the current time are displayed.



2. View the results on the screen or swipe to see additional results. If desired, sort by tapping on a column header.

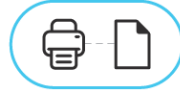
LEGEND

	Selection box
	Time
	Donor ID
	Illumination status
	Blood product code
	Processing set code
	Username

3. Print or export the data.
There are several options shown here.



Today's Treatments Report—prints a line list report in the same format as shown on the screen



Print Treatment report—allows re-printing full treatment reports for each record selected



Print Label—allows re-printing labels for each record selected.



Export CSV— allows re-exporting treatment results if needed.

4. Tap **Home** to return to the Home screen.



Search records

Quick links

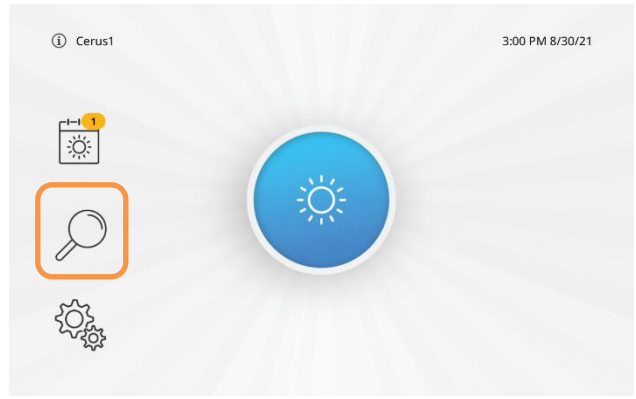
[Search for treatments](#)

[Search event history](#)

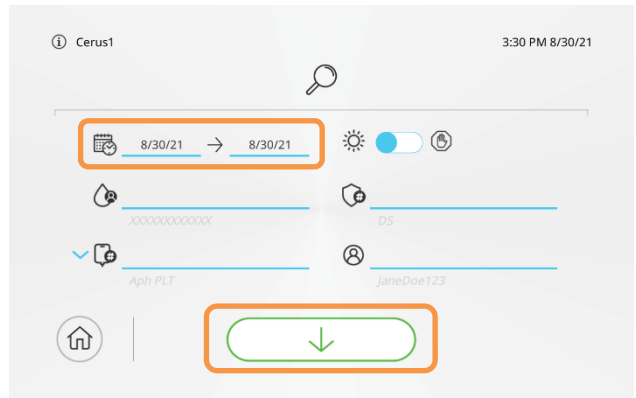
Search for treatments

Use the following directions to search treatment records.

1. Tap **Search**.



2. Select date range.
Further narrow search by entering values for Donor ID, blood product code, set code, or username, as desired.



3. Tap **Continue**.
The search results display.

4. View the results on the screen or swipe to see additional results. If desired, sort by tapping on a column header.

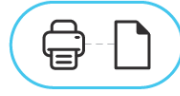
LEGEND

<input type="checkbox"/>	Selection box
	Date and time
	Donor ID
	Illumination status
	Blood Product Code
	Set code
	Username

-
5. Print or export the data. There are several options shown here.



Search Results Report— prints a line list report in the same format as shown on the screen



Print Treatment report— allows re-printing full treatment reports for each record selected



Export CSV-- allows re-exporting treatment results if needed.

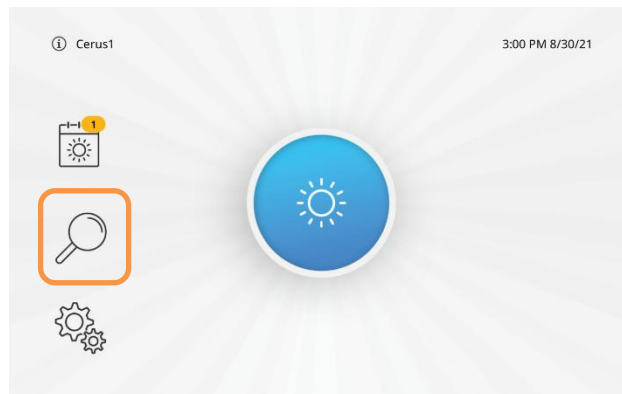
-
6. Tap **Return to Search** and perform additional searches.




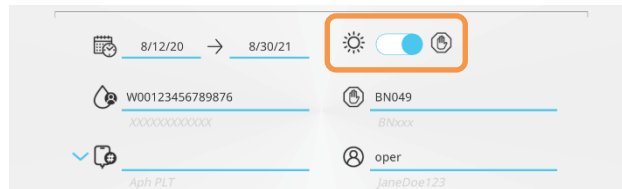
Search event history

Many different events are tracked by the Illuminator. They include errors, notifications, cleaning events, and self tests. Use the following directions to search event records.

-
1. Tap **Search**.



-
2. Toggle to  **Event history**.
3. Select date range. Further narrow the search by entering values for Donor ID, blood product code, event code, and username, as desired.



Examples of searching for special events

You can search for specific events by their code:

NN088	Drawer opened for cleaning/disinfecting or accessing the air filter
PN050	The self-test performed at start-up was successful
NN097	Service user logged in to perform service. Next service due date or calibration due date have been set.

For other codes to search with see [Appendix B: System Messages](#).

4. Tap **Continue**.

The search results display.



5. View the results on the screen or swipe to see additional results. If desired, sort by tapping on a column header.

LEGEND



Date and time



Event code



Drawer used



Donor ID



Blood product code



Username

6. To print the list, tap **Search Results Report**.



7. Tap button to return to Search screen and perform additional searches.



Treatment report





As noted earlier, records with data about the treatments can be printed, exported or both.

Printed Treatment Report

At the top of each report you will see the date and start time of the treatment, as well as the username of who performed the treatment. Below this you will see the information scanned into the instrument – the

donation identification number, the blood product code, the set code and the lot number. Then, the following information is shown: treatment dose, treatment duration (in minutes and seconds), the set removal time (in hours and minutes) and hold duration (in minutes and seconds). If an error occurred during treatment, the report will show the error code plus description.

The following icons on the report provide at-a-glance information:

Treated in top drawer (Drawer 1)	
Treated in bottom drawer (Drawer 2)	
Treatment successful	
Treatment not successful	

If there were two sets treated together, as noted earlier, there is a configuration that would allow showing the treatment records from both drawers on one page. Alternatively, the records could be printed on two separate pages.

- ☒ **NOTE:** If two sets are treated together, the hold duration on the treatment reports will show as the same value for both sets. The value will correspond to the hold duration for the set with the shortest treatment time.

Data export


Treatment data can be exported in comma delimited fields with the CSV file format. The fields are listed below in the order they appear, separated by commas:

- Instrument ID
- Donation identification number
- Blood product code
- Treatment start date and time
- Treatment time
- Treatment dose received
- Whether treatment was successful or not (Success or Fault)
- Target dose
- Username
- Drawer (1 for Top and 2 for Bottom)

- Hold duration
- Error code, if there was an error
- Software version for the user interface on the instrument
- Lot number of the set
- Set code
- Checksum value

If there were two sets treated together, the automatic export after the treatment will be one CSV file with data from both drawers. If the user manually exports a single record from the Today's Treatment or Search Results screens, then just the record selected will be included in the CSV file.

- ☒ **NOTE:** If there were two sets treated together, the hold duration will be shown as the same value for both sets. The value will correspond to the hold duration for the set with the shortest treatment time.

Event history data can also be exported in comma delimited fields with the CSV file format. After performing a search (see Search event history), tap Export CSV . This will send all the records in the search to the network file location. The primary fields in the export are listed below in the order they appear:

- Date and time
- Event code
- Drawer
 - 1 – Top
 - 2 – Bottom
 - 3 – Both
- Donation ID
- Blood Product Code
- Several fields that may or may not have additional info on the event
- User ID
- Set Code
- Illuminator serial number
- Software version number for the user interface on the instrument

Appendix A: Treatment Confirmation and Calibration



The INTERCEPT Illuminator provides a controlled dose of Ultraviolet A (UVA) light for the INTERCEPT pathogen reduction process. UVA light is delivered by two opposing arrays of LEDs, which are mounted above and below the illumination tray in each chamber. Calibrated UVA detectors are also mounted above and below each chamber to measure the UVA light dose delivered to the blood product being treated in each chamber. The target doses delivered are 3.0 J/cm² for the SV set, 3.3 J/cm² for the Platelet LV and DS sets, and 6.4 J/cm² for the Plasma set.

At the end of a successful treatment, the user will see a check mark on the screen, on the printout and on the printed label. This check mark is confirmation that the UVA light dose was delivered successfully and within specified tolerance per the set code. If the treatment was unsuccessful, then the failed treatment will be shown with an “X” mark on the user interface, report, and label. In addition, an error message and code will also be displayed on the user interface and on the treatment report. The specific error codes are described in [Appendix B: System Messages](#).

The Illuminator is calibrated and verified at the time of manufacture, at the time of installation at the customer site, and during periodic service visits thereafter. Cerus Technical Service or authorized representatives perform calibration and verification activities.

The Illuminator calibration is performed using a calibrated External Radiometer (ER) that was specifically designed for use with the Illuminator. The ER contains UVA detectors on both the top and bottom surfaces that are arranged over the UVA light field seen by the blood product during treatment. The ER is calibrated at regular intervals. When calibrating the INTERCEPT Illuminator, the ER is placed in each illumination tray and connected by a cable to the computer of the INTERCEPT Illuminator.

During the Illuminator calibration process, the ER measures UVA dose emitted from the Illuminator UVA LEDs. The instrument software then uses these measurements to calibrate the UVA detectors inside the Illuminator.



Appendix B: System Messages

While operating the Illuminator, system messages may display that describe errors or general procedure information. Some events may be stored in memory with no on-screen message.

Each system message contains 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 Cerus Technical Service or authorized representative for assistance.

Event Codes

Event codes are five-digit alphanumeric strings: NN555. The meaning of the characters is shown in the following table:

Item	Values	Icon
First letter	B = Before treatment N = Other normal time P = Power-on self test T = During treatment	
Second letter	E = Error F = Fault N = Notification U = User error Z = Unknown	! !  
Numbers	Unique event code number	

Special Events

Event Code	What happened?
NN088	A drawer was opened for cleaning / disinfecting or accessing the air filter
PN050	The self-test performed at start-up was successful
NN097	Service user logged in to perform service. Next service due date or calibration due date has been set.
PN017	The system detected that power was lost during treatment and treatment resumed within 10 minutes
NU074	Service log-in was attempted
NU075*	Print report button was tapped
NU076*	Data export button was tapped
NU077*	Service log file export button tapped

* NOTE: Only visible on the event history report printout, exported file and service event history logfile.

Errors

Event Code	What happened?	Message Displayed: Event Description	Message Displayed: Instructions
BE001, BE002, BE003, BE009, BE016, BE040, BE042, BE043, BE044, BE045, BE046, BE048, BE052, BE054, BE063, BE065, BE066	The system detected a fault in a drawer during load but before illumination	Service Required	Remove Untreated Product Contact Administrator
BF031, BF038, BF053, BF059	Unrecoverable system fault	System Fault	Restart device. Note: If this message continues to occur, contact Service.
BN013	Label printer was unable to print	Label Printer Error	Contact Administrator
BN014	Report printer was unable to print	Printer Error	Contact Administrator
BN026	Device scanner is not working	Device Scanner Error	Use USB Scanner or Touchscreen Contact Service
BN027	Handheld scanner is not working	USB Scanner Error	Use Device Scanner or Touchscreen

Event Code	What happened?	Message Displayed: Event Description	Message Displayed: Instructions
BN028	Label printer was unable to print	Label Printer Error	Contact Administrator
BN029	Report printer was unable to print	Printer Error	Contact Administrator
BN041	The system detected a problem with the drawer latch	Drawer Latch Error	Check Drawer or Manually Override
BU034	Expired password	Password Expired	Contact Administrator
BU047	Drawer closed with a bag in place but the barcode entry was bad or incomplete	Barcode Entry Incomplete	Open Drawer and Complete Entry
BU049	This set was already illuminated	Prior Illumination	Remove Product Contact Administrator
BU051	The second drawer was closed without a set inside after the user confirmed that a second set is expected.	Loading Incomplete	Complete loading
BU061	Load time of max 10 minutes was exceeded during the loading process.	Load Time Exceeded	Contact Administrator
NE001, NE002, NE003	System check failed or service is due	Service Required	Contact Service
NE007	The temperature in one or both drawers was out of range (not during treatment)	Temperature Error	Contact Administrator
NE009	System check failed or service is due	Service Required	Contact Service
NE036	The system detected that a tray needs to be cleaned	Window Not Clean	Clean Window to Proceed
NE040, NE042, NE043, NE044, NE045, NE046, NE048, NE054, NE065, NE066, NE067	System check failed or service is due	Service Required	Contact Service



























Event Code	What happened?	Message Displayed: Event Description	Message Displayed: Instructions
NF031, NF038, NF053, NF059	Unrecoverable system fault	System Fault	Restart device. Note: If this message continues to occur, contact Service.
NN013	Label printer was unable to print	Label Printer Error	Contact Administrator
NN014	Report printer was unable to print	Printer Error	Contact Administrator
NN026	Device scanner is not working	Device Scanner Error	Use USB Scanner or Touchscreen Contact Service
NN027	Handheld scanner is not working	USB Scanner Error	Use Device Scanner or Touchscreen
NN029	Report printer was unable to print	Printer Error	Contact Administrator
NN032, NN033	The system determined that service will be needed soon	Service Required Soon	Contact Service
NN041	The system detected a problem with the drawer latch	Drawer Latch Error	Check Drawer or Manually Override
NU016	Drawer was detected as open when it should not have been	Drawer Open	Close Drawer
NU037	Data export failed	Data Export Failed	Check Network or Contact Service
PE001, PE002, PE003, PE009	The system detected a fault in a drawer during self-test.	Service Required	Contact Service
PE008	The temperature in one or both drawers was out of range (not during treatment)	Temperature Error	Contact Administrator
PE018	The system detected that power was lost during treatment and it has been more than 10 minutes since power loss	Power Loss	Remove Product Contact Administrator
PE019, PE020, PE021, PE022	System check failed or service is due	Service Required	Contact Service

































Event Code	What happened?	Message Displayed: Event Description	Message Displayed: Instructions
PE023	The temperature in one or both drawers was out of range (not during treatment)	Temperature Error	Contact Administrator
PE036	The system detected that a tray needs to be cleaned	Window Not Clean	Clean Window to Proceed
PE039, PE040, PE042, PE043, PE044, PE045, PE046, PE048, PE054, PE056, PE058, PE063, PE065, PE066, PE067	System check failed or service is due	Service Required	Contact Service
PF031, PF038, PF053, PF059	Unrecoverable system fault	System Fault	Restart device. Note: If this message continues to occur, contact Service.
PN024, PN025	The system determined that service will be needed soon	Service Required Soon	Contact Service
PN026	Device scanner is not working	Device Scanner Error	Use USB Scanner or Touchscreen Contact Service
PN027	Handheld scanner is not working	USB Scanner Error	Use Device Scanner or Touchscreen
PN062	The system determined that service will be needed soon	Service Required Soon	Contact Service
PU016	Drawer was detected as open when it should not have been	Drawer Open	Close Drawer
PU035	System detected that a drawer has a set in it when it should not have one	Unexpected Set	Remove Set
TE001, TE002, TE003, TE004, TE005, TE006	Treatment in all drawers failed	Treatment Failed Device Error	Remove Product Contact Administrator
TE001, TE002, TE003, TE004, TE005, TE006	Treatment in one drawer failed but the other was successful	Treatment Failed Drawer Error	Remove Product Contact Administrator

Event Code	What happened?	Message Displayed: Event Description	Message Displayed: Instructions
TE008	Treatment in one or both drawers failed due to high temperature	Treatment Failed Temperature Error	Remove Product Contact Administrator
TE009	Treatment in one or both drawers failed	Treatment Failed Device Error	Remove Product Contact Administrator
TE010	Hold time expired after treatment	Treatment Failed Hold Time Exceeded	Remove Product Contact Administrator
TE016	Treatment in one or both drawers failed	Treatment Failed Device Error	Remove Product Contact Administrator
TE036	The system detected that a tray needs to be cleaned	Window Not Clean	Clean Window to Proceed
TE040, TE042, TE043, TE044, TE045, TE046, TE048, TE054, TE065, TE066	Treatment in all drawers failed	Treatment Failed Device Error	Remove Product Contact Administrator
TE040, TE042, TE043, TE044, TE045, TE046, TE048, TE054, TE065, TE066	Treatment in one drawer failed but the other was successful	Treatment Failed Drawer Error	Remove Product Contact Administrator
TF031, TF038, TF053, TF059	Unrecoverable system fault	System Fault	Restart device. Note: If this message continues to occur, contact Service.
TN014	Report printer was unable to print	Printer Error	Contact Administrator
TN041	The system detected a problem with the drawer latch	Drawer Latch Error	Check Drawer or Manually Override
TU012	Treatment was canceled by the user	Treatment Incomplete	Contact Administrator
TU035	Product detected in drawer that should be empty	Product in Drawer	Remove Product to Continue
TU037	Data export failed	Data Export Failed	Check Network or Contact Service

Appendix C: System Icons

The following table describes the icons that are shown on the INTERCEPT Illuminator user interface.

Icon	Definition	Icon	Definition
	Today's Treatments		Begin treatment
	Settings		Search
	Top drawer		Bottom drawer
	Both drawers		Home
	Open drawer		Continue
	Cancel treatment		About
	Save		Do Not Save
	Labels		Printer
	Operator		Administrator
	Service		Inactive
	User management		Clean
	Configuration		Date and Time settings
	Data transfer		Printer settings

Icon	Definition	Icon	Definition
	Label printer settings		Language settings
	Illuminator information		Password settings
	Service settings		Return to Search
	Blood product code		Date and time
	Donor ID		Drawer
	Event		Set code
	First name		Last name
	Successful treatment		Username
	Clear scans		Return to Load screen
	Return to Settings		Return to Configuration
	Return to User Management		Caution
	Temperature error		Time error
	Illumination error		Processing set error
	Barcode		Service needed
	Barcode error		Scanner error
	Power failure		System failure

Appendix D: Cybersecurity

Security Controls

- Role-based Access Controls - the product restricts access to authorized users via role-based access controls, which allow a product operator to assign users with predefined permissions to the product software and software functions in the form of roles.
- Password hashing - The product uses secure hashing SHA256 to store a representation of user's passwords as an unintelligible series of numbers and letters, such that the product does store passwords in a form that could be decoded or if breached in their hashed form, cannot be used to authenticate a user.
- Kiosk Hardening - The product implements an operating system feature that restricts the product to allow only the product software to operate and is used to lock down the product to its verified and validated functions only.
- Software Integrity and Whitelisting - The product implements whitelisting to control authorized software that may operate on the product. Unauthorized software installation and execution is blocked by default.
- Anti-malware - The product runs a commercial anti-malware software to protect the operating system and product software from malicious software, also called malware. The anti-malware software scans the product automatically to prevent, detect and remove malware.
- Firewall - The product implements a software firewall to permit or block incoming and outgoing network traffic. The product is set by default to block all inbound traffic and allow only SFTP and Network Printing services outbound.

System Interfaces

- Touchscreen User Interface - A touchscreen is available on the product for use as both a user input and output display device. The touchscreen interface is the primary mechanism with which users will interact with the device. The touchscreen interface is protected by access controls requiring authentication with a username and password.
- SFTP - The product provides a Secure File Transfer Protocol (SFTP) client which uses SSH encryption to securely transfer files between the product and a customer-hosted SFTP server. Configuration of the SFTP server will be performed during initial product installation by the manufacturer in consultation with the customer.
- USB - Universal serial bus (USB) is a standardized technology for attaching peripheral devices to a computer. The product provides multiple USB ports to support a barcode reader and printer. The product does not provide support for USB storage media. USB storage media functions can be made accessible during manufacturer servicing only.

- Ethernet - The product provides an ethernet port to connect the product via ethernet cable to a customer-managed local area network.
- Network Printer - The product provides support for a network-connected printer that is accessible through the product's network connection, allowing the printing of reports.
- Barcode Scanner - The product provides support for a barcode scanner to read printed barcodes and decode the data contained in the barcode.

System Access

The product requires that users authenticate themselves to use the Illuminator. Cerus will provide credentials for the default operator account.

There is no network or remote access enabled by the product and all inbound network-based communications to the product are restricted by the product's software firewall.

Anti-Malware

The product contains anti-malware software which is enabled to automatically quarantine and prevent execution of malicious files and content, with no exclusions. Signature and engine updates for anti-malware software will be provided in product updates coordinated by Cerus.

Software Updates

It is anticipated that the software and operating system will require updates throughout its operational life. General users are not provided with the capability to update the product. Software updates will be coordinated by Cerus.

Password Management

The product implements username and password access controls to ensure users are authorized and authenticated prior to allowing use of the product. Users should maintain the confidentiality of passwords by ensuring the passwords are protected from disclosure and unique to everyone who requires access. Passwords can be configured to expire by an administrator within the product configuration screens. Accounts with default passwords provided with the product to establish initial installation, configuration, and user access should be changed. Access credentials should be removed from the product after departure of a person who has access.

The manufacturer maintains an account for servicing the product, which provides access to advanced calibration functions for the device. The product will alert the user in the case of a

system failure, or a safety halt has been triggered. If the product becomes unresponsive or alerts the user to a system malfunction, contact Cerus Technical Service or authorized representative.

Application Logs

The user may review the treatments log and event history log for activity and indications of system compromise. Users may contact the manufacturer to service the system in case of a security event or intrusion.

Digital Certificates

The product uses Digital Certificates for the purpose of validating authorized software included in the product whitelisting controls. The product also uses digital certificates for product updates. All digital certificates used within the product are managed by the manufacturer and are not presented to product users for any purpose.

Portable Media

The product restricts the capability to interact with portable storage media such as USB storage devices. Cerus Technical Service or authorized representatives will perform product updates using USB-based storage media.

Wireless Security

The product does not provide wireless capabilities, does not contain wireless chipsets, and does not broadcast any wireless signals.

Network Security

A software firewall hosted by the Illuminator blocks incoming network access to ports and services while permitting authorized outgoing communication.

Despite the firewall restrictions, the product should be additionally protected on a secure, trusted, non-public network. The product should not be connected directly to the internet without a boundary device or network appliance (e.g., firewall) acting as an intermediary. It is recommended that anti-malware scanning is performed for all endpoints and devices that share the same network as the product. It is also recommended to log and monitor network traffic for suspicious or unusual activity using dedicated network security appliances, devices, and tools.

Additional network monitoring, intrusion detection, and customer specific security tools and software cannot be directly installed on the product.

Secure File Transfer Protocol (SFTP)

The product can be configured to deliver treatment logs through SFTP in an outbound manner to a customer-managed SFTP server. The SFTP server must be designed and maintained with security best practices to reduce the risk to the product, including:

- Hardening the SFTP server according to manufacturer and industry recommendations
- Using up-to-date and current encryption
- Hosting the SFTP server on a private network and making SFTP or the host server available over the public internet.
- Using long and complex passwords for SFTP server access by SFTP clients, at least 12 characters in length and at least 3 of the following 4 complexity classes: upper case letters, lower case letters, numbers, and special characters

Physical Security

The product should only be accessible to qualified personnel. Store the product in a physically secured location to prevent unintentional or intentional misuse.

Do not attempt to open or disassemble the product and its associated components unless instructed per this User Manual.

System Decommissioning

System decommissioning requires coordination with the manufacturer to ensure treatment data and user access to the product is removed. Do not attempt to dispose or transfer ownership of the product without prior consultation with the manufacturer.

Security Incidents and Vulnerabilities

If you suspect a security incident has occurred involving the product, are concerned about a security vulnerability involving the product, or if you require assistance to investigate any activity identified on your product, please contact Cerus Technical Service or an authorized representative.

Appendix E: Care & Maintenance

Accessing drawers when not performing a treatment

1. Tap **Settings**.



2. Enter credentials.

3. Tap **Clean**.



4. Tap which drawer to open.
The selected drawer opens.



5. Clean or disinfect the drawer. Or, clean or replace the air filter per the instructions below.

6. Close the drawer.

To open the other drawer, you can repeat steps 4 through 6.

7. Tap **Home**.

NOTE: The home button is only available if both the drawers are closed.

NOTE: An event record (NN088) is created when you log in.

Cleaning or disinfecting surfaces and touch areas

Cleaning and disinfecting should be performed on the internal drawer surfaces and operator touch areas using a soft cloth and any of the solutions stated below. Operator touch areas include the product tray, drawer fronts, touchscreen, and power switch.

! **CAUTION:** Use only approved solutions to clean and disinfect the internal drawer surfaces and operator touch areas.

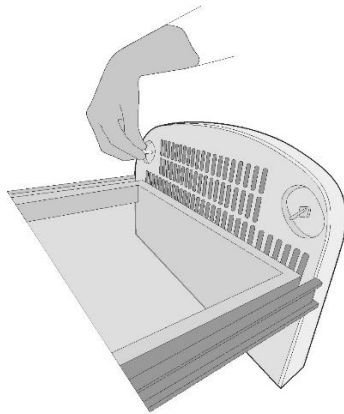
Cleaning solutions are: mild soapy water (2%) and isopropyl alcohol (70% in aqueous solution).

Blood borne pathogen disinfecting solution⁴: bleach (10% in water).

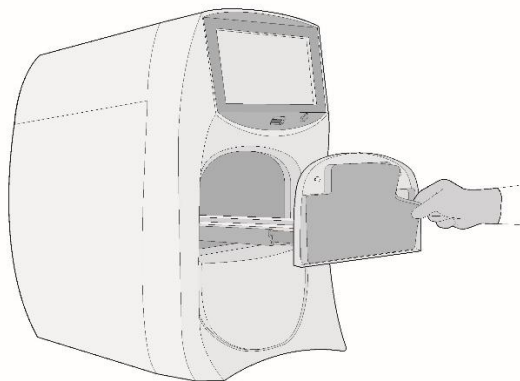
Clean or change air filters

! **CAUTION:** The air filter must be cleaned or replaced periodically to ensure adequate air flow to keep the blood product cool during treatment.

1. Rotate latches counterclockwise on both sides and remove the drawer faceplate.

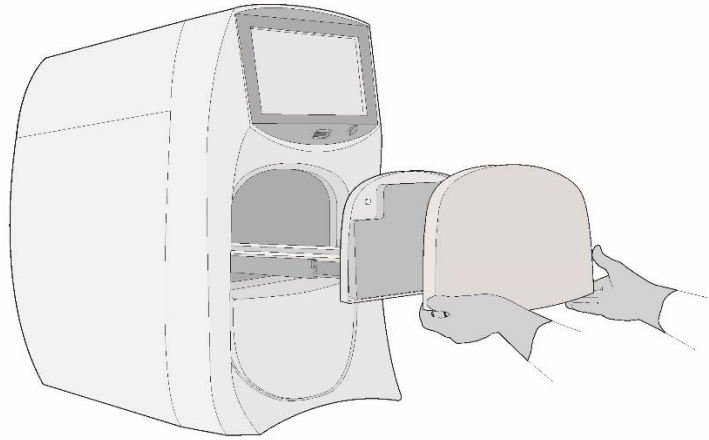


2. Peel off the filter.



3. Clean the filter with mild soapy water. Allow filter sufficient time to dry. Or, replace the filter.
4. To replace the top faceplate, snap the bottom in first and then the top portion. To replace the bottom faceplate, snap the top in first and then the bottom portion.

⁴ US Centers for Disease Control and Prevention, Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)



5. Rotate latches back clockwise.

Electrical Cords

Periodically inspect electrical cords for signs of wear or damage. Contact Cerus Technical Service or its authorized representatives if you identify an issue.

Useful Life

The INTERCEPT Illuminator has been designed with an expected useful life of 10 years. This is based on the following annual usage scenario: 4 illumination cycles per hour using both chambers, over an 8 hour day, 5 days a week for 52 weeks per year. This assumes maintenance is performed as described in this Appendix and Cerus Technical Service or its authorized representatives perform periodic calibration and preventative maintenance. Software updates and part replacements may take place as needed.

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