



Intelliguard[®] Mira Care[™] Station Instructions for Use (IFU)

Model 5800-MCS





Intelliguard



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Product Description

Intended Use:

Mira Care is intended to be used to store medications and controlled substances with secure access. The product is capable of the following convenience features for uses such as administrative, inventory, and diversion prevention purposes: tracking drug storage, tracking cabinet access, and logging waste witness events.

Intended Users:

The product is intended for use by authorized clinicians and staff members.

Indications For Use:

Mira Care stores and automatically tracks controlled and non-controlled medication inventories, which are administered to patients during medical procedures.

Reasonably Foreseeable Misuse:

The Mira Care Station is equipped with a manual override access system intended for emergency situations when the authorized electronic locking system is inoperable due to a power loss or lock failure. Healthcare providers may misuse this emergency feature as the primary means of accessing the medications. Relying on the manual override as the main access method can compromise accurate traceability of medications dispensed by authorized clinicians and staff members.

Duration of Use:

The Intelliguard Mira Care Station's duration of use is 5 years. This is assuming product is used under proper and intended use while maintaining maintenance services from Intelliguard, when needed.

Contraindications:

Mira Care is contraindicated in the use of tracking drug administration to patients for clinical purposes. Mira Care is contraindicated for the storage of life saving medication in the controlled substances drawer.

If there are any questions, call our 24-hour customer support line using the contact information on the title page.

Warnings, Cautions and Notes

Read and follow any warnings, cautions and notes throughout this manual. Examples are shown below.

A warning is provided when actions may result in a serious outcome (injury, serious adverse event, death). Example Warning:

WARNING: THIS IS AN EXAMPLE OF A WARNING.

A caution is provided when special care is needed by the patient or user to avoid injury to the patient or damage to the system. Example Caution:



CAUTION: This is an example of a caution

A note is provided when extra general information is applicable. Example Note:

Note: This is an example of a note.

Compliance

Federal Communications Commission (FCC) Part 15 Compliance

Contains FCC ID: TWYIPJREV

Contains FCC ID: M9MLC8008U



CAUTION: Changes to this product or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate per FCC Part 15.

Industry Canada (IC) Compliance

Contains IC: 6324A-IPJREV

Contains IC: 6571A-LC8008U

General Safety Guidelines

UL 62368

IEC 60601-01-02



CAUTION! Possible tipping hazard.



CAUTION! Disconnect power before servicing. The power switch does not disconnect or isolate unit from the facility (A/C) power circuit. If the unit is to be disconnected from facility power, it must be un-plugged.



CAUTION: For protection against electrical shock hazards, the equipment must be directly connected to an approved power supply with the power supply cord set which is provided by the manufacturer. Do not use an ungrounded receptacle. Any break in the electrical ground path could be hazardous. If the power cord becomes cracked, frayed, broken, or otherwise damaged, contact the manufacturer. Do not replace it with a lower rated cord set.

To prevent serious injury or damage to the unit, follow these simple rules when operating or moving the Mira Care Station:

- Always power down the Mira Care Station prior to transport.
- Do not exceed the rated weight limit of the drawers.
- Use the provided handles to relocate the Mira Care Station.
- Lock the wheels when not relocating the Mira Care Station.
- Make sure all drawers are closed completely and locked prior to relocating the Mira Care Station.
- Move slowly and carefully when relocating the Mira Care Station.
- Do not sit or lean on any open drawers.
- Do not sit or lean on the Mira Care Station.
- Immediately report any drawers that are not working properly.
- Avoid colliding with the station, including open drawers, to prevent injury and to prevent damage to the drawers.
- Avoid contact with surrounding equipment that may damage the station's external connections and/or caster wheels. If damaged, caster wheels may be difficult to operate.

To prevent serious injury or damage of the unit, follow these simple rules when operating or moving surrounding equipment near the Mira Care Station:

- Avoid contact with Mira Care external connections and/or caster wheels. Contact with these components may cause damage to the Mira Care Station. If damaged, caster wheels may be difficult to operate.

Note: An accessory ground conductor is provided on the back panel as a convenient testing point for earth bond integrity testing.

Note: The power inlet accepts a 250VAC/3.15A fast-blow fuse. Users should never attempt to fix and/or service the unit themselves; instead, users should contact Intelliguard for additional support.

Specifications

The Specifications section provides data essential for the safe operation, transport, and storage of the Mira Care Station and measures or conditions for installation and preparing the Mira Care Station for use.

Mira Care Station Physical Characteristics

Height	<i>Overall</i>	68.0" (172.7 cm)
Width	<i>With handles</i>	36.9" (93.7 cm)
	<i>Cabinet base</i>	32.1" (81.5 cm)
Depth	<i>Drawer closed</i>	29.0" (73.7 cm)
	<i>Drawer fully extended</i>	43.7" (111.0 cm)
Weight	<i>Empty</i>	288 lbs. (130 kg)
Drawer Storage Limits	<i>Half-width drawer</i>	15 lbs. (6.8 kg)
	<i>Full-width drawer</i>	25 lbs. (11.3kg)

Power Supply

Connection	One three-prong (grounded) NEMA 5-15 utility outlet
Input	100-240 VAC @ 50/60 Hz, 2.0/1.0A
Detachable power cord length	12 ft

Connectivity

LAN	CAT-5e (or compatible) cable is required for data connectivity
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Environmental

Operating Conditions	Temperature: 50°F – 86°F (10°C – 30°C) Relative Humidity: 10% - 95% non-condensing
Transport and Storage Conditions	Temperature: -4°F – 140°F (-20°C – 60°C) Relative Humidity: 10% - 95% non-condensing

IFU-02-01 (DOC-1703) Ver. 2

Approved By:

[\(CO-534\) Updates to IFU-02-01](#)

Description

Updating IFU-02-01 contents

Justification

Updating IFU-02-01 contents to align with Intelliguard requirements.

Assigned To:

Hylene Kevorkian

Initiated By:

Hylene Kevorkian

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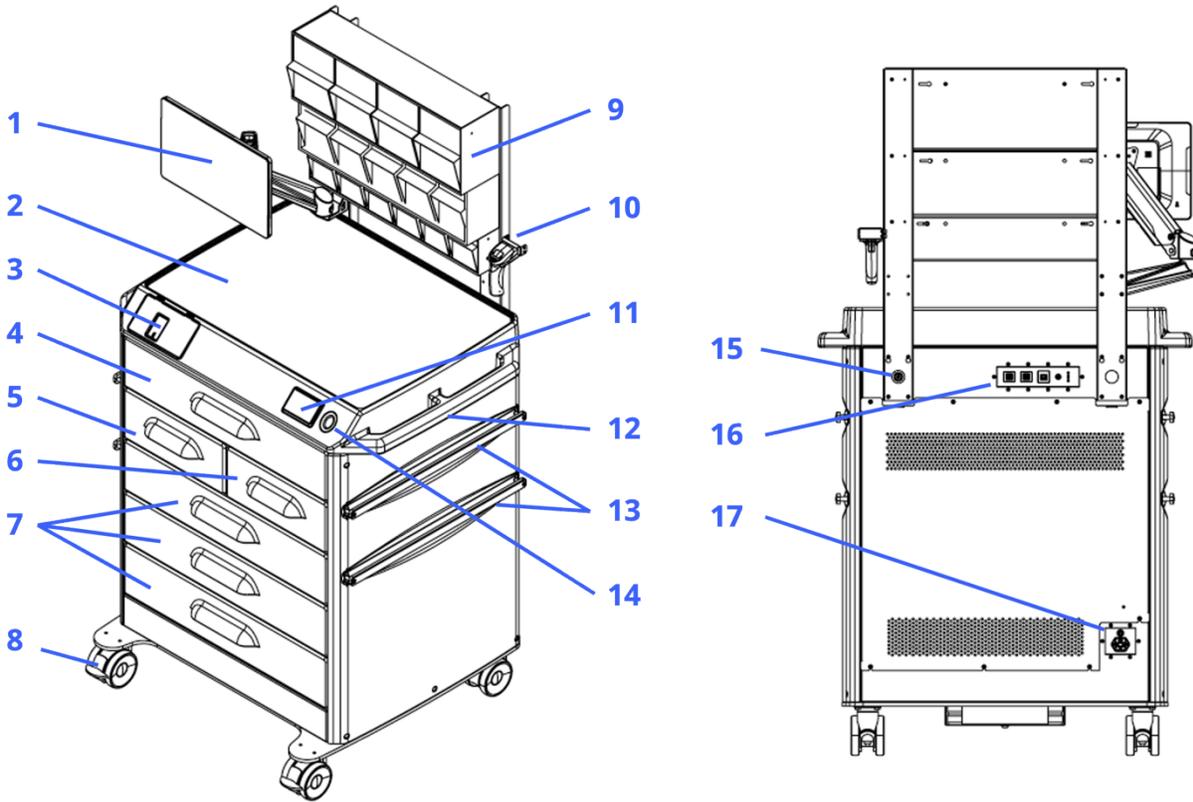
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Introduction

Mira Care™ Station



Number	Description
1	Touchscreen Monitor
2	Work Surface
3	Emergency Access Manual Override
4	RFID Enabled Medication Large Drawer (Drawer 1)
5	RFID Enabled Medication Small Drawer (Drawer 2)
6	RFID Enabled Medication Controlled Substances Drawer (Drawer 3)
7	Supply Drawers
8	Caster Wheel
9	Supply Tilt Bins & Rack
10	Barcode Scanner
11	Badge Scanner
12	Transport Push/Pull Handle
13	Accessories Rails
14	Fingerprint Bio-ID Scanner

INTELLIGUARD® MIRA CARE™ STATION: INTRODUCTION

15	Power Button
16	Rear Bulkhead Panel (See detail in Installation/Setup)
17	Power Cord Conduit

Intelliguard Mira Care™ Station components

Table of Symbols

Symbol	Description	Location(s)
	Caution	<ul style="list-style-type: none"> • Rear access panel • Drawers
	Manufacturer	<ul style="list-style-type: none"> • Rear access panel
	Date of Manufacture	<ul style="list-style-type: none"> • Rear access panel
	Serial Number	<ul style="list-style-type: none"> • Rear access panel • Technical support label
	Ingress Protection Rating	<ul style="list-style-type: none"> • Rear access panel
	Wave Badge Here	<ul style="list-style-type: none"> • Badge reader on front bevel
	Emergency Access	<ul style="list-style-type: none"> • Emergency override access door on front bevel
	Main Ground Stud	<ul style="list-style-type: none"> • Interior of side wall

Radio Frequency Identification (RFID) Technology Enabled

The Intelliguard Mira Care™ Station tracks medication inventory by reading previously encoded and assigned medication-specific RFID tags.

Best practices for using RFID tagged inventory include:

- Never return used or partially used vials or syringes directly into a drawer of the Mira Care™ Station. Returning such inventory items will cause inventory inaccuracies and potentially endanger patients when used medications are mistaken for unused.
- RFID tracking requires tags that are associated (“encoded”) with critical information about the contents of the medications they are attached to, such as medication name, strength, expiration date and manufacturer data. The Mira Care™ Station should never be used to track untagged inventory. Tracking untagged inventory may affect the Mira Care™ Station’s ability to maintain accurate inventory counts and ensure expiration dates are tracked.
- Users must follow their hospital protocols for disposing of medication waste and sharps. These items should not be disposed of inside the Mira Care™ Station. Each of the three drawers has been designed to accommodate a tray in which RFID-tagged medications are to be placed. Contact the appropriate Customer Service listed inside the front cover of this user’s guide with any questions related to tray loading.
- Users should never remove/dissociate RFID tags from medications or place a dissociated tag in an RFID enclosure. Any tag that becomes unassociated from a medication should be removed from the RFID enclosure.

Indicators

Note: Indicators are visible only on the display screen

Plug Indicator



The plug indicator designates whether the Mira Care™ Station is plugged into a power outlet. If the Mira Care™ Station is unplugged, the battery indicator will be displayed in place of the plug indicator.

Mains power outlet indicator colors:

- Green indicates that the Mira Care™ Station is plugged into a power outlet.

Battery Indicator



In the event the Mira Care™ Station is unplugged or there is a power outage, the Mira Care™ Station will continue to operate on battery power. The battery alone will allow the Mira Care™ Station to continue operating normally for up to 2 ½ hours depending on usage. The battery indicator will be green if the Mira Care™ Station battery is sufficiently charged. If the user does not wish to operate in battery mode, plug the Mira Care™ Station into a power outlet.

Battery indicator colors:

- Green indicates approximately > 25% battery capacity remaining
- Red indicates approximately < 25% battery capacity remaining

Note: As noted above, the battery indicator has two status indications. When the indicator is red, the Mira Care™ Station will have less than 25% of its battery capacity remaining. When this level is reached, Intelliguard recommends closing the drawers to initiate a scan to update the inventory database. The user may log out and stop using the Mira Care™ Station or log back in and leave the drawer open for access to emergency medications. In the event the user needs to use the emergency access for medication inventory, follow the facility's standard operating procedures for managing medication inventory while experiencing a power interruption.

Note: Users can subscribe to Notifications that trigger if a station is on battery power and has less than 25% battery capacity remaining.

Network Connectivity Indicator



The Network Connectivity indicator allows the user to see if the Mira Care™ Station is communicating with the network.

- Green indicates successful communication
- Red indicates the Mira Care™ Station is not connected and/or communicating

Note: The pharmacy and system administrator will receive a Notification when the Mira Care™ Station indicators are red or yellow for a sustained period. Brief color changes are not a concern.

Note: Contact the pharmacy or system administrator when the indicator is yellow or red for an extended period for information about repairs or expected return of service.

Rebooting the Mira Care™ Station

Hard Reboot

The Mira Care™ Station can be hard rebooted by holding the power button through two short beeps and waiting for one long beep to begin. Releasing the button will cause the unit to turn off. Wait at least one minute. Next, power the Mira Care™ Station back on by pressing the power button on the back of the unit. If a hard reboot does not resolve the issue, contact customer support for assistance.

Installation/Setup



CAUTION: For protection against electrical shock hazards, the equipment must be directly connected to an approved power supply with the power supply cord set which is provided by the manufacturer. Do not use an ungrounded receptacle. Any break in the electrical ground path could be hazardous. If the power cord becomes cracked, frayed, broken, or otherwise damaged, contact the manufacturer. Do not replace it with a lower rated cord set.

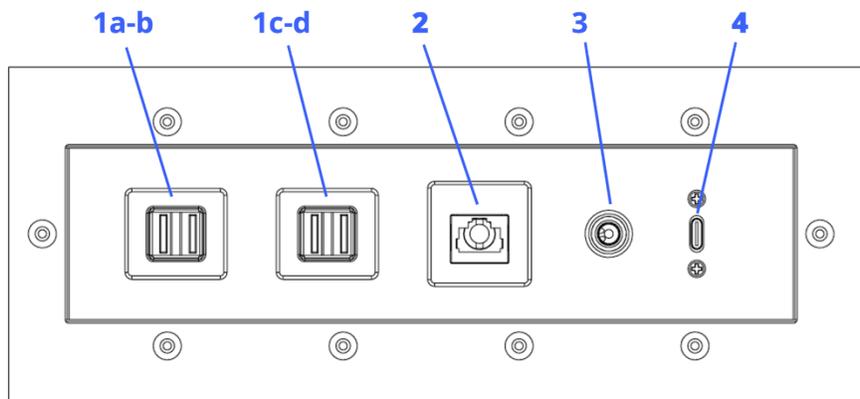


CAUTION: The power switch does not disconnect or isolate unit from the facility (A/C) power circuit. If the unit is to be disconnected from facility power, it must be unplugged.

Note: The Mira Care™ Station is not for use in a computer room as defined in the Standard for the Protection of Information Technology Equipment, ANSI/NFPA 75.

Note: Do not position the equipment in such a way as to block easy access to any main disconnect apparatus (appliance coupler) or in any way that makes it difficult to operate the main disconnect apparatus. The equipment shall be near the outlet and the outlet shall be easily accessible.

Note: Position the equipment in such a way to prevent risk of injury, particularly where children are likely to be present.



Number	Description
1 a-d	USB-A 3.0 Ports (Use only with Intelliguard-approved products)
2	Ethernet Port
3	Monitor Power Port

4	USB-C 3.0/3.1 Port (Reserved for monitor)
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Intelliguard Mira Care™ Station rear bulkhead panel connectors

Installing the System

1. Locate the Mira Care™ Station near a power receptacle. Position the Mira Care™ Station such that the receptacle remains easily accessible.
2. Lock the front caster wheels.
3. Connect a CAT-5e (or compatible) Ethernet cable to the Ethernet port.
4. Plug the other end of the Ethernet cable into an active facility LAN port.
5. Plug the power cord into a grounded receptacle.
6. Push the power button to the “ON” position.

Running on Battery Power

Under normal operation, the Mira Care™ Station is intended to be plugged into a power receptacle. If power loss occurs, a fully-charged unit will continue to operate as intended on battery power for up to 2 hours, depending on usage.

Note: To ensure real-time data availability, an active LAN connection must be maintained while in use.

Storage/Transport

If the unit will be left unplugged for more than 2 ½ hours, or stored, the station must be powered off. During unit transportation, disconnect the power cable from the unit and store it in one of the supply drawers.

After unlocking the wheel casters, use the provided handles to roll the Mira Care™ Station about the facility. To prevent injury or damage to the unit, do not lift the Mira Care™ Station.

Cybersecurity

WARNING: USERS SHOULD ENSURE THAT THEIR HOSPITAL NETWORK HAS SUITABLE CYBERSECURITY PROTECTIONS IN PLACE SUCH AS FIREWALLS, NETWORK SECURITY, DATA SECURITY, AND ANTI-VIRUS PROTECTIONS, SUBJECT TO HIPAA COMPLIANCE.

WARNING: INTELLIGUARD STRONGLY ADVISES THE USER NOT TO MODIFY, ALTER, OR RESET THE SOFTWARE. EXCEPTIONS TO THIS ARE AS FOLLOWS: WHEN THE MIRA CARE™ STATION'S SOFTWARE PROMPTS THE USER TO PERFORM A SOFTWARE UPDATE OR WHEN AN INTELLIGUARD TECHNICAL ASSISTANCE REPRESENTATIVE INSTRUCTS/GUIDES THE USER THROUGH MAINTENANCE AND/OR TROUBLESHOOTING.

User Notice:

- The Mira Care™ Station should be stored in a secured area.
- Users should log out of any activities open on the Mira Care™ Station when finished with use.
- Intelliguard does not make any commercial use of or disclose any private information of Mira Care™ Station users
- Users should follow their hospital's emergency data backup process where applicable to ensure data can be recovered after an emergency. Intelliguard technical support can also be contacted to assist with disaster recovery.
- Users should not connect personal or unsupported USB apparatuses to the Mira Care™ Station.

Intelliguard recommends that users take the following precautions and controls with their Mira Care™ Station in order to ensure and maintain the security of their equipment:

- Intelliguard personnel will never request your PIN or additional login information. Notify Intelliguard immediately if you receive unexpected or confusing emails, phone calls, or other forms of communication regarding your Mira Care™ Station.
- Do not share login information (e.g. PIN) for your Mira Ecosystem account.
- Do not share your badge and/or use of your fingerprint with any other person to access your Mira Ecosystem account.
- When a cybersecurity incident is reported by the user to Intelliguard:
 - A confirmation letter will be provided to the user within 24 hours of reporting.

- Suggested actions will be provided to the user within 15 days from the date of reporting, if applicable.
- An incident vulnerability disclosure will be provided to Information Sharing and Analysis Organizations (ISAOs) from Intelliguard within 30 days from the date of reporting, if applicable.

Note: If a unit is disconnected from the network for an extended period of time, it will require updates to be pushed before it can be used again. Please reach out to the Intelliguard support team.

Login and Use

Login Authentication

Access to certain areas of the software may not always be available or user access may be restricted or limited based on pre-set permissions. If access is restricted, some buttons will appear inactive or will not appear on the screen.

If the individual is not registered to use the Mira Care™ Station, see the facility's system administrator to get authentication rights activated.

Note: Do not use another user's login or allow anyone to use your login.

Note: The fingerprint scanner must be clean and free of debris. If not cleaned properly, the fingerprint scanner may not work as effectively.

Note: When using the fingerprint scanner, ensure that the user's finger is flat against the fingerprint scanner surface. If not, the user's fingerprint may not be read.



Finger alignment for fingerprint scanner

The Mira Care™ Station offers three methods of authentication for login: scanning a badge, scanning a fingerprint, and entering a PIN.

Login Icons Table

Icon	Description
	Badge scan. Badge scan is available for first and second level of authentication.
	Fingerprint Bio ID scan. Fingerprint Bio ID is available for the first and second level of authentication.
	PIN. PIN entries are entered by touching the PIN icon on the screen. Only 4-digit PINs are allowed. PIN is available for second level of authentication only.
	Indicates login method is a success.
	Indicates login method has failed.

Two-Factor Authentication

Certain authentication steps require two-factor authentication. Any two of the three methods of authentication are allowed. The following authentication events require two-factor authentication:

- Initial login for pharmacy personnel performing restocks.
- Initial login for providers starting cases.
- User logging in to perform a mid-case station restock, using the “Restock” button on the main dashboard.
- User assuming a reassigned case.

One-Factor Authentication

Certain authentication steps require one-factor authentication. Only Badge and Bio ID methods of authentication are allowed. The authentication steps include:

- Unlocking all drawers while already logged into the station. This is used to:
 - Unlock Drawer 3 after it closes, since it auto-locks upon closure.
 - Unlock the drawers after the user touches the “Lock All Drawers” button.

Note: Only the user currently logged in can authenticate to unlock drawers.
- User logging in to witness the provider’s waste.

Intelliguard Mira Care™ Station Login

Note: If a problem occurs when logging in, see the troubleshooting section in this document or contact the system administrator for assistance.

Note: If the system has a timeout function and the Mira Care™ Station has not been used within the allotted time the user may need to log back in to continue using the Mira Care™ Station.

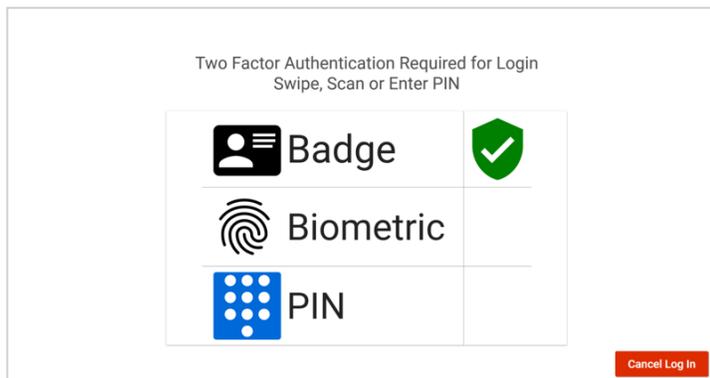
Note: The user must always logout prior to stepping away from the unit.

1. Touch the Logo Screen to display the Login Screen.



Intelliguard Mira Care™ Station IG Logo Screen

2. Log in to the Mira Care™ Station using the required two-factor authentication.



Login Screen with one successful authentication. A second authentication method will be required for some authentication events.

Using the Intelliguard Mira Care™ Station: Provider Workflow

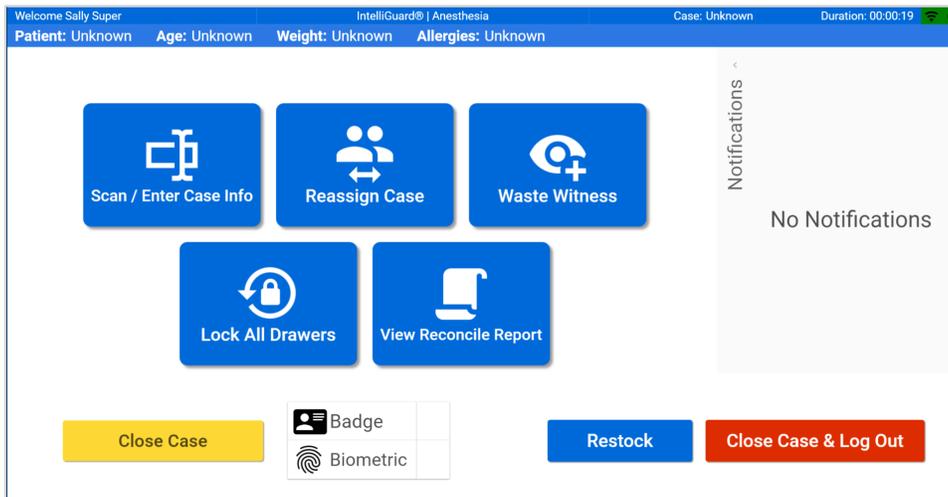
WARNING: USED, AND PARTIALLY USED, VIALS OR SYRINGES SHOULD NEVER BE RETURNED TO THE MIRA CARE™ STATION AS THIS WILL CAUSE INCORRECT INVENTORY LEVELS AND POSSIBLY IMPACT PATIENT SAFETY.

Note: When closing the drawer, the user may push the drawer closed and when the drawer is about a half inch from the cabinet, the self-close mechanism will complete the closure and ensure the drawers will lock properly when the system log out occurs.

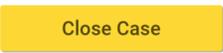
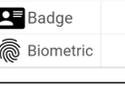
It is the responsibility of the user to ensure all drawers are closed and locked. If drawers are unable to lock, contact Intelliguard as soon as possible for assistance.

Note: The Mira Care™ Station is a medication inventory system but does not offer waste or sharps management. To ensure proper disposal of waste and sharps, it is important for users to follow standard hospital protocols.

Dashboard



Application Appearance during Intraoperative Session for a Provider

Icon	Description
	Use this button to scan a patient wristband or enter an ID. For users with EHR authentication, a Case Selection screen will be displayed.
	Use this button to transfer the ongoing patient case to another provider. This allows the new provider to log in and will log out the current provider.
	Use this button to record controlled substance administration and/or waste, and to have waste witnessed.
	Use this button to lock all the RFID-enabled medication drawers.
	Use this button to view the reconcile report and see details about which medications have been removed from the Mira Care™ Station. Note: Date and time parameters must be correctly selected.
	Use this button to close the current case.
	Indicates successful or failed authentication attempts for the purpose of unlocking drawer(s) while logged into the Mira Care™ Station.
	Use this button to allow another user to log in and perform a station restock in the middle of a case.
	Use this button to close the case and log out of the Mira Care™ Station.

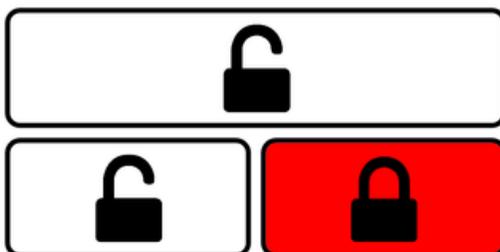
Drawer Lock Indicators

Note: The indicators appear only on the display screen.

The drawer status indicators of the Mira Care™ Station indicate the locked or unlocked status of each drawer. The lock on top corresponds to the larger drawer and the two locks on the bottom correspond to the bottom drawers.

The drawer status indicators will be in the locked position with a red background prior to login. A successful login will open all drawers. The controlled substances drawer indicator will be in the unlocked position with a yellow background flashing. After the controlled substances drawer is opened and then closed, it will automatically lock.

Note: The drawers will self-close when they are within a half inch of the cabinet. Any drawer left open more than a half inch may not self-close and will trigger a Notification at log out.



Drawer Status Indicators

Indicator	Description
	Indicates drawer is unlocked.
	Indicates drawer is locked.
	Indicates drawer scan when blue is flashing. Scanning will update the inventory database.

Accessing the Station

1. Log in to the Mira Care™ Station.

Case Selection

Note: You can log in without entering or selecting a case.

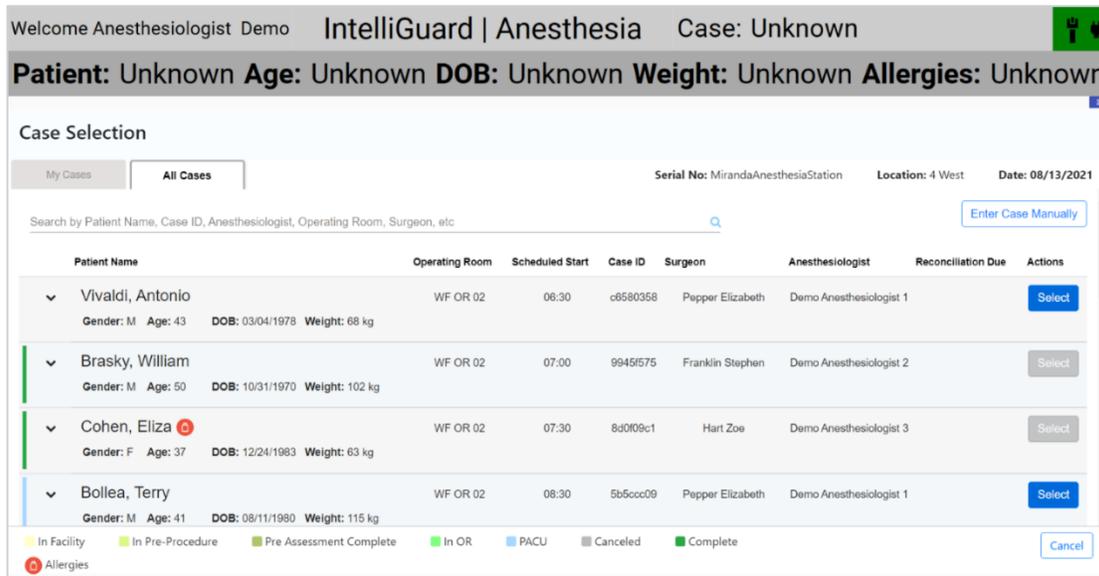
2. Select case.

There are two methods for case selection in the Mira Care™ Station. Use one of these methods to select the case.

- Select the patient information via integration with your Electronic Health Record (EHR)
- Patient wristband scan or manual entry of the patient identifier

Electronic Health Records

Case Selection will display a list of cases on the screen following a successful two-factor authentication. Select the desired case from the list under the applicable tab (My Cases or All Cases).



Example of Case Selection Screen

Wristband Scan or Manual Entry

Scan the patient wristband or enter the patient identifier.



Wristband Scan or Manual Entry Screen

Dispensing Medication

3. Following login, providers can remove required medication from the applicable drawer.
 - a. An RFID scan of the drawer will begin when the drawer is closed. If a drawer is opened before scanning completes, scanning will stop and will start over the next time the drawer is closed.
4. If a controlled substance is needed and the drawer is locked, complete authenticate using the badge or Bio ID (fingerprint) method, remove the controlled substance from the drawer, and close the drawer.

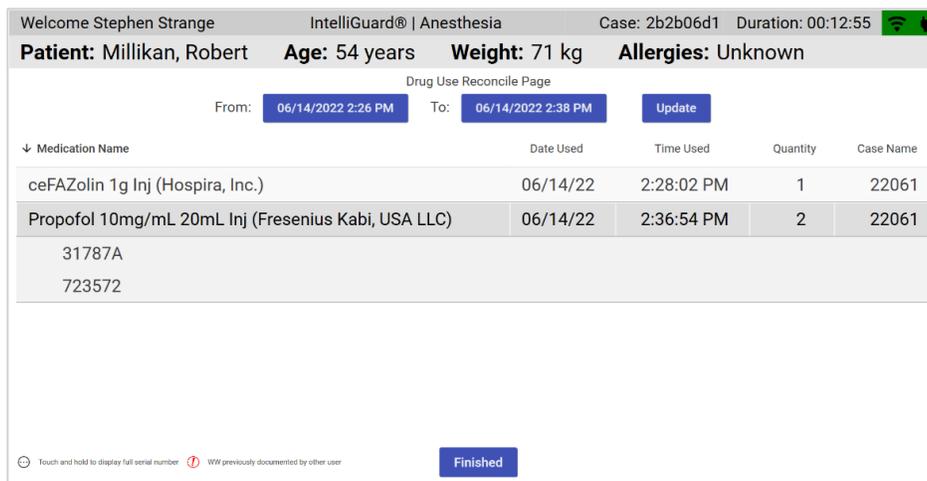
Viewing the Reconcile Report

To see a list of medications taken out of the station, select the View Reconcile Report from the dashboard.

5. Medications removed from the station in the selected timeframe will be displayed on the screen.

Note: The default timeframe selection is from the start of the current case to the current time. Ensure that the desired timeframe is selected.

6. Adjust the timeframe selection by touching the current selections, opening a calendar and opening the clock tool.
7. Touch the Update button to refresh the page. This is necessary if a drawer has been opened and medication has been removed or added during the time the current screen was open.
8. Select a row to expand it. Each Tag ID of the medication removed will be displayed.
9. If the medication is incorrect, return the medication to the applicable drawer.
10. Touch the Finished button to close the page and return to the dashboard.



Example of Reconcile Report Screen

Reassign Case

If a case needs to be reassigned to a different provider, the Reassign Case button can be used.

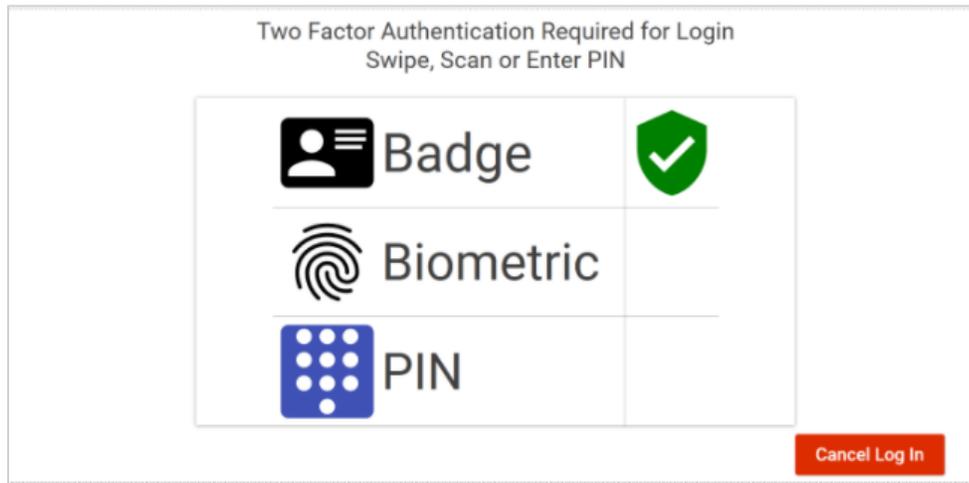
Note: Any medication, including controlled substances will now be the responsibility of the person to whom the case was reassigned. Best practice would be for the original provider to record and complete any narcotic administration and complete the transaction prior to reassigning a case.

11. Touch the Reassign Case button.



Dashboard with Reassign Case Button

12. Perform two-factor authentication to finish reassigning the case.

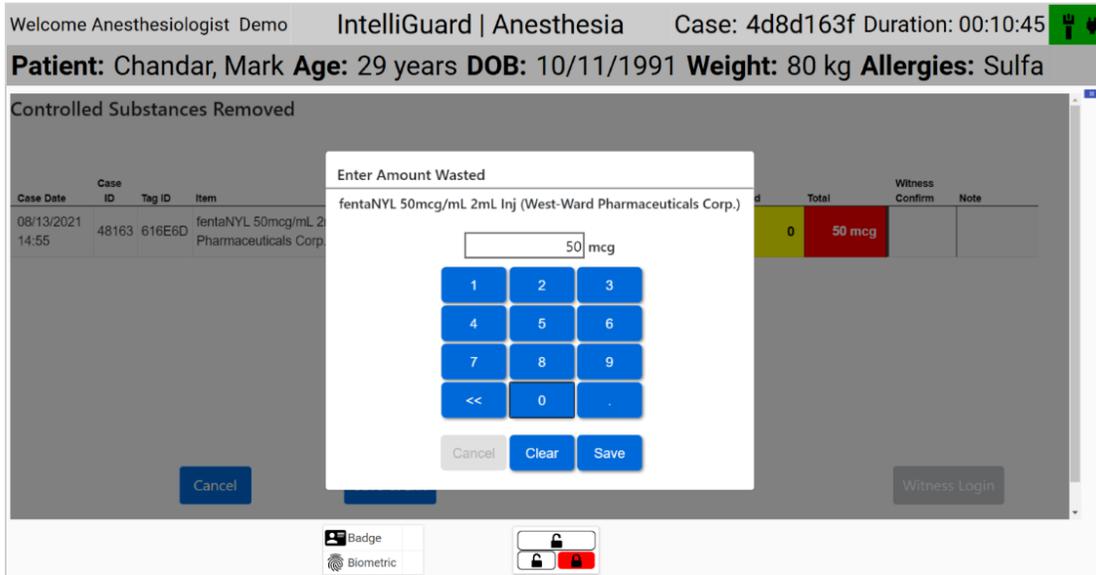


Login Screen

Waste Witness

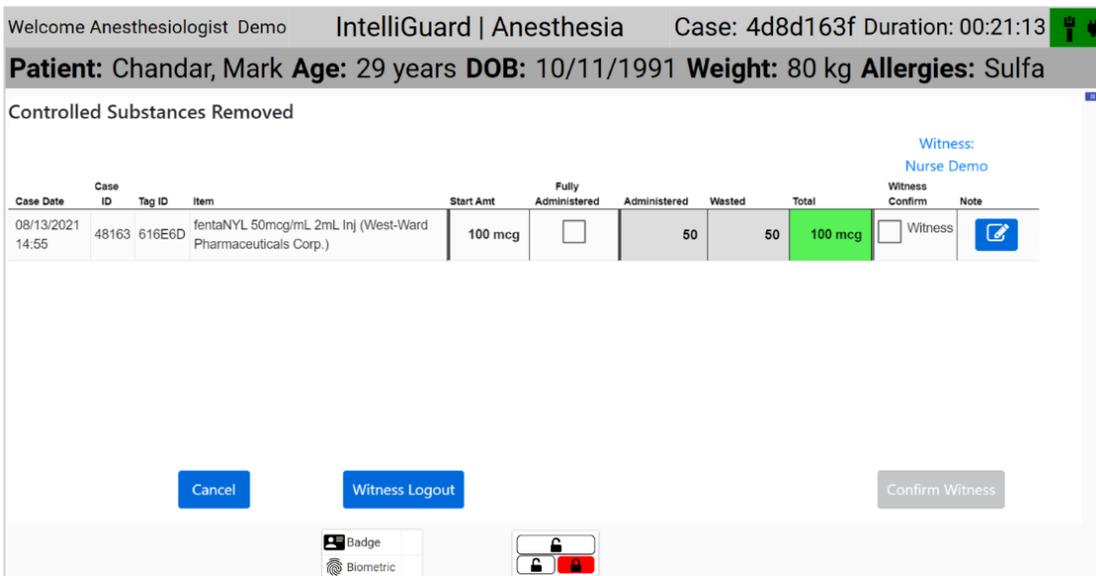
The administration and waste of controlled substances can be documented using the Waste Witness button.

13. Touch the Waste Witness button.
14. Enter quantity administered and quantity wasted in applicable fields or, if the entire quantity has been administered, select the Fully Administered option. The waste witness shall observe the medication being wasted and the accuracy of the quantity amount entered into the system.



Example of Waste Screen

- The green background in the total field indicates that the total of the quantity administered and the quantity wasted matches the starting amount.



Example of Waste Screen with Correct Total

Note: For split medication (not available for use in the United States), see page 28.

Witnessing Waste

- Touch Witness Login button.

17. Scan badge or fingerprint.



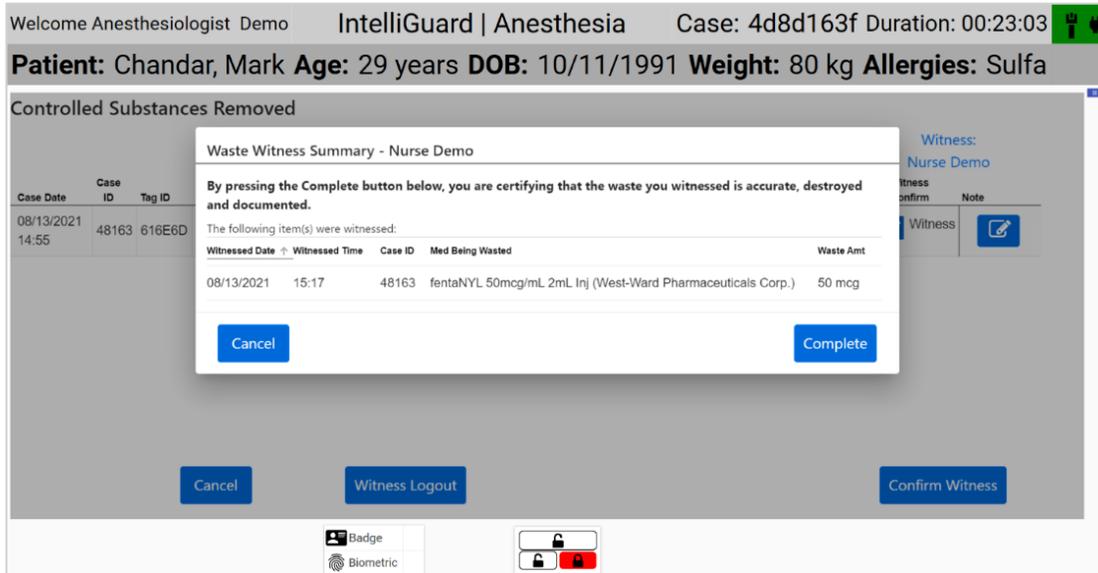
Example of Waste Scan Screen

18. Verify waste information is correct and touch Witness checkbox. The Witness checkbox will change to blue.



Example of Waste Witness Screen with Witness Unchecked

19. Touch Confirm Witness button. The name of the witness, date and time will display in the Witness column.



Example of Waste Witness Screen following Confirm Witness

20. Touch Witness Logout button when witness verification is complete.

Note: The witness will also be logged out automatically once the verification process is complete.

Lock All Drawers

21. Touch the Lock All Drawers button to lock all of the RFID Enabled Medication drawers. Before walking away, ensure all drawers are properly locked. If drawer(s) are not locking, contact the pharmacy to secure the medication then contact Intelliguard support for potential servicing.

Close the Case

22. Select the desired Close Case button
 - To close the current case and stay logged in, including if you wish to open a new case, touch the Close Case button.
 - To close the current case, resolve any outstanding issues, and log out, touch the Close Case & Log Out button.

Split Medication

Note: This functionality is not currently enabled for United States clients due to its conflict with Institute for Safe Medication Practices (ISMP) guidelines.

The administration and waste of controlled substances can be documented using the Waste Witness button.

1. Click the "Split" button under the ACTION column of the medication.
2. A new row has been added to the screen. (Refer the screenshot on the following page.)
3. Select the corresponding Patient information from the dropdown for each row.
4. Enter quantity administered and quantity wasted in applicable fields or, if the entire quantity has been administered, select the Fully Administered option.
5. The green background in the total field indicates that the total quantity administered and wasted matches the starting amount.
6. Login to the waste witness.

Note: If it did not match with the start amount the total amount column will be highlighted in Red. See the images on the following page for reference.

INTELLIGUARD® MIRA CARE™ STATION: OPERATION

Dispensed Date	Tag ID	Item	Patient	Start Amt	Administered	Wasted	Total	Witness confirm	Note	Action
05/22/2023 16:53	737175	Ketamine 50 mg IM, Intramus...		50 mg	0	0				
★ 05/22/2023 16:53			69		0	0				

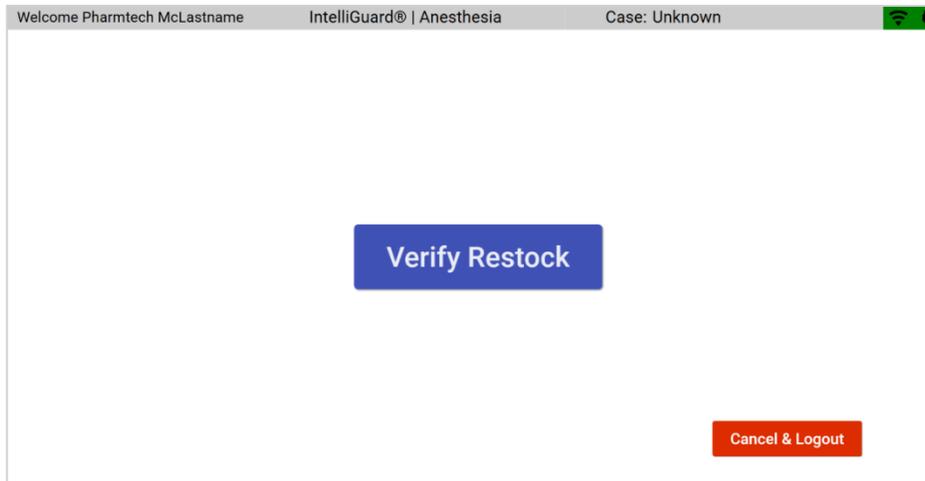
Example of a Split Medication Screen

Dispensed Date	Tag ID	Item	Patient	Start Amt	Administered	Wasted	Total	Witness confirm	Note	Action
05/22/2023 16:53	737175	Ketamine 50 mg IM, Intramus...		50 mg	10	10	20 mg			
★ 05/22/2023 16:53			69		10	10	20 mg			
▶ 05/22/2023 18:06			15		0	0				

Example of a Split Medication Screen with Multiple Splits

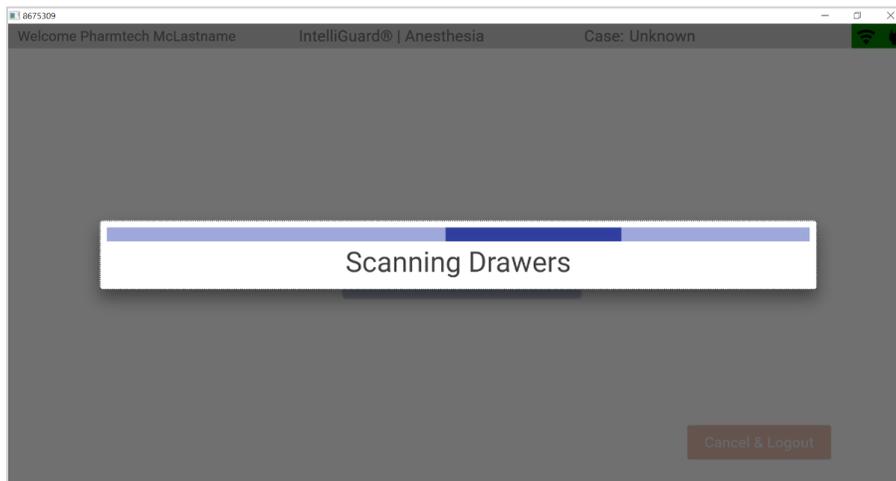
Using the Intelliguard Mira Care™ Station: Pharmacy Workflow

1. Log in to the Mira Care™ Station. All the drawers will unlock.
2. For each drawer that needs to be restocked, remove the tray from the drawer and replace it with the approved, fully restocked tray.
3. Close all drawers and touch Verify Restock. If medications and/or supplies are not stocked properly, this may obstruct and/or prevent drawers from opening and/or closing.



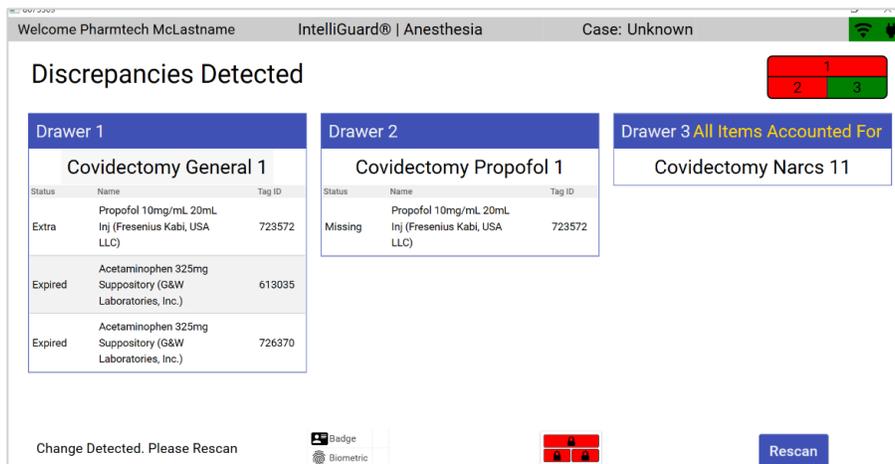
Verify Restock Screen

4. All the RF-Enabled Medication drawers will be scanned.



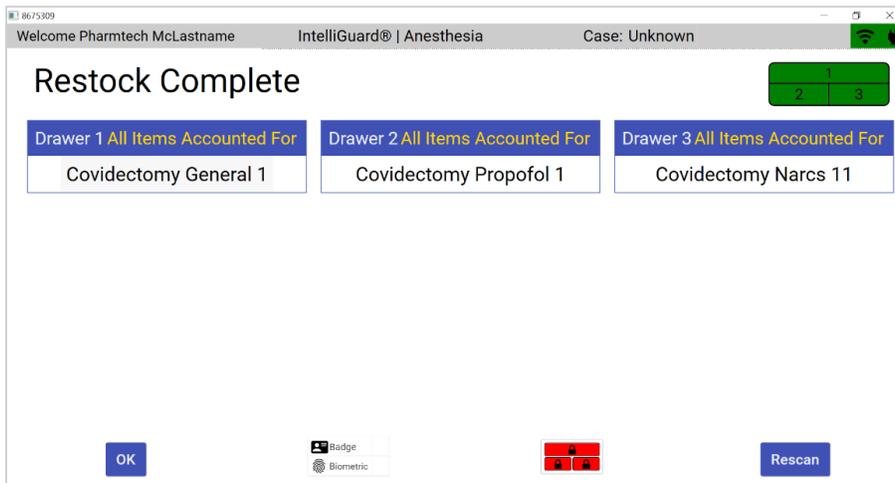
Example of Screen while Drawers are Scanned

- If discrepancies are detected, resolve the discrepancies. See the Troubleshooting section of this manual.



Example of Discrepancies Detected Screen

- Touch OK button to log out.



Restock Complete Screen

Note: Users selecting “OK” button will complete the Restock process. User can see the Restock complete page for the status of all the drawers and whether all items are accounted for.

Note: If the restock was not completed by the previous user, any unresolved discrepancies will appear for the next person attempting to restock.

Notifications:

Note: Notifications can be configured during implementation by Intelliguard and by the pharmacy team.

Note: When dismissing an Emergency Access Override/Unauthorized Access notification, follow institutional security procedures for emergency or unauthorized access.

Mira Care™ Station users can also receive Notifications on cell phones via text or in email. The types of Notification vary based on the facility's use of Notifications

Examples of the types of notifications available for text and email are listed in the table below. Expired Products are identified based on dates set in Intelliguard Pharmacy and only triggered on expiration. Product Recall status is set by marking a medication as recalled in Mira Prep.

of the types of Notifications available for text and email.

Notification Name	Who gets the Notification?	How is this Notification resolved?
Emergency access override/Unauthorized access	Mira Prep users (Pharmacy) Mira Care™ users	Restarting the unit.
Expired/recalled medication	Mira Prep users (Pharmacy) Mira Care™ users	Removing the expired or recalled medications from the Mira Care™ Station.
Power outage/network down	Mira Prep users (Pharmacy) Intelliguard	Resolving the power or network problem.
Overdue Waste witness	Mira Prep users (Pharmacy) Mira Care™ Users	Completing waste witness.
Fully or partially, medication has been previously wasted	Mira Prep users (Pharmacy) Mira Care™ Users	Removing the medication from the Mira Care™ station.
Controlled substance in a wrong drawer	Mira Prep users (Pharmacy) Mira Care™ Users	Transfer the controlled substance medications from unsecured drawers to the secured drawer- Mira Care™ Station.

Emergency Access Override

The Mira Care™ Station has an emergency access override to enable access to the RFID Enabled Medication drawers in the event of a power outage or other technology issue. When the Mira Care™ Station senses that an override event has occurred, the system will notify the pharmacy to ensure prompt attention and resolution of any impediment to using the product.

1. Remove the tear-away lock or contact pharmacy to open the door to the emergency override panel. If the tear-away lock cannot be removed, please contact Intelliguard as soon as possible.



Locked Emergency Access Override Door



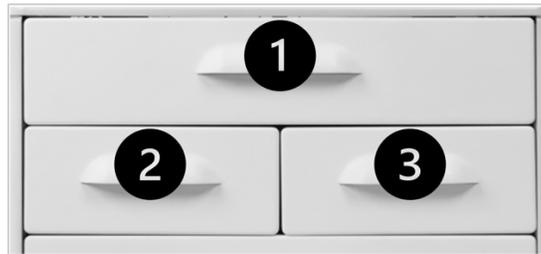
Unlocked Emergency Access Override Door

INTELLIGUARD® MIRA CARE™ STATION: EMERGENCY ACCESS OVERRIDE

- The emergency access override door will open and allow access to the emergency access levers and keyhole. If the emergency access levers fail, contact Intelliguard as soon as possible.



Emergency Access Levers and Keyhole



Drawer Numbers

- Perform the action to open the drawer. A “Manual Override Detected” message will appear at the top of the touchscreen monitor.
 - Drawer 1: Pull the lever on the left and hold while opening drawer. Once the drawer is open, the lever may be released.
 - Drawer 2: Pull the lever in the middle and hold while opening drawer. Once the drawer is open, the lever may be released.
 - Drawer 3: Insert key into the keyhole to the right of the levers for access to the controlled substances drawer. Turn the key 90° clockwise. It should remain in the new vertical orientation when released. If it starts to return to the starting position, manually hold it in place while opening the drawer. Once the drawer is open, return the key to the original orientation and remove it from the keyhole. [Note: Always rotate key back into original orientation before attempting to remove key.](#)

INTELLIGUARD® MIRA CARE™ STATION: EMERGENCY ACCESS OVERRIDE

Note: Please follow the hospital protocol or contact the Pharmacy Administrator regarding the override key location. Hospital protocols shall ensure the emergency access key cannot be lost, misplaced and/or damaged.

Frequently Asked Questions (FAQs)

What if I leave one OR and go to another one in my facility?

The user's authentication credentials/badge or bio-ID will work for any Mira Care™ Station at the user's facility.

Is the Mira Care™ Station mobile?

The Mira Care™ Station is movable and is equipped with four casters, two of which are locking and all of which all will swivel. However, it is recommended that the Mira Care™ Station be used in a fixed location, such as an operating room or procedural area.

What happens in a power outage?

Always follow the facility's standard operating procedures should there be a power outage. The Mira Care™ Station is equipped with a backup battery and will continue to be available for use up to 2 ½ hours, depending on usage. See the battery mode section of this document for more information. The users will be able to continue using the Mira Care™ Station and the cache memory will retain the user and inventory data, which will automatically update the database records when the power returns.

What if I can't get access to the Mira Care™ Station drawers in an emergency or non-emergency situation?

The Mira Care™ Station has an emergency access override panel on the top left side. See the Emergency Access Override section in this manual for instructions on using the switch and accessing the drawers.

If the drawer is stuck in the closed position, such as if medications and/or supplies are obstructing the drawers from opening, and medications cannot be accessed via the emergency access override, contact the Intelliguard support team for assistance and next steps. In the meantime, follow internal protocols, if applicable, and obtain medication from other Intelliguard stations, if available, and/or the crash cart.

Why is the software not detecting some medication that is in the tray?

If there are medications in the Mira Care™ Station that are not RFID-tagged the Mira Care™ Station can't accurately manage inventory. Notify the pharmacy if there is medication without a tag.

Is RFID safe in the operating room?

Intelliguard products utilize ultra-high frequency (UHF) RFID. Further information is available by contacting Customer Service as shown on the title page of this user's guide.

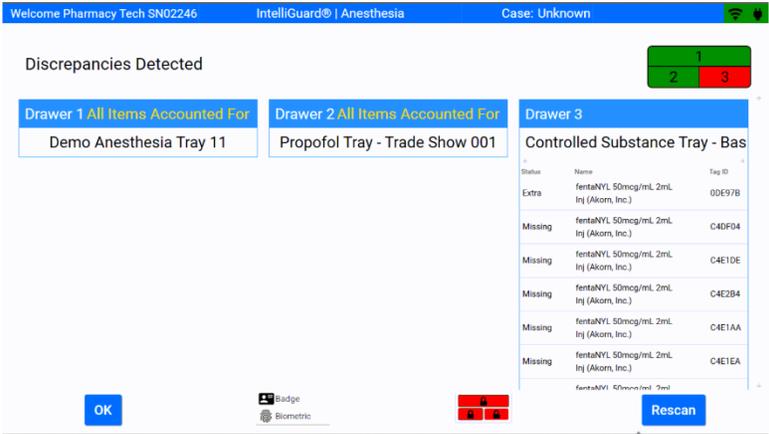
Intelliguard RAIN RFID (UHF) Solutions operate according to FCC Part 15 regulations. These regulations and the related established exposure limits assume the transmission of UHF energy in free space

INTELLIGUARD® MIRA CARE™ STATION: FREQUENTLY ASKED QUESTIONS

(transmission of energy in open areas). Unlike free space applications, Intelliguard RAIN RFID Solutions employ metal enclosures which capture the UHF energy, thus preventing the energy from being transmitted in free space.

Troubleshooting

Problem	Recommendation
<p>Cannot log in to the Mira Care™ Station or access the drawers.</p>	<p>If the user is unable to log in and a Mira Care™ Station account has been created, contact the system administrator for assistance.</p> <p>If the Mira Care™ Station drawers remain locked after login, the user may need to enter a code/use the bio-ID or scan a badge as a secondary authentication to unlock the drawers.</p>
<p>The Mira Care™ Station has no indicators lighting up and I can't log in.</p>	<p>Check to ensure that the Mira Care™ Station is plugged in and that the station is powered on.</p>
<p>The Mira Care™ Station is displaying flashing lights in all the indicators.</p>	<p>Occasionally the Mira Care™ Station will need a reboot. Follow the instructions in the user manual to reboot the Mira Care™ Station.</p>
<p>The Mira Care™ Station has no power.</p>	<p>Check to ensure that the Mira Care™ Station is plugged in and that the station is powered on. Contact Customer Support if the Mira Care™ Station will not power on.</p>
<p>Discrepancy detected during restock – “Missing” status.</p>	<p>If the medication is in the tray, rescan the drawers. If the medication is not recognized by the RFID reader a second time, there may be a problem with the RFID tag and it should be returned to the pharmacy for investigation. Medication with a damaged and/or defective tag should be returned to the pharmacy for investigation; do not return to or place in the Mira Care™ Station.</p> <p>If the medication is “Missing” from one drawer and “Extra” in another drawer, move the medication from the drawer indicating “Extra” to the drawer indicating “Missing” and rescan the drawers. Note: Verify the TagId displayed on the screen and move the corresponding medications from the drawer.(TBD)</p> <p>If the medication is actually missing, return the tray to pharmacy for investigation or report it to your supervisor.</p>

Problem	Recommendation
<p>Discrepancy detected during restock – “Extra” status.</p>	<p>If the medication is “Extra” from one drawer and “Missing” in another drawer, move the medication from the drawer indicating “Extra” to the drawer indicating “Missing” and rescan the drawers.</p> <p>If an excessive number of medications are listed as “Extra” and the drawer is in red with “No Tray Detected” then rescan the drawers.</p> <p>If an excessive number of medications are listed as “Extra” and the tray name is listed, then the tray may not have been properly processed in pharmacy and should be returned for proper processing.</p> <p>Check for tags that may have fallen off / disassociated from a medication. Remove extra tags found in RFID drawers/enclosures.</p> <p>If there are any extra medications, then return the medication to the pharmacy and inform your supervisor.</p> 
<p>Discrepancy detected during restock – “Expired” or “Recalled” status.</p>	<p>The medication should be removed from the station.</p>

INTELLIGUARD® MIRA CARE™ STATION: TROUBLESHOOTING

Problem	Recommendation
Discrepancy detected during restock – “No Tray Detected” status.	<p>If there are no medications listed as “Extra” in the drawer, the drawer probably does not contain an RFID medication tray. If this is intentional, ignore the discrepancy and continue. If the drawer is supposed to contain a tray, place a tray in the drawer and rescan the drawers.</p> <p>If an excessive number of medications are listed as “Extra” and the drawer is in red with “No Tray Detected” then rescan the drawers.</p>
<p>Note: Users should never attempt to fix and/or service the unit themselves; instead, Users shall contact Intelliguard for additional support. Only trained authorized Users shall attempt to troubleshoot the unit.</p>	

Cleaning and Maintenance

Cleaning and Caring for the Intelliguard Mira Care™ Station

Mira Care™ Station

To clean the exterior of the Mira Care™ Station, use a slightly damp cloth, ensuring not to allow any liquid to seep into the interior of the Mira Care™ Station. The cabinet was designed to withstand the typical cleaners used in healthcare facilities, but limited fluid contact is preferred. Abrasive cleaners should never be used. Take care not to leave a wet surface and to avoid dust accumulation.

Do not store fluids or leave IV bags on top of the Mira Care™ Station for extended periods of time. If any fluid is spilled, wipe it off immediately.

Although most common hospital cleaners should be acceptable for use on the Mira Care™ Station's external surfaces, the following cleaners have been tested and are known not to cause damage to or alter the appearance of the surfaces.

- 3M™ HB Quat Disinfectant Cleaner
- Super Sani-Cloth® Germicidal Disposable Wipes
- 70% Isopropyl Alcohol

Ensure the unit is cleaned with recommended disinfectants to avoid damage to the station.

Touchscreen Monitor

Note: This section's information regarding cleaning and disinfecting your touchscreen monitor taken from the Elo website: <https://myelo.elotouch.com/support/s/article/Cleaning-Methods-for-Elo-Touchscreens-COVID-19>

Cleaning and disinfecting are two steps. Cleaning removes dirt, grease, dust and other contaminants. Disinfecting is a separate process that uses a chemical designed to destroy pathogens.

Cleaning the touchscreen monitor:

1. To prepare for cleaning the touchscreen, power down the Station (if possible), or ensure your on-screen software can tolerate false touches while you clean.
2. Do not get liquids inside the unit. Do not spray the touchscreen monitor directly. Instead, use wet wipes, a sprayed cloth or a dampened cloth.
3. Select only non-abrasive cleaning wipes or cloths to avoid scratching touchscreens.

INTELLIGUARD® MIRA CARE™ STATION: CLEANING AND MAINTENANCE

4. Avoid highly concentrated alcohol (> 70%), non-diluted bleach or ammonia solutions, as these may cause discoloration.
5. Wipe the surfaces with the appropriate wipes or cloths and approved cleaning products, and allow them to dry.

Disinfecting your touchscreen monitor

1. To prepare for disinfecting the touchscreen, power down the Station (if possible) or ensure your on-screen software can tolerate false touches while you clean.
2. Dampen a new clean, non-abrasive cloth with a disinfectant chosen from the list below. Ensure excess liquid is squeezed from the cloth. You may also use recommended pre-dampened wipes.
3. Read the manufacturer's instructions carefully. Many manufacturers require the surface to remain wet for a few minutes, so continuous wiping might be required.
4. Disinfect the surfaces by wiping them with the cloth or wipe and allow the surface to dry.
5. For disinfectant solutions that are safe for use with your touchscreen monitor, see below.

US CDC-recommended disinfectant solutions safe for your touchscreen monitor

- Household bleach solution (1/3 cup of bleach per gallon of water)
- Isopropyl alcohol (\leq 70% alcohol)

More information from the CDC on disinfecting procedures for Coronavirus Disease 2019 (COVID-19) can be found here: <https://www.cdc.gov/coronavirus/2019-ncov/community/home/cleaning-disinfection.html>

US EPA-recommended disinfectants safe for your touchscreen monitor (registration number included)

- | | |
|--|-------------------|
| • CaviWipes | Reg. No. 46781-13 |
| • Clorox Disinfecting Wipes | Reg. No. 5813-79 |
| • Clorox Healthcare Bleach Germicidal Wipes | Reg. No. 67619-12 |
| • Clorox Commercial Solutions Hydrogen Peroxide | |
| • Cleaner Disinfectant Wipes | Reg. No. 67619-25 |
| • Lonza Disinfectant Wipes | Reg. No. 6836-313 |
| • Lysol Brand Clean & Fresh Multi Surface | |
| • Cleaner (20% cleaner solution to water ratio) | Reg. No. 777-89 |
| • Purell Professional Surface Disinfectant Wipes | Reg. No. 84150-1 |
| • Sani-Cloth Prime Germicidal Disposable Wipes | Reg. No. 9480-12 |

INTELLIGUARD® MIRA CARE™ STATION: CLEANING AND MAINTENANCE

More information from the EPA on recommended disinfectants for Coronavirus Disease 2019 (COVID-19) can be found here: <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2>

Do NOT use the following materials when cleaning/disinfecting your touchscreen monitor.

- Isopropyl Alcohol at concentration > 70%
- Methyl Alcohol or Ethyl Alcohol at concentration > 35%
- Ion based solutions such as Salt Water
- Thinner or benzene
- Strong alkali lyes
- Strong solvents
- Acids
- Detergents with fluoride
- Detergents with ammonia at concentration > 1.6%
- Abrasive cleaners
- Detergents with abrasives
- Formula 409
- Steel wool
- Sponges with abrasives
- Steel blades
- Cloth with steel threads

More information regarding cleaning and disinfecting your touchscreen monitor can be found here:

<https://myelo.elotouch.com/support/s/article/Cleaning-Methods-for-Elo-Touchscreens-COVID-19>

Equipment Maintenance

While there are no user serviceable components, Intelliguard recommends performing the following at least every 12 months:

- Inspect the speckled gray fiber RF seal around the perimeter of the drawer opening. Note any damage or gaps in seals.
- Perform OPS check for each drawer.
- Open each drawer and ensure that each slide is uninhibited until their extension stops activate.

Note: Open and close each drawer and inspect open/close function to ensure smooth operation. If there is excessive friction, grinding, or misalignment, contact technical support.

INTELLIGUARD® MIRA CARE™ STATION: CLEANING AND MAINTENANCE

The Intelliguard® Mira Care™ Station must be maintained by a qualified service technician. Contact Intelliguard using the information on the cover of this document for any needed unscheduled maintenance or repair. Do not attempt nor conduct maintenance and/or repair activities.

WARNING: FAILURE TO PERFORM THE ABOVE MAINTENANCE MAY INCREASE THE LIKELIHOOD OF IDENTIFYING TAGGED MEDICATIONS NOT ACTUALLY PRESENT IN THE INDICATED DRAWER OR ON THE TOP SURFACE. FAILURE TO MAINTAIN THE EQUIPMENT AS SPECIFIED MAY INCREASE ITS INTERFERENCE POTENTIAL.



Intelliguard



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IFU-02-02 (DOC-1704) Ver. 2

Approved By:

[\(CO-537\) Updates to IFU-01 and IFU-02-02](#)

Description

Updates to IFU-01 and IFU-02-02

Justification

Updating IFU-01 and IFU-02-02 to be compliance with the new regulatory status of the organization.

Assigned To:	Initiated By:	Priority:	Impact:
Sona Baghoyan	Sona Baghoyan	High	Major

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