BD Anesthesia System

Instructions for Use Manual

Injecting Confidence™

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Other patents pending.

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Important information is highlighted by these icons and terms:

WARNING indicates a potential for personal injury or death.

CAUTION indicates either potential damage to the hardware or loss of data and instructs how to avoid the problem.

NOTE NOTE indicates important information to make better use of the Anesthesia System.

Section I Background

Introduction

Thank you for choosing the BD Anesthesia System (Anesthesia System). The Anesthesia System can be used when intravenous bolus injections of medication are given to a patient by a nurse or anesthetist for automated documentation of medication, concentration, dose, volume and time of each IV injection during an operation, recovery and procedural event.

During treatment, the clinician connects an intelligent injection port, called the Intelliport™ device, to a patient's fluid-delivery line and performs standard drug-delivery activities. The Intelliport device automatically captures information about drugs injected, and wirelessly transmits that information in real-time to the Tablet computer. The Tablet computer uses that information and other manually-entered information to display a time-stamped medication record. It provides the clinician with clinical decision support. It also makes that information available for reporting and electronic recordkeeping purposes.

The Anesthesia System has two operating modes. The first configuration is a stand-alone system that supports a paper anesthesia record. The second configuration involves integration with electronic medical records or perioperative information management systems (PIMS).

This guide provides instructions for the safe and proper operation of the device, as well as set-up, configuration, and care information. Read this entire manual carefully and familiarize yourself with the features and operation of the Anesthesia System prior to use.

Product Description

There are four components to the Anesthesia System:

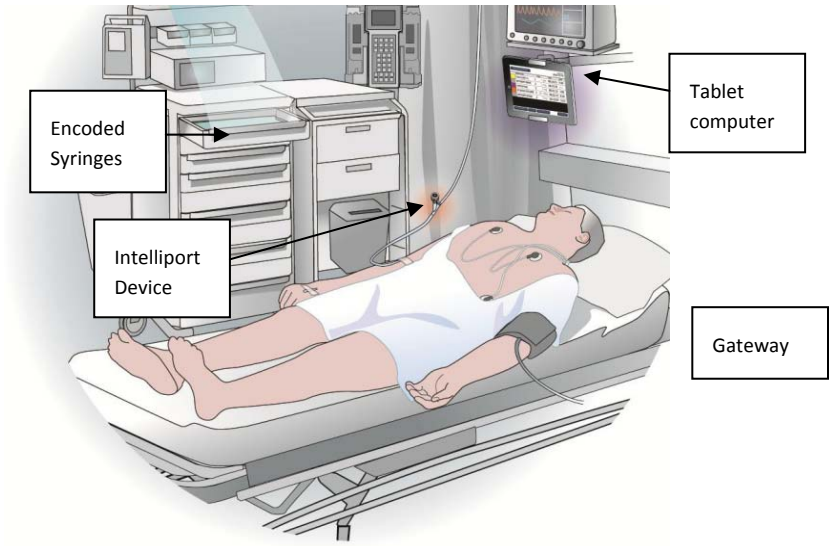


Figure 1 Anesthesia System Components

Intelliport device is an intelligent injection port. It attaches to an injection site ("Y Site" or stop cock) for manually administered IV injections. It is comprised of a Sensor and a Base, which snap together prior to use. The Intelliport Sensor is a sterile disposable having an injection port and a Luer connection. The Intelliport Sensor is supplied in a sterile package for single patient use. The Intelliport Base is a non-sterile, reusable device that houses the electronics and wireless transmitter. It is battery powered, and rechargeable. A separate Recharger recharges a battery in the reusable Intelliport Base prior to each use.

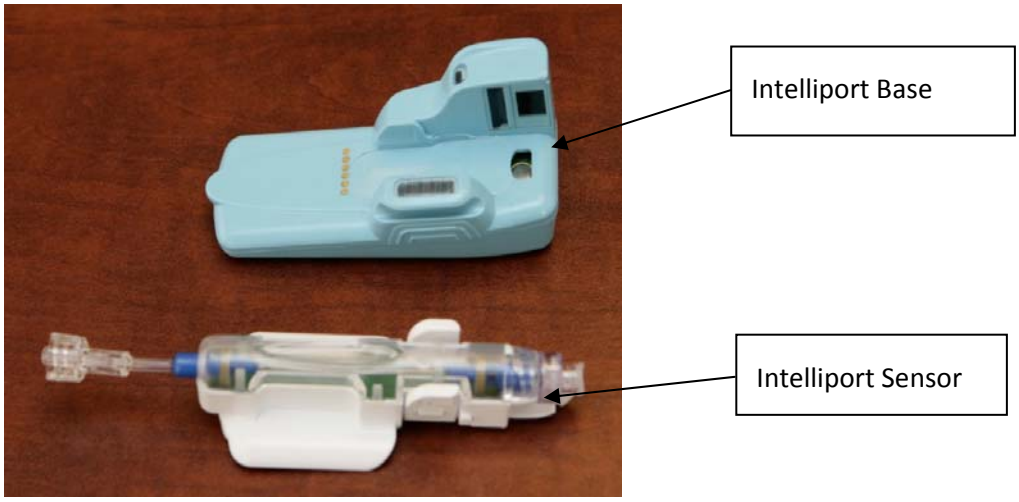


Figure 2 Intelliport Device

Encoded Syringes are commercially-available drugs in prefilled syringes with a special identifier, called "encoding", that stores information about the medication contained within the syringe. Encoded syringes are ready-to-use, passive and disposable. The Anesthesia System also accommodates syringes not having encoding.

Tablet Computer runs the Anesthesia System software. It continuously captures and displays the medication administration record (MAR) data from the Intelliport device each time an injection occurs. It also enables clinicians to manually document other pertinent clinical information, and it provides clinical decision support to help improve safety and aid clinicians during treatment.

Gateway is software that enables the Anesthesia System to function as an enterprise device and information system. The Gateway provides a central hub to which all Tablet computers connect via the hospital network. It also includes an interface engine for the Anesthesia System to exchange data with other networked hospital information systems, along with a suite of utilities for general Gateway implementation, operation, and maintenance.

The Gateway includes a browser-based user interface for administrators of the Anesthesia System to configure the device library and Tablet computer default settings.

How it Works

The medication administration process using the Anesthesia System is illustrated in Figure XXX. Prior to treatment, the clinician primes and connects the Intelliport device to the patient's catheter or injection port (y-site). During medication administration, the clinician performs standard drug-delivery of bolus medications.

When a syringe is attached to the injection port, the Intelliport device identifies the medication and concentration for an encoded syringe by optically imaging and decoding a barcode on the tip of the syringe. This information is wirelessly transmitted to the Tablet computer, and the Tablet computer displays and announces the drug attached. It also may perform safety checks.

As drug is pushed, the Intelliport device measures the volume dosed ultrasonically. The Intelliport device wirelessly sends volume measurement information to the Tablet computer. The Tablet computer uses this information to provide clinicians with clinical information. The medication administration information is time stamped and displays for clinical reference during surgical procedures. Manually entered infusions and other information pertaining to non-encoded drug injections may be included in the patient medication record.

The Tablet computer wirelessly communicates with the Gateway on the hospital network, and it may send medication administration to Hospital Information Systems, when configured, for reporting and electronic recordkeeping purposes.

Indications for Use

The Anesthesia System provides a record keeping system with patient safety features.

Electronic availability of the patient's allergies allows for proactive adverse drug event screening when the patient is in the perioperative environment prior to any anesthesia drug delivery.

The Anesthesia System automatically documents medications in the pre-op, intra-op, and PACU areas when using an encoded prefilled syringe. The clinician can enter drug medication by manually selecting the drug from a list when using a syringe that is not encoded. A drug library, managed by pharmacy, contains drug specific information used for documenting drugs on the anesthesia record, performing adverse drug event checks, and submitting medication utilization information for billing purposes.

Availability of the patient's specific drug allergies provides for pre-screening of the medications that are connected to the Intelliport device for injection to check for any potential adverse drug events. It also provides a methodology for narcotics tracking through its comprehensive medication tracking and wasting feature.

The Anesthesia System is to be used in the hospital peri-operative environments (inpatient and outpatient) and special procedure rooms. The Anesthesia System may also be used in nursing care units for the treatment of pre and post surgical patient care. Surgical/procedure patients should weigh greater than 35 kgs , and have an intravenous line established. The system may also be used in nursing care units for the treatment of pre- and post-surgical patient care.

The clinicians that are intended to use the CRISI Anesthesia System include physicians with a specialty in anesthesiology, Certified Registered Nurse Anesthetists and Registered Nurses. These individuals are licensed to deliver medications through a patient's venous access point. (IFU026)

The Intelliport Sensor may be used up to 72 hours. It is not intended to be reused.

The Intelliport Base is intended for use with the Intelliport Sensor. It may be reused unless it has a exceeded its Useful Life. It should be disinfected and fully re-charged between patient uses.

Intended Use

The Anesthesia System is an automated record keeping system for use in perioperative and procedural settings. The system is comprised of a injection port that measures administration of medications to patients, and a data processing module to automate tracking. The system also incorporates patient safety features (alerts for patient allergies) that are aligned with hospital patient records and protocols, and it includes a methodology for narcotics tracking through a comprehensive medication tracking and wasting feature. The Anesthesia System has both disposable and reusable parts, and the overall system is intended for prescription use only.

The Intelliport device is intended to be used on a Y-site, stop-cock or IV manifold injection port of any peripheral intravenous established line. This includes a central venous line or peripherally inserted central catheter (PICC) line. It is not intended to be used in the intra-arterial or epidural lines. Venous lines can be established in the subclavian, femoral, intraosseous or various peripheral arm locations. The Intelliport device may rest or be secured to the patient's skin in either of these locations.

Section II Safety Precautions

The information contained in these Instructions for Use is intended to assist in the safe operation of the Anesthesia System. This product is to be used as specified within these Instructions for Use and in accordance with federal guidelines.

READ ALL INSTRUCTIONS BEFORE USING.

SAVE THESE INSTRUCTIONS.

Warnings and Precautions

General

Do not use the Anesthesia System near Magnetic Resonance Imaging (MRI) equipment, including stereotaxis technology.(IFU017) Remove the Intelliport device from the IV Y-site prior to imaging.

Do not use the Anesthesia System near therapeutic radiation equipment, such as linear accelerators. Remove the Intelliport device from the IV Y-site prior to imaging.

Shock hazard: do not attempt to connect or disconnect the Tablet computer or Intelliport Recharger power cord with wet hands. Make certain that your hands are clean and dry before pressing the power cord.

Use only the power cord supplied by the manufacturer for the Tablet computer or Intelliport Recharger. Never adapt the plug to fit a nonstandard outlet.

Inspect the power supply cord for damage prior to use. Replace the Tablet computer power supply only with the CRISI approved power supply.

Observe requirements for proper grounding. The power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three prong plug from the Tablet computer to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the Tablet computer. Provide an isolated power supply for operation.

Universal precautions should be observed to prevent contact with blood or other potentially infectious materials. Place contaminated materials in a regulated waste container.

Do not mix disinfecting solutions (e.g., bleach and ammonia) near the Anesthesia System, as hazardous gases may result.

Use accessory equipment recommended by the manufacturer. The use of non-approved accessory equipment with the Anesthesia System is not recommended, and may lead to unsafe conditions.

CAUTION

Do not modify or tamper with system components for any reason. Doing so will void the manufacturer warranty. The system does not include serviceable components. Contact

your Anesthesia System representative for all repairs.

CAUTION Do not use damaged equipment, frayed or damaged power cords. (IFU023)

CAUTION Do not expose the Anesthesia System to gas or heat sterilization. Autoclaving will seriously damage the Intelliport Base and Tablet computer.

CAUTION Avoid liquid ingress to the Tablet computer or Intelliport Base. Fluids may interfere with their performance.

CAUTION Operation of electro convulsive therapy (ECT) equipment during use of the Anesthesia System may temporarily result in signal loss between the Intelliport device and Tablet computer.

NOTE If any part of the Anesthesia System (Tablet computer, Intelliport device, Recharger) is dropped or severely damaged, immediately remove it from use and have it inspected by service personnel. Ensure its proper function prior to reuse.

Tablet computer

The ground leakage current is less than specified limits established for commercial Tablet computer power supplies. As a matter of safe practice, your facility should conduct periodic tests to verify these currents. It is recommended that the Tablet computer AC power adapter be connected to an isolated power supply.

Electrical shock hazard: Do not remove the Tablet computer cover. There are NO serviceable parts inside the Tablet computer.

If the integrity of the external protective earth ground is in doubt, the Tablet computer can be operated from its internal battery power source.

Sustained contact of the Tablet computer with skin can cause discomfort or burns. Do not allow the Tablet computer to rest directly on exposed skin for extended periods. The surface temperature of the Tablet computer may rise during normal operation particularly when operating under AC power.

Be sure the Tablet computer is mounted securely in place to avoid falling and sustaining injury.

CAUTION To completely remove power from the unit, disconnect the power cord from the power receptacle of the Tablet computer.

CAUTION Properly secure the Tablet computer prior to use or after positioning. Do not loosely place the Tablet computer on other equipment. (IFU 022)

CAUTION Do not block ventilation inlet holes on the underside of the Tablet computer.

Do not open or modify the Tablet computer for any reason. There is a seal to prevent liquids from entering, which may be damaged if opened.

NOTE The Tablet computer can only be used with the Anesthesia System.

NOTE Before each use, check the volume of audible alerts to ensure they are not muted. Silencing the alerts may adversely affect patient safety.

NOTE Do not push any objects into the air vents or other opening on the Tablet computer. Doing so can cause fire or electric shock.

NOTE Do not use pressurized sprays when cleaning the Tablet computer screen.

NOTE Do not use hard or pointed objects on the Tablet computer screen.

Intelliport device

Intelliport device should not be used with an Arterial or epidural line. This may result in serious injury to the patient. Verify the line placement prior to Intelliport Y-site attachment. (IFU011)

Do not use a needle or blunt plastic tip cannula with the Intelliport Sensor. This may result in port valve damage resulting in fluid leaks, air intake and bacterial contamination. Replace the Intelliport Sensor immediately.

Prime the intravenous line and Intelliport Sensor with flush solution prior to beginning an injection. Trapped air may affect Intelliport Sensor performance and the injected volume measurement. Failure to prime the Intelliport Sensor correctly may cause the volume of injected medication to read lower than the actual total delivered to the patient.

Check for an blocked fluid path or leaking fittings when priming the Intelliport Sensor.

Secure the Intelliport device to the patient prior to patient transport to avoid intravenous line disruption.(IFU 021)

Note the clarity of the IV tubing and Intelliport Sensor during use to minimize bacteria growth. Replace the Intelliport Sensor if a high lipid medication has been injected or blood is visible inside the lumen of the Intelliport Sensor or port.

Do not use the Intelliport Sensor with an IV line using a high pressure infusion flow system. Verify the line placement prior to Intelliport Y-site attachment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for Class B Digital Device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment

Les changements ou modifications non approuvés expressément par la partie responsable de la conformité pourrait annuler l'autorité de l'utilisateur à faire fonctionner l'équipement.

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.)

Do not use the Intelliport Sensor with an IV line using a high pressure infusion flow system. Verify the line placement prior to Intelliport Y-site attachment.

Verify the encoding label is clean and secure to the syringe tip prior to attaching to the Intelliport Sensor.

Dispose of the Intelliport Base it according to your facility's protocol for battery disposal of lithium ion batteries.

Discard the Intelliport Sensor if its sterile packaging is not intact or the protector cap is detached.

Clinicians must be familiar with and be trained in the use of the Anesthesia System. Its use should be preceded by an established facility protocol.

Swab the injection port with 70% isopropyl alcohol (or the agent that is hospital standard) and allow to dry prior to each syringe injection to minimize the potential for cross contamination.

Change the Intelliport Sensor according to facility policy for IV set change or CDC (USA) Guidelines; or if the integrity of the Intelliport device has been compromised. (IFU025)

The Anesthesia System is neither designed nor intended to detect nor alert if there are needle infiltrations. Hospital/facility personnel must ensure the performance of the common IV site, prior to conducting bolus injections.

NOTE Verify that the Intelliport device is securely luer locked to the Y-site and the IV tubing is free from kinks before operating.

NOTE The Intelliport Sensor does not have a stop valve (check valve); therefore, it is recommended to close the upstream flow on the IV line during injection to limit retrograde flow.

Section III Description of Anesthesia System Components

The Anesthesia System is designed with your needs, safety and workflow in mind. This section will familiarize you with the Anesthesia System components, operational modes, display views, controls, and indicators.

Supplies and Equipment

The Anesthesia System is designed for use with the following equipment.

- IV venous line with Y-site needleless port(s), stop cock or manifold
- Intelliport device (sterile packaged Intelliport Sensor and charged Intelliport Base)
- Medication syringes (having encoding and without encoding)
- Tablet computer
- Recharger

Intelliport

The Intelliport device is an intelligent injection port. It attaches to an injection site ("Y Site" or stop cock) for manually administered IV injections. It is comprised of a single-use Intelliport Sensor and a reusable Intelliport Base, which snap together prior to use. Up to three Intelliport devices may be in use with a patient at one time. These may be attached to two or three separate IV lines for the patient or attached via a manifold or different Y-sites on the same IV line. The Intelliport device has memory that will store a time-based medication history log from the time of activation to the time when the data is sent to a Tablet computer.

Intelliport Sensor

The Intelliport Sensor is a sterile disposable having an injection port and a Luer-lock connection. The Intelliport Sensor is supplied in a sterile package for single patient use. (IFU020) The Intelliport Sensor has a male Luer-lock connection on a one-inch IV tubing pig tail. This can be attached to an IV line at a Y-site or IV manifold. An Intelliport Sensor cannot be reused with a different patient. Each Intelliport Sensor has a unique serial number. The last 4 digits of the serial number are imprinted on the surface next to its bar code. This number is used to identify an Intelliport Sensor within wireless range using the Tablet computer.

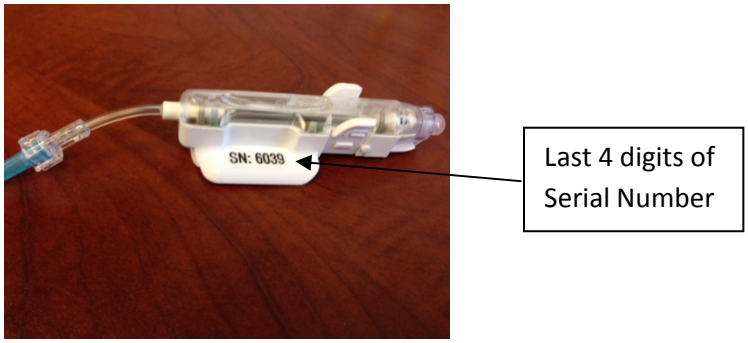


Figure 3 Intelliport Sensor with last 4 digits of the Serial Number

Figure 4 Intelliport Device Components

The Intelliport Sensor includes an injection port and an IV connection to the IV line. The injection port is a common needleless, Luer-lock type. It may be cleaned prior to giving an injection according to hospital policy. Priming with an IV fluid (e.g. normal saline syringe, or pull back from IV line) is required before use. The injection port on the Intelliport Sensor supports up to 100 injections.

CAUTION — The Intelliport Sensor is packaged sterile, do not use if package is damaged or protector cap is not attached.

CAUTION — Do not use a needle or blunt tip plastic cannula. Replace immediately if either is inadvertently used resulting in damage to the Intelliport Sensor (typically leaks).

CAUTION — Prime Intelliport Sensor before use. Attach a flush syringe to the injection port and purge infusion fluid to remove air from the Intelliport Sensor.

CAUTION — Confirm the Luer lock is securely connected to a fully primed primary infusion set before use.

CAUTION — Discontinue use of the Intelliport Sensor if the syringe is securely attached and you observe leaking (droplets forming at the injection port) during an injection.

NOTE Use Aseptic Technique when handling the Intelliport Sensor.

Intelliport Base

The Intelliport Base is a non-sterile, reusable device that houses the battery, electronics and wireless transmitter (called a Radio). It is battery powered, and rechargeable. Do not discard after use. An Intelliport Base is designed to be reusable. It supports up to 500 re-uses with different patients. Each Intelliport Base has a unique serial number imprinted on its surface. This number is transmitted to the Tablet computer during use. The distance between the Intelliport device and a Tablet computer should be 10 meters or less in order for the Intelliport device to send and receive wireless communications.

The rechargeable lithium battery is not removable. The entire Intelliport Base connects to the Recharger. A fully-charged Intelliport Base is suitable for up to 24 hours of use, under typical conditions.

When the Intelliport Base is connected to a Recharger, up to 4 green light bars will illuminate. The number of solid green light bars indicates the level of charge. The blinking light will indicate it is recharging.

up to 25% charged

up to 50% charged

up to 75% charged

fully charged

very low battery ≤ 5 %

When the Intelliport Base is connected to a Recharger a red light indicates the Intelliport Base has exceeded its Useful Life. Refer to Section XX Care & Maintenance for more information.

<u>Status</u>

The Intelliport Base is equipped with status indicators to convey the following information:

Operating	A double-blinking, green light indicates the Intelliport device is powered on and not yet wirelessly connected to a Tablet computer.
Error	A red light indicates an error is present. Refer to Section XX Troubleshooting for more information.
Identify	Green/yellow lights flash for 3 seconds when an Intelliport device has been selected at the Tablet computer.
Clinical Alert	Red/green/yellow lights flash for 3 seconds when a priority clinical alert has been triggered. This informs the clinician of an alert message on the Tablet computer. (e.g. a known allergy to a drug in a connected syringe). (IFU010)
End of Use	A red light in the lowest battery charge position indicates the Intelliport Base has been used with more than 500 Intelliport Sensors.

Recharger

A separate Recharger recharges the battery in the reusable Intelliport Base prior to each use. To use the Recharger, snap onto the Intelliport Base.

Encoded Syringes

The Anesthesia System supports injections using any Luer-lock type syringe. In addition, the system has been designed to work with encoded syringes that have a special barcode identifier on the syringe tip, called “encoding”. The encoding stores information about the medication contained within the syringe.

When an Encoded syringes is attached to the injection port, this information is wirelessly transmitted by the Intelliport device to the Tablet computer.

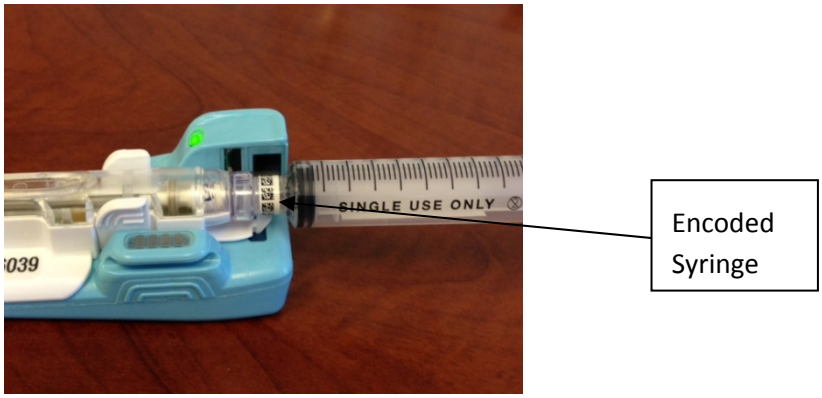


Figure 5 Encoded Syringe Attachment

Tablet computer

The Tablet computer is a standard, commercial Tablet computer having Anesthesia System software, a press screen, wireless communications (Radio). It is typically mounted near the clinician's work envelop. It may also be removable for hand-held use. The On-Off switch is located at the top, right of the Tablet computer. It includes an AC power adapter. It also supports up to 4 hours of battery-powered use, under typical operating conditions.

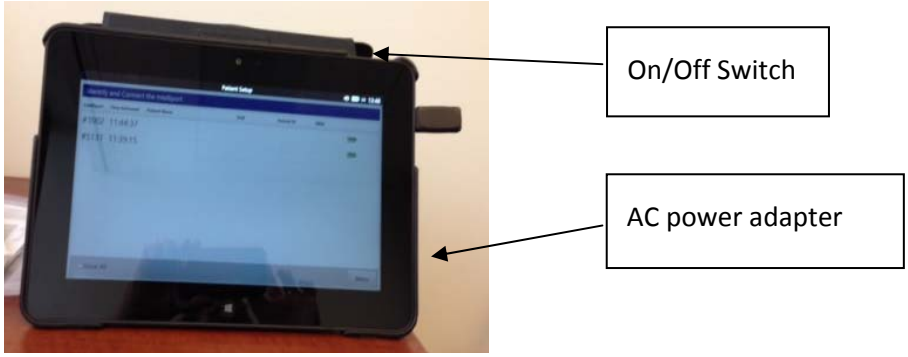


Figure 6 Tablet computer Feature Layout

Review Tablet computer Warnings listed on pages XX prior to use.

The Tablet computer supports one patient at a time. So long as a case is ongoing at the Tablet computer, no other cases or patients can be accessed. In addition, only one clinician may be logged into a Tablet computer at a time.

Software Running in Standalone Mode

When used in a hospital having a paper anesthesia record, the Tablet computer supports features that assist with documenting the flow sheet portion and may help with decisions by the clinician. In this configuration, the Tablet computer complements the paper recordkeeping activities by tracking and

displaying injections given through the Intelliport device. It also enables clinicians to manually document other pertinent IV drug injection and infusion information.

The software screens follow a three-step approach consisting of 1) connecting the Intelliport device, 2) setting up the patient, and 3) viewing medication administration in either the Anesthesia View or Nursing View. Refer to Sections XX for information on connecting the Tablet computer to an Intelliport device and setting up a patient.

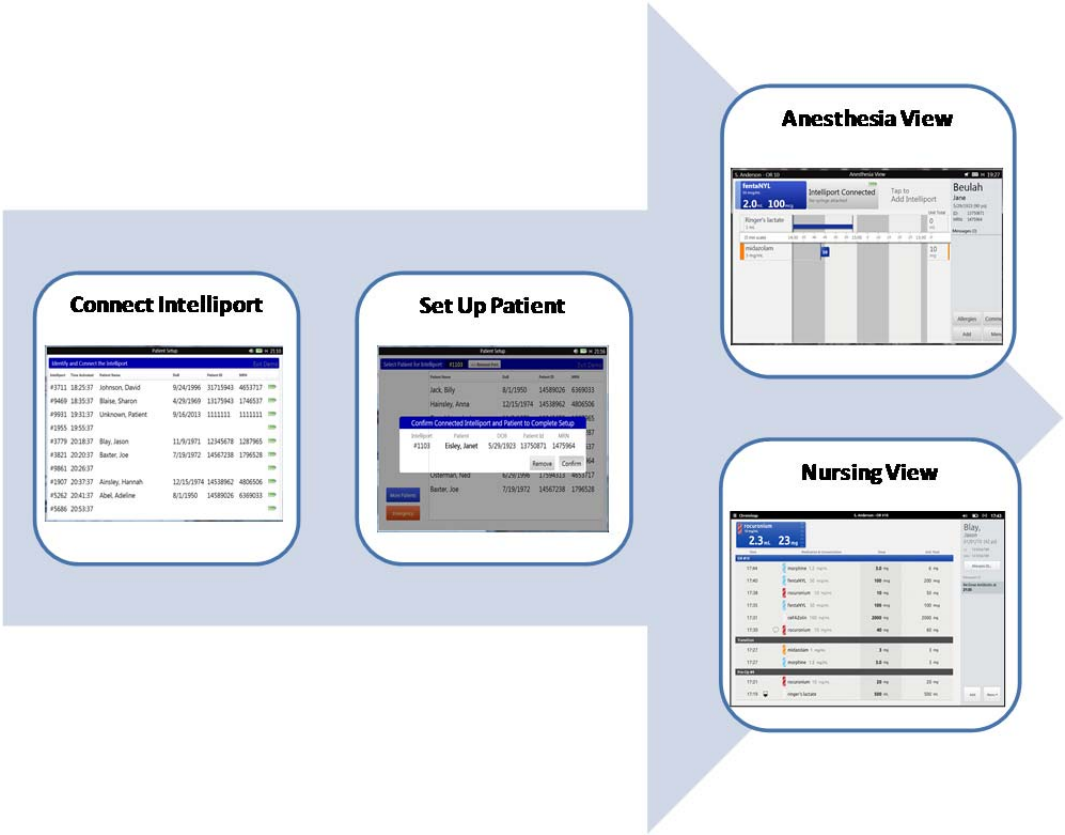


Figure 7 Stand Alone Mode

The following section describes the basic screens on the Tablet computer:

Anesthesia View

The Anesthesia View is a primary screen for clinicians to interface with the Anesthesia System. This view provides information about the patient, displays drug name/concentration and dose for a current injection as well as a historical list of medications that have been delivered to the patient. If may also include a listing of infusions given to the patient, if recorded by the clinician.

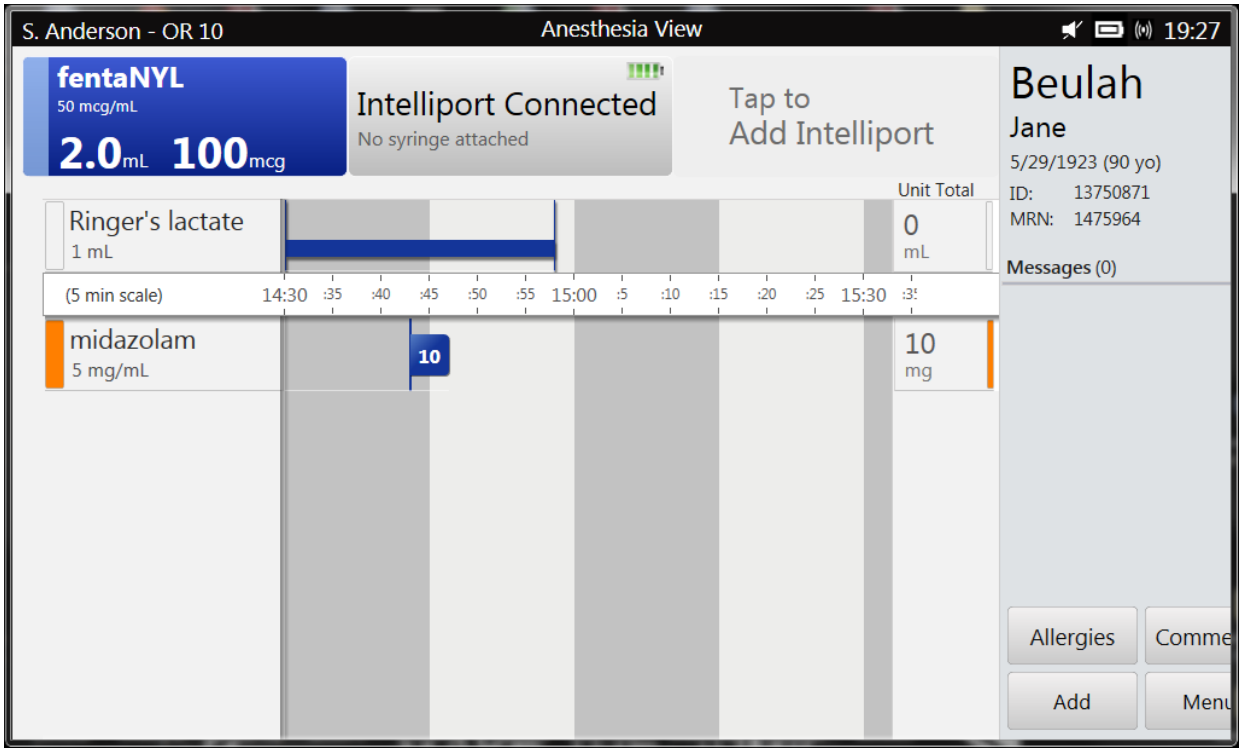


Figure 8 Anesthesia View

Injection Bars - Up to three injection bars display across the top of the screen, one corresponding to each wirelessly connected Intelliport. Each injection bar is a real time representation of the medication being administered through an Intelliport device. When an encoded syringe is attached to an Intelliport device, the injection bar displays the drug name and concentration. When an unencoded syringe is attached, the Injection Bar will read "Select Med" prompting the clinician to identify the medication and concentration. As the medication is being delivered, the volume pushed (in mL) and the corresponding dose displays in real time in the injection bar.

Medication History - The Anesthesia View includes a historical list of mediations that have been delivered to the patient organized by care area (medications given in the transition time between care areas, will post to the next care area) arranged in a flow sheet format. This includes all medications that were administered to the patient since the Intelliport device has been activated with the more recent medication administrations at the bottom of the list. A scroll bar is enabled when the list exceeds the visible space on the screen. When a new medication is added, the medication list will scroll automatically so the new medication name is visible. Hand gesturing in the flowsheet will scroll the flowsheet to view hidden medication administrations.

NOTE For anesthesia medications, a color tile corresponding to the American Society of Anesthesiology (ASA) guidelines displays adjacent to the drug name. (Refer to Appendix X for more information).

The flow sheet time scale is adjustable and it can show 1 minute, 5 minute, and 10 minute increments.

"Dose" is shown on a flag based on the time in which it was delivered. Pressing the flag for a specific medication will display the “Modify Selected Medication” pop up. From this pop up, the medication administration can be viewed and modified. A clinician can modify the concentration, dose. This screen is also used to specify a cocktail (mixed medication), a diluted or reconstituted medication.

Pressing the “Unit Total” number for a medication will display a pop-up screen indicating the medication and concentration, total dose given, number of doses given by care area, and time of each dose. To close, press “OK” on the bottom of the pop-up screen.

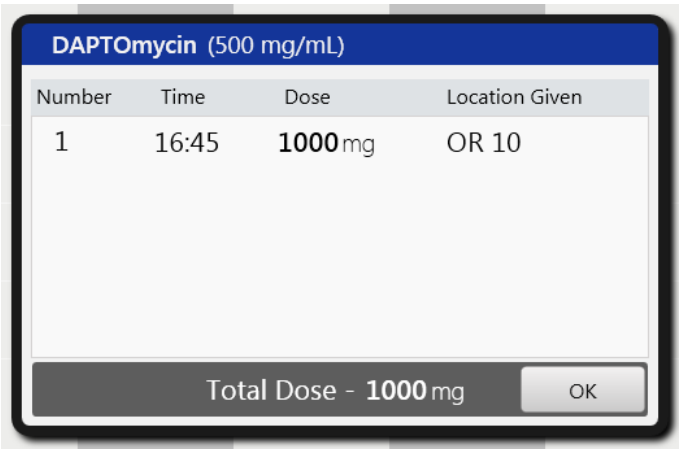


Figure 9 Unit Total

The Infusion section is located above the time scale. It displays all continuous infusions recorded by the clinician. Those that are currently active are shown with a blue bar and those that are inactive have a black bar. This feature can be hidden to show additional injections by pressing “Hide Infusions” from the Menu.

The Case Header information lists the patient name, date of birth, age in years, medical record number and patient identification number.

The Message Section displays clinical and system messages prioritized by importance and time. The Message icon will show the number of unaddressed messages for the clinician. Clinical messages that have higher importance, such as allergy alerts, will appear in the center of the display screen. (Figure XX)

The Title Bar displays across the top of the screen. It includes the name of the clinician logged in (if so configured) and the location assigned to the Tablet computer. The first icon to the right of the Bar indicates if wireless communication between the Gateway and the Tablet computer are active. A second icon specifies whether the Tablet computer speakers are muted or unmuted. The battery icon indicates the remaining amount of charge on the Tablet computer and lastly, the hospital network time is shown.

Nursing View

The Nursing View is a second screen for clinicians to interact with the Anesthesia System. Like the Anesthesia View, this view provides information about the patient, displays drug name/concentration

and dose for a current injection as well as a historical list of medications that have been delivered to the patient. It may also include a listing of infusions given to the patient, if recorded by the clinician.

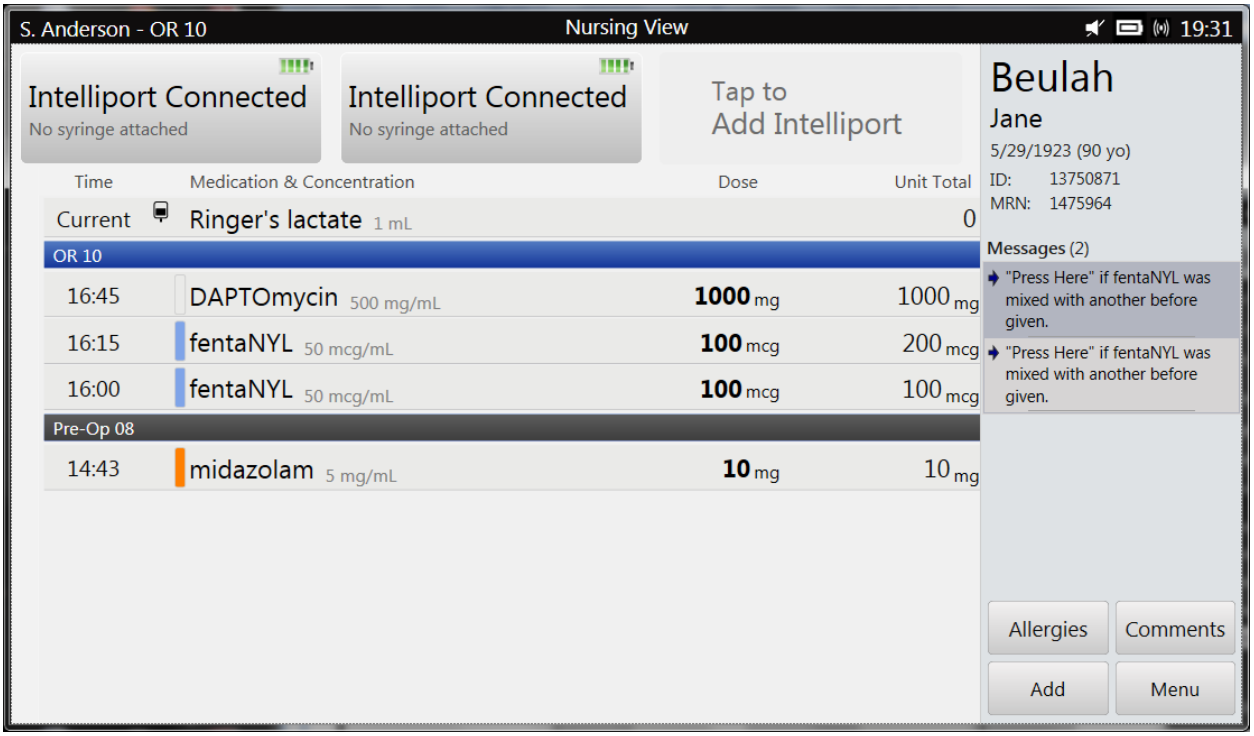


Figure 10 Nursing View

The Nursing View has many of the features in the Anesthesia View; however it is arranged in a tabular format. The table headings in this view include medication with concentration, time administered, dose, and unit total. The medications are displayed in reverse chronological order with most recent medication administered at the top of the list. A scroll bar is enabled when the list exceeds the visible space on the screen. Hand gesturing in the table will scroll to view hidden medication administrations. The black horizontal bars identify the care area in which the medications were given to the patient, or when transitioning from one care area to another.

Button and Menu Options

The following features are available from the four buttons located in the lower right corner of the screen (Allergies, Comments, Add, Menu):

Add	Infusion	Select this option to record details about an infusion. Refer to Section X for more information.
Add	Injection	Select this option to record details about an injection given prior to activating an Intelliport device or given through a port other than the Intelliport device. Refer to Section X for more information.
Add	Comment	Select this option to record general comments. (there are additional ways to pair a comment with an allergy or drug

		injection). Refer to Section X for more information.
Allergies		Select this option to view the list of allergies, including severity and type of reaction.
	Pause Case	Press this button when transferring a patient to another care area. In doing so, it disconnects all connected Intelliport devices in preparation for transfer. Refer to Section X for more information.
	Close Case	Press this button when the case is complete and the patient is being prepared for transfer out of the perioperative area. In doing so, it powers down all connected Intelliport devices. Refer to Section X for more information. **NOTE:** Pressing this button will close the case record on the Anesthesia System. The case will no longer be available to the next care area.
	Switch User	Select this option to change the clinician logged in, if so configured. Refer to Section X for more information.
	Show/Hide Infusions	Press this button to toggle between displaying or hiding infusions on the Anesthesia View flowsheet. Refer to Section X for more information.
	Change Time Scale	Press this button to toggle between 1 minute, 5 minute and 10 minute time intervals on the Anesthesia View flowsheet.
	Sound/Mute	Press this button to toggle between audible announcements and mute. Refer to Section X for more information.
	Preferences	Select this option to view and modify preferences for announcements, volume and screen brightness. Refer to Section X for more information.
	Reports	Select this option to view and print the Controlled Substance, Handoff, and Medication Administration reports. Refer to Section X for more information.
	Handoff View	Press this button to view the Handoff screen. Refer to Section X for more information.
	Nursing View	Press this button to view the Nursing View screen. Refer to Section X for more information.

	Anesthesia View	Press this button to view the Anesthesia View screen. Refer to Section X for more information.
	Help	Select this option when seeking assistance in operation. It provides helpful information, including the Directions for Use. (IFU028)
	Shut Down	Press this button to power off the Tablet computer. Refer to Section X for more information.

Software Running in EMR-Integrated Mode

When used in a hospital having electronic medical records (EMR) in the perioperative care areas, the Tablet computer serves as a companion to the EMR system or perioperative information management system (called a PIMS). In this configuration, the Tablet computer provides a real-time display while the drug is being injected, then it sends the injections data in real time to the EMR. The clinician refers to the EMR for a history of medications given - - unlike the paper anesthesia record configuration.

The software screens follow a three-step approach consisting of 1) connecting the Intelliport device, 2) verifying the patient information received from the EMR, and 3) giving injections. Refer to Sections XX for information on connecting the Tablet computer to an Intelliport device and setting up a patient.

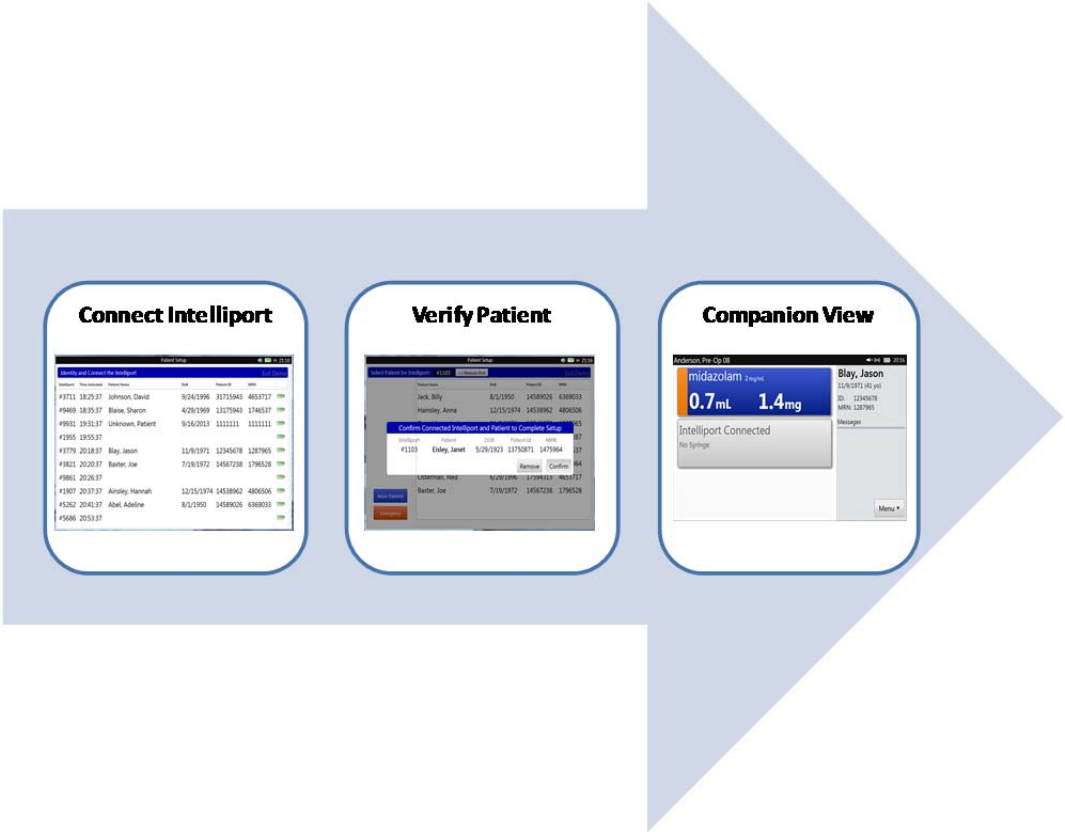


Figure 11 EMR Integrated Mode

The Companion View has a primary screen for clinicians to interface with the Anesthesia System. This View provides information about the patient, displays drug name/concentration and dose for the current injection and relevant clinical and system messages.

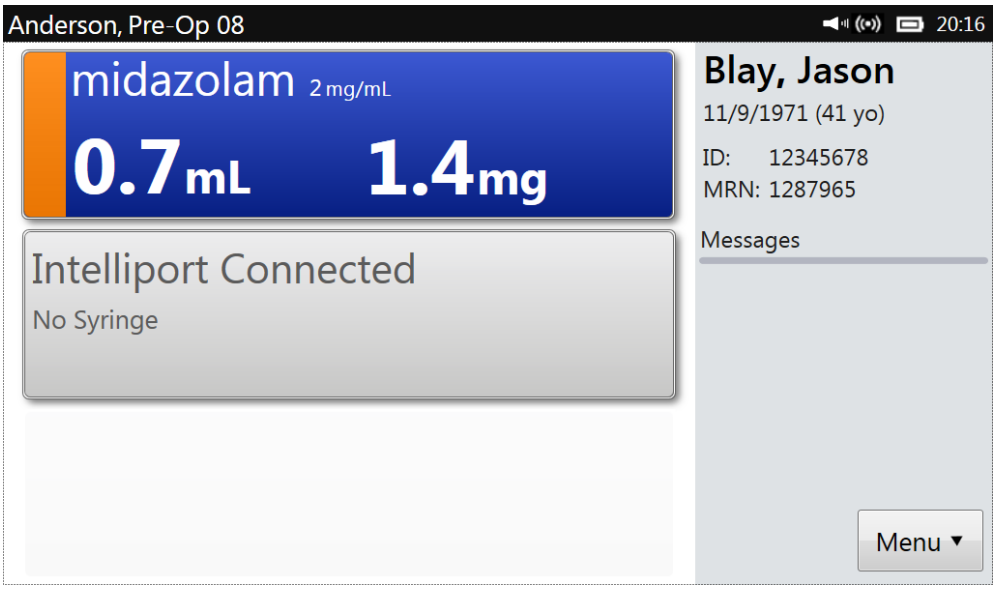


Figure 12 EMR Integrated (Companion View)

The Companion View consists of the following screen features: 1) Active Injection Bar; 2) Title Bar with clinician name and location of display Tablet computer; 3) Case Header information on patient name, MRN, Patient identification number; 4) Allergies; 5) Clinical or System Messages.

Injection Bars - Up to three injection bars display on the screen, one corresponding to each wirelessly connected Intelliport device. Each injection bar is a real time representation of the medication being administered through an Intelliport device. When an encoded syringe is attached to an Intelliport device, the injection bar displays the drug name and concentration. When an unencoded syringe is attached, the Injection Bar will read "Select Med" prompting the clinician to identify the medication and concentration. As the medication is being delivered, the volume pushed (in mL) and the corresponding dose displays in real time in the injection bar. Upon completion of the syringe push, the medication administration will pass immediately to the EMR with a confirmation message confirming such in the message area.

NOTE For anesthesia medications, a color tile corresponding to the American Society of Anesthesiology (ASA) guidelines displays adjacent to the drug name. (Refer to Appendix X for more information).

The Case Header information lists the patient name, date of birth, age in years, medical record number and patient identification number.

The Message Section displays clinical and system messages prioritized by importance and time. The Message icon will show the number of unaddressed messages for the clinician. Clinical messages that have higher importance, such as allergy alerts, will appear in the center of the display screen. (Figure XX)

The Title Bar displays across the top of the screen. It includes the name of the clinician logged in (if so configured) and the location assigned to the Tablet computer. The first icon to the right of the Bar indicates if wireless communication between the Gateway and the Tablet computer are active. A

second icon specifies whether the Tablet computer speakers are muted or unmuted. The battery icon indicates the remaining amount of charge on the Tablet computer and lastly, the hospital network time is shown.

Section IV Operations

The Anesthesia System is designed with your needs, safety and workflow in mind. This chapter will acquaint you with the Anesthesia System operational modes, display views, controls, and indicators. It also provides general information on use of the device.

Quick Guide

Prepare the Intelliport

The Intelliport device must be primed, attached to an IV line and assembled in preparation for use.

1. Gather an Intelliport Sensor in its sterile packaging and a fully-charged and disinfected Intelliport Base.
2. Prime by flushing with sterile IV fluid before attaching to the Y-site **OR** by aspirating IV solution through a syringe attached to the port.
3. Attach the Intelliport Sensor to the Intelliport Base by joining the Intelliport Sensor (tubing side) and Intelliport Base front sections first, then snap the two together. One should audibly hear the "snap".
4. Verify proper seating of Intelliport Sensor to the Intelliport Base by checking for a blinking green light on the Intelliport device. If this is not seen, view the Intelliport device on its side to determine if the two are properly connected. If a space is seen between the Intelliport Sensor and Intelliport Base, then separate and re-attach properly.
5. The Intelliport device is now ready for delivery of IV medications. Any medications given through the Intelliport device will be saved to the Intelliport memory.

Set up the Tablet computer

The Tablet computer must be set up to wirelessly communicate with the Intelliport device and to be associated with a patient record. Any Medications given prior to association to a Tablet computer will be held in the Intelliport memory. Three Intelliport devices can be synchronized to one patient.

6. Power on the Tablet computer by pressing and holding the button located on top of Tablet computer.
7. The first screen supports log-in, if so configured. Enter Username and Password
8. Identify the 4 digit number on the Intelliport Sensor.
9. From the Intelliport Setup screen, select (highlight) the Intelliport device corresponding to the four digits number on the Intelliport Sensor.
10. Verify the correct Intelliport device has been selected by checking that the green and yellow lights are blinking.
11. If the identified Intelliport device is correct, press "Connect".
12. Verify the Intelliport device flashes a single, repeating green light when it is wirelessly connected to the Tablet computer.
13. Identify the patient's full name, patient ID, medical record number and birth date.
14. From the Patient Setup screen, select the patient from the list. Press "Emergency" to begin a

case where patient demographics are not available.

NOTE After starting a case using the Emergency button, the patient can be identified at any time prior to closing the case.

15. "Confirm" the correct Intelliport device and patient to complete the setup. Once confirmed, the Anesthesia System has established a permanent association between the patient and Intelliport Sensor.

Give IV injections and View Medication Administrations

16. Clean the Intelliport Sensor injection port by swabbing the hub according to your hospital protocol.
17. Attach a syringe to the Intelliport Sensor injection port.
18. Verify the drug displayed and announced by the Tablet computer is the intended drug and concentration. When using a syringe without encoding, "Select Med" will announce and display a list of medications to identify. (Press "More" if you do not see the medication name).
    a. Identify the medication before or after dose delivery. Confirm medication and press "Save".
    b. Frequently diluted or reconstituted drugs shall display no dose value until the clinician identifies the given dose on the "Modify Selected Medication" screen. The identified dose will appear on the flag.
    c. Cocktail (mixing two medications in one syringe) can be identified by pressing the "Cocktail" button from the "Select Med" screen.

Use clinical judgment before proceeding when the Tablet computer announces and displays a known allergy for the drug attached to the Intelliport device, if so configured.

19. The volume and dose will display on the Tablet computer when the syringe is removed or at end of the injection, if the syringe is left attached to the Intelliport device.

Detailed Operating Instructions

Prepare the Intelliport

The Intelliport device must be primed, attached to an IV line and assembled in preparation for use.

1. Gather an Intelliport Sensor in its sterile packaging and a fully-charged and disinfected Intelliport Base.

NOTE A fully-charged Intelliport Base has sufficient power for 24 hours of use under typical conditions. Inspect the Intelliport Base charge level. Replace an Intelliport Base with less than 25% charge. This can be done at anytime so long as an injection is not being given.

Verify the Intelliport Base has been cleaned and disinfected before use.

Verify the Intelliport Sensor sterile package is intact and the tubing end cap is still in place.

2. Prime by flushing with sterile IV fluid before attaching to the Y-site **OR**, by aspirating solution from the IV line through a syringe attached to the port. (IFU01)

NOTE After priming, visually inspect for leaks or blockage to the IV line.

3. Attach the Intelliport Sensor to the Intelliport Base by joining the Intelliport Sensor (tubing side) and Intelliport Base front sections first, then snap the two together. One should audibly hear the "snap". Connecting Intelliport Sensor to Intelliport Base will automatically power on the Intelliport device.

NOTE The connection of Intelliport Sensor to the Intelliport Base is verified by a blinking green light on the Intelliport device. If this is not seen, view the Intelliport device on its side to determine if the two are properly connected. If a space is seen between the Intelliport Sensor and Intelliport Base, then they are not attached properly. Separate the two pieces and re-attach.

4. Where appropriate, secure the Intelliport device to a surface in preparation for giving injections. Avoid kinks in the line between the Intelliport device and IV line.

CAUTION

Secure an Intelliport device prior to patient transport.

5. The Intelliport device is now ready for delivery of IV medications. Any medications given through the Intelliport device will be recorded in the Intelliport memory.

In the event of a System or Intelliport failure, (excluding the fluid pathway), the Intelliport device will allow standard medication or fluid delivery.

Set up the Tablet computer –Paper Anesthesia Record

The Tablet computer must be set up to wirelessly communicate with the Intelliport device and to be associated with a patient.

6. Turn on the Tablet computer by pressing and holding the power switch on top of Tablet computer.

NOTE The Tablet computer can operate for 4 hours on battery power (not plugged in to a power supply) under typical conditions. Verify the Tablet computer is plugged in prior to use by checking the power indicator on the Title bar on the Tablet computer screen.

NOTE On start up, the initial screen will display information about the software, drug library and configuration versions – as well as information on network connectivity. Contact your System Administration if so instructed.

7. The Login screen will display if the Anesthesia System is configured for user login. Type the User Name and Password, then press the "Log in" button.

Figure 13 Login

NOTE The Tablet computer will lock the user out after several unsuccessful login attempts. Follow the screen directions for contacting the System Administrator.(IFU029)

8. Identify the 4 digit number on the Intelliport Sensor.

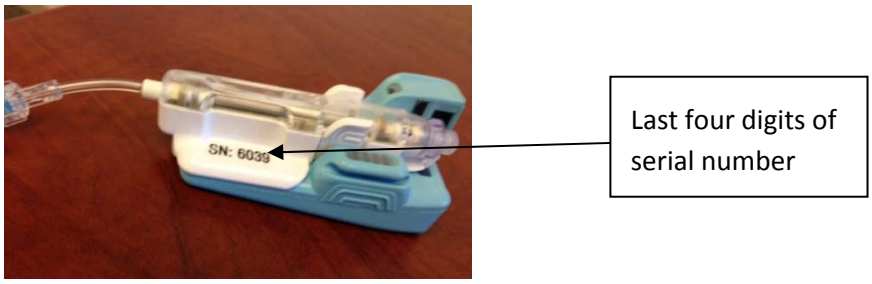


Figure 14 Login

9. A list of Intelliport devices within wireless range are viewable on the Intelliport Setup screen. Select (highlight) your Intelliport device by time of initial activation and last four digits of the serial number on the Intelliport Sensor.

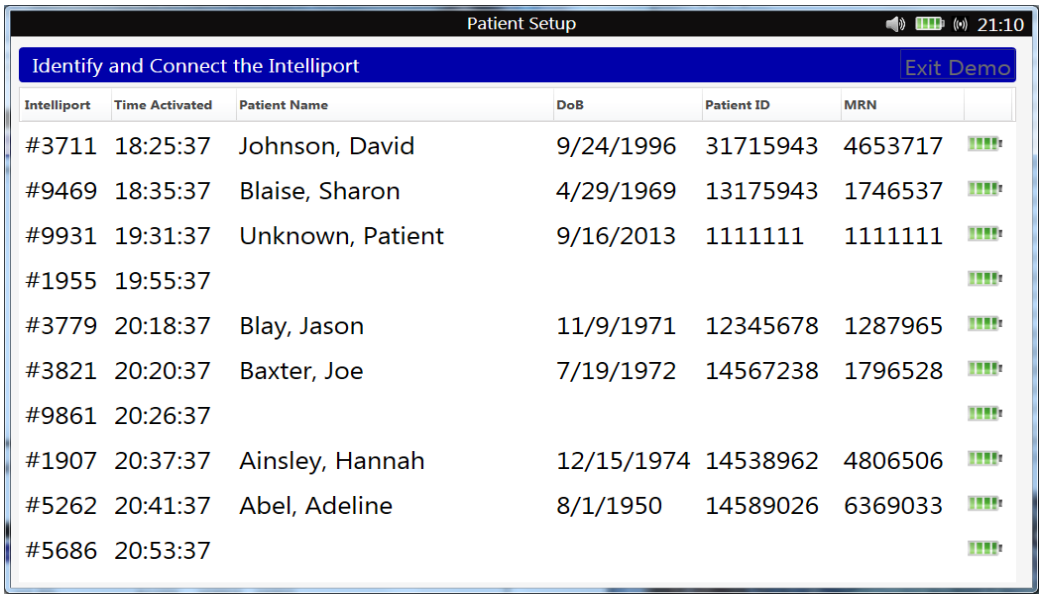


Figure 15 Connecting an Intelliport

NOTE A low battery icon will display for a listed Intelliport when less than 25% of battery charge remains (approximately 4 hours under typical conditions). Consider replacing with a fully-charged Intelliport Base before connecting.

10. Select the Intelliport device for your patient by pressing and highlighting the appropriate Intelliport serial number.
11. Verify that the green and yellow lights are flashing for the correct Intelliport device.

NOTE Should you miss the visual confirmation, highlight the appropriate Intelliport device again to initiate the blinking lights.

12. The screen will highlight your connection.
13. The Intelliport device will illuminate a single, repeating green light when it is wirelessly connected to the Tablet computer.
14. Identify the patient's full name, patient ID, medical record number and birthdate from the patient and wrist band.
15. From the Patient Setup screen, select the patient from the list.

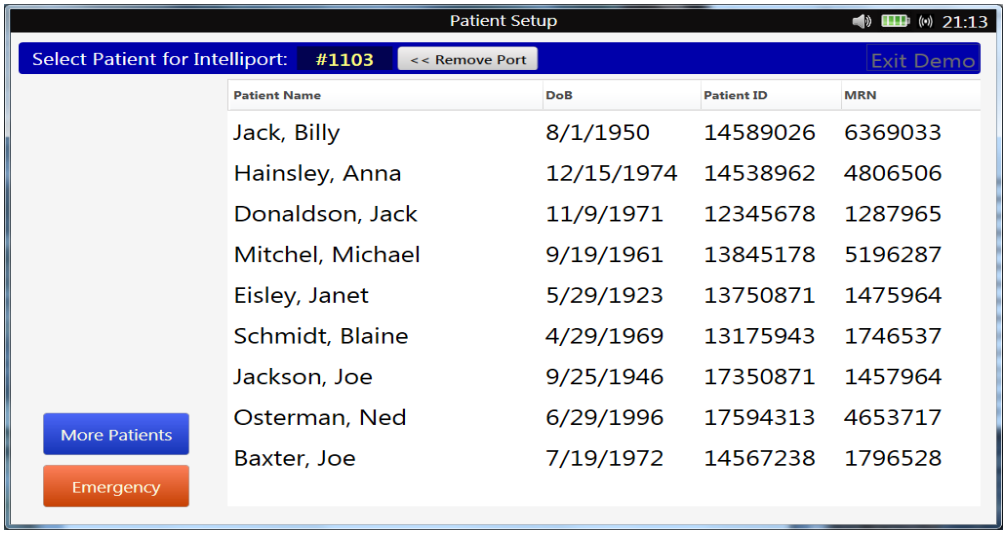


Figure 16 Patient Setup

If the patient is not listed, press the "More Patients" button to find the patient on the ADT list by filtering this longer list by the patient name, patient ID or MRN. A keyboard will appear to type the first letters of the Last Name.

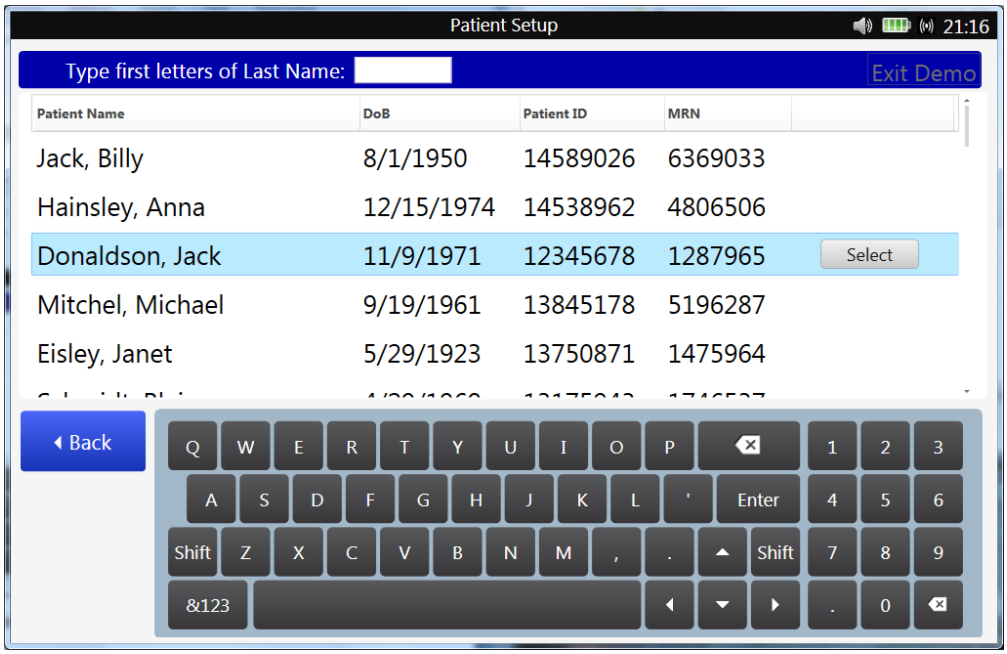


Figure 17 ADT Patient List

NOTE There is an "Emergency" button on the Tablet computer screen for patients whose name is not known or the clinician determines an emergent situation to start medication treatment.

16. Press the "Confirm" button to complete the setup. (IFU 027)Should any part of the association be incorrect, there is an opportunity to press the "Remove" button and repeat the patient identification step process. (Figure 18) Once confirmed, the Anesthesia System has established a permanent association between the patient and Intelliport Sensor. The Intelliport Sensor can only be paired with one patient.

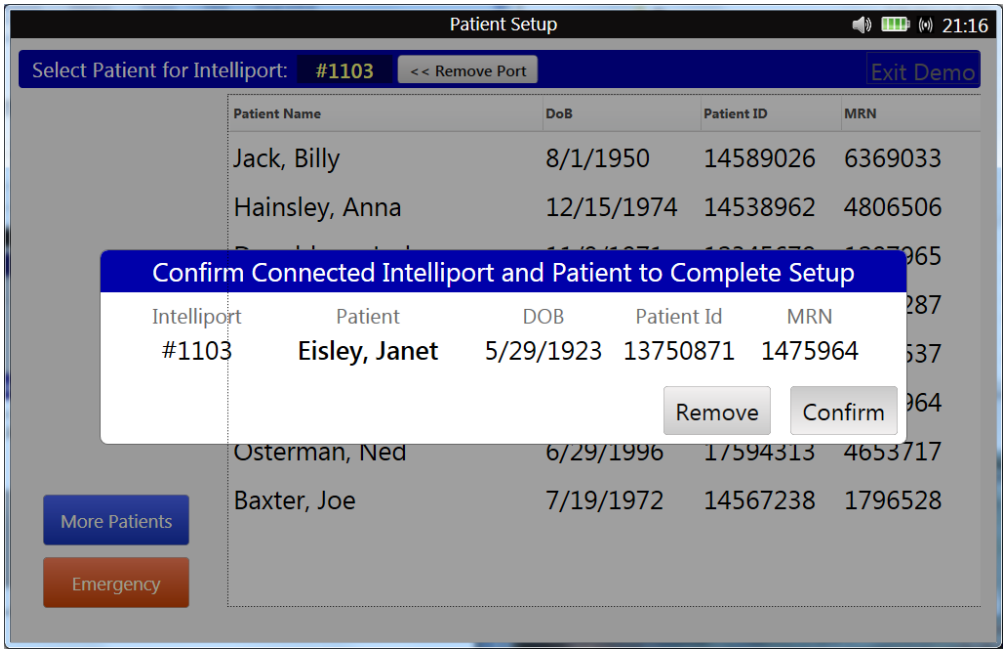


Figure 18 Confirm Patient Association

NOTE If the wrong patient was inadvertently confirmed to the Intelliport device, there is a "Remove Intelliport" button on the Main Menu button that will disassociate the patient from the Intelliport device and undo any medication administration history.

Should the Intelliport Base become disconnected from the Intelliport Sensor during operation, reattach and verify patient association.

17. Following Patient Setup, the Tablet computer displays allergies for the selected patient, if so configured. Known allergies, with severity and type of reaction will display (Figure XX).

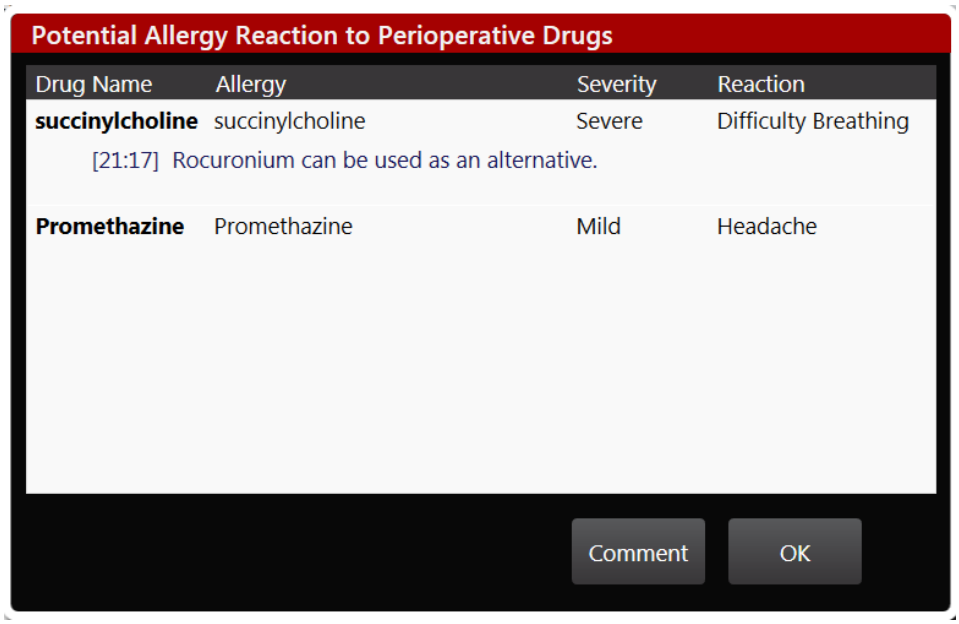


Figure 19 Patient Allergies

NOTE If the patient allergies are not available for the Tablet computer, the clinician will see a message “Unable to Obtain”.

NOTE The Tablet computer checks for updates to patient allergy information during a case.

18. There is an opportunity to type a comment for an allergy by selecting the Allergy and pressing the Comment button. A keyboard will display to type a comment. (Figure xx)
19. Once the comment is recorded, press the “OK” button to save. This will return to the Allergy list.

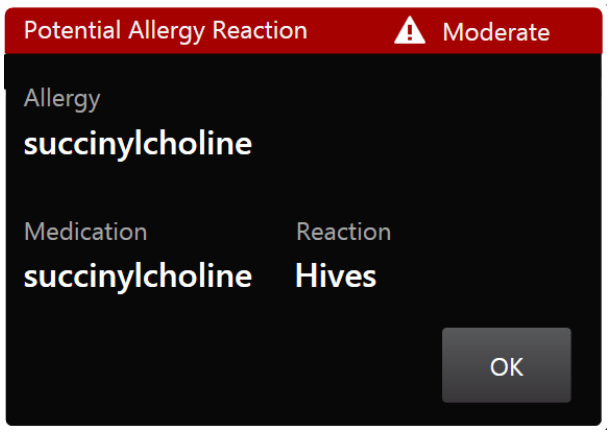
Give an IV injection Using the Intelliport Device

20. Clean the injection port by swabbing the hub according to your hospital procedure. (IFU013)
21. Attach a syringe to the Intelliport injection port.

Double check each medication name and concentration on the syringe prior to attachment to the injection port to assure “right medication.” (IFU 02)

1. Verify the drug displayed and announced by the Tablet computer is the intended drug and concentration. (IFU 019)For syringes not having encoding, refer to Section: Special Activities; Medication Delivery when Syringes Not Encoded, then return to this step. (IFU 04)
2. The Intelliport device will flash red, green and yellow lights if a medication allergy is detected, if so configured.

Use clinical judgment before proceeding when the Tablet computer announces and displays a known allergy for the drug attached to the Intelliport device. Allergy messages will display as below:



3. There is no check valve in the Intelliport Sensor, so close or pinch the upstream IV tubing or use a check valve IV set to prevent medication traveling towards the IV bag during injection. (IFU 009)

NOTE Alternatives to prevent retrograde flow include: 1) attaching a three-way stopcock onto the Y-site and luer locking the Intelliport Sensor onto the stopcock; 2) attaching a manifold to the IV or extension tubing and luer lock the Sensor directly to the manifold.

4. When delivering medications, observe the graduations on the syringe to check the amount of drug delivered. (IFU003) Verify dose shown in the active injection bar of the Tablet computer. (IFU 007) The Intelliport device measures 0.4 mL to 55 mL per injection. (IFU 008)

NOTE If the injection flow rate is very slow, a message will display on the Tablet computer. (IFU 031) If the amount of injected medication is not measurable, the active injection bar will indicate “dashes” for volume and dose. A message will instruct the clinician to enter the dose manually through the “Modify Selected Medication” screen. Once completed, the dose will display. Refer to Section XXX for more information.

NOTE Pushing medication from a 50 mL syringe rapidly has the potential to cause collapse of the IV line. Push slower to accommodate delivery of a large amount of medication.

5. Follow all injections through the Intelliport device with an encoded Normal Saline flush to ensure the full dose of medications reaches the patient, especially when successively delivering two incompatible medications. (IFU06)

NOTE Normal Saline will appear on the active injection bar with the amount of mL delivered. Normal saline may not display on the medication history, if so configured.

6. Make adjustments to the medication administration record on the Tablet computer for injections involving a diluted drug, reconstituted drug, or mixed drugs, if so configured.

Injections are recorded whether or not the Intelliport device is wirelessly connected to the Tablet computer. The Intelliport Base stores injection information in its memory and transmits this information upon wireless connection to the Tablet computer. (IFU030)

Special Activities

Setting User Preferences

The Anesthesia System supports user preferences to determine the sound volume, screen brightness and audible announcements, reminders and messages. (IFU016)The hospital has configured default preferences that may be modified temporarily during a case. To verify the Tablet computer preferences prior to starting a case, perform the following:

1. Select Preferences from the Menu.
2. Adjust preference for the work environment.
3. Press "Save" button when completed.

CAUTION Check whether alerts have been muted when relieving a clinician during a case.

Preference changes are retained during the case. When the case has closed or when a new clinical user logs in, the settings revert to the default configuration.

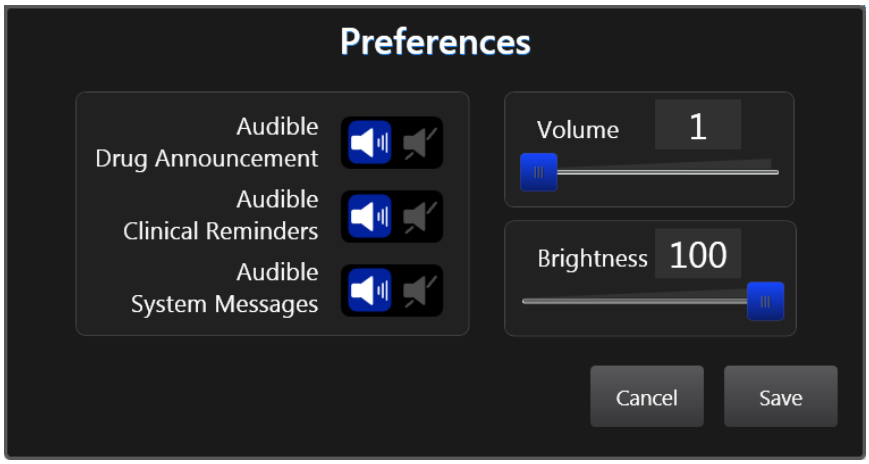


Figure 20 User Preferences

CAUTION Selecting the "Mute" option from the Menu will override all of the above selections and mute all drug announcements, clinical reminders and system messages. To hear the medication announcements, select "Unmute".

Adding Additional Intelliports

The Anesthesia System can accommodate up to 3 Intelliport devices connected to one patient at a time. An additional Intelliport device can be added at any time during a case. The first connected Intelliport device will display in the left most injection bar. The second in the middle, and the third the rightmost injection bar. Refer to Figure 6.

NOTE When an Intelliport is connected to a Tablet computer and there is no syringe attached to the Intelliport device, the active injection bar shall read "Intelliport Connected, No syringe attached". A battery status icon will indicate battery charge level in the corner of the injection bar.

To add an Intelliport device:

1. Prepare an Intelliport device according to the instructions in Section X.
2. Press “Tap to Connect” on any of the remaining Active Injection Bar spaces to display a pop-up window that lists available Intelliport devices within wireless range.
3. Identify the 4 digit number on the Intelliport Sensor.
4. Select (highlight) your Intelliport device based on the time of initial activation and the four digit number on the Intelliport Sensor.

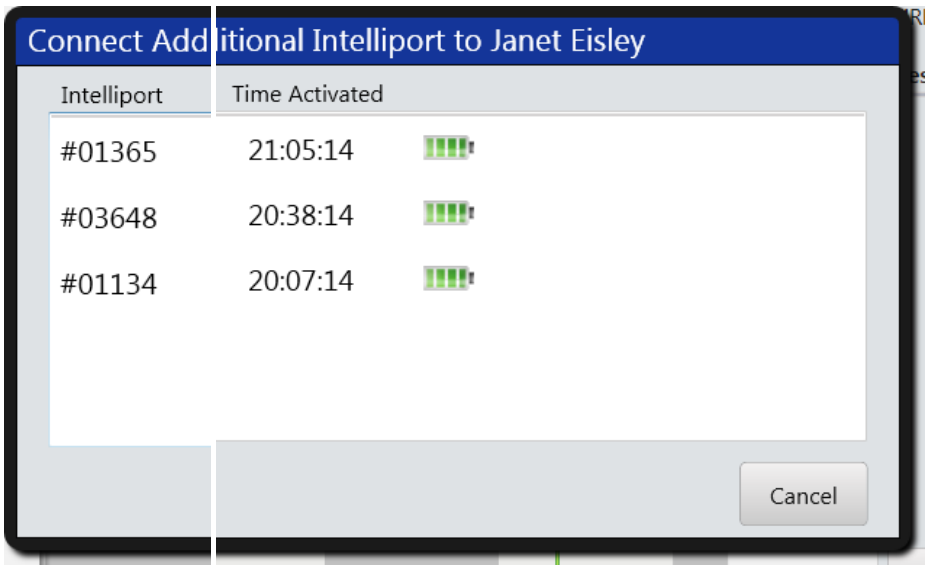


Figure 21 Connecting Additional Intelliports

NOTE A low battery icon will display when the selected Intelliport device has less than 10% of battery power remaining.

5. The selected Intelliport device will flash lights for 3 seconds.
6. Verify the green and yellow lights are flashing for the correct Intelliport device .

NOTE Should you miss the visual confirmation, highlight the appropriate Intelliport device again to initiate the flashing lights.

7. If the identified Intelliport device is correct, press “Connect”.
8. Verify the Intelliport device is flashing a single, repeating green blinking light indicating it is wirelessly connected to the Tablet computer.
9. Press Confirm. An Active Injection Bar will display the connected Intelliport device.

Medication Delivery with Syringes Not Encoded

The Anesthesia System is designed to work with both encoded syringes (those having a special barcode identifier on the syringe tip) and unencoded syringes. When an unencoded syringe is attached to the Intelliport device, the Tablet computer will display the “Select Medication” pop-up having a perioperative medication list. (IFU018) A clinician can identify the medication in the syringe before

giving the injection (recommended) or afterwards. If postponed, the Tablet computer tracks injections not yet identified and later prompts the clinician to resolve.

1. Select the medication and concentration from the Frequent Use list by highlighting the name. This list includes medications previously identified during the case as given by an unencoded syringe.

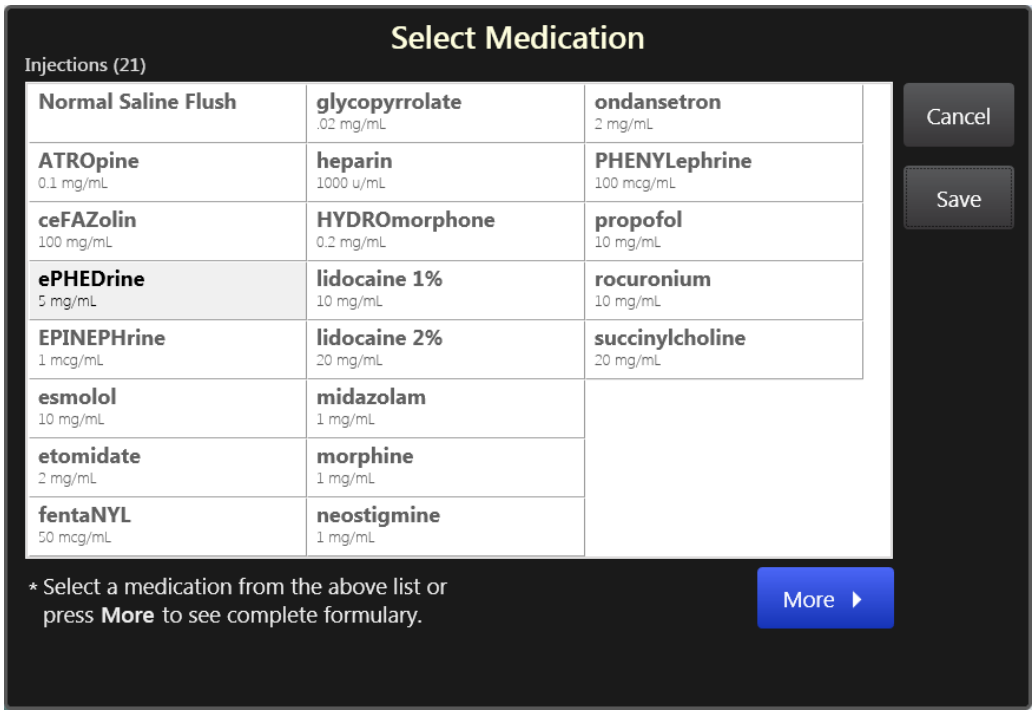


Figure 22 Select Medication

2. If the desired medication is not found on the Frequent Use list, press “More” to view a longer list of perioperative medications.
3. Filter the list by pressing the first letters of the drug name using the keypad.
4. Highlight the desired medication and concentration, verify the information and press “Save”.(IFU 05)

Specifying a Diluted or Reconstituted Medication

The Tablet computer provides a simple approach to document medications that require dilution or reconstitution from a powder form prior to preparation for injection. It tracks frequently diluted and reconstituted medications. The Tablet computer prompts the clinician to confirm whether a drug has been diluted or reconstituted. If not, no user action is required.

NOTE Reconstituted drugs do not display a dose value until the clinician modifies the medication.

5. To specify a dilution or reconstitution, press “Modify” on the “Select Medication” pop up. Or press on the dose flag (Anesthesia View flowsheet) or dose row (Nursing view) and press Modify.
6. Change the medication concentration or dose by pressing the Concentration box, then enter the

concentration value using the numerical keypad.

7. Review the numbers entered, then press “Save” button to record the new value. (IFU017) This change will be reflected in the medication administration history.

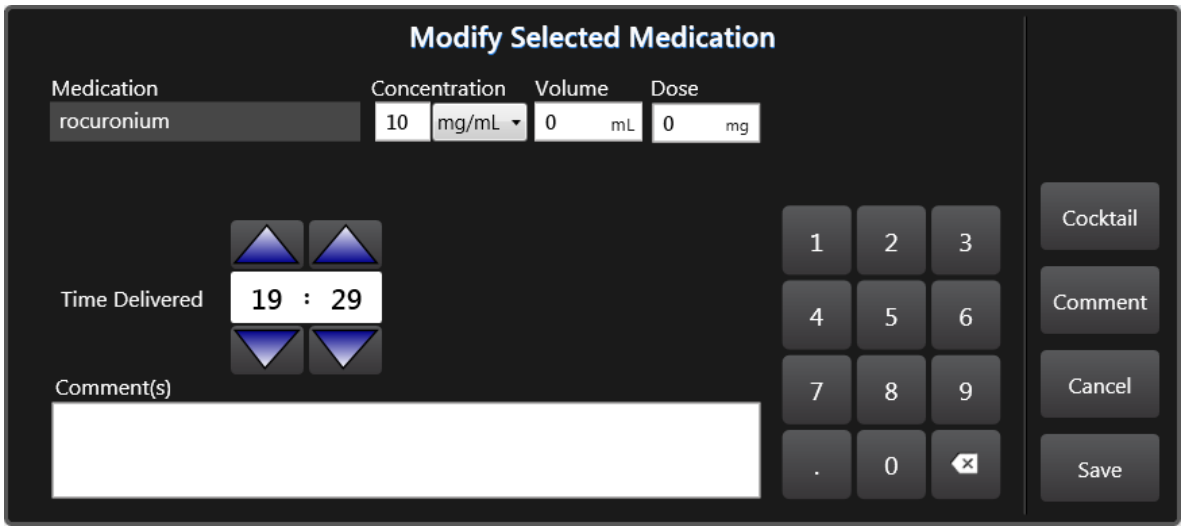


Figure 23 Modify Selected Medication

Specifying a Mixed Medication (Cocktail)

Adding two medications into one syringe is called a mixed medication or cocktail. Depending on your institution, mixed medications may include the following:

- Propofol/lidocaine
- Propofol/fentanyl
- Propofol/ketamine
- Neostigmine methylsulfate/glycopyrrolate
- Atropine/edrophonium
- Narcan/edrophonium

The Tablet computer provides a simple approach to document mixed medications. It tracks frequently mixed medications, and it prompts the clinician to confirm whether a drug has been mixed. If not, no user action is required.

1. To specify a mixed medication, press “Cocktail” on the “Select Medication” pop up. Or press on the dose flag (Anesthesia View flowsheet) or dose row (Nursing view) and press “Cocktail.”
2. The “Modify Selected Medication” pop up (Figure 24) displays two medication names; with the first one already identified.
3. Select the second Medication from the list. If the intended medication is not listed, press “More” and the clinician may identify the correct medication from the “Frequent Use” or perioperative drug library list.

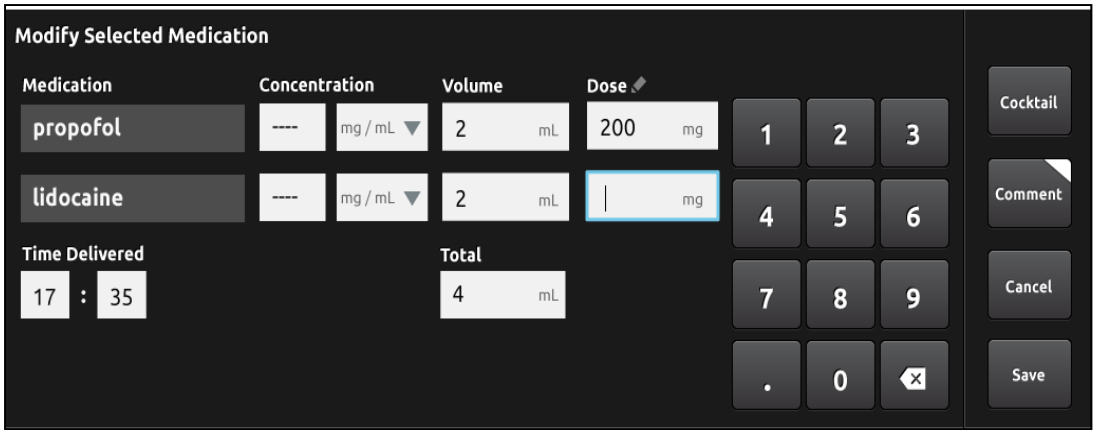


Figure 24 Cocktail Medication

4. Enter the volume injected for either drug. The Tablet computer will calculate the volume for the other medication using the total volume injected.
5. Press “Save”.

Adding Manual Injection (for Paper Anesthesia Records)

The Tablet computer provides the means to document IV injections given prior to activating an Intelliport device or given through an IV port other than the Intelliport device. (ICU016)

1. Press the “Add” button, then press “Add Injection”. The Frequent Use medication list will display.
2. Highlight the desired medication and concentration. Indicate the volume or dose.
3. Change the time by pressing on the appropriate arrows to the correct time of administration.
4. Press “Save” and the medication will list in the medication history area at the indicated time.

NOTE A medication administration time cannot be in the future nor more than one hour before the first Intelliport device has been activated.

Adding Infusions (for Paper Anesthesia Records)

The Tablet computer provides the means to document infusions.

1. Press the Add button, then press “Add Infusion.”
2. The Infusion medication list will display having four categories: Fluids, Medications, Titratable Medications, and Blood Products. Select the appropriate category.

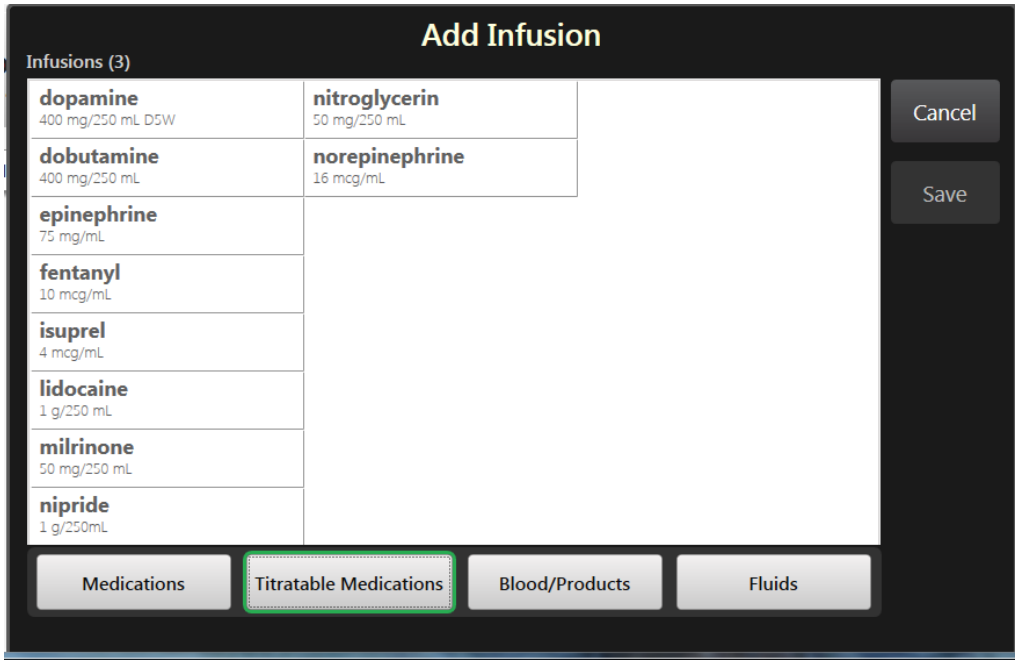


Figure 25 Add Infusion

3. Select the appropriate infusion, bag size and concentration. Press ”Save”.
4. Specify a time point. To change the time, press the arrows of the hour and minutes up to increase and down to decrease.

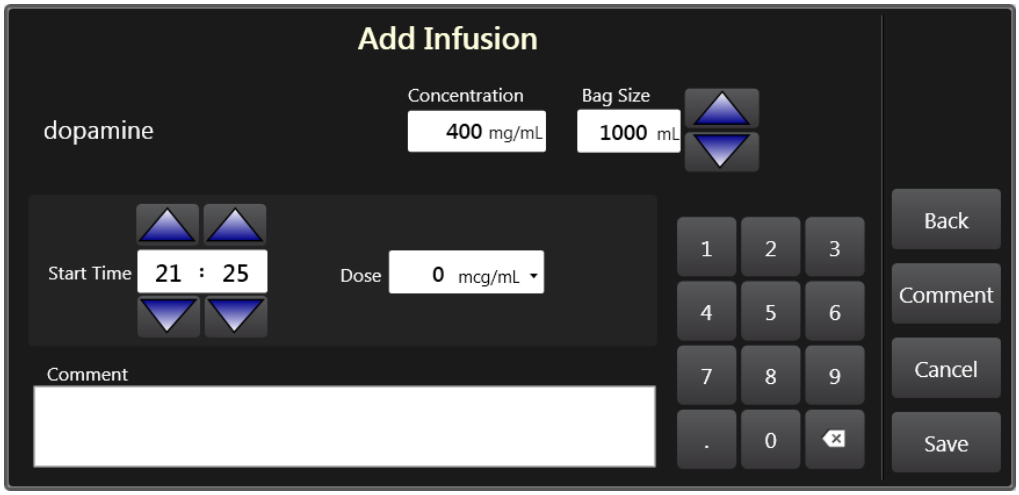


Figure 26 Modify Infusion

NOTE A medication administration time for an infusion cannot be in the future nor more than one hour before the first Intelliport device was activated.

5. Specify the amount infused as of that time (Optional).
6. Press “Save”.

A clinician can add the volume infused for a care area at any point during a case by pressing on the infusion bar, entering volume infused and press “SAVE”. To stop an infusion, press the “Stop” button and press “Save”. Inactive infusions will display a black bar and the time the infusion was stopped.

Adding a Comment (for Paper Anesthesia Records)

A comment is a free text entry that is relevant to the anesthesia record. The Tablet computer supports four methods to add to a comment:

- *Allergies – comments for a specific drug allergy*. To make a comment on the allergy pop-up screen, highlight the allergy medication, then press "Comment" button. This will automatically display a keyboard along with standard comment options. The clinician can press one of the standard options or type a comment and press "Save". The recorded comment is displayed with each allergy pop-up. (The allergy pop-up screen is displayed on Patient Setup or by pressing the "Allergies" button in the lower right corner.)
- *Time – comments tied to a specific time during a case*. To add a general comment for a case, press the "Comment" button and a keyboard will pop-up. Type the comment and press "Save". The recorded comment display whenever you press "Comment" button and will be listed as a "Case Comment" in the clinical report.
- *Injections – comment for a specific drug administration*. To make a comment about an injection, press a medication administration event in the medication history. This will display the "Modify Selected Injection" pop-up. Press the "Comment" button in the pop up to display a keyboard. Type the comment and press "Save". This comment will display near the dose/time when the comment was written.
- *Infusions – comment for a specific drug administration*. To make a comment on an infusion, press an infusion event. This will display the "Modify Selected Infusion" pop-up screen. Press the "Comment" button to display the keyboard to type a comment. Type the comment and press "Save". This comment will display next to the infusion event.

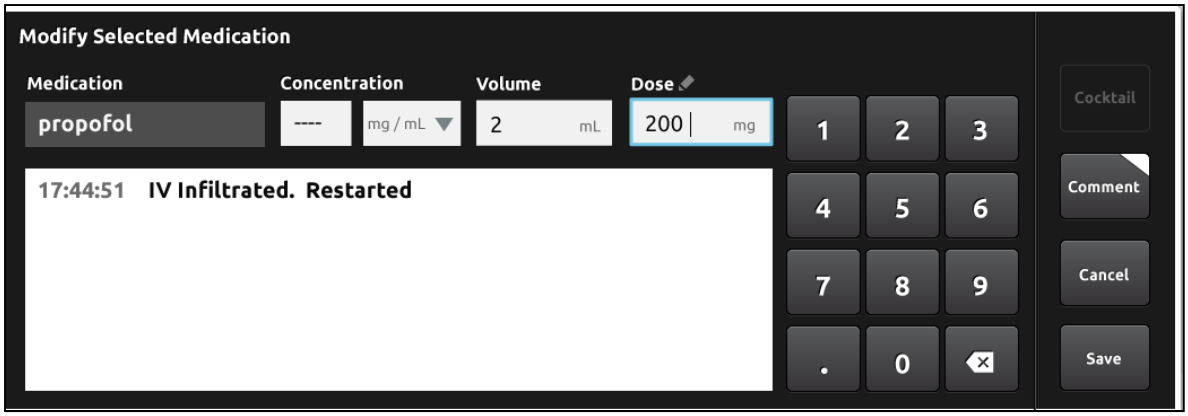


Figure 27 Add Comment

Transfer Patients from One Care Area to Another

It is important to prepare the patient and Tablet computer prior to moving the patient from one care area to another. Pressing "Pause Case" from the Menu instructs the Tablet computer to disconnect the Intelliport device thereby enabling another Tablet computer in a subsequent care area to connect to it.

The Intelliport device will remain wirelessly connected to the earlier tablet if "Pause Case" has not been pressed and the patient has been moved to a subsequent care location that is within 30 feet of the earlier Tablet computer. In this situation, the clinician can disconnect the Intelliport by pressing "Show All" from the Patient Setup screen and following the screen instructions.

Working with Orders

The Anesthesia System supports medication orders at hospitals that use Computerized Physician Order Entry (CPOE). When injections are given in perioperative nursing care areas that use CPOE, the Tablet computer can match the injection to a physician order and send this information to the hospital's clinical information system. Observe the following steps when the Anesthesia System is configured for medication orders in the nursing care areas:

1. Review the patient's medication order at the clinical information system.
2. Prepare the syringe and Intelliport device for use.
3. Attach the syringe for the medication order to the Intelliport device.

For an encoded syringe, the Tablet computer compares the medication in the attached syringe to pending medication orders and displays a pop up confirming a match. Verify the medication order matches. If correct, press "Select". If incorrect, press "Select Other".

Figure 28 Medication Orders

For an unencoded syringe, the Tablet computer displays a pop up listing the active medication orders for the patient and prompts the clinician to select the medication corresponding to the attached syringe. Highlight the medication order and press Save.

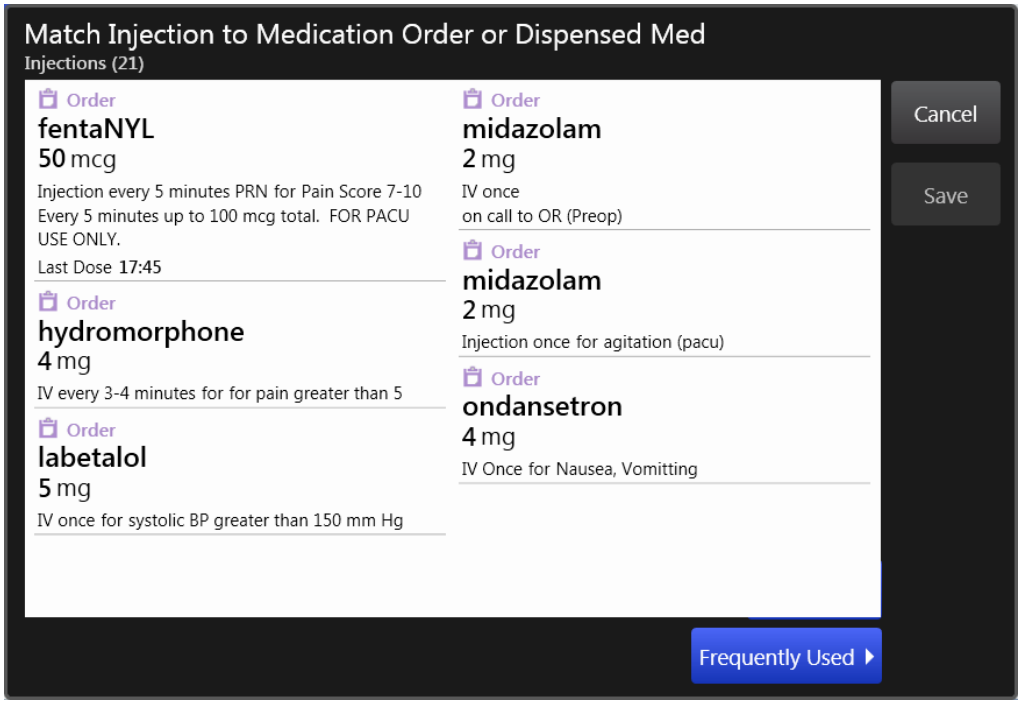


Figure 29 Selecting an Order when Using Unencoded Syringes

Responding to Messages

The Anesthesia System provides two types of messages: "System" and "Clinical." "Clinical" messages are "alerts and reminders" that relate directly to an aspect of patient care delivery (e.g. contraindication or a reminder that it may be time to re-dose antibiotics). System messages provide status on relevant system operating parameters.

Messages provide instructions and a button for acknowledging or resolving. Refer to Appendix X for a list of messages. Messages display in the Message section of the Tablet computer until they are acknowledged or are no longer clinically relevant. Messages can be answered any time during a case. Prior to pausing or closing a case, a clinician is prompted to respond/answer unresolved medication messages generated during the case.

Clinical Messages

- *Allergy alert* - An allergy alert displays when a clinician attaches an encoded syringe or selects a medication for an unencoded syringe to which the patient has a known allergy.
- *Antibiotic redosing reminder* - The Tablet computer tracks elapsed time since an antibiotic is administered and displays an antibiotic redosing message if the configured redosing interval has elapsed. The redosing interval is individual to each antibiotic, and it is configured in the drug library.
- *Medication* - The Tablet computer tracks medications given that are reconstituted, diluted or given as cocktails, (mixed meds) and displays a message for the clinician to specify. The message is individual to each medication, and it is configured in the drug library.

Reviewing the Medication Record (for Paper Anesthesia Records)

The Anesthesia System requires the clinician to review the medication record for accuracy prior to printing a report. This is called "finalizing" and it ensures the accuracy of the report.

NOTE A clinician is able to correct and amend (adding information to) the patient's the medication record so long as an Intelliport for that patient is connected and the case has not yet been "finalized".

1. From the main Menu, Press "Reports".
2. The Tablet computer will provide a pop up with messages for a clinician to verify or adjust the following data:
   - Check for reconstituted, diluted or mixed medications given. A message is individual to each medication, and it is configured in the drug library.
   - Check for missing infusion data
   - Check for medications given in nursing areas by an anesthetist that are to be charted in the anesthesia record
   - Clock adjustment - Press "Clock" to adjust the time for the printed reports to synchronize an anesthetist clock with the flowsheet. A pop up displays showing a clock with up and down arrows for hours and minute adjustment. Press "Save"

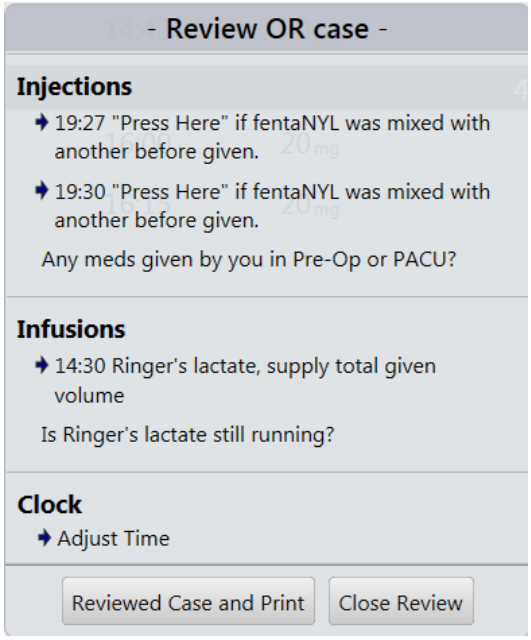


Figure 30 Review Case

3. If there are unresolved messages, the clinician can come back and answer the questions at any time prior to Closing the case (Close Case).
4. Press "Reviewed Case and Print". Once finalized, the medication administration history for recorded medication administrations will no longer be editable.

If all questions are not answered prior to case closure, the clinician can come back and answer the questions up to 24 hours after the case is closed. If the 24 hour window is exceeded, the case can only

be printed out and changes manually made with a pen, signed and dated by the clinician and submitted to Medical Records to be attached to the patient's electronic record.

Printing a Report (for Paper Anesthesia Records)

The following reports are available for printing:

- *Anesthesia Flow Sheet Record* – This report lists of the medications and infusions provided during the OR suite in a flowsheet format. This is comparable to the Anesthesia Record that is manually recorded by anesthesiologists for all cases.
- *Controlled Substance Usage* -This report provides a list of all controlled drugs used during the OR case, with dose amount, mLs used and time given.
- *Handoff* – This report is used as a communication tool to convey information pertinent to the ongoing care of the patient, especially when the patient transfers from one care area to another and a new primary caregiver assumes care of the patient.
- *Perioperative Medication Administration* - This report lists each medication and fluid administered showing the time, dosage and route. It also provides a summary showing total dosage by mediation and fluid.

1. To print a report, press Reports from the Menu.

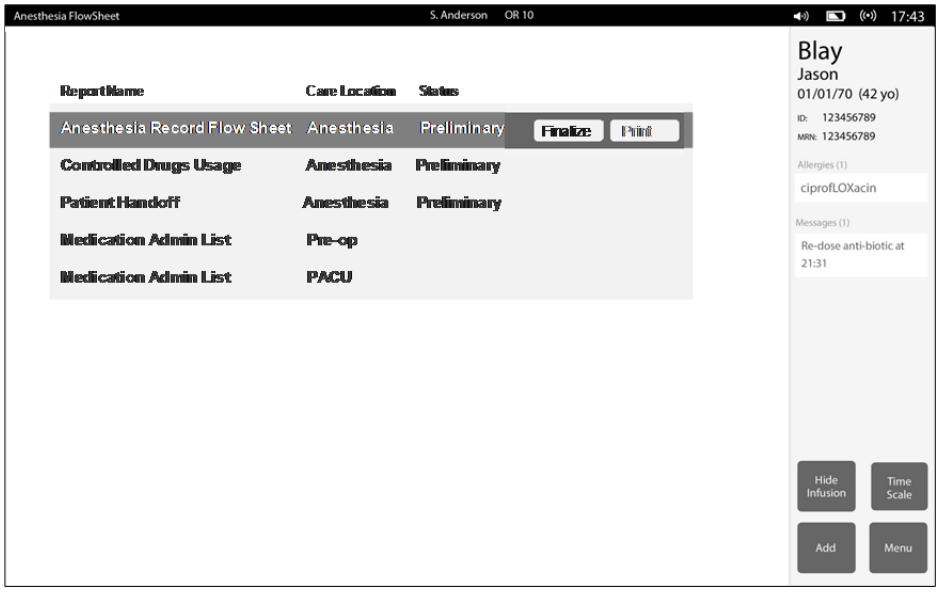


Figure 31 Print Reports

2. Select the appropriate report to print.
3. Specify the printer, if different from default, and the number of copies.
4. Press Print.

Address Pending Medications (EMR Integration)

When configured for EMR integration, the Tablet computer sends medication administration information in real time unless information is missing. The missing information includes the drug name/concentration of an unencoded syringe, the dose of a reconstituted drug, or use of a cocktail. In

these situations, the Tablet computer retains this medication administration in a pending list until it is resolved by the clinician.

NOTE It is good practice to resolve medication administrations prior to a care transition or closing a case. (IFU032)

5. From the Menu, press "Pending Meds". A pop-up lists medication administrations that require resolution.
6. Press each item to resolve. As each resolution on medication occurs, the query will disappear and a resulting medication message will indicate the information sent to the Anesthesia Information Management System (AIMS) system.

Deactivate Intelliport, Dispose of Intelliport Sensor, and Prepare Intelliport Base for Reuse

1. When the Intelliport device is no longer in use; disconnect the Intelliport Sensor from the Intelliport Base by squeezing together the two finger tabs on top of the Intelliport Sensor while lifting up to disengage from the Intelliport Base.
2. When properly separated, the Intelliport device will power off and no longer transmits wirelessly to a Tablet computer.
3. Dispose of the Intelliport Sensor according to your hospital's medical waste protocols.

NOTE Avoid inadvertently discarding the Intelliport Base after use. It is intended for reuse with multiple patients.

4. Clean and disinfect the Intelliport Base. First clean it with a commercial hospital disinfectant and secondly, disinfect it secondly with a commercial hospital disinfectant. Follow manufacturer's instructions. For a list of approved hospital approved products to use, refer to Appendix X.
5. Allow it to dry.
6. Inspect the Intelliport Base for cracks or damage. If damage is evident, then dispose of it according to your hospital's protocols.
7. Connect the Intelliport Base to the Recharger.

NOTE It takes approximately 2-4 hours to fully recharge an Intelliport Base when discharged to <25% of power.

8. If the Intelliport Base has exceeded its Useful Life, then dispose of it according to your hospital's protocols for electrical waste. The Intelliport Base contains a Lithium battery.

NOTE The Intelliport Base will illuminate a red light while charging if it has exceeded its Useful Life.

Power Down the Tablet computer

The Tablet computer may remain powered down between uses.

1. Confirm the Tablet computer does not have Intelliport devices connected and it is no longer in use.
2. Press the "Shut down" button located on the Menu bar.

3. Press “Yes”, to confirm and power down the Tablet computer.

Section V Troubleshooting

In the event you experience difficulty operating the Anesthesia System, this section of the manual provides a troubleshooting guide for operational problems. If the response to a specific question is not found, contact your Service Representative:

Phone:

Website:

Email:

Question	Answer
How do I return to the Clinical Main Screen or Home?	From Main Menu press "Anesthesia" or "Nursing" view.
What do I do if the Battery in the Base runs out of charge during a case?	A Base can be exchanged at any time without affecting the case. Exchanges take less than 30 seconds. If it is more than 30 seconds, the case will require resynchronization of Intelliport device to Tablet computer.
What if I pressed "Close Case" or "Shut down" by mistake during an active case?	Once you resynchronize the patient and Intelliport device to the Tablet computer, all information is retrievable, even if the Intelliport Sensor is replaced.
What causes me to lose historical medication information? And what can I do to retrieve it?	It is not possible to lose historical medication information if the Intelliport device and patient have been synchronized to the Tablet computer. Medications given prior to Intelliport synchronization are retained in memory on the Intelliport Base.
What if I forgot to chart a medication or identify a "Select Med" and the patient is now in the Med-Surg floor or ICU?	If it has not been more than 24 hours since the OR case, the case can be retrieved from the hospital server and editing of the case can occur via a Tablet computer. However, if greater than 24 hours, the case report can be printed, and manual edits made with dates and signatures and returned to Medical Records for a case update.
What do I do if the Intelliport Sensor no longer is working and the case is not over?	An Intelliport Sensor can be replaced at any time. Resynchronization is required.
What if the case is over and I just noticed the wrong patient appears on the screen?	Go to Main menu and press the "Remove Patient" button. TBD.

Section VI Care and Maintenance

Observe the following procedures for care of the Anesthesia System. Components of the Anesthesia System do not require user maintenance. There are no user serviceable parts.

Care

Clean and Disinfect the Intelliport Base for Reuse

1. Clean the Intelliport Base with a commercial hospital disinfectant. Then disinfect the Intelliport Base with a commercial hospital disinfectant. (IFU0024) For a list of approved hospital cleaning products to use on the Intelliport Base, please refer to Appendix B.
2. Allow it to dry.
3. Inspect the Intelliport Base for cracks or damage. If damage is evident, then dispose of it according to your hospital's protocols.

Recharging the Intelliport Base for Reuse

4. Plug the Recharger into an isolated AC outlet.
5. Attach the Recharger to a clean and disinfected Intelliport Base by joining the Recharger and Intelliport Base front sections first, then snap the two together. One should audibly hear the "snap".
6. Verify proper seating of Recharger to the Intelliport Base by checking for a "charging" light on the Intelliport Base. If this is not seen, view the Intelliport device on its side to determine if the two are properly connected. If a space is seen between the Recharger and Intelliport Base, then separate and re-attached properly.
7. The Intelliport Base will illuminate showing the amount of charge in the battery. Refer to the following section should a red indicator light illuminate.

NOTE Four bars indicate a full charge. The Intelliport Base is not damaged when left on the Recharger after being fully charged.

Clean and disinfect the Recharger by using the procedure used for the Intelliport Base.

Determining Useful Life for a Intelliport Base

The Intelliport Base is designed to be reusable. After 500 uses, the components may be susceptible to wear and it is no longer suitable for use with patients. Use the following procedure to determine if an Intelliport Base has exceeded its useful Life.

NOTE Avoid using an Intelliport Base that has exceeded its Useful Life.

1. Connect the Intelliport Base to a Recharger.
2. If the Intelliport Base has exceeded its Useful Life, then the Intelliport Base will illuminate a red light while charging. If so, discontinue use.

NOTE If an Intelliport Base has exceeded its Useful Life, then dispose of it according to your hospital's protocols for electrical waste. The Intelliport Base contains a Lithium battery.

Should an Intelliport Base be used after it has exceeded its Useful Life, a message will display when the Intelliport device is wirelessly connected to the Tablet computer during Patient Setup. Should you experience this message, replace the Intelliport Base with another and repeat the wireless connection to the Tablet computer.

Cleaning the Tablet computer

1. Turn the Tablet computer off and disconnect the power cable.
2. Clean the Tablet computer with a soft cloth dampened with water. Moisten a soft, lint-free cloth with either water or a display cleaner, and wipe the surface of the Tablet computer until it is clean.

Do not use aerosol cleaners, which may contain flammable substances.

Do not allow water from the cloth to seep down to the Tablet computer ports and the buttons.

To avoid damaging the Tablet computer or display, do not spray cleaning solution directly onto the display.

Only use products specifically designed for cleaning Tablet computers, and follow the manufacturer's instructions that are included with the product. For a list of approved hospital cleaning products to use on your Tablet computer, please refer to Appendix F.

Storage

Components of the Anesthesia System do not require user maintenance. There are no user serviceable parts. Contact Technical Support in the event a Tablet computer or Intelliport Base is not functioning properly.

Tablet computer

When not in use, the Tablet computer may remain mounted and powered on, when connected to an isolated AC power source.

NOTE Do not remove the Tablet computer from its protective case for storage.

Intelliport Base

When not in use, a clean and disinfected Intelliport Base should remain on the Charger.

NOTE Do not place an Intelliport Base in storage without first cleaning and disinfecting according to Hospital policy.

NOTE For hospitals that keep a spare Intelliport Base in the OR, be sure to periodically swap out Intelliport Base to ensure it is fully charged.

Intelliport Sensor

Intelliport Sensors are stored in the sterile packaging.

Intelliport Sensors have a “Use By” date to ensure sterility. Discard Intelliport Sensors that have not been used by their Use By date.

Maintenance

Components of the Anesthesia System do not require user maintenance. There are no user serviceable parts. Contact Technical Support in the event a Tablet computer or Intelliport Base is not functioning properly.

Administration and Service

To Be Determined

Section XIII. Appendix

Appendix A Intelliport Technical Specifications

Specification	Description
Fluid connection	2 ports, Luer lock type fittings
Volume measurement accuracy	± 5%
Injection port capacity	100 injections
Prime volume	5 mL
Dead volume /retained fluid	0.3 mL following injection
Exterior size (excluding tubing)	< 4.5 cubic inches
Weight	72 gm (Intelliport Base and Intelliport Sensor)
Operation on a Single charge	24 hours
Recharge speed	Up to 4 hours from <25%
Wireless range (Intelliport device)	5 m
Operating Temperature	12˚ C - 40˚ C (IFU014)
Operating Humidity	20% to 85% relative humidity (IFU 015)
Shipping and Storage Temperature	-20˚ C - 60˚ C
Shipping and Storage Humidity	15% to 90% relative humidity

Appendix B Disinfectant Agents

The following disinfectants are suitable for use with the Intelliport Base and Recharger.

Disinfectant	**Type of disinfectant**
Cavi Wipes 1 (By Metrex)	Alcohol-based quaternary ammonium
Super Sani Cloth (purple top) (by PDI)	Alcohol-based quaternary ammonium

Appendix C Standards

The Anesthesia System is intended for use under the supervision of healthcare professionals only. This is a Class II medical device. The Anesthesia System conforms to the following standards.

IEC 60601-1	Medical Electrical Equipment - Part 1. General Requirements for Safety
IEC 60601 -1-2	Collateral Standard: Electromagnetic compatibility - Requirements and testing

Appendix D Glossary

The following terms are used in these Instructions for Use.

Configuration	The way the Anesthesia System is set up, or the assortment of components that make up the Anesthesia System. The Gateway manages the configuration settings. All Tablet Computers for a care area have the same settings, except for wireless and printers.
EMR integrated mode	System configuration that supports integration with electronic medical records or perioperative information management systems (PIMS)
Encoded Syringes	Syringes having a special barcode identifier on the tip
Encoding	A special barcode identifier on the tip of prefilled syringes
Gateway	A software application that enables the Anesthesia System to function as an enterprise device and information system. The Gateway provides a central hub to which all Tablet computers connect via the hospital network. It also includes an interface engine for the Anesthesia System to exchange data with other networked hospital information systems, along with a suite of utilities for general Gateway implementation, operation, and maintenance.
Injection port	The split septum port on the Intelliport Sensor where the syringe attaches
Intelliport Base	The Intelliport Base is a non-sterile, reusable device that houses the electronics and wireless transmitter. It is battery powered, and rechargeable. A separate Charger recharges the battery in the reusable Intelliport Base prior to each use.
Intelliport device	An intelligent injection port. It attaches to an injection site ("Y Site" or stop cock) for manually administered IV injections. It is comprised of a Intelliport Sensor and a Intelliport Base, which snap together prior to use.
Intelliport Sensor	A Intelliport Sensor is a sterile disposable device having an injection port and a Luer connection. The Intelliport Sensor is supplied in a sterile package for single patient use.
Luer-lok	A standard fitting used for making leak-free connections. A luer fitting that securely locks together using threads.
Non-encoded syringes	Syringes that do not have special encoding on the tip. The Intelliport device cannot identify the drug contents of this type of syringe.
Perioperative Drug Library	The Anesthesia System operates using the hospital's perioperative drug library. The Gateway manages the drug library. When an unencoded syringe is attached, the pick list is derived from the perioperative drug library.
Recharger	A separate Recharger recharges the battery in the reusable Intelliport Base prior to each use.
Stand-alone mode	System configuration that supports a paper anesthesia record

Tablet computer	A commercial Tablet computer with embedded software for the Anesthesia System operation. It continuously captures and displays the medication administration record (MAR) data from the Intelliport device each time an injection occurs. It also enables clinicians to manually document other pertinent clinical information, and it provides clinical decision support to help improve safety and aid clinicians during treatment. Information technology wirelessly transfers the data to the Gateway.

Appendix E ASA Drug Category Color Schema

Drug Class	Pantone Color
Induction Agents	Process Yellow C (RGB 255.255.0)
Benzodiazepines and Tranquilizers	Orange 151 (RGB 255.102.0)
Benzodiazepines Antagonists	Orange 151 (RGB 255.102.0)/White Diagonal Stripes
Muscle Relaxants	Florescent Red 805 (RGB 253.121.86)
Relaxant Antagonists	Florescent Red 805 (RGB 253.121.86)/White diagonal stripes
Narcotics	Blue 297 (RGB 233.299.227)
Narcotic Antagonists	Blue 297 (RGB 233.299.227)/White diagonal stripes
Major Tranquilizers and Anti-Emetics	Salmon 156 (RGB 237.194.130)
Narcotic/Tranquilizer Combinations	Blue 297 (RGB 233.299.227)/Salmon 156 (RGB 237.194.130)
Vasopressors	Violet 256 (RGB 222.191.217)
Hypotensive Agents	Violet 256 (RGB 222.191.217)/White Diagonal Stripes
Local Anesthetics	Gray 401 (RGB 194.184.171)
Anticholinergic Agents	Green 367 (RGB 163.217.99)

Appendix F Messages

	Name & Trigger	Message Text	Clearing the Message
1.	Tablet computer software is unable to verify its configuration settings (e.g. no wireless to Gateway)	Software configuration or formulary versions cannot be verified. Using current settings. Notify your system administrator.	- Persists with boot up screen. Will timeout in 10 seconds.
2.	While the Tablet computer software is receiving and updating the Tablet computer software Configuration Profile.	Updating DPM, configuration to version [xx].	- Persists while updating file(s)
3	While the Tablet computer software is receiving and updating the Drug Formulary.	Updating Formulary to version [xx].	- Persists while updating file(s)
4	Configuration update not successful	New configuration settings not updated. Using current settings. Notify your system administrator.	- Persists with boot up screen
5	Intelliport Base- End of Life - Intelliport device transmits # of uses upon synchronization.	Intelliport device has reached its end of life	- OK clears the message - Confirm (completes patient association)
6	Drug connected or subsequently identified matches a contraindicated drug based on the patient's allergy	Screen -"[Drug name] - Potential Allergy Reaction" Patient has a known allergy to : [allergy description] " Severity:" [severity] "Reaction:" [reaction]	- OK button - Automatically upon syringe disconnect if not pushed.
7	Antibiotic redosing interval exceeds configuration value for the antibiotic.	[Antibiotic Drug Name] given X.X hours ago. Consider redosing.	-OK button -Automatically upon subsequent antibiotic injection connected/ identified.
8	The drug connected or injected has been identified as frequently diluted in configuration.	"Press Here if [Drug Name] was diluted before given.	- Pressing the Dilution message text opens the manual injection entry screen with volume and dose fields editable.
9	The drug connected or injected has been identified as frequently mixed in configuration.	"Press Here" if [Drug Name] was mixed before given.	- Pressing the Mixed message text opens the manual injection entry

	Name & Trigger	Message Text	Clearing the Message
			screen with fields for a second drug.
10	Tablet computer software receives unmeasured in lieu of volume from the Intelliport device	“Amount injected not measured”. “Press Here” to enter the volume given.	- Pressing the Not Measured message text opens the manual injection entry screen with cursor focus on volume field.
11	Intelliport device transmits a low battery message	Low Intelliport battery (10% remaining). Replace Intelliport Base.	-Automatically upon Intelliport unsynchronization or Intelliport Base replacement.
12	Intelliport device transmits a powering down message	Low Intelliport battery. Intelliport device powered down.	-Automatically upon synchronization of Intelliport device having low battery.
13	Tablet computer has less than 20 minutes of power remaining	Low Tablet computer battery. (10% remaining).	- Automatically when Tablet computer on AC power
14	Tablet computer software powering down message	Low Tablet computer battery. Tablet computer powering down.	N/A
15	An Intelliport device is no longer communicating with the Tablet computer software after 5 seconds of polling by the Tablet computer software	Intelliport wireless connection lost.	- Automatically upon Intelliport synchronization of same serial number Intelliport Sensor/Intelliport Base.
16	An Intelliport device has been connected communicating with the Tablet computer software after polling by the Tablet computer software.	Intelliport wireless connection restored.	- 1 minute timeout.
17	Intelliport error condition transmitted to Tablet computer software	Intelliport error occurred. Replace Intelliport Base.	- Press ”Clear” if resolved
18	Intelliport error condition transmitted to Tablet computer software	Tablet computer error occurred. Restart Tablet computer.	- OK button. - Press “Clear” if resolved
19	Tablet computer software error condition present	Tablet computer error occurred. Restart Tablet computer	-OK button - Press “Clear” if resolved
20	User presses Shut Down button with no Intelliport devices synchronized.	Tablet computer shutting down.	N/A

	Name & Trigger	Message Text	Clearing the Message
21	User presses the Shut Down button while an Intelliport device is synchronized.	Shut Down the Tablet computer and disconnect the Intelliport device?	Yes – continue with shutdown No – cancel shutdown
22	User presses Print button on Reporting Screen	Printing to XXX printer.	N/A
23	Failed login. User Name and Password combination not valid	Text provided by Gateway or "Incorrect Password. Re-enter".	Next login attempt
24	Dose exceeds ordered Dose	"Check dose on order"	Syringe is disconnected
25	Intelliport Sensor not primed. No Sensor signal at initial Intelliport Sensor attachment	"Prime Intelliport Sensor before use"	Intelliport Sensor signal level achieved.
26	Air detected in the Intelliport Sensor. Occurs after proper priming with fluid and air entrapped in the Intelliport Sensor.	"Air detected in the Intelliport Sensor".	Intelliport Sensor signal level achieved. (returned)

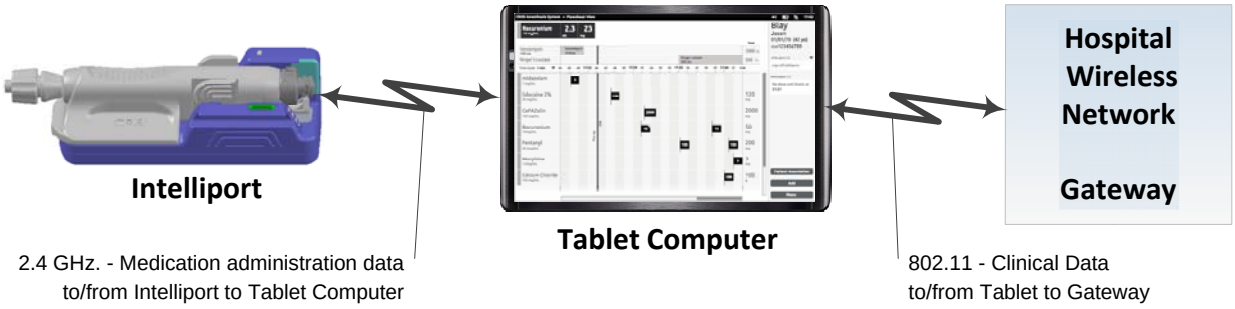
Appendix G Accessories

- Charger (part number 2284) - This accessory is used to recharge the Intelliport Base in preparation for reuse.

- Radio (part number 2285) – This accessory is used by the Tablet computer to communicate with Intelliport devices.

Appendix H Radio Frequency Wireless Technology

There are two wireless technologies used in the Anesthesia System as depicted in Figure X below.



The radio frequency (RF) signal power has been limited to a very low level to negate any electromagnetic potential interference in co-existence with other medical devices. Both wireless technologies utilized have been approved for use by the (Federal Communications Commission) FCC and meet Federal EMC and EMI guidelines. In the event of a potential signal loss of these RF communications a "lost wireless link message" will be displayed on the Tablet computer to inform the operator. The Tablet computer will indicate when communications are resumed. Information on proper set-up, configuration and performance with the Hospital Network is provided at time of system installation. No set-up is required for Intelliport device to Tablet computer communications. Confirmation of appropriate patient identification is required.

Other medical equipment such as an electrosurgical unit (ESU) may briefly interfere with these wireless communications. Communications should automatically resume after the interference and lost messages will be resent. The Tablet computer will indicate when lost communications exist. The Intelliport status indicator will double blink when communication with the Tablet computer is lost.

Intelliport to Tablet computer

The Tablet computer uses an Intelliport Radio to wirelessly communicate with the Intelliport device using an RF signal at 2.4 GHz to form a local medical device network. A number of Intelliport devices and Tablet computers may be used in the same vicinity such as a Pre-operative care area or a PACU. A license has been issued by the Federal Communications Commission (FCC) to operate this medical device in hospitals and clinics. Testing has been performed to demonstrate conformance to IEC 60601-1-2 for the correct, timely and secure transmission of medical data (injected drug identification codes and volume measurements) and alert messages. Alert messages are communicated between the Intelliport device and the Tablet computer to advise the User of various operational characteristics of the system. Some of these alerts inform the operator of potential hazardous situations to allow user action to prevent harm to the patient or loss of medical data.

Intelliport devices using proprietary 2.4GHz technology are associated (linked) with specific patients using the Tablet computer IEEE standards based on 802.11a/b/n (2.4GHz-5GHz) technology. The User identifies the Intelliport Sensor by serial number and selects a specific patient from the hospital's patient

listing. All medication administration data from the Intelliport device is transferred to the specific patient's medical record. In the event of a communication loss, medication administration data will be stored locally at the Intelliport device and transferred to the Tablet computer when communications are resumed.

Tablet computer to Gateway through the Hospital Network

The Tablet computer wirelessly communicates with the existing Hospital Network using a standards based IEEE 802.11a/b/g/n enterprise WLAN network. The networking topology that includes this Tablet computer will follow the best of practice deployment guidelines that complies with the right quality of service (QoS) and security. The Gateway software and accompanied database will be a part of the hospital's enterprise information system. A number of Tablet computers may be connected to the healthcare enterprise wireless network and to the intended Gateway software and database. The Gateway and accompanied database provides a list of patients for the User to select and a Formulary library of medications and fluids for injection or infusion. Actual medication and fluid administration data is sent to the Gateway and accompanied database for recordkeeping. Once recorded on the Gateway and accompanied database this data is automatically available in other care areas when the patient is transferred and the Intelliport device is wirelessly connected to a Tablet computer.

Summary of IEC 60601-1-2 Testing and Specifications

Specifications	Intelliport to Tablet computer	Tablet computer to Hospital Network and Gateway
Technology Type	2.4 GHz proprietary messaging	802.11 a b, g, n secure wireless connection with the correct quality of service (QoS)
Effective Power		
Effective transmission distance	10 meters or less	Xx meters to hospital wireless access point (WLAN AP)
Data throughput and latency	Real-time information, no delays	Subject to hospital network performance
Lost Communications Message on the Tablet computer display	"Intelliport communication lost"	"Gateway communication lost"
Limitations	3 Intelliport devices to one Tablet computer	200 Tablet computers to Hospital Network and Gateway
FCC License	####	####
Limitations found during testing to IEC 60601-1-2	Xxxx	Not tested – conforms to IEEE 802.11 standards.

Quality of Service		
Wireless Coexistence		
Security of wireless signal/data		
EMC information		

Appendix I Reference Documents

Available documentation and training for the Anesthesia System includes:

Order Number	Document Name
2300	Anesthesia System Instructions for Use
XXXXX	Anesthesia System Quick Reference Cards
XXXXX	User Training Video and DVD

Appendix J Description of Symbols

The following symbols are used by the Anesthesia System.

Symbol	Description
	Warnings
IPX2	Ingress Protection from falling water drops
	Refer to user operating instructions
	Do not use if package is damaged or protector cap is unattached.
	Type BF/Defibrillation Proof applied part
	Single Use Only. Do not reuse!
	Identifies the component manufacturer
	Keep dry
45°C	Upper temperature limit
	Expiration Date, end of shelf life December, 2013
	Lot number
Sterile EO	Supplied Sterile, Ethylene Oxide gas

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Revision Date: 2/21/2013
Part No.: 2300_R1 FCC-IC