Essential Prescribing Information and User Manual
CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

TECHNICAL SUPPORT:
Dial 866-488-1408 and select option 4

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Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417 USA

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Chapter 1. Product Description

The BD Intelliport™ Medication Management System (system) can be used when intravenous bolus injections of medication are given to a patient by an anesthetist/physician for automated documentation of medication, concentration, dose, volume and time of each intravenous injection during a surgical case or patient procedure.

The system is connected to the intravenous line and automatically captures information about drugs injected, and wirelessly transmits that information in real-time to the BD Intelliport™ Tablet (tablet). The tablet uses that information and other manually-entered information to display a time-stamped medication record. It provides you with data to help you make clinical care decisions. It also makes that information available for reporting and electronic recordkeeping purposes.

The system has two operating configurations.

The first configuration is a system that supports a paper anesthesia record. This configuration is designed for recording manual IV bolus medication administrations at hospitals using a paper anesthesia record. The BD Intelliport™ system records information about medication administrations and provides this in printable reports.

The second configuration involves integration with an anesthesia information management system (AIMS). (Requires a software interface). This configuration is designed for recording manual IV bolus medication administrations at hospitals using an AIMS for documenting the anesthesia record. The BD Intelliport™ system records and shares information about medication administrations with the AIMS. Medications delivered through the injection site are automatically charted to the AIMS flowsheet.

There are four components to the BD Intelliport™ System:

**BD Intelliport™ Injection Site** is an intelligent injection port. It attaches to a “Y Site” or stopcock for manually administered IV injections. It is comprised of the BD Intelliport™ Sensor (sensor) and the BD Intelliport™ Base (base), which snap together prior to use (Figure 2). The BD Intelliport™ Sensor is a sterile disposable having an injection port and a BD Luer-Lok™ connection. The BD Intelliport™ Sensor is supplied in a sterile package for single patient use. The BD Intelliport™ Base is a non-sterile, reusable device that houses the electronics and wireless transmitter. It contains a non-replaceable rechargeable battery. A separate BD Intelliport™ 5-Bay Charger (charger) recharges the battery as needed. (In the tablet’s screens the term “sensor” is used to refer to the sensor and base combination to preserve screen space).
1. Product Description

Encoded syringes are syringes with a special barcode that stores information about the medication contained within the syringe. Encoded syringes are ready-to-use, passive and disposable. The BD Intelliport™ system also accommodates syringes not having encoding.

**Encoded Syringe**

Includes a barcode label on the syringe tip that provides information on the medication and concentration in the syringe. User interaction at the tablet is generally not required for recording medication administrations.

**Syringe without Encoding**

Non-encoded syringe does NOT include a barcode label on the luer tip of the syringe.
1. Product Description

**BD Intelliport™ Tablet** (tablet) runs the BD Intelliport™ system software. It continuously captures and displays the medication administration record (MAR) data from the BD Intelliport™ Injection Site (injection site) 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.

![Figure 5 Tablet with Mounting Arm (not included)](image)

Typically the tablet is mounted to the anesthesia machine in operating room and adjacent to the treatment space in the perioperative nursing care areas. Refer to Appendix B for mounting specifications.

**BD Intelliport™ Gateway** (gateway) is software that enables the BD Intelliport™ system to function as an enterprise device and information system. The gateway provides a central hub to which all tablets connect via the hospital network. It also includes an interface engine for the BD Intelliport™ 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 BD Intelliport™ system to configure the Device Drug Library and the tablet settings.

**BD Intelliport™ 5-Bay Charger** (charger) is used to charge the BD Intelliport™ Base. It can charge up to five (5) bases at a time.

In this manual “you” refers to a clinician using the system
Chapter 2. Indications for Use

The BD Intelliport™ system is an automated record keeping system that incorporates patient safety features that are aligned with hospital patient records and protocols. The system is comprised of an injection port and software that enables the identification, measurement, alerting and documentation of the administration of medications to patients.

The BD Intelliport™ system allows the clinician to record anesthesia-related, medication administration events in the pre-op, intra-op, and PACU. The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.

The BD Intelliport™ system is intended for patients whose body weights are >20kg.

The BD Intelliport™ system is not intended for use with blood, blood products, biologics, or chemotherapeutics.

The BD Intelliport™ system is not intended for use with refrigerated medications (excluding cefazolin).
Chapter 3. Contraindications

Volume measurements are not intended for refrigerated medications (excluding cefazolin).

The BD Intelliport™ system is not intended for use with blood, blood products, biologics, or chemotherapeutics.
Chapter 4. Warnings

⚠️ **WARNING:** Indicates a potential for personal injury or death.

**General**

⚠️ **Flush the injection site with a normal saline syringe after each dose where retained medication in the injection site has clinical implications.**

- Unless flushed using a syringe, 0.334 mL of medication will remain in the injection site after each dose. This is different from your current practice. Your IV line will not flush the injection site.
- Failure to flush the injection site with a syringe may result in under-dosing of the patient.
- Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site.

⚠️ **DO NOT LOOK** at the tablet screen while administering a medication. The only accurate way to administer a medication is to look at the graduations on the syringe. Looking at the tablet screen during medication administration can lead to underdose and overdose and the user may not be aware that the incorrect dose was given.

⚠️ Do not use the BD Intelliport™ system near Magnetic Resonance Imaging (MRI) equipment, including stereotaxis technology. Remove from the IV Y-site prior to imaging.

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

⚠️ Shock hazard: do not attempt to connect or disconnect the tablet or charger power cord with wet hands. Make certain that your hands are clean and dry before touching the power cord.

⚠️ If you observe the measured dose incrementing up although medication is not being pushed through the injection site (runway lights may illuminate), then disconnect the syringe and edit the recorded dose accordingly. A bubble may have become lodged momentarily in the Sensor affecting the ultrasonic measurement.

⚠️ Use only the power cord supplied by the manufacturer for the tablet or charger. Never adapt the plug to fit a nonstandard outlet.

⚠️ Inspect the tablet and charger power supply cords for damage prior to use. Replace the two power cords only with the BD 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 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. 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) as hazardous gases may result in unsafe conditions or patient/clinician harm.

⚠️ Use accessory equipment recommended by the manufacturer. The use of non-approved accessory equipment with the BD Intelliport™ system is not recommended, and may lead to unsafe conditions or patient/clinician harm.
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 extouchément 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 license-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.

**BD Intelliport™ Tablet**

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

- Electrical shock hazard: Do not remove the tablet cover. There are NO user serviceable parts inside the tablet.

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

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

- Be sure the tablet is mounted securely to avoid falling and resulting in patient/clinician injury.

- Do not maintain contact with the patient and the tablet or between the BD Intelliport™ system and the touch screen of the tablet simultaneously.
Double check each medication name and concentration on the syringe prior to attachment to the injection port to assure “right medication.”

If there is a power failure of the tablet while injecting a medication the dose will not be recorded. Verify entire medication administration record once power has been restored.

Use clinical judgment before proceeding when the tablet announces and displays a known allergy for the drug attached to the BD Intelliport™ system.

The tablet does not display nor alert to food or environmental allergies.

The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.

If communication between the tablet and gateway has been disrupted, information regarding the patient’s allergies may be incomplete.

The BD Intelliport™ system receives drug allergy information from the hospital information system (HIS). The tablet will not display an allergy alert if the allergy has not been recorded in the HIS or if the medications is not listed in the Device Drug Library.

When the BD Intelliport™ system is integrated with an AIMS, all medications given through the injection site are automatically charted to the anesthesia record. To prevent duplicate charting of medications, only use the injection site for medications intended for the anesthesia record.

When the BD Intelliport™ system is integrated with an AIMS, all medications given through the injection site are automatically charted to the anesthesia record. To prevent duplicate charting of medications, do not manually chart at the AIMS workstation for those medications administered using the injection site.

**BD Intelliport™ Injection Site**

BD Intelliport™ Injection Site 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 BD Intelliport™ Injection Site Y-site attachment.

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

Verify the BD Intelliport™ Sensor sterile packaging (pouch) is intact prior to opening, including all the packaging surfaces (edges, top and bottom plastic surfaces). Discard Sensor if packaging is damaged and replace with new Sensor.

Verify that the BD Intelliport™ Sensor tubing end cap is still in place. Discard Sensor if the end cap has become detached. Replace with another Sensor.

Prepare the BD Intelliport™ Sensor prior to use. Trapped air may affect sensor performance. Not preparing the Sensor may cause inaccurate dose measurement.

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

Check for a blocked fluid path or leaking fittings when preparing the BD Intelliport™ Sensor.

Visually inspect the BD Intelliport™ Sensor and IV tubing to make sure they are clear. Replace the BD Intelliport™ Sensor if a high lipid medication (e.g. propofol) has been injected and leaves a visible residue.

Do not use the BD Intelliport™ Sensor with an IV line using a high pressure infusion flow system (greater than 80 psi). Verify the line placement prior to BD Intelliport™ Injection Site Y-site attachment.

Charging of the BD Intelliport™ Base should not occur on or in immediate proximity to the patient.
4. Warnings

- 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.

- Prior to patient transport, secure the IV and the BD Intelliport™ Injection Site with the patient to avoid intravenous line disruption and patient injury.

- After preparing, visually inspect the IV line for leaks, air, or blockage. Check the syringe has medication.

- Confirm the sensor’s BD Luer-Lok™ is securely connected to a fully primed primary infusion set before use.

- Antibiotic redosing reminders are based on preconfigured, medication-specific time intervals which do not take into consideration renal or hepatic dysfunction, excessive blood loss, obesity, or other clinical factors which may affect serum drug levels. Redosing reminders should be responded to in a timely manner.

- Check whether alerts have been muted when relieving another clinician during a case. 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”. Silencing the announcements may adversely affect patient safety.

- 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.

- The BD Intelliport™ system is neither designed nor intended to detect nor alert if there are IV infiltrations or extravasations. Hospital/facility personnel must ensure the performance of the common IV site, prior to conducting bolus injections.

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

- BD Intelliport™ Sensors have an expiration date to ensure sterility. Discard BD Intelliport™ Sensors that have not been used by their expiration dates.

- Verify the medication record is correct if the BD Intelliport™ Base shows a red light while in use.

- Use aseptic technique when handling the sensor IV connections.

- There is no check valve in the BD Intelliport™ Sensor, nor is one needed to use the BD Intelliport™ Sensor safely and effectively. Should you choose a stopcock, manifold or check valve can be used. If you leave a syringe in place for long durations it is recommended that you use a check valve to prevent backflow.

- The BD Intelliport™ Base should have a BD Intelliport™ Sensor attached when in use near the patient. The contacts on the BD Intelliport™ Base should not be exposed to patient contact.
Chapter 5. Precautions

⚠️ PRECAUTION: Indicates either potential damage to the hardware or loss of data and instructs how to avoid the problem.

General

⚠️ Do not modify or tamper with BD Intelliport™ system components for any reason. Doing so will void the manufacturer warranty. The BD Intelliport™ system does not include serviceable components. Contact your BD Intelliport™ system representative for all repairs.

⚠️ Do not use damaged equipment, frayed or damaged power cords.

⚠️ Do not expose the BD Intelliport™ system to gas or heat sterilization. Autoclaving will seriously damage the BD Intelliport™ Base, charger and tablet.

⚠️ Avoid liquid ingress to the tablet or BD Intelliport™ Base. Fluids may interfere with their performance.

⚠️ Operation of electro convulsive therapy (ECT) equipment during use of the BD Intelliport™ system may temporarily result in signal loss between the BD Intelliport™ Site and tablet.

⚠️ If any part of the BD Intelliport™ system (tablet, injection site, charger) is dropped or severely damaged, immediately remove it from use and have it inspected by service personnel. Ensure its proper function prior to reuse.

⚠️ Federal (U.S.A.) law restricts this device to sale on or by the order of a physician. Rx only.

⚠️ If the BD Intelliport™ system is not working or not recording injections, use manual documentation process to capture delivered injections.

BD Intelliport™ Tablet

⚠️ To completely remove power from the unit, disconnect the power cord from the power receptacle of the tablet.

⚠️ Properly secure the tablet prior to use or after positioning. Do not loosely place the tablet on other equipment.

⚠️ Do not block the ventilation inlet holes on the underside of the tablet.

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

⚠️ The tablet can be used only with the BD Intelliport™ system.

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

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

⚠️ Do not allow fluid to seep down to the tablet ports and the buttons.

⚠️ To avoid damaging the tablet’s touch screen, do not spray cleaning solution directly onto the touch screen.

⚠️ Do not use aerosol cleaners or pressurized sprays, which may contain flammable substances, when cleaning the tablet screen.

⚠️ Do not use hard or pointed objects on the tablet touch screen.

If the patient allergies are not available for the tablet, the message “Unable to Obtain” displays.
If the patient does not have allergies, the message “No Known Allergies” displays.

The tablet checks for updates to patient allergy information at the start of a case and upon a care transition.

“Normal Saline flush” will appear on the active injection bar with the amount of mL delivered. If so configured, Normal saline flush” will not display on the medication history.

Reconstituted drugs will not display a dose value on the medication flag until the clinician modifies the medication.

A medication administration time cannot be in the future nor more than one hour before the first BD Intelliport™ Injection Site has been activated.

If communication between the tablet and gateway has been disrupted, users may not be able to print clinical reports from the tablet.

A clinician is able to correct and amend (adding information to) the patient’s medication record so long as a BD Intelliport™ Injection Site for that patient is connected or if it has been less than 24 hours since powering down ports but has not yet been “finalized “.

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

Perioperative nurses should not inject through the BD Intelliport™ System.

Do not power down the Injections Site unless the injection site is no longer in use. Doing so will prevent additional medication administrations from being recorded for this case.

Do not remove the tablet from its protective case for storage.

**BD Intelliport™ Injection Site**

- Verify the encoding label is clean and secured to the syringe Luer collar prior to attaching to the BD Intelliport™ Sensor.

- Check the medication syringe before connecting to the BD Intelliport™ injection site for air or bubbles. If present, make sure all air or bubbles are removed from the syringe before connecting the medication syringe and injecting the medication.

- When reconstituting medications in a syringe, make sure the granules/powder is completely dissolved prior to connecting the medication syringe to the BD Intelliport™ injection site.

- When connecting the syringe to the sensor, attach the syringe with the label facing up and rotate the syringe barrel a full 180 degrees (and not beyond) to ensure the syringe is properly seated. When properly attached, the syringe graduations will be visible when viewed from above.

- When connecting and disconnecting the syringe always use a “straight-on/straight off” approach. Once the syringe is attached, make sure the syringe and injection port are aligned in a straight line with no angles at the connection.” Incorrect seating of the syringe may result in the tablet not announcing the medication and recording dose.

- Should the injection site not measure the injected volume upon syringe removal, the tablet temporarily records a placeholder dose and prompts you to specify a dose. Discontinue use of the BD Intelliport™ Sensor if the syringe is securely attached and you observe leaking (droplets forming at the injection port) during an injection.

- Dispose of the BD Intelliport™ Base according to your facility’s protocol for battery disposal of lithium ion batteries.

- Clinicians must be familiar with and be trained in the use of the BD Intelliport™ system. Its use should be preceded by an established facility protocol.

- Change the BD Intelliport™ Sensor according to facility policy for IV administration set change or using CDC (USA) Guidelines; or if the integrity of the BD Intelliport™ Injection Site has been compromised.
The charger should be cleaned with a disinfectant cloth. Unplug before cleaning.

The distance between the BD Intelliport™ Injection Site and a tablet should be 10 meters or less in order for the BD Intelliport™ Injection Site to send and receive wireless communications.

Verify that the BD Intelliport™ Injection Site is securely Luer locked to the Y-site and the IV tubing is free from kinks before operating.

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

If a new base is required, disconnect sensor from IV line. Flush sensor with normal saline until “Ready” displays on tablet or base lights are seen.

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

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

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

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

Avoid using a BD Intelliport™ Base that has exceeded its Useful Life.

Do not place a BD Intelliport™ Base in storage without first cleaning and disinfecting according to hospital policy.

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

Should you miss the visual confirmation, highlight the appropriate BD Intelliport™ Injection Site again to initiate the blinking lights.

If the wrong patient was inadvertently confirmed to the BD Intelliport™ Tablet when configured for paper charting, use the “Remove Patient” button on the Preferences Screen to disassociate the patient from the BD Intelliport™ Injection Site and undo any medication administration history.

If the wrong patient was inadvertently confirmed to the BD Intelliport™ Tablet when configured for an AIMS, then the injection site cannot be used. Discard the sensor and replace it with an unused sensor. If an injection has been recorded at the AIMS, then correct the patient’s medical record at the AIMS by removing the doses that were assigned to the wrong patient as a result of the mistake.

Should the BD Intelliport™ Base become disconnected from the BD Intelliport™ Sensor during operation, reattach and verify patient association. Verify entire patient case record to confirm all information is correct.

If air is detected in the sensor fluid path, a message may display prompting you to confirm the amount measured. Refer to Chapter 4 for more information.

If the medication is administered slowly, the green lights on the base will not illuminate and a message may display prompting you to confirm the amount measured. Refer to Chapter 9 Responding to Messages for more information.

Verify the green “Ready” icon displays on the tablet before confirming the set up. Not preparing the sensor before use may introduce air into the IV line or cause inaccurate dose measurement.

The system is not recommended for use with non-BD Luer-Lok™ syringes. When using a syringe without a BD Luer-Lok™,
medication should be administered through an available y-site on the primary IV line and documented manually.

⚠ For sensors sufficiently prepared, green lights on the base illuminate to provide a visual confirmation that the volume being injected is measured.

⚠ Avoid disconnecting the sensor from the base and replacing it with a different sensor before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

⚠ Avoid completely depleting the battery charge on the base before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

⚠ If a small volume (<0.4 mL) is administered or the volume given is not measured accurately, a message will display “Confirm volume and dose.” prompting you to confirm the amount measured. Refer to Chapter 9 Responding to Messages for more information.
Chapter 6. How Supplied

- **BD Intelliport™ Base** – Reusable BD Intelliport™ Bases are supplied non-sterile and require disinfection and charging before use. Each BD Intelliport™ Base is identified by labeling on the bottom of the device. BD Intelliport™ Bases are provided in individual boxes and 10 bases per case. Disinfect each base before first use.

- **BD Intelliport™ Sensor** – BD Intelliport™ Sensors are supplied sterile, packaged in individual sterile packaging (pouches) for single patient use. Sensors are provided 50 sensors per case. Each BD Intelliport™ Sensor is identified by a serial number on the upper side on the sensor. Labeling is printed on the individual sterile packaging (pouch).

- **BD Intelliport™ 5-Bay Charger** – Chargers are supplied non-sterile in individual packages capable of charging five bases simultaneously. Each charger is identified by labeling on the underside of the charger.

- **BD Intelliport™ Tablet** – The BD Intelliport™ system software is provided pre-installed on a commercial tablet computer. Each tablet is identified by a serial number located on the back of the computer. Labeling is provided in the User Manual. Each tablet includes an AC power adapter and a BD Intelliport™ Radio for communication with the BD Intelliport™ Base. Tablets are provided in the original computer manufacturer’s shipping box.
Chapter 7. Maintaining Device Effectiveness

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

Care

Observe the following procedures for care of the BD Intelliport™ system. Components of the BD Intelliport™ system do not require user maintenance. There are no user serviceable parts. The BD Intelliport™ system has been designed to work in normal perioperative environment lighting, outside of a surgery site focal light point. Do not use within six inches of the surgical site focal light.

Cleaning and Disinfecting the BD Intelliport™ Base for Reuse

1. Clean and disinfect the BD Intelliport™ Base and charger with a commercial hospital disinfectant. For a list of approved hospital cleaning products to use on the BD Intelliport™ Base, please see Cleaning and Disinfectant Agents in Appendix C.

   △ The charger should be cleaned with a disinfectant cloth. Unplug the charger before cleaning.

2. Allow it to dry.

3. Inspect the BD Intelliport™ Base for cracks or other damage. If damage is evident, then dispose of it according to your facility’s protocols for disposing of electronic waste.

Recharging the BD Intelliport™ Base for Reuse

1. Plug the charger into an isolated AC outlet.

2. Clean the base with an approved disinfectant before charging.

3. Insert the BD Intelliport™ Base into one of the five recharging ports in the charger. The BD Intelliport™ Base will illuminate showing the amount of charge in the battery. See below should a red indicator light illuminate.

   △ Four bars indicate a full charge. The BD Intelliport™ Base is not damaged when left on the charger after being fully charged.

4. Clean and disinfect the charger by using the procedure used for the BD Intelliport™ Base.

Determining the Useful Life for a BD Intelliport™ Base

The BD Intelliport™ Base is designed to be reusable. A solid red light will illuminate on the BD Intelliport™ Base when the unit is charging to indicate it is no longer suitable for use with patients (exceeded its Useful Life).

△ Avoid using a BD Intelliport™ Base that has exceeded its Useful Life.

1. Insert the BD Intelliport™ Base into a charger.

2. If the BD Intelliport™ Base has exceeded its Useful Life, then the BD Intelliport™ Base will illuminate a red light while charging. If so, discontinue use.
If a BD Intelliport™ Base has exceeded its Useful Life, then dispose of it according to your hospital's protocols for electrical
waste. The BD Intelliport™ Base contains a lithium ion battery.

Should a BD Intelliport™ Base be used after it has exceeded its Useful Life, a message will display when the BD Intelliport™
Injection Site is wirelessly connected to the tablet during Patient Setup. Should you see this message, replace the BD Intelliport™
Base with another and repeat the wireless connection to the tablet.

Cleaning the BD Intelliport™ Tablet

1. Turn the tablet off and disconnect the power cable.
2. Wipe the surface of the tablet with one of the approved disinfectant wipes:
   - PDI Super Sani-Cloth® germicidal wipes
   - Clorox® germicidal wipes

Turn the tablet off and unplug the power cord from AC power before cleaning. Do not spray fluids directly onto the tablet
or into any connector or opening. Do not steam autoclave, EtO sterilize, immerse the tablet, or allow fluids to enter the
tablet case. Failure to follow these instructions might result in an electrical hazard.

Do not use aerosol cleaners or pressurized sprays, which may contain flammable substances, when cleaning the
tablet screen.

Do not allow a fluid to seep into the computer ports or buttons.

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

Use only products specified for cleaning the tablet, and follow the manufacturer’s instructions that are included with the product.
For a list of approved cleaning products to use on your tablet, please see Cleaning and Disinfectant Agents in Appendix C.

Maintenance

Components of the BD Intelliport™ system do not require user maintenance. There are no user serviceable parts. Contact
Technical Support in the event a tablet or a BD Intelliport™ Base is not functioning properly.

BD Intelliport™ Tablet

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

Do not remove the tablet from its protective case for storage.

BD Intelliport™ Base

When not in use, a clean and disinfected BD Intelliport™ Base should remain in the charger.

Do not place a BD Intelliport™ Base in storage without first cleaning and disinfecting it according to hospital policy.

If your hospital keeps a spare BD Intelliport™ Base in the OR, be sure to periodically swap out the BD Intelliport™ Base
to ensure it is fully charged.

BD Intelliport™ Sensor

BD Intelliport™ Sensors are stored in the sterile packaging.

BD Intelliport™ Sensors have an expiration date to ensure sterility. Discard BD Intelliport™ Sensors that have not been
used by their expiration dates.
Chapter 8. Complete Device Description

The BD Intelliport™ system is designed with your needs, safety and workflow in mind. This chapter will familiarize you with the BD Intelliport™ system components, operational modes, display views, controls, and indicators.

⚠ Review Chapter 4. Warnings and Chapter 5. Precautions prior to use.

The BD Intelliport™ system is designed for use with the following equipment:

- Intravenous (IV) line (not to be used with arterial lines) with Y-site needleless port(s), stopcock or manifold
- BD Intelliport™ Injection Site (sterile packaged BD Intelliport™ Sensor and charged BD Intelliport™ Base)
- Medication syringes (with encoding and without encoding)
- Tablet
- Charger

**BD Intelliport™ Injection Site**

The BD Intelliport™ Injection Site is an intelligent injection port. It attaches to an injection site (“Y Site” or stopcock) for manually administered IV injections. It comprises a single-use BD Intelliport™ Sensor and a reusable BD Intelliport™ Base, which snap together prior to use. Up to three BD Intelliport™ Injection Sites 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 BD Intelliport™ Injection Site has memory that will store a time-based medication history log from the time of activation to the time when these data are sent to a tablet.

**BD Intelliport™ Sensor**

The BD Intelliport™ Sensor is a sterile disposable having an injection port and a BD Luer-Lok™ connection. The BD Intelliport™ Sensor is supplied in a sterile package for single patient use. The BD Intelliport™ Sensor has a male Luer-Lock connection on a one-inch IV tubing pigtail. This can be attached to an IV line at a Y-site or IV manifold. A BD Intelliport™ Sensor cannot be reused with a different patient. Each BD 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 a BD Intelliport™ Sensor within wireless range using the tablet.
The BD Intelliport™ Sensor includes an injection port and an IV connection to the IV line. The injection port is a common needleless, BD Luer-Lok™ type. It should be cleaned prior to giving an injection according to hospital policy. Preparing the BD Intelliport™ Sensor is required before use. The injection port on the BD Intelliport™ Sensor supports up to 100 injections.

⚠️ The BD Intelliport™ Sensor is packaged sterile; do not use if the package is damaged or protector cap is not attached. Replace the sensor if it becomes contaminated during use.

⚠️ Do not use a needle or blunt plastic cannula. Replace immediately if either is inadvertently used resulting in damage to the sensor (typically leaks).

⚠️ Prepare the BD Intelliport™ Sensor prior to use. Trapped air may affect Sensor performance. Not preparing the Sensor may cause inaccurate dose measurement.

⚠️ Use aseptic technique when handling the sensor IV connections.

⚠️ Confirm the BD Luer-Lok™ is securely connected to a fully primed primary infusion set before use.
Discontinue use of the sensor if the syringe is securely attached and you observe leaking (droplets forming at the injection port) during an injection.

**BD Intelliport™ Base**

The BD Intelliport™ Base is a non-sterile, reusable device, rechargeable and battery-operated. It can be used until it has exceeded its useful life (red light illuminates while charging). Each base has a unique serial number printed on its surface. This number is transmitted to the tablet during use.

⚠️ The distance between the BD Intelliport™ Injection Site and a tablet should be 10 meters or less in order for the BD Intelliport™ Injection Site to send and receive wireless communications.

The rechargeable lithium ion battery is not removable. The entire BD Intelliport™ Base connects to a charger. A fully-charged base will accommodate an entire patient case. When the base is connected to a charger, up to four green light bars will illuminate on the top. The number of solid green light bars indicates the level of charge. A green blinking light will indicate it is recharging.

- ..........greater than 20% charged
- ..........greater than 40% charged
- ..........greater than 60% charged
- ..........greater than 80% charged, fully charged after 4 hours

When the BD Intelliport™ Base is connected to a charger, a red light indicates the base has exceeded its Useful Life. Refer to Chapter 7. Maintaining Device Effectiveness for more information.

**Status Indicators**

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

<table>
<thead>
<tr>
<th>Operating</th>
<th>A double-blinking, green light indicates the BD Intelliport™ Injection Site is powered on and not yet wirelessly connected to a tablet. A single blinking light indicates the BD Intelliport™ Injection Site is linked to the tablet and communicating OK.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Error</td>
<td>A red light indicates an error is present. Refer to Messages and Troubleshooting for more information.</td>
</tr>
<tr>
<td>Identity</td>
<td>Green/yellow lights flash for 3 seconds when a BD Intelliport™ Injection Site has been selected at the tablet.</td>
</tr>
<tr>
<td>Push Speed</td>
<td>Green lights illuminate in sequence during medication delivery when the injection rate is adequate to determine a dose.</td>
</tr>
<tr>
<td>Clinical Alert</td>
<td>Red/green/yellow lights flash for 3 seconds when a priority clinical alert has been triggered. This informs you of an alert message on the Tablet. (e.g., a known allergy to a drug in a connected syringe).</td>
</tr>
<tr>
<td>End of Use</td>
<td>A red light in the lowest battery charge position indicates the Base has exceeded its Useful Life.</td>
</tr>
</tbody>
</table>

*Table 1 - Status Indicators*
8. Complete Device Description

BD Intelliport™ Tablet

The tablet is a standard, commercial computer with embedded BD Intelliport™ system software for operations, a touch screen, and a wireless communications (Radio). It is typically mounted near your work envelope. The On-Off switch is located at the top right of the tablet. It includes an AC power adapter.

The tablet can be associated with only one patient at a time and one clinician at a time. During an active case, no other cases can be accessed.

Encoded Syringes

The BD Intelliport™ system supports injections using any BD Luer-Lok™ syringe. In addition, the system has been designed to work with encoded syringes that have a special barcode identifier on the syringe BD Luer-Lok™ collar, called “encoding”. The encoding stores information about the medication contained within the syringe. When an encoded syringe is attached to the injection port, this information is wirelessly transmitted by the BD Intelliport™ Injection Site to the tablet.
**BD Intelliport™ 5-Bay Charger**

A separate charger charges the battery that is inside the reusable BD Intelliport™ Base as needed. To use the charger, plug it into an electrical wall outlet and insert a BD Intelliport™ Base into it. The charger can recharge up to five bases at the same time. Keep bases in the charger when not in use. The batteries will not be harmed by being left in the charger when fully charged.

**Configuration for Paper Anesthesia Records**

When used in a hospital having a paper anesthesia record, the tablet supports features that assist with documenting the flow sheet portion and may help you make the right decisions. In this configuration, the tablet complements the paper recordkeeping activities by tracking and displaying injections given through the BD Intelliport™ Injection Site. It also enables clinicians to manually document other pertinent IV drug injection information.

The software screens follow a three-step approach consisting of:

1. Connecting the BD Intelliport™ Injection Site
2. Setting up the patient
3. Viewing medication administration in either the Anesthesia View or Nursing View.

Refer to the detailed operating instructions for information on connecting the tablet to an injection site and setting up a patient.

---

**Anesthesia View**

The Anesthesia View is a primary screen for you to interface with the BD Intelliport™ system when configured for paper anesthesia records. It is accessed by touching the Anesthesia View button on the Main menu. 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 since the current case was opened.
8. Complete Device Description

**Injection Bars** - Up to three injection bars display across the top of the screen, one corresponding to each wirelessly connected BD Intelliport™ Injection Site. Each injection bar is a real-time representation of the medication being administered through an injection site. When an encoded syringe is attached to an injection site, the injection bar displays the drug name and concentration. When a non-encoded syringe is attached, the Injection Bar will read “Select Med” prompting you 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 medications delivered to the patient organized by the surgical care area (medications given in the transition time between care areas, will post to the tablet in the next care area) arranged in a flow sheet format. This includes all medications that were administered to the patient since the BD Intelliport™ Injection Site was 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 scrolls automatically so the new medication name is visible. Horizontal hand gesturing in the flow sheet will scroll the flow sheet to view hidden medication administrations.

A color tile corresponding to American Society for Testing and Materials International (ASTM) standards and endorsed by the American Society of Anesthesiologists displays to the left of the drug name. (See Appendix K for a list of the colors). The flow sheet time scale is adjustable between 1-minute, 5-minute, and 10-minute increments by repeatedly touching the Change Time Scale menu option.

“Dose” is shown on a flag based on the time in which it was delivered (the Dose Flag). Touching the flag for a specific medication displays the “Modify Selected Medication” pop-up. From this pop-up, you can view and modify the medication concentration and dose. This screen is also used to specify an admixture (mixed medication), or a diluted or reconstituted medication.

The total amount of medication delivered per care area is shown on the Unit Total on the right side of the medication row for you to check. In addition, touching the “Unit Total” number for a specific medication displays a pop-up box indicating the medication and concentration, total dose given, number of doses given by care area, and time of each dose. To close, touch the OK button on the pop-up window.
**NOTE:** The Unit Total shows a running total of how much of the dose has been delivered of the medication and concentration. Medication administrations will not be included in the Unit Total if the dose is has not yet been ascertained. The Unit Total resets upon a care transition and when the injection site has been connected to another tablet.

![Figure 12 - Unit Total](image)

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 ordered by importance and time. The Message icon shows the number of unaddressed messages for you. Clinical messages that have higher importance, such as allergy alerts, will appear in the center of the display screen (See Figure 28).

In Figure 10 the patient has “No known allergies”. If the patient has allergies that text is replaced by a button. The number on the button indicates the number of allergies. Touching the button opens the Potential Allergic Reaction pop-up.

![Figure 13 - Allergies Button](image)

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. The first icon to the right of the Bar specifies whether the computer speakers are muted or unmuted. The battery icon indicates the remaining amount of charge on the computer. A third icon indicates if wireless communication between the gateway and the tablet are active. Lastly, the hospital network time is shown. Should the gateway/hospital server lose communication, a yellow message will display in the center of the Title Bar to inform you.
Nursing View

The Nursing View is a second screen for you to interact with the BD Intelliport™ system. It is accessed by touching the Nursing View button from the Main menu. 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.

![Figure 14 - Nursing View](image)

The Nursing View has many of the features of the Anesthesia View; however it is arranged in a tabular format. The column headings in this view include time administered, medication with concentration, 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. Vertical touch motion on the tablet 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 functions are available from this screen.

The Add menu is accessed from the Add Button in the lower right corner of the screen.

<table>
<thead>
<tr>
<th><strong>Add Menu Options</strong></th>
<th><strong>Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Add Injection" /></td>
<td>Select this option to record details about an injection given prior to activating an Injection Site, given through a port other than the BD Intelliport™ Injection Site. See “Adding Manual Injection” for more information.</td>
</tr>
<tr>
<td><img src="image" alt="Add Comment" /></td>
<td>Select this option to record general comments. (there are additional ways to pair a comment with an allergy or drug injection). See “Adding a Comment” for more information.</td>
</tr>
</tbody>
</table>

Table 2 - Add Menu Options
**Pause Case**
Select this option when transferring a patient to another care area. In doing so, it disconnects all connected BD Intelliport™ Injection Sites in preparation for transfer. See Transferring a Patient from One Care Area to Another on page 51.

**Power Down Port(s)**
Select this option when the case has ended. This powers down the Injection Site. See Power Down the Injection Site at the End of a Case on page 71.

**Switch User**
Select this option to change the clinician logged in, if so configured.

**Print Reports**
Select this option to print the Controlled Substance, Handoff, and Medication Administration reports. See Printing a Report (for Paper Anesthesia Records) on page 81 for more information.

**Change Time Scale**
Select this option to toggle between 1 minute, 5 minute and 10 minute time intervals on the Anesthesia View flow sheet.
<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmute (Mute)</td>
<td>Select this option to toggle between audible announcements and mute. This button overrides the setting made in the Preferences screen.</td>
</tr>
<tr>
<td>Preferences</td>
<td>Select this option to view and modify preferences for announcements, volume and screen brightness. See Setting User preferences on page 83.</td>
</tr>
<tr>
<td>Review Case</td>
<td>Select this option to review and finalize the Medication Administration report. It’s available in the Paper Anesthesia Records mode only. See Reviewing the Medication Record (for Paper Anesthesia Records) on page 80 for more information.</td>
</tr>
<tr>
<td>Controlled Drugs</td>
<td>Select this option to switch to the Controlled Drugs screen. See Viewing Controlled Drugs on page 56 for details on the screen.</td>
</tr>
<tr>
<td>Nursing View</td>
<td>Touch this button to switch to the Nursing View from the Anesthesia View. See Nursing View on page 30.</td>
</tr>
<tr>
<td>Anesthesia View</td>
<td>Touch this button to view the Anesthesia View from the Nursing View. See Anesthesia View on page 28 for more information.</td>
</tr>
<tr>
<td>Help</td>
<td>Select this option when seeking assistance in operation. It provides helpful information, including the Directions for Use.</td>
</tr>
</tbody>
</table>

**Table 3 - Main menu buttons**

**Configuration for AIMS**

**NOTE:** The gateway has an interface engine to exchange data with networked hospital information systems. When configured as a companion to an Electronic Medical Record (EMR) system, the gateway is designed to send medication administration data to the EMR system across a common software interface. A software interface with the corresponding EMR system is required for the system to operate as described in this section.

When used in a hospital having electronic medical records in the perioperative care areas, the tablet serves as a companion to the EMR system or anesthesia information management system (called an AIMS). In this configuration, the tablet provides a real-time display while the drug is being injected, then it sends the injection data in real time to the EMR. Refer to the tablet for immediate information about a medication being administered; refer to the AIMS for a history of medications given.
The Configuration for an AIMS varies slightly based on the care area:

- **Operating Room** - Each tablet in an operating room gets assigned to an AIMS workstation when it is registered at the gateway. The tablet communicates with the AIMS workstation, and the AIMS workstation automatically shares the case and patient with the tablet. Medications administrations from an injection site wireless synchronized with the tablet are assigned to the patient at the AIMS. The tablet sends reviewed medication administrations automatically to the AIMS workstation whereby they display in the anesthesia flowsheet.

- **PACU/Recovery** - Tablets in the recovery area do not require an AIMS workstation assignment. Medications administrations from an injection site wireless synchronized with the tablet are allocated to the patient assigned to the injection site in the operating room. The tablet sends reviewed medication administrations automatically to the AIMS. And the AIMS routes it to the appropriate workstation displaying the patient’s record.

The tablet workflow follows a three-step approach consisting of 1) connecting the BD Intelliport™ Injection Site, 2) verifying the patient information received from the EMR, and 3) giving injections. Refer to Chapter 9, Directions for Use, which starts on page 35 for information on connecting the tablet to an injection site and setting up a patient.

The Companion View is the primary screen for clinicians to interface with the BD Intelliport™ system. This View provides information about the patient, displays drug name/concentration and dose for the current injection, relevant clinical and system messages and a history of medications delivered.

![Figure 16 - Configuration for AIMS](image)

The Companion View consists of the following screen features: 1) Active Injection Bar; 2) Title Bar with clinician name and configured tablet location; 3) Case Header information on patient name, MRN, Patient identification number; 4) Allergies; 5) Clinical or system Messages; and 6) history of medications delivered.
8. Complete Device Description

**Injection Bars** - Up to three injection bars display on the screen, one corresponding to each wirelessly connected injection site. Each injection bar is a real-time representation of the medication being administered through an injection site. When an encoded syringe is attached to an injection site, the injection bar displays the drug name and concentration. When a non-encoded syringe is attached, the Injection Bar will read “Select Med” prompting you 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 medication dosing, the medication and dose will pass immediately to the EMR with a confirmation message confirming such in the message area. See Figure 17.

A color tile corresponding to American Society for Testing and Materials International (ASTM) standards displays to the left of the drug name.

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

Historical Medication List displays in reverse order of medications delivered. **The Message Section displays clinical and system messages prioritized by importance and time.** The Message icon shows the number of unaddressed messages for you. Clinical messages that have higher importance, such as allergy alerts, will appear in the center of the display screen (see figure 28 on Page 42).

**The Title Bar** displays across the top of the screen. It includes the name of the clinician logged in (if so configured by the Administrator) and the location assigned to the tablet. The name of the companion workstation location displays when paired with a companion AIMS workstation in the operating room. The first icon to the right of the Bar specifies whether the computer speakers are muted or unmuted. A second icon, the battery icon, indicates the remaining amount of charge on the tablet. The third icon indicates if wireless communication between the gateway and the tablet are active and lastly, the hospital network time is shown. Should the gateway/hospital server lose communication, a yellow message will open in the center of the Title Bar to inform you.
Chapter 9. Directions For Use

READ ALL INSTRUCTIONS BEFORE USING. SAVE THESE INSTRUCTIONS.

The BD Intelliport™ system is designed with your drug administration needs, safety and workflow in mind. This chapter acquaints you with the BD Intelliport™ system operational modes, display views, controls and indicators. It also provides general information on use of the device.

How it Works

The medication administration process using the BD Intelliport™ system is illustrated in Figure 4. Prior to treatment, you prepare and connect the injection site to the patient’s catheter or injection port (Y-site). During medication administration, you perform standard drug-delivery of bolus medications.

When a syringe is attached to the injection port, the injection site identifies the medication and concentration for an encoded syringe by optically imaging and decoding a barcode on the BD Luer-Lok™ collar of the syringe. This information is wirelessly transmitted to the tablet and the tablet displays and audibly announces the drug attached. It also may perform allergy safety checks.

As the drug is pushed, the injection site measures the volume dosed ultrasonically. The BD Intelliport™ Injection Site wirelessly sends volume measurement information to the tablet. The tablet uses this information to provide clinicians with a medication administration record which is time stamped and displays for clinical reference during surgical procedures. Manually entered information pertaining to non-encoded drug injections may be included in the patient medication record.

The tablet 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.

Operation: AIMS Configuration

This Section describes how to operate the system when configured to record manual IV bolus medication administrations at hospitals using an Anesthesia Information Management System (AIMS) for the anesthesia record. The BD Intelliport™ system records and shares information about medication administrations with the AIMS. Medications delivered through the injection site are automatically charted in the AIMS flowsheet. Refer to Section Operation: Paper Charting Configuration for operating instructions if your hospital is configured for paper anesthesia record keeping.

Preparing the BD Intelliport™ Injection Site

The BD Intelliport™ Injection Site must be assembled, prepared and attached to an IV line before use. Follow the instructions located on the BD Intelliport™ Sensor packaging (pouch).

1. Gather a BD Intelliport™ Sensor in its sterile packaging and a fully-charged and disinfected BD Intelliport™ Base and three (3) 10mL flush syringes. Before attaching to the Y-site of the primary IV fluid line follow instructions on the BD Intelliport™ Sensor packaging (pouch).

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

NOTE: Confirm that both Sensor tabs are fully engaged to base.
9. Directions For Use

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

⚠️ Verify the BD Intelliport™ Sensor sterile packaging (pouch) is intact prior to opening, including all the packaging surfaces (edges, top and bottom plastic surfaces). Discard Sensor if packaging is damaged and replace with new Sensor.

⚠️ Verify that the BD Intelliport™ Sensor tubing end cap is still in place. Discard Sensor if the end cap has become detached. Replace with another Sensor.

**NOTE:** **Keep the end cap on the BD Intelliport™ Sensor while the Injection Site is being assembled and being prepared. Failure to prime with a cap may prevent the sensor from going ready.**

2. Attach the BD Intelliport™ Sensor to the BD Intelliport™ Base by joining the BD Intelliport™ Sensor (tubing side) and BD Intelliport™ Base front section first, and then snap the two together.

An audible snapping sound should be heard and both white tabs on the Sensor should be fully engaged to the base. Connecting the BD Intelliport™ Sensor to the BD Intelliport™ Base automatically powers on the injection site.

![Attach Sensor to base by hooking base tab into Sensor hole first]

![Then “snap” together by pressing firmly on Sensor and hear a “click”]

![Press Firmly Here]

![Hook tab into Hole]

![Tabs]

![Green light will flash green when the BD Intelliport™ Sensor is properly attached to the BD Intelliport™ Base]

![“Runway lights” — sequential green lights will illuminate during flush, when the sensor is deemed ready]

**Figure 18 - Connect BD Intelliport™ Sensor to BD Intelliport™ Base**

The connection of BD Intelliport™ Sensor to the BD Intelliport™ Base is verified by a blinking green light on the BD Intelliport™ Base. If you don’t see this, view the injection site on its side to determine if the two are properly connected. If you see a space between the BD Intelliport™ Sensor and the BD Intelliport™ Base, then they are not attached properly. Separate the two pieces and re-attach. Confirm that both Sensor tabs are fully engaged to base. If you don’t see a blinking green light, replace the BD Intelliport™ Sensor and the BD Intelliport™ Base as needed.

**Figure 19 - BD Intelliport™ Base lights**
9. Directions For Use

NOTE: the Injection Site should not be attached to the patient IV line at this point.

3. With the end cap in place, attach the 10mL flush syringe (purged of air bubbles) to the BD Intelliport™ Site and push 4mL sterile IV fluid with full force. Wait 5 seconds, then push an additional 5mL of fluid with full force.

NOTE: Avoid pushing the plunger to the bottom of the flush syringe. The injection site measures the medication ultrasonically. When the plunger reaches the bottom, residual bubbles in the flush syringe can become introduced into the injection site - resulting in additional user interaction at the Tablet.

4. As you push, watch for sequential green flow indicator lights (runway lights) on the base.

5. If the sequential green flow indicator lights do not illuminate, wait 5 seconds and repeat Steps 3 and 4 with additional flush syringes, until the runway lights illuminate.

If the sequential green flow indicator lights illuminate, then the Injection Site is ready for use.

⚠️ Use aseptic technique when handling the BD Intelliport™ Sensor IV connections

⚠️ Check for a blocked fluid path or leaking fittings when preparing the BD Intelliport™ Sensor.

Recognizing a sufficiently prepared Injection Site: A sufficiently prepared injection site displays a series of green indicator lights on the base when flushing the Sensor. If green lights are not visible when flushing the Sensor, repeat steps 3 and 4 above.

Recognizing a sufficiently prepared Sensor when in the vicinity of a tablet having a case underway: A sufficiently prepared injection site displays a green “Ready” message on the tablet. If there is a yellow “Continue Flushing” message, repeat steps 3 and 4 above.

⚠️ If the Sensor is not sufficiently prepared it may cause inaccurate dose measurement.

6. Attach the injection site to the Y-site of the primary IV fluid line.

⚠️ Verify that the BD Intelliport™ Injection Site is securely Luer locked to the Y-site and the IV tubing is free from kinks before operating.

⚠️ After flushing, visually inspect the IV line for leaks, air, or blockage.

⚠️ There is no check valve in the BD Intelliport™ Sensor, nor is one needed to use the BD Intelliport™ Sensor safely and effectively. Should you choose a stopcock, manifold or check valve can be used. If you intend to leave a syringe in place for a long duration, it is recommended that you use a check valve to prevent backflow.

7. Where appropriate, secure the injection site to a surface in preparation for giving injections. Avoid kinks in the line between the injection site and IV line.

The BD Intelliport™ Injection Site is now ready for delivery of IV medications. Any medications given through the injection site will be recorded in the BD Intelliport™ Base memory. You should see the sequential green flow indicator lights during all injections.

⚠️ If a new base is required (mid-case), disconnect sensor from IV line. Flush sensor with normal saline until “Ready” displays on Tablet or base lights are seen.
Set up the Tablet at the Start of a Case

Before each use with a patient, the tablet must be set up to wirelessly communicate with the injection site and to be associated with a patient.

1. Touch the screen to undim. If not powered on, turn on the tablet by pressing and holding its power switch.

The tablet can operate on battery power alone (not plugged in to a power supply) for a few hours. For extended use verify the tablet is plugged in prior to use by checking the power indicator icon on the Title bar on the tablet screen.

On startup, the initial screen displays information about the software, drug library and configuration versions—as well as information on network connectivity. Take time to allow the tablet to boot-up prior to using. Contact your System Administration if so instructed.

The Login screen will display.

2. Type your User Name and Password, and then touch the Log In button.

The Login screen hides when the user name and password has been authenticated.

A blue pop-up displays so long as the case has not yet started at the AIMS. You are unable to proceed with the tablet until a case has been started at the companion AIMS workstation.
3. Confirm the patient’s full name, patient ID, medical record number and birth date from the patient and wrist band match the information on the screen. Press the Verify button to confirm. Do not proceed if the patient information does not match. Otherwise, proceed to wirelessly connect the injection site to the tablet.

4. Identify the 4-digit number on the BD Inteliport™ Sensor.

A list of BD Inteliport™ Injection Sites within wireless range is viewable as well. The distance between the BD Inteliport™ Injection Site and a tablet should be 10 meters or less in order for the BD Inteliport™ Injection Site to send and receive wireless communications.
5. Identify the 4-digit number on the BD Intelliport™ Sensor that is connected to the patient’s IV line.

6. Match the serial number on the Sensor to a serial number on the setup screen.

7. Check the injection site has a fully charged battery and sufficiently prepared.

   **Sufficiently Prepared** – A sensor that was sufficiently prepared has a green “Ready” icon to the right of the MRN. If a Sensor was not sufficiently prepared (sufficiently flushed), a yellow icon stating “Continue Flushing” will display on the right hand side of the screen. The Sensor is not ready. Remove the injection site from the IV line and repeat the injection site preparation steps in the Prepare the BD Intelliport™ Sensor section above. Attach the fully prepared BD Intelliport™ injection site to the Y-site of the patient’s primary IV fluid line.

   **⚠️ Not preparing the Sensor before use may introduce air into the IV line or cause inaccurate dose measurement.**

   **Fully Charged Battery** – A fully charged battery icon shows four green bars. A fully-charged BD Intelliport™ Base has sufficient power for 24 hours of use under typical conditions. Inspect the BD Intelliport™ Base charge level. Replace a BD Intelliport™ Base with less than 25% charge. This can be done at any time, so long as an injection is not being given.
The battery icon will be yellow when less than 25% of battery charge remains (approximately 4 hours under typical conditions).

⚠️ Consider replacing with a fully-charged BD Intelliport™ Base before connecting.

8. Select the injection site for your patient by touching and highlighting the appropriate BD Intelliport™ Injection Site serial number.

9. A dose can be edited at the AIMS at any time or at the Tablet when there is a message present (prior to it being sent to the AIMS).

10. Verify that the green and yellow lights are flashing on the injection site itself. Should you miss the visual confirmation, touch appropriate BD Intelliport™ Injection Site on the tablet again to initiate the blinking lights.

The screen will highlight your selection.

11. Touch the Confirm button to complete the setup.

The BD Intelliport™ Injection Site will illuminate a single, repeating green light when it is wirelessly connected to the tablet and associated with a patient.

If the wrong patient was inadvertently confirmed to the tablet, then the injection site cannot be used. Discard the Sensor and replace it with an unused Sensor. If an injection has been recorded at the AIMS, then correct the patient’s medical record at the AIMS by removing the doses that were assigned to the wrong patient as a result of the mistake.

Following Patient Setup, Tablet displays a reminder to flush the injection site with a flush syringe after each dose. Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site. Read and acknowledge. “The tablet displays medication allergies for the selected patient. Food and environmental allergies are not available (figure below).
The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.

The tablet does not display nor alert to food or environmental allergies.

The BD Intelliport™ system receives drug allergy information from the hospital information system (HIS). The tablet will not display an allergy alert if the allergy has not been recorded in the HIS or if the medications is not listed in the Device Drug Library.

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

If the patient allergies are not available for the tablet, the message “Unable to Obtain” displays. Verify allergy information following your current practice (or hospital guidelines).

If the patient does not have allergies, the allergy screen with “No Known Allergies” message displays.

11. Removing Injection Site Preparation Flushes from the Record

Because the flushes used to prepare the sensor are not administered to the patient, it is important to distinguish those at the Tablet. Each flush syringe attached to the Injection Site during preparation will display in the medication history section as a “Select Med” (if not encoded) or “Normal Saline Flush” (if encoded).

**NOTE:** Normal saline flush may not display on the medication history, if so configured.

Locate each flush and modify the volume to 0mL to remove it from the medication history.

- For syringes not having encoding refer to the Medication Delivery with Syringes Not Having Encoding section for instruction to modify.

- For encoded flush syringes touch the Edit button. The Modify Selected Medication box will appear. Change the volume to 0mL and tap “Save”.

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**Figure 28 - Patient Allergies**
Giving an IV Injection Using the BD Intelliport™ Injection Site

In the event of a BD Intelliport™ system or BD Intelliport™ Injection Site failure, (excluding the IV fluid pathway), the injection site will allow standard medication or fluid delivery through the port.

1. Clean the injection port by swabbing the hub according to your hospital procedure.

   ▶ 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.

   ▶ Check the medication syringe before connecting to the BD Intelliport™ Injection Site for air or bubbles. If present, make sure all air or bubbles are removed from the syringe before connecting the medication syringe and injecting the medication.

2. Double check each medication name and concentration on the syringe prior to attachment to the injection port to assure "right medication."

3. Attach a syringe to the BD Intelliport™ Injection Site starting with the barrel label visible on top, and rotate the syringe barrel a full 180 degrees (and not beyond) to ensure the syringe is properly seated (graduations will be visible on top).

   When connecting and disconnecting the syringe always use a "straight-on/straight off" approach. Once the syringe is attached, make sure the syringe and injection port are aligned in a straight line with no angles at the connection.” Incorrect seating of the syringe may result in the tablet not announcing the medication and recording dose.

   ![Figure 29 - Proper Syringe Alignment](image1)
   ![Figure 30 - Improper Syringe Alignment](image2)

   ▶ The system is not recommended for use with non-BD Luer-Lok™ syringes. When using a syringe without a BD Luer-Lok™, medication should be administered through an available y-site on the primary IV line and documented manually.

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

4. Verify the drug and concentration displayed and announced by the tablet is the intended drug and concentration.

   For syringes not having encoding, see Medication Delivery when Syringes Not encoded on page 46, then return to this step. The BD Intelliport™ Injection Site will flash red, green and yellow lights if a medication allergy is detected.

   ▶ Use clinical judgment before proceeding when the tablet announces and displays a known allergy for the drug attached to the injection site. Allergy messages display as below:
Figure 31 - Potential Allergy Reaction Screen

The Potential Allergy Reaction screen appears when either of these conditions is true:

- An encoded syringe is inserted into the Sensor and the drug matches the patient’s allergy profile.
- A non-encoded syringe is inserted into a Sensor and you select a drug from the Select Medication screen (Figure 34) that matches the patient’s allergy profile.

4. If the Potential Allergy Reaction box has appeared take the appropriate action and then touch the OK button to close the box.

5. While delivering the medication, observe the graduations on the syringe to determine the amount of drug delivered.

**DO NOT LOOK at the tablet screen while administering a medication. The only accurate way to administer a medication is to look at the graduations on the syringe. Looking at the tablet screen during medication administration can lead to underdose and overdose and the user may not be aware that the incorrect dose was given.**

Figure 32 - Medication Administration

For Sensors sufficiently prepared, green lights on the base illuminate to provide a visual confirmation that the volume being injected is measured.

- Do not lift up on the syringe while delivering medication.
- 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.

6. Disconnect the syringe, and verify dose shown in the tablet.
In the event of a BD Intelliport™ system or BD Intelliport™ Injection Site failure, (excluding the IV fluid pathway), the injection site will allow standard medication or fluid delivery through the port.

**7. Flush the injection site with a normal saline syringe after each dose where retained medication in the injection site has clinical implications.**

- Unless flushed using a syringe, 0.334 mL of medication will remain in the injection site after each dose. This is different from your current practice. Your IV line will not flush the injection site.
- Failure to flush the injection site with a syringe may result in under-dosing of the patient.
- Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site.

If encoded, “Normal Saline flush” appears on the active injection bar with the amount of mL delivered. Normal saline flush may not display on the medication history, if so configured.

8. A dose can be edited at the AIMS at any time or at the Tablet when there is a message present (prior to it being sent to the AIMS).

9. If the tablet determines user interaction for this dose is required, a message will display. Read the message and respond accordingly. Refer to Section Responding to Messages for information.

Otherwise, the tablet sends medication administration information directly to the AIMS when the dose has been completed. The tablet will display the Sending message until it gets confirmation that the AIMS has received the message. It displays Sent when confirmed.

10. Verify each medication administered and associated dose using the injection site displays in the AIMS flowsheet. Edit if needed.

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

When the BD Intelliport™ system is integrated with an AIMS, all medications given through the injection site are automatically charted to the anesthesia record. To prevent duplicate charting of medications, do not manually chart at the AIMS workstation for those medications administered using the injection site.
Medication Delivery with Syringes Not Having Encoding

The BD Intelliport™ system is designed to work with both encoded and non-encoded syringes. When a non-encoded syringe is attached to the Sensor, the blank collar triggers the base and the tablet displays the Select Medication pop-up, which contains the perioperative medication list.

1. Deliver the medication as described in Section Giving an IV injection using the BD Intelliport™ Injection.

When the syringe attaches to the injection site, the tablet announces “Select Medication” and a pop-up displays prompting you to specify the medication. Medications for which the patient has an allergy will be highlighted in red (e.g. cefazolin in Figure 34).

You can identify the medication in the syringe before giving the injection (recommended) or afterwards. You should verify all medication selections on the tablet. If postponed, the tablet tracks injections not yet identified and later prompts you to resolve them.

2. Select the medication, concentration and container type from the Select Medication dialog box by touching its name.

NOTE: The tablet provides pre-configured medication concentrations that align with those in the AIMS workstation. To record a medication concentration other than one listed at the tablet, make the change at the AIMS workstation.

3. If the desired medication is not found on the Select Medication dialog touch the View All Meds button to view a longer list of perioperative medications.
4. You can filter the list by touching the first letters of the drug name using the keypad.

5. Highlight the desired medication and concentration, verify the information and touch the Save button.

The tablet sends the medication administration information to the AIMS upon saving.

**Specifying a Diluted or Reconstituted Medication**

The tablet provides a simple approach to document medications given with a non-encoded syringe that require dilution or reconstitution from a powder form prior to preparation for injection. It tracks frequently diluted and reconstituted medications. The tablet prompts you to confirm dilution or reconstitution by a message and an accompanying Edit button.

**NOTE:** The tablet provides pre-configured medication concentrations that align with those in the AIMS workstation. To record a medication concentration other than one listed at the tablet, make the change at the AIMS workstation.

⚠️ When reconstituting medications, make sure the granules/powder is completely dissolved prior to connecting the medication syringe to the BD Inteliport™ injection site.

1. Pick the medication and concentration from the list in the Select Med popup.

2. Press Save.

   A prompt displays if the concentration selected is typically diluted before being administered to the patient or if it is reconstituted and you want to adjust the volume to have the dose match the dose given.

3. Press the Send button adjacent to the medication in the pending medication list if the appropriate dose displays. Otherwise, press the Edit button to select a different dilution or to modify the volume given.

The tablet sends the medication administration information to the AIMS upon saving.

**Specifying a Mixed Medication (Admixture)**

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

- Propofol/lidocaine
- Propofol/Fentanyl
- Propofol/Ketamine
- Neostigmine/Glycopyrrolate
- Atropine/Edrophonium
- Naloxone/Edrophonium
The tablet provides a simple approach to document mixed medications. It tracks frequently mixed medications, if configured on the tablet, and it prompts you to confirm whether a drug has been mixed. If not configured, no user action is required.

1. To specify a mixed medication, Press the Edit button adjacent to the medication in the pending medication list.

   The Modify Selected Medication pop up displays two medication name slots, with the first one already identified.

2. Touch the bottom field. The Select Medication pop-up opens.

3. Select the desired drug from the list.

   Touching the Other button allows you to identify the correct medication from the Frequent Use or perioperative drug library list.

4. Enter the total dose injected followed by one of the medications partial doses in it’s respective text field. The other will auto-populate.

5. Touch the Save button.

The tablet sends the medication administration information to the AIMS upon saving.

**Address Pending Medications**

When configured for AIMS integration, the tablet sends medication administration information in real time unless a user response to a message is required or information is missing. The missing information could include the drug name/concentration of a non-encoded syringe, the dose of a reconstituted drug, or use of an admixture. In these situations, the tablet retains this medication administration in a pending list until you resolve it.
Directions For Use

Promptly resolve pending medications. It is good practice to resolve medication administrations prior to a care transition or closing a case.

A list of medication administrations display below the Active Injection Bar, when the Show All check box is selected (lower left corner). This includes medications that have previously been sent to the AIMS as well as those that require resolution. The tablet does not send medication administrations to the companion AIMS when information is pending.

**NOTE:** Unselecting the Show All checkbox will show pending medications administrations (requiring resolution) and hide medication administrations that have been sent.

1. Review the list after each injection. The list includes the time administered, medication and concentration, volume, dose and reason for review (e.g. unencoded syringe, medication identified as frequently diluted).
2. Touch the Show All button at the bottom of the screen to display all medications. The display indicates any that require resolutions.
3. Read each medication administration and answer those that have not been sent because a question exists.

For example, a question may prompt you to confirm whether epinephrine has been diluted.

A. Touch the Send button if no changes are required for that medication administration. Doing so will send this information to the companion AIMS and display a message that it was sent.

B. Touch the Edit button to answer questions about the medication administration (e.g. concentration, volume or dose).

As each medication administration is resolved, the unresolved record will no longer display.

**Responding to Messages**

The BD Intelliport™ system provides two types of messages: “Clinical” and “System.” “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, such as tablet battery charge.
Messages provide instructions and a button for acknowledging or resolving. Refer to Messages and Troubleshooting on page 85 for resolving messages. Messages display in the Message chapter of the tablet 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, you are prompted to respond/answer unresolved medication messages generated during the case.

Clinical messages originating in a prior care area will display in subsequent care areas, if not already acknowledged by the user.

**Transferring a Patient from One Care Area to Another**

**Prepping to Leave the Operating Room**

It is important to prepare the patient and tablet prior to moving the patient from one care area to another.

1. Pause (also called suspending, or closing) a case at the AIMS as you typically do. The tablet will prompt you to review each dose for accuracy at the EMR. A medication administration may have been automatically sent to the EMR which does not exactly match what you intend to have charted. Review and adjust at the EMR, as appropriate.

   The tablet will prompt you to confirm you want to Pause the tablet. Doing so will disconnect the injection site(s) from the current tablet. This enables another tablet in a subsequent care area to connect to the injection site(s).

2. Respond to any messages for Pending meds.

   It is good practice to resolve Pending meds before the care transition. If any medication administrations have been incompletely processed (Sending, Resolution pending, manual verification), those messages will also be available following the care transition at the next tablet.

3. Press Confirm at the tablet.

   **NOTE:** Injections given through the injection site while not connected with a tablet will be saved in the Injections Site's memory and uploaded to the next tablet when wirelessly connected.

   ! Prior to patient transport, secure the IV and the BD Intelliport™ Injection Site with the patient to avoid intravenous line disruption and patient injury.

**Continuing at the Recovery Area**

    ! When the BD Intelliport™ system is integrated with an AIMS, all medications given through the injection site are automatically charted to the anesthesia record. To prevent duplicate charting of medications, only use the injection site for medications intended for the anesthesia record.

Before viewing patient information at a tablet in the recovery area, the tablet must be set up to wirelessly communicate with the injection site.

1. If not powered on, turn on the tablet by pressing and holding its power switch.

   The tablet can operate on battery power alone (not plugged in to a power supply) for a few hours. For extended use verify the tablet is plugged in prior to use by checking the power indicator icon on the Title bar on the tablet screen.

   On startup, the initial screen displays information about the software, drug library and configuration versions—as well as information on network connectivity. Take time to allow the tablet to boot-up prior to using. Contact your System Administration if so instructed.

   The Login screen will display.

2. Type your User Name and Password, and then touch the Log in button.

3. At the new care area, a list of BD Intelliport™ Injection Sites within wireless range is viewable on the Patient Setup screen.

4. Identify the patient’s full name, patient ID, medical record number and birth date from the patient and wrist band. Locate the patient information on the setup screen.
9. Directions For Use

NOTE: If the case was not paused at the tablet and the patient is moved to a subsequent care location that is within about 30 feet of the earlier tablet, the injection site(s) will remain wirelessly connected to the earlier tablet. In this situation, you can disconnect the BD Inteliport™ Injection Site by touching the Show All button from the Patient Setup screen and following the screen instructions.

5. Select the injection site for your patient by touching and highlighting the appropriate BD Inteliport™ Injection Site serial number.

6. Verify that the green and yellow lights are flashing on the injection site itself. Should you miss the visual confirmation, highlight by touching the appropriate BD Inteliport™ Injection Site again to initiate the blinking lights.

The screen will highlight your selection.

7. Touch the Confirm button to complete the setup.

The BD Inteliport™ Injection Site will illuminate a single, repeating green light when it is wirelessly connected to the tablet and associated with a patient.
If the wrong patient was inadvertently confirmed to the tablet, then the injection site cannot be used. Discard the Sensor and replace it with an unused Sensor. If an injection has been recorded at the AIMS, then correct the patient’s medical record at the AIMS by removing the doses that were assigned to the wrong patient as a result of the mistake.

8. The Tablet displays a reminder to flush the injection site with a flush syringe after each dose. Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site. Read and acknowledge.

Following Patient Setup, the tablet displays medication allergies for the selected patient. (figure below).

![Figure 40 - Patient Allergies with Flush reminder](image)

- The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.
- The tablet does not display nor alert to food or environmental allergies.
- The BD Intelliport system receives drug allergy information from the hospital information system (HIS). The tablet will not display an allergy alert if the allergy has not been recorded in the HIS or if the medications is not listed in the Device Drug Library.
- Before using the tablet, check the volume of audible alerts to ensure they are not muted. Silencing the alerts may adversely affect patient safety.
- If the patient allergies are not available for the tablet, the message “Unable to Obtain” displays. Verify allergy information following your current practice (or hospital guidelines).
- If the patient does not have allergies, the allergy screen with “No Known Allergies” message displays.

The tablet displays the Active Injection bar. The system is ready to continue care.

Power Down the Injection Site at the End of a Case

It is good practice to power down the injection site when the surgical case has ended. Once powered down you will be unable to record injections using that injection site.

Do not power down the Injection Site unless the injection site is no longer in use. Doing so will prevent additional medication administrations from being recorded for this case.

1. From the tablet menu, Press Power Down Ports.
2. A message will prompt you to confirm. The tablet will prompt you to review each dose for accuracy at the EMR. A medication administration may have been automatically sent to the EMR which does not exactly match what you intend to have charted. Review and adjust at the EMR, as appropriate.
NOTE: If you do not power down an Injection site - but instead deactivate it by disengaging the Sensor from the base, the gateway will administratively close the case if a specified time has elapsed without activity. The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.

**Deactivating a Device, Disposing of the Sensor, and Preparing the Base for Reuse**

When the injection site is no longer in use:

1. Disconnect the Sensor from the base by squeezing together the two finger tabs on top of the Sensor while lifting up to disengage from the base.

   When properly separated, the base will power off and stop transmitting wirelessly to the tablet.

![Image: Sensor Removal]

   2. Dispose of the Sensor according to your hospital’s medical waste protocols.

   ![Image: Sensor Removal]  
   To remove Sensor from Base, Squeeze together white Sensor tabs

   ![Image: Sensor Removal]  
   Lift Sensor from Base, Dispose of Sensor. Clean and recharge Base.

   3. Clean and disinfect the base. The first wipe with a commercial hospital disinfectant will clean and the second wipe will disinfect. Follow the disinfectant manufacturer’s instructions.

   For a list of approved hospital products to use, refer to Appendix C on page 90.

4. Allow it to dry.

5. Inspect the base for cracks or damage.

6. If damage is evident, then dispose of it according to your hospital’s protocols.

7. Insert the base into the charger.

   ![Image: Sensor Removal]  
   Charging of the BD Intelliport™ Base should not occur on or in immediate proximity to the patient. The plug on the power supply is used for isolation from the supply mains.

8. If the base has reached its End of Life as indicated by a message on the tablet screen or by a persistent red light when seated on the charger, then dispose of it according to your hospital’s protocols for electrical waste.

   The base contains a lithium ion battery.

   ![Image: Sensor Removal]  
   The base will illuminate a red light while charging if it has exceeded its Useful Life.
Special Activities

Giving Injections Without a Tablet Present

We recommend administering medications while the injection site is wireless connected to the tablet. The tablet provides medication announcement/identification, dose measurement, alerting and documentation in the AIMS anesthesia flowsheet. The injection site also supports medication administrations when a tablet is not present. In this situation, the injection site operates like a standard y-site. It also retains the dose information until it later connects to a tablet.

1. Deliver medication according to the instructions described in the Section Giving an IV injection using the BD Intelliport™ Injection Site.

⚠ Avoid disconnecting the Sensor from the base and replacing it with a different Sensor before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

⚠ Avoid completely depleting the battery charge on the base before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

2. When the patient moves to another care area having a tablet present, follow the instructions to in Section Set up the Tablet.

Once connection to a tablet, prior medication administration history displays along with allergy alerts, if any.

3. Respond to messages, as appropriate and confirm all doses given while not connected to the tablet are correctly recorded.

Adding Additional Sensors

The BD Intelliport™ system can accommodate up to three BD Intelliport™ Injection Sites connected to one patient at a time. An additional BD Intelliport™ Injection Site can be added at any time during a case. The first connected BD Intelliport™ Injection Site displays at the topmost injection bar. The second in the middle and the third the lowermost injection bar. See Figure 17.

When an injection site is connected to a tablet and there is no syringe attached to the Sensor, the active injection bar reads “Sensor Connected, No syringe attached”.

A battery status icon in the upper right corner of the injection bar indicates the battery charge level of the base to which the Sensor is connected. The battery status icon in the upper right corner of the screen indicates the battery charge level of the tablet. See Figure 42.

To add an injection site:

1. Prepare an injection site according to the instructions in Preparing the Sensor on page 35.

   Verify green “Ready” on the tablet screen. If the Sensor is not sufficiently prepared it may cause inaccurate dose measurement.

2. Touch “Add Port” button to display a pop-up window that lists available BD Intelliport™ Injection Sites within wireless range.

3. Identify the 4-digit number on the BD Intelliport™ Sensor.

4. Highlight (select) your BD Intelliport™ Injection Site based on the time of initial activation and the four-digit number on the BD Intelliport™ Sensor.
A low battery icon displays when the selected base has less than 10% of battery power remaining. The selected base flashes for three seconds.

5. Verify that the green and yellow lights are flashing for the correct base.

⚠️ Should you miss the visual confirmation, highlight the appropriate BD Intelliport™ injection site again to initiate the blinking lights.

1. If the identified Sensor is correct, touch Connect.

2. Touch Confirm.

3. Verify the base is flashing a single, repeating green blinking light indicating it is wirelessly connected to the tablet.

   An Active Injection Bar displays the connected Sensor. See Figure 33.

**Viewing Controlled Drugs**

The Controlled Drugs screen lists all controlled drugs administered from the beginning of the case. It’s accessed by selecting the Controlled Drugs option on the Main Menu.
The screen shows this information on each injected controlled drug:

- **Drug Name and Concentration**
- **Volume Given** – displayed in mL rounded to the nearest 0.1 mL
- **Number** – Injection sequence number
- **Time** – Time injection ended (syringe removed or timeout)
- **Dose** – dose from the medication administration history
- **Dose Changed** – If the medication administration occurred through the Sensor and a clinician has changed the dose, the text displays along with the original volume.

If the sequential green flow indicator lights illuminate, then the Injection Site is ready for use.

⚠ Use aseptic technique when handling the BD Intelliport™ Sensor IV connections

⚠ Check for a blocked fluid path or leaking fittings when preparing the BD Intelliport™ Sensor.

**Recognizing a sufficiently prepared Injection Site:** A sufficiently prepared injection site displays a series of green indicator lights on the base when flushing the Sensor. If green lights are not visible when flushing the Sensor, repeat steps 3 and 4 above.

**Recognizing a sufficiently prepared Sensor when in the vicinity of a tablet having a case underway:** A sufficiently prepared injection site displays a green “Ready” message on the tablet. If there is a yellow “Continue Flushing” message, repeat steps 3 and 4 above.

⚠ If the Sensor is not sufficiently prepared it may cause inaccurate dose measurement.

- **Volume Changed** – If the medication administration occurred through the Sensor and a clinician has changed the volume, the text displays along with the new volume.
- **Manually Recorded** – if the dose has been entered manually. To exit the screen select another view from the menu.
TECHNICAL SUPPORT:
Dial 866-488-1408 and select option 4
OPERATION: PAPER CHARTING CONFIGURATION

This Section describes how to operate the system when configured to record manual IV bolus medication administrations at hospitals using a paper anesthesia record. Refer to Section Y for operating instructions if your hospital is configured differently.

Preparing the BD Intelliport™ Injection Site

The BD Intelliport™ Injection Site must be assembled, prepared and attached to an IV line before use. Follow the instructions located on the BD Intelliport™ Sensor packaging (pouch).

1. Gather a BD Intelliport™ Sensor in its sterile packaging and a fully-charged and disinfected BD Intelliport™ Base and three (3) 10mL flush syringes. Before attaching to the Y-site of the primary IV fluid line follow instructions on the BD Intelliport™ Sensor packaging (pouch).

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

Verify the BD Intelliport™ Sensor sterile packaging (pouch) is intact prior to opening, including all the packaging surfaces (edges, top and bottom plastic surfaces). Discard Sensor if packaging is damaged and replace with new Sensor.

Verify the BD Intelliport™ Sensor tubing end cap is still in place. Discard Sensor if the end cap has become detached. Replace with another Sensor.

NOTE: Keep the end cap on the BD Intelliport™ Sensor while the Injection Site is being assembled and being prepared. Failure to prime with a cap may prevent the sensor from going ready.

2. Attach the BD Intelliport™ Sensor to the BD Intelliport™ Base by joining the BD Intelliport™ Sensor (tubing side) and BD Intelliport™ Base front section first, and then snap the two together.

An audible snapping sound should be heard and both white tabs on the Sensor should be fully engaged to the base. Connecting the BD Intelliport™ Sensor to the BD Intelliport™ Base automatically powers on the injection site.

NOTE: Confirm that both Sensor tabs are fully engaged to base.

The connection of BD Intelliport™ Sensor to the BD Intelliport™ Base is verified by a blinking green light on the BD Intelliport™ Base. If you don’t see this, view the injection site on its side to determine if the two are properly connected. If you see a space between the BD Intelliport™ Sensor and the BD Intelliport™ Base, then they are not attached properly. Separate the two pieces and re-attach. Confirm that both Sensor tabs are fully engaged to base. If you don’t see a blinking green light, replace the BD Intelliport™ Sensor and the BD Intelliport™ Base as needed.
NOTE: the Injection Site should not be attached to the patient IV line at this point.

3. With the end cap in place, attach the 10mL flush syringe (purged of air bubbles) to the Intelliport Site and push 4mL sterile IV fluid with full force. Wait 5 seconds, then push an additional 5ml of fluid with full force (avoid pushing the plunger to the bottom of the flush syringe).

NOTE: Avoid pushing the plunger to the bottom of the flush syringe. The injection site measures the medication ultrasonically. When the plunger reaches the bottom, residual bubbles in the flush syringe can become introduced into the injection site - resulting in additional user interaction at the Tablet.

4. As you push, watch for sequential green flow indicator lights (runway lights) on the base.

5. If the sequential green flow indicator lights do not illuminate, wait 5 seconds and repeat Steps 3 and 4 with additional flush syringes, until the runway lights illuminate.

If the sequential green flow indicator lights illuminate, then the Injection Site is ready for use.

⚠️ Use aseptic technique when handling the BD Intelliport™ Sensor IV connections.

⚠️ Check for a blocked fluid path or leaking fittings when preparing the BD Intelliport™ Sensor.

Recognizing a sufficiently prepared Injection Site: A sufficiently prepared injection site displays a series of green indicator lights on the base when flushing the Sensor. If green lights are not visible when flushing the Sensor, repeat steps 3 and 4 above.

Recognizing a sufficiently prepared Sensor when in the vicinity of a tablet having a case underway: A sufficiently prepared injection site displays a green “Ready” message on the tablet. If there is a yellow “Continue Flushing” message, repeat steps 3 and 4 above.

⚠️ If the Sensor is not sufficiently prepared it may cause inaccurate dose measurement.
6. Attach the injection site to the Y-site of the primary IV fluid line and follow instructions on the BD Intelliport™ Sensor package.

⚠ Verify that the BD Intelliport™ Injection Site is securely Luer locked to the Y-site and the IV tubing is free from kinks before operating.

⚠ After flushing, visually inspect the IV line for leaks, air, or blockage.

⚠ There is no check valve in the BD Intelliport™ Sensor, nor is one needed to use the BD Intelliport™ Sensor safely and effectively. Should you choose a stopcock, manifold or check valve can be used. If you leave a syringe in place for long durations it is recommended that you use a check valve to prevent backflow.

7. Where appropriate, secure the injection site to a surface in preparation for giving injections. Avoid kinks in the line between the injection site and IV line.

The BD Intelliport™ Injection Site is now ready for delivery of IV medications. Any medications given through the injection site will be recorded in the BD Intelliport™ Base memory. You should see the sequential green flow indicator lights during all injections.

8. Attach the injection site to the Y-site of the primary IV fluid line and follow instructions on the BD Intelliport™ Sensor package.

⚠ Verify that the BD Intelliport™ Injection Site is securely Luer locked to the Y-site and the IV tubing is free from kinks before operating.

⚠ After flushing, visually inspect the IV line for leaks, air, or blockage.

⚠ There is no check valve in the BD Intelliport™ Sensor, nor is one needed to use the BD Intelliport™ Sensor safely and effectively. Should you choose a stopcock, manifold or check valve can be used. If you leave a syringe in place for long durations it is recommended that you use a check valve to prevent backflow.

9. Where appropriate, secure the injection site to a surface in preparation for giving injections. Avoid kinks in the line between the injection site and IV line.

The BD Intelliport™ Injection Site is now ready for delivery of IV medications. Any medications given through the injection site will be recorded in the BD Intelliport™ Base memory. You should see the sequential green flow indicator lights during all injections.

**Set up the Tablet for the Start of a Case**

Before each use with a patient, the tablet must be set up to wirelessly communicate with the injection site and to be associated with a patient.

1. Touch the screen to undim. If not powered on, turn on the tablet by pressing and holding its power switch.

   The tablet can operate on battery power alone (not plugged in to a power supply) for a few hours. For extended use verify the tablet is plugged in prior to use by checking the power indicator icon on the Title bar on the tablet screen.

   On startup, the initial screen displays information about the software, drug library and configuration versions—as well as information on network connectivity. Take time to allow the tablet to boot-up prior to using. Contact your System Administration if so instructed.

   The Login screen will display.

2. Type your User Name and Password, and then touch the Log In button.
Figure 47 - Login

The Login screen hides when the user name and password has been authenticated. A list of BD Inteliport™ Injection Sites within wireless range is viewable on the Patient Setup screen. The distance between the BD Inteliport™ Injection Site and a tablet should be 10 meters or less in order for the BD Inteliport™ Injection Site to send and receive wireless communications.

3. Identify the 4-digit number on the BD Inteliport™ Sensor connected to the patient’s IV line.

Figure 48 - Serial Number on BD Inteliport™ Sensor

4. Match the serial number on the Sensor to a serial number on the setup screen.

Figure 49 - Connecting a BD Inteliport™ Injection Site
5. Check the injection site has a fully charged battery and sufficiently prepared.

*Sufficiently Prepared* – A sensor that was sufficiently prepared has a green “Ready” icon to the right of the MRN. If a sensor was not sufficiently prepared (sufficiently flushed), a yellow icon stating “Continue Flushing” will display on the right hand side of the screen. The Sensor is not ready. Remove the injection site from the IV line and repeat the injection site preparation steps in the Prepare the BD Intelliport™ Sensor section above. Attach the fully prepared BD Intelliport™ injection site to the Y-site of the patient’s primary IV fluid line.

⚠️ Not preparing the Sensor before use may introduce air into the IV line or cause inaccurate dose measurement.

*Fully Charged Battery* – A fully charged battery icon shows four green bars. A fully-charged BD Intelliport™ Base has sufficient power for 24 hours of use under typical conditions. Inspect the BD Intelliport™ Base charge level. Replace a BD Intelliport™ Base with less than 25% charge. This can be done at any time, so long as an injection is not being given.

A yellow battery icon will display at the extreme right-hand side of a listed injection site when less than 25% of battery charge remains (approximately 4 hours under typical conditions).

⚠️ Consider replacing with a fully-charged BD Intelliport™ Base before connecting.

6. Select the injection site for your patient by touching and highlighting the appropriate BD Intelliport™ Injection Site serial number.

7. Verify that the green and yellow lights are flashing on the injection site itself. Should you miss the visual confirmation, highlight by touching the appropriate BD Intelliport™ Injection Site again to initiate the blinking lights.

The screen will highlight your selection.

8. Identify the patient’s full name, patient ID, medical record number and birth date from the patient and wrist band.

---

Figure 50 - Matching a Patient Wrist Band to the List

9. On the Patient Setup screen, select the patient from the list.
If the patient’s name is unknown, see Using the System with an Emergency Patient on page 73.

10. Touch the Confirm button to complete the setup.

The BD Intelliport™ Injection Site will illuminate a single, repeating green light when it is wirelessly connected to the tablet and associated with a patient.

Should any part of the association be incorrect, there is an opportunity to touch the Remove button and repeat the patient identification step process. (See Figure 39 Confirm Connected Sensor) Once confirmed, the BD Intelliport™ system has established a permanent association between the patient and BD Intelliport™ Sensor. A BD Intelliport™ Sensor can be paired with only one patient.
If the wrong patient was inadvertently confirmed to the BD Intelliport™ Tablet, use the “Remove Patient” button on the Preferences Screen to disassociate the patient from the BD Intelliport™ Injection Site and undo any medication administration history.

Should the BD Intelliport™ Base become disconnected from the BD Intelliport™ Sensor during operation, reattach and verify patient association. Verify entire patient case record to confirm all information is correct.

Figure 53 - Confirm Connected Sensor and Patient

⚠️ If the wrong patient was inadvertently confirmed to the BD Intelliport™ Tablet, use the “Remove Patient” button on the Preferences Screen to disassociate the patient from the BD Intelliport™ Injection Site and undo any medication administration history.

Should the BD Intelliport™ Base become disconnected from the BD Intelliport™ Sensor during operation, reattach and verify patient association. Verify entire patient case record to confirm all information is correct.

Figure 54 - Flush Reminder and Patient Allergies

Following Patient Setup, the Tablet displays a reminder to flush the injection site with a flush syringe after each dose. Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site. Read and acknowledge.

The tablet displays medication allergies for the selected patient. Food and environmental allergies are not available (figure above).
9. Directions For Use

⚠ If the patient allergies are not available for the tablet, the message “Unable to Obtain” appears. Verify allergy information following your current practice.

⚠ If the patient does not have allergies, the allergy screen with “No Known Allergies” message appears.

⚠ The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.

⚠ The tablet does not display nor alert to food or environmental allergies.

⚠ The BD Intelliport™ system receives drug allergy information from the hospital information system (HIS). The tablet will not display an allergy alert if the allergy has not been recorded in the HIS or if the medications is not listed in the Device Drug Library.

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

11. Removing Injection Site Preparation Flushes from the Record

Because the flushes used to prepare the sensor are not administered to the patient, it is important to distinguish those at the Tablet. Each flush syringe attached to the Injection Site during preparation will display in the medication history section as a “Select Med” (if not encoded) or “Normal Saline Flush” (if encoded).

Note: Normal saline flush may not display on the medication history, if so configured.

Locate each flush and modify the volume to 0mL to remove it from the medication history.

- For syringes not having encoding refer to the Medication Delivery with Syringes Not Having Encoding section for instruction to modify.

- For encoded flush syringes touch the Edit button. The Modify Selected Medication box will appear. Change the volume to 0mL and tap “Save”.

There is an opportunity to type a comment for an allergy. To add a comment:

1. Touch the Comment button. A keyboard displays to type a comment.
2. Type the comment.
3. Touch the Save button. This will return you to the Allergy list.
4. Touch the OK button to close the allergy dialog box.

Giving an IV injection using the BD Intelliport™ Injection Site

In the event of a BD Intelliport™ system or BD Intelliport™ Injection Site failure, (excluding the IV fluid pathway), the injection site will allow standard medication or fluid delivery through the port.

1. Clean the injection port by swabbing the hub according to your hospital procedure.

⚠ 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.

⚠ Check the medication syringe before connecting to the BD Intelliport™ Injection Site for air or bubbles. If present, make sure all air or bubbles are removed from the syringe before connecting the medication syringe and injecting the medication.
2. Double check each medication name and concentration on the syringe prior to attachment to the injection port to assure “right medication.”

3. Attach a syringe to the BD Inteliport™ Injection Site starting with the barrel label visible on top and rotate the syringe barrel a full 180 degrees (and not beyond) to ensure the syringe is properly seated (graduations will be visible on top).

When connecting and disconnecting the syringe always use a “straight-on/straight off” approach. Once the syringe is attached, make sure the syringe and injection port are aligned in a straight line with no angles at the connection.” Incorrect seating of the syringe may result in the tablet not announcing the medication and recording dose.

⚠️ The system is not recommended for use with non-BD Luer-Lok™ syringes. When using a syringe without a BD Luer-Lok™, medication should be administered through an available y-site on the primary IV line and documented manually. Documentation of the medication, dose and time should be entered through the Add button (in the lower right corner of the Nursing View screen), by selecting Add Injection.

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

4. Verify the drug and concentration displayed and announced by the tablet is the intended drug and concentration.

For syringes not having encoding, see Medication Delivery with Syringes Not Having Encoding on page 46, then return to this step. The BD Inteliport™ Injection Site will flash red, green and yellow lights if a medication allergy is detected.

⚠️ Use clinical judgment before proceeding when the tablet announces and displays a known allergy for the drug attached to the injection site. Allergy messages display as below:

⚠️ Figure 55 - Proper Syringe Alignment

⚠️ Figure 56 - Improper Syringe Alignment

⚠️ Figure 57 - Potential Allergy Reaction screen
The Potential Allergy Reaction screen appears when any of these conditions is true:

- An encoded syringe is inserted into the Sensor and the drug matches the patient’s allergy profile.
- A non-encoded syringe is inserted into a Sensor and you select a drug from the Select Medication screen (Figure 34) that matches the patient’s allergy profile.

5. If the Potential Allergy Reaction box has appeared take the appropriate action and then touch the OK button to close the box.

There is no check valve in the BD Intelliport™ Sensor, nor is one needed to use the BD Intelliport™ Sensor safely and effectively. Should you choose a stopcock, manifold or check valve can be used. If you leave a syringe in place for long durations it is recommended that you use a check valve to prevent backflow.

6. While delivering the medication, observe the graduations on the syringe to determine the amount of drug delivered.

**DO NOT LOOK** at the tablet screen while administering a medication. The only accurate way to administer a medication is to look at the graduations on the syringe. Looking at the tablet screen during medication administration can lead to underdose and overdose and the user may not be aware that the incorrect dose was given.

For Sensors sufficiently prepared, green lights on the base illuminate to provide a visual confirmation that the volume being injected is measured.

**Do not lift up on** the syringe while delivering medication.

**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.**

7. Disconnect the syringe, and verify dose shown in the tablet. Note that the Tablet records the dose in increments of 0.5mL, which aligns with standard dosing points for most medications.

**8. Flush the injection site with a normal saline syringe after each dose where retained medication in the injection site has clinical implications.**

- Unless flushed using a syringe, 0.334 mL of medication will remain in the injection site after each dose. This is different from your current practice. Your IV line will not flush the injection site.
- Failure to flush the injection site with a syringe may result in under-dosing of the patient.
- Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site.

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

10. A dose can be edited at any time on the Tablet.

11. If the tablet determines user interaction for this dose is required, a message will display. Read the message and respond accordingly. Refer to section Responding to Messages for information.

**Medication Delivery with Syringes Not Having Encoding**

The BD Intelliport™ system is designed to work with both encoded and non-encoded syringes. When a non-encoded syringe is attached to the Sensor, the blank collar triggers the base and the tablet displays the Select Medication pop-up, which contains the perioperative medication list.

1. Deliver the medication as described in Section Giving an IV injection using the BD Intelliport™ Injection.

   When the syringe attaches to the injection site, the tablet announces “Select Medication” and a pop-up displays prompting you to specify the medication.

   Medications for which the patient has an allergy will be highlighted in red (e.g. cefazolin in Figure 58).

   You can identify the medication in the syringe before giving the injection (recommended) or afterwards. You should verify all medication selections on the tablet. If postponed, the tablet tracks injections not yet identified and later prompts you to resolve them.

2. Select the medication, concentration and container type from the Select Medication dialog box by touching its name.

   This list includes medications previously identified during the case as given by a non-encoded syringe.
9. Directions For Use

Specifying a Diluted or Reconstituted Medication

The tablet provides a simple approach to document medications given with a non-encoded syringe that require dilution or reconstitution from a powder form prior to preparation for injection. It tracks frequently diluted and reconstituted medications. The tablet prompts you to confirm dilution or reconstitution by a message.

⚠️ When reconstituting medications, make sure the granules/powder is completely dissolved prior to connecting the medication syringe to the BD Intelliport™ injection site.

⚠️ Reconstituted drugs will not display a dose value on the medication flag until you modify the medication.

1. To specify a dilution or reconstitution, touch on the dose flag (Anesthesia View flowsheet) or dose row (Nursing view). The Modify Selected Medication dialogue box appears.

3. If the desired medication is not found on the Select Medication dialog touch the View All Meds button to view a longer list of perioperative medications.

4. You can filter the list by touching the first letters of the drug name using the keypad.

5. Highlight the desired medication and concentration, verify the information and touch the Save button.
2. Change the medication concentration or dose by touching the Concentration or Dose box, and entering the value using the numerical keypad.

3. Review the numbers entered, then touch the Save button to record the new value. This change is now reflected in the medication administration history.

**Figure 60 - Modify Selected Medication**

**Specifying a Mixed Medication (Admixture)**

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

- Propofol/lidocaine
- Propofol/Fentanyl
- Propofol/Ketamine
- Neostigmine/Glycopyrrolate
- Atropine/Edrophonium
- Naloxone/Edrophonium

**Figure 61 - Admixture Medication**

The tablet provides a simple approach to document mixed medications. It tracks frequently mixed medications if configured on the tablet, and it prompts you to confirm whether a drug has been mixed. If not configured, no user action is required.

1. To specify a mixed medication, touch the Admixture button on the Select Medication pop-up.
OR

1. Touch the dose flag (Anesthesia View, Figure 11).

OR

1. Touch the Dose row (Nursing view, Figure 14). The Modify Selected Medication pop up displays two medication name slots, with the first one already identified.

2. Touch the bottom field. The Select Medication pop-up opens.

3. Select the desired drug from the list.

Touching the Other button allows you to identify the correct medication from the Frequent Use or perioperative drug library list.

4. Enter the total dose injected followed by one of the medications partial doses in it’s respective text field. The other will auto-populate.

5. Touch the Save button.

Transferring a Patient to Another Care Area

It is important to prepare the patient and tablet prior to moving the patient from one care area to another.

1. Touch the Pause Case button from the Menu to disconnect the injection site(s) from the current tablet.

   This enables another tablet in a subsequent care area to connect to the injection site(s).

2. If the Pause Case button has not been touched and the patient is moved to a subsequent care location that is within about 30 feet of the earlier tablet, the injection site(s) will remain wirelessly connected to the earlier tablet.

3. In this situation, you can disconnect the BD Intelliport™ Injection Site by touching the Show All button from the Patient Setup screen and following the screen instructions.

   ▶️ Prior to patient transport, secure the IV and the BD Intelliport™ Injection Site with the patient to avoid intravenous line disruption and patient injury.

Power Down the Injection Site at the End of a Case

It is good practice to power down the injection site when the surgical case has ended. Once powered down you will be unable to record injections using that injection site.

Do not power down the Injections Site unless the injection site is no longer in use. Doing so will prevent additional medication administrations from being recorded for this case.

1. From the tablet menu, Press Power Down Ports.

2. A message will prompt you to confirm.

3. Press yes. **NOTE:** If you do not power down an Injection site - but instead deactivate it by disengaging the Sensor from the base, the gateway will administratively close the case if a specified time has elapsed without activity. The tablet checks for updates to patient allergy information at the start of a case and upon each care transition.

Deactivating a Device, Disposing of the Sensor, and Preparing the Base for Reuse

When the injection site is no longer in use:
1. Disconnect the Sensor from the base by squeezing together the two finger tabs on top of the Sensor while lifting up to disengage from the base.

When properly separated, the base will power off and stop transmitting wirelessly to the tablet.

![Image of sensor removal](image1.png)

**Figure 62 - BD Intelliport™Sensor Removal**

2. Dispose of the Sensor according to your hospital's medical waste protocols.

   ▼ Avoid inadvertently discarding the base after use. It is intended for reuse with multiple patients.

3. Clean and disinfect the base. The first wipe with a commercial hospital disinfectant will clean and the second wipe will disinfect. Follow the disinfectant manufacturer’s instructions.

   For a list of approved hospital products to use, refer to Appendix C on page 90.

4. Allow it to dry.

5. Inspect the base for cracks or damage.

6. If damage is evident, then dispose of it according to your hospital’s protocols.

7. Insert the base into the charger.

   ▼ Charging of the BD Intelliport™ Base should not occur on or in immediate proximity to the patient. The plug on the power supply is used for isolation from the supply mains.

   ▼ It takes approximately 2-4 hours to fully recharge a BD Intelliport™ Base when discharged to < 25% of power.

8. If the base has reached its End of Life as indicated by a message on the tablet screen or by a persistent red light when seated on the charger, then dispose of it according to your hospital’s protocols for electrical waste.

   The base contains a lithium ion battery.

   ▼ The base will illuminate a red light while charging if it has exceeded its Useful Life.

**Special Activities**

**Giving Injections Without a Tablet Present**

We recommend administering medications while the injection site is wirelessly connected to the tablet. The tablet provides medication announcement/identification, dose measurement, alerting and documentation. The injection site also supports
medication administrations when a tablet is not present. In this situation, the injection site operates like a standard y-site. It also retains the dose information until it later connects to a tablet.

1. Deliver medication according to the instructions described in the Section Giving an IV injection using the BD Intelliport™ Injection Site.

⚠️ Avoid disconnecting the Sensor from the base and replacing it with a different Sensor before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

⚠️ Avoid completely depleting the battery charge on the base before wirelessly connecting to a tablet. This will erase the medication administration data from the base.

2. When the patient moves to another care area having a tablet present, follow the instructions to in Section Set up the Tablet. Once connection to a tablet, prior medication administration history displays along with allergy alerts, if any.

3. Respond to messages, as appropriate.

Using the System With an Emergency Patient

You may often have to start medications before patient information has been entered into the system.

Some hospitals assign placeholder patient IDs for unknown emergency patients receiving treatment. In those situations, select the patient record that corresponds to the patient’s wristband.

In other situations, the Emergency button on the select patient screen may be used to identify a patient who is not known or when you do not have time to select the patient due to an emergency.

If the patient is unknown (picking up from step 7 on page 63):

1. On the Patient Setup screen, touch the Emergency button.

---

![Figure 63 - Patient Setup Screen](image)

![Figure 64 - Unknown Patient Confirmation](image)
Since no patient was identified, “Unknown, Patient” will display as the patient’s name during the confirmation step. Press the Confirm button to proceed.

2. The allergy screen will then display to let you know that the system is unable to obtain patient-specific allergies.

![Allergies Pop-up for an Unknown Patient](image)

Figure 65 - Allergies Pop-up for an Unknown Patient

3. Touch the Ok button to proceed.

   The Main Anesthesia Screen will display and you are ready for injections. Note the “Allergy Checking is Not Available” message is displayed on the right of the screen and patient name is listed as “Unknown”.

Identifying an Unknown Patient

Once a patient has been identified you can associate the patient’s name with an injection site.

1. From the Main Menu choose Review Case.

![The Review Case Option on the Main Menu](image)

Figure 66 - The Review Case Option on the Main Menu
The Review Case screen opens.

2. Touch the Select Patient row.

   The Patient Setup screen will display next for you to select the patient. Please note that the system updates periodically to include new additions to the ADT list.

3. Touch the name of the patient.

4. Touch the Confirm button to associate the patient with the injection site. The patient name will now appear instead of "Unknown Patient".
Adding Additional Sensors

The BD Intelliport™ system can accommodate up to three BD Intelliport™ Injection Sites connected to one patient at a time. An additional BD Intelliport™ Injection Site can be added at any time during a case. The first connected BD Intelliport™ Injection Site displays as the leftmost injection bar. The second in the middle and the third the rightmost injection bar. See Figure 72.

When an injection site is connected to a tablet and there is no syringe attached to the Sensor, the active injection bar reads “Sensor Connected, No syringe attached”.

A battery status icon in the upper right corner of the injection bar indicates the battery charge level of the base to which the Sensor is connected. The battery status icon in the upper right corner of the screen indicates the battery charge level of the tablet. See Figure 72.

To add an injection site:

1. Prepare an injection site according to the instructions in Preparing the Sensor on page 35.

2. Touch “Tap to Add Sensor” on a remaining Active Injection Bar space to display a pop-up window that lists available BD Intelliport™ Injection Sites within wireless range.

3. Identify the 4-digit number on the BD Intelliport™ Sensor.

4. Highlight (select) your BD Intelliport™ Injection Site based on the time of initial activation and the four-digit number on the BD Intelliport™ Sensor.

Figure 69 - Confirm Connected Sensor and Patient
A low battery icon displays when the selected base has less than 10% of battery power remaining. The selected base flashes for three seconds.

5. Verify that the green and yellow lights are flashing for the correct base.

⚠️ Should you miss the visual confirmation, highlight the appropriate BD Intelliport™ Injection Site again to initiate the blinking lights.

6. If the identified Sensor is correct, touch Connect.

7. Touch Confirm.

8. Verify the base is flashing a single, repeating green blinking light indicating it is wirelessly connected to the tablet. An Active Injection Bar displays the connected Sensor. See Figure 17.

Adding a Comment

A comment is a free text entry that is relevant to the anesthesia record. The tablet supports three methods to add to a comment:

- **Allergies** – comments for a specific drug allergy. To make a comment on the allergy pop-up screen:
  
  A. Highlight the medication the patient is allergic to.
  
  B. Touch the Comment button. A keyboard opens on screen with standard comment options.
  
  C. Touch one of the standard options or type a comment.
  
  D. Touch the Save button.

  The recorded comment is displayed with each allergy pop-up. (The allergy pop-up screen is displayed on Patient Setup or by touching the Allergies button on the right side.)

- **Time** – comments tied to a specific time during a case. To add a general comment for a case:
  
  A. Touch the Comment button. A keyboard opens on screen.
  
  B. Type the comment.
C. Touch the Save button.

The recorded comment displays whenever you touch the Comment button. It will be listed as a Comment in the clinical report.

- Injections – comment for a specific drug administration. To make a comment about an injection:
  
  A. Touch a medication administration event in the medication history. The Modify Selected Injection pop-up opens.
  
  B. Touch the Comment button. A keyboard opens on screen.
  
  C. Type the comment.
  
  D. Touch the Save button. This comment will display near the dose/time at which the comment was written.

Adding Manual Injection

The tablet provides the means to document IV injections given prior to activating an Injection Site, given through an IV port other than the injection site or when using a syringe without a BD Luer-Lok™.

1. Touch the Add button

2. Touch the Add Injection button.

   The Frequent Use Medication list opens in the Anesthesia View and in the Nursing View.

3. Highlight the desired medication and concentration. Indicate the volume or dose on the Modify Selected medication popup.

4. Change the time delivered by touching the appropriate arrows to the correct time of administration.

5. Touch the Save button after verifying the entry and the medication will list in the medication history area at the indicated time.

⚠️ A medication administration time cannot be in the future nor more than one hour before the first BD Intelliport™ Injection Site has been activated.
Responding to Messages

The BD Intelliport™ system provides two types of messages: “Clinical” and “System.” “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 Messages and Troubleshooting on page 85 for resolving messages. Messages display in the Message chapter of the tablet 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, you are prompted to respond/answer unresolved medication messages generated during the case.

Reviewing the Medication Record

The BD Intelliport™ system enables you to review the medication record for accuracy and completeness prior to printing a report and prior to closing the case.

⚠️ You are able to correct and amend (add information to) the patient’s medication record so long as an BD Intelliport™ Injection Site for that patient is connected or if the case is within 24 hours from powering down ports but has not yet been “finalized”.

1. From the Main menu, touch the Review Case button.
The Review Case window opens. It lists unresolved medication administrations with the time administered, medication and concentration, volume, dose and reason for review (e.g., unencoded syringe, medication identified as frequently diluted). Touching the Show All button displays all medications given to provide a context for a certain medication administration listed, if needed.

2. Read the reason for review for each med administration and indicate an answer to each question. For example, a question may prompt you to confirm whether epinephrine has been diluted.

3. Select OK if no changes are required for that medication administration.

OR

3. Touch the Edit button to modify an attribute of the medication administration (e.g. concentration, volume, or dose).

4. If the anesthetist clock is not synchronized with the tablet’s clock, touch the Change Case Time button to adjust the tablet’s time for the printed reports to synchronize them with the flowsheet. A pop up displays showing a clock with up and down arrows for hours and minute adjustment.

5. Adjust the clock as required.

6. Touch the Save button.

If there are unresolved messages, you can come back and answer the questions at any time prior to touching the Power down Port(s) button (which closes the medication administration record) on the Main menu.

If not all questions are answered prior to touching the Power down Port button you can reopen the case within 24 hours after the Power down Port(s)” button was touched. Follow hospital procedures for editing records.

You can touch the Past Cases button on the Patient Setup screen to select the patient name to review the record. Upon completion of resolving any medication queries, touch the Exit Case button from the menu. If the 24 hour window was exceeded, follow hospital procedures for editing and finalizing the records.

Printing a Report

The following clinician reports are available for printing only if the medication record has been finalized:

- **Anesthesia Flowsheet Record** – This report lists of the medications 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 Report** – 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 Report** – This report lists each medication and fluid administered showing the time, dosage and route. It also provides a summary showing total dosage by medication and fluid.
1. To print a report, touch Print Report from the Main Menu.

2. Select the appropriate report to print.

3. Specify the printer, if different from the default, and the number of copies.

4. Touch Print. A message displays indicating “Printing to XXX Printer”.

5. Touch the “Power Down Ports” button from the Main Menu to exit the case.

**Viewing Controlled Drugs**

The Controlled Drugs screen lists all controlled drugs administered from the beginning of the case. It’s accessed by selecting the Controlled Drugs option on the Main Menu.
The screen shows this information on each injected controlled drug:

- **Drug Name and Concentration**
- **Volume Given** – displayed in mL rounded to the nearest 0.1 mL
- **Number** – Injection sequence number
- **Time** – Time injection ended (syringe removed or timeout)
- **Dose** – dose from the medication administration history
- **Dose Changed** – If the medication administration occurred through the Sensor and a clinician has changed the dose, the text displays along with the original volume.
- **Volume Changed** – If the medication administration occurred through the Sensor and a clinician has changed the volume, the text displays along with the new volume.
- **Manually Recorded** – if the dose has been entered manually. To exit the screen select another view from the menu.

When configured with an AIMS, a print button is available.
Utilities

Shutting Down the Tablet
The tablet may remain powered down between uses. However, there may be situations in which you are instructed to power down the tablet. This includes the procedure to update the Device Drug Library.

1. Confirm the tablet does not have BD Intelliport™ Injection Sites connected and it is no longer in use.
2. Touch the Shut Down Tablet button located on the Patient Setup menu or the Shutdown Tablet button on the Log in screen.

Setting User Preferences
The BD Intelliport™ system supports user preferences to determine the sound volume, screen brightness and audible announcements, reminders and messages. The hospital has configured default preferences that may be modified temporarily during a case. To verify the tablet preferences prior to starting a case, perform the following:

1. From the Menu select Preferences.
2. Adjust preferences for the work environment.
3. Touch the Save button when completed.

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

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

⚠️ Selecting the Mute option from the Menu overrides all of the above selections and mutes all drug announcements, clinical reminders and system messages. To hear the medication announcements, select Unmute.
### Chapter 10. Messages and Troubleshooting

You can refer to this section in the event the Tablet displays a message or you experience difficulty operating the BD Intelliport™ system. It provides a description of messages as well as troubleshooting tips for operational problems. If the BD Intelliport™ system is not working or not recording injections, use manual documentation process to capture delivered injections. If the response to a specific question is not found, contact your Service Representative:

**Phone: 866-488-1408 select option 4**

When talking with your Service Representative, you may be asked to provide the system’s version. Locate information about your system version by pressing About from the tablet Help menu. Alternatively, system information is displayed upon login to the gateway.

⚠️ **Electrical shock hazard:** Do not remove the tablet cover. There are NO user serviceable parts inside the tablet.

| **Why does the BD Intelliport™ Base show a red light while on a charger?** | The BD Intelliport™ Base has reached its End of Life. It is no longer suitable for use. Dispose of it according to your hospital’s policy for electronics. |
| **The sensor and base are connected, but the Base does not display a blinking green light.** | The connection of BD Intelliport™ Sensor to the BD Intelliport™ Base is verified by a blinking green light on the BD Intelliport™ Base. If this is not seen, determine if the two are properly connected. Separate the two pieces and re-attach. If a blinking green light is not observed, replace the BD Intelliport™ Sensor and the BD Intelliport™ Base as needed. |
| **BD Intelliport™ Injection Site has stopped displaying an intermittent green light.** | A BD Intelliport™ Sensor or Base can be replaced at any time during a case. Prepare a second BD Intelliport™ Injection Site and connect it to the Tablet before disconnecting the first. |
| **What do I do if the Battery in the Base runs out of charge during a case?** | When connected to a Tablet, a low battery message displays when less than 10% charge remains. Replace the BD Intelliport™ Base with different Base. A Base can be exchanged at any time without affecting the case if it is less than 30 seconds. If it is more than 30 seconds, the case will require resynchronization of the Injection Site to Tablet. |
| **The BD Intelliport™ Base shows a red light while in use.** | The BD Intelliport™ Base has reported an error. Verify the medication record is correct if a medication was given at the time of the red light. To reset the Base to full function, first clean and disinfect it, then place it in the Charger. A BD Intelliport™ Sensor or Base can be replaced at any time during a case. Prepare a second BD Intelliport™ Injection Site and connect to the Tablet before disconnecting the first. |
| **I powered down the Injection Site inadvertently during a case.** | Replace the BD Intelliport™ Sensor during a case. Prepare a second Injection Site and connect to the Tablet to continue. However, the historical medication information will not be available during the case. |
| **I am unable to log in or I forgot my user name or password.** | The BD Intelliport™ System uses the hospital’s active directory for login. After three unsuccessful attempts, the Tablet locks for that user. Contact the system administrator. |
| **I cannot print my report from the Tablet.** | Tablets are assigned to a specific care area and cannot be moved. The printing of reports and routing of patient information relies on the tablet being located where it has been assigned during configuration. Contact the system administrator. |
| **I noticed the new configuration settings were not updated.** | A Tablet configuration update was not successful. Notify your system administrator. |
| **I do not know the name of the patient or patient name is not in the ADT list.** | There is an Emergency button on the Patient Set Up screen for patients whose name is not known or you determine an emergency that requires the immediate start medication treatment. |
| **The wrong patient was inadvertently confirmed.** | When configured for use with an EMR, discard the Sensor and prepare a new Sensor. When configured for paper charting, select Preferences from the Main Menu button. Touch the “Remove Patient” button to disassociate the patient from the Injection Site and undo any medication administration history linked to that patient. |
| **The wrong BD Intelliport™ Injection Site was inadvertently confirmed.** | Undo any medication administration incorrectly linked to the patient (at AIMS in EMR mode and on the tablet in paper charting mode), then pause the case and resume with the correct BD Intelliport™ Injection site. |
| **The Tablet displays a low battery icon.** | Verify the tablet is plugged in and charging on AC power. |
| **There is no sound coming from the Tablet.** | Check whether the mute icon is displayed in the title bar. If so, touch the Preferences button from the Menu, and unmute or adjust the volume. |
| **How do I return to the main screen on the Tablet?** | From the Main menu, select the “Anesthesia” or “Nursing” view. |
| **A recent medication administration is not visible on the Tablet.** | Medications given through BD Intelliport™ Injection Site are stored in memory while the Injection Site is not communicating with the Tablet. The Tablet displays the medications when communications are restored. |
| **The recorded dose does not match what I administered.** | The Tablet records the dose in increments of 0.5mL, which aligns with standard dosing points for most medications. In most cases, it displays a message if software determines there to be lower confidence in the accuracy of the calculated dose. In the absence of a message, the dose can be edited at any time. |
| | ❚ If you observe the measured dose incrementing up although medication is not being pushed through the injection site (runway lights may illuminate), then disconnect the syringe and edit the recorded dose accordingly. A bubble may have become lodged momentarily in the Sensor affecting the ultrasonic measurement. |
| | When configured for paper charting, the dose can be edited at any time. Touching the flag for that dose in Anesthesia View or the dose row in Nursing View to change the volume or dose. |
| | When configured for EMR integration, the dose can be edited at the EMR at any time or at the Tablet while there is a message present (prior to it being sent to the EMR). Touch the Edit button to change the volume or dose. |
| **BD Intelliport™ Base wireless communications lost** | BD Intelliport™ Base communications to the Tablet are lost. |
| | • Synchronization should automatically resume. |
| | • BD Intelliport™ Base may be shielded from the Tablet |
| | • Radio interference may be present (Electrosurgical Unit or other device is interfering) |
| **The Handoff Report can’t be printed because there is a communications problem** | Contact the Anesthetist who administered the drugs in the OR to get an oral report. |
| **Med admin does not display in the companion AIMS** | Verify the tablet has the appropriate assignment. Identify the name of the companion AIMS assigned to the tablet by clicking on the About. |

Table 4 - Messages and Troubleshooting
### On Power up

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet Configuration Profile</td>
<td>On power up, the Tablet displays a message whether the Tablet Configuration Profile has been verified current. If unable to do so, the Tablet will prompt you to contact your system administrator.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Drug Library</td>
<td>On power up, the Tablet displays a message whether the Drug Library has been verified current. If unable to do so, the Tablet will prompt you to contact your system administrator.</td>
<td>EMR and Paper Charting</td>
</tr>
</tbody>
</table>

### Start of case

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Login</td>
<td>If user login cannot be authenticated, the Tablet shall display a message for you to contact the network administrator</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>End of life</td>
<td>When the base meets or exceeds the end of life usage then a message displays at the Tablet prompting you to replace it with another base.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Sensor not ready</td>
<td>If the Sensor has not been adequately prepared with flush solution, a message displays at the Tablet prompting you to continue flushing with a normal saline syringe.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Unable to obtain patient allergies</td>
<td>The Tablet indicates when it is unable to obtain patient allergies from the Gateway and allergy checking has not been performed.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Flush reminder</td>
<td>At the start of a case, a message reminds you to use your clinical judgment when deciding whether to flush the injection site. Unless flushed using a syringe, 0.334 mL of medication will remain in the injection site after each dose. Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Dose measurement reminder</td>
<td>At the start of a case, a message reminds you that volume measurements by the injection site is not intended for refrigerated medications (excluding cefazolin).</td>
<td>EMR and Paper Charting</td>
</tr>
</tbody>
</table>
## Delivering medications using the injection site

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enter dose</td>
<td>The Tablet prompts you with a message of “Enter Dose” for the following reasons:</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td></td>
<td>• The drug being administered is unmeasurable (i.e., not being listed in Appendix M).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The volume is partially or inaccurately measured because of the syringe not being fully engaged, bubbles, slow push, a measured volume out of range (i.e., &lt;0.4mL), or if the sensor prime status changes during an injection delivery.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Respond to “Enter Dose” messages by entering (on the tablet) the dose you observed by looking at the syringe graduations.</td>
<td></td>
</tr>
<tr>
<td>Frequently diluted medications</td>
<td>If a medication administered using the injection site has been configured as frequently diluted in the drug library, then the Tablet may prompt you whether a dilution was performed.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Reconstituted medications</td>
<td>If you administer a lyophilized medication using the injection site, then the Tablet may prompt you to confirm the concentration or dose in the un-encoded syringe.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Frequently mixed</td>
<td>If a medication administered using the injection site has been configured as frequently mixed in the drug library, then the Tablet may prompt you whether another medication is in the syringe (e.g. admixture).</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Manual verification</td>
<td>If the selected drug has been delivered one hour or more before it has been charted, then the Tablet will remind you to confirm the dose at the EMR (Epic).</td>
<td>EMR</td>
</tr>
<tr>
<td>Duplicate dose</td>
<td>If an encoded syringe is attached and detached without an injection in series of a dose of same medication and concentration, then the Tablet prompts you whether the charted medication administration is a duplicate to be discarded.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Redose Antibiotic</td>
<td>The Tablet prompts you with if a second antibiotic dose has not been delivered through the injection site before the re-dosing interval for that medication has elapsed, if so configured..</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Allergy alert</td>
<td>The Tablet displays an allergy alert when the medication in the attached syringe or subsequently identified matches a contraindicated drug based on the patient’s allergy. Use your clinical judgment before proceeding.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Sending</td>
<td>The Tablet displays “Sending” when a dose has been transmitted to the EMR and the Gateway has not yet received an acknowledgement of its receipt from the EMR.</td>
<td>EMR</td>
</tr>
<tr>
<td>Sent</td>
<td>The Tablet displays “Sent” when a dose has been transmitted to the EMR and the Gateway has received an acknowledgement from the EMR.</td>
<td>EMR</td>
</tr>
</tbody>
</table>
## 10. Messages and Troubleshooting

### Care Transition

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paused</td>
<td>The Tablet confirms it has been paused and the injection site is no longer wirelessly synchronized with a message when you have pressed the Pause button at the EMR or from the Tablet menu.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Not paused in OR</td>
<td>If the Tablet has not been paused in the operating room and you are attempting to connect the injection site to another Tablet in recovery, then Tablet prompts you to release the injection site. This allows you to wirelessly connect it to another Tablet in the recovery area.</td>
<td>EMR and Paper Charting</td>
</tr>
</tbody>
</table>

### Charting

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print report</td>
<td>When you print a report, the Tablet displays a message indicating the printer name for the print job.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Clock adjustment</td>
<td>If you adjust the Tablet clock, then the Tablet displays a message reminding you to include the time adjustment in the anesthesia record comments.</td>
<td>Paper Charting</td>
</tr>
<tr>
<td>HIPPA compliance</td>
<td>If you generate a report with an email destination, then the Tablet displays a HIPAA-compliant warning message.</td>
<td>Paper Charting</td>
</tr>
<tr>
<td>Finalized Medical Record</td>
<td>The Tablet displays a message if the medication record has been finalized at the Tablet and sent to the Gateway reminding you that any changes must be manually made to the printed report according to hospital policy.</td>
<td>Paper Charting</td>
</tr>
<tr>
<td>Confirm each dose at the EMR</td>
<td>The Tablet displays a message reminding you to confirm each dose for accuracy at EMR before finalizing the case.</td>
<td>EMR</td>
</tr>
</tbody>
</table>

### General

<table>
<thead>
<tr>
<th>Message Type</th>
<th>Description</th>
<th>Configuration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wireless connection lost</td>
<td>The Tablet alerts you if there is a temporary disruption in wireless communications between the injection site and the Tablet. In most situations, it will automatically re-synchronize. If it persists for more than 30 seconds, then the current case will be paused.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Low injection site battery charge</td>
<td>The Tablet informs you if there is less than 5% of power charge remaining in the Base. Retrieve another Base having sufficient charge, then swap the bases out.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Low tablet battery charge</td>
<td>The Tablet informs you if there is less than 10% of power remaining. Confirm that the Tablet is plugged into a power outlet. The Tablet will automatically shut down when the Tablet battery has less than 6% power charge.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Message</td>
<td>Description</td>
<td>Category</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Tablet error</td>
<td>If the Tablet experiences an error condition, then it displays the message “Tablet error occurred. Restart Tablet.” and automatically restarts the Tablet.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>Gateway not connected</td>
<td>If communications between the Tablet and Gateway have experienced communication disruption, the Tablet displays a message that “Gateway not connected. Allergies may not be current.” in the Title Bar. Note: clinical data may not be complete in those instances where a case was not properly paused or closed due to operational disruption of the DPM or Gateway.</td>
<td>EMR and Paper Charting</td>
</tr>
<tr>
<td>User shutdown tablet</td>
<td>The Tablet displays a confirmatory message when you presses the Shut Down button.</td>
<td>EMR and Paper Charting</td>
</tr>
</tbody>
</table>
### Fluid connection
2 ports, BD Luer-Lok™ type fittings

### Volume measurement accuracy
±10% for bolus volumes > 1.0 mL to 65 mL
± 0.2 mL for bolus volumes of 0.4 to 1.0 mL

### Volume measurement resolution
Increments of 0.5 mL

### Injection Port Capacity Dead Volume / retained fluid
100 injections ≤ 0.334 mL following injection

### Exterior Size (excluding tubing)
< 4.5 cubic inches

### Weight
70 gm (Base and Sensor)

### Operation on a Single Charge
24 hours

### Recharge speed
Up to 4 hours from < 25%

### Wireless range (BD Intelliport™ Injection Site)
10 meters maximum

### Operating Temperature
15˚ C to 29˚ C

### Operating Humidity
20% to 85% relative humidity

### Base Shipping and Storage Temperature
-20˚ C to 60˚ C

### Sensor Shipping and Storage Temperature
-20˚ C to 40˚ C excursions permitted to 60˚ C

### Shipping and Storage Humidity
15% to 90% relative humidity

### Operating Atmospheric Pressure
84 kPa to 101kPa (12.2 psi to 14.7 psi)

### Shipping and Storage Atmosphere Pressure
57 kPa to 101kPa (8.3 psi to 14.7 psi)

### FCC/IC Radio ID
**BD Intelliport™ Base Model:** B1 FCC ID: 2ABS9IPORT1 IC: 11742A-IPORT1
**BD Intelliport™ Radio Model:** 1 FCC ID: 2ABS9RADIO1 IC: 11742A-RADIO1
**BD Intelliport™ Radio Model:** 2 FCC ID: 2ABS9RADIO2 IC: 11742A-RADIO2

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**NOTE:** System accuracy is measured under nominal conditions, defined as: gravimetric testing of water using a precision pump across a volume range 0.4-65mL and flow-rate range 10-400mL/min in a temperature and humidity controlled environment.
### BD Intelliport™ 5-Bay Charger Specifications

<table>
<thead>
<tr>
<th>Specified Cleaning Agents</th>
<th>PDI Super Sani-Cloth® wipes Bleach-based germicidal wipes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operating Temperature</td>
<td>12˚ C – 35˚ C (54˚ F – 95˚ F)</td>
</tr>
<tr>
<td>Operating Humidity</td>
<td>20% – 85% RH (non-condensing)</td>
</tr>
<tr>
<td>Rated Voltage</td>
<td>Input: 100 – 240 VAC 50 – 60 Hz Output: 5 VDC</td>
</tr>
<tr>
<td>Rated Current</td>
<td>4 A</td>
</tr>
<tr>
<td>Model Number</td>
<td>516751</td>
</tr>
</tbody>
</table>

#### Table 6 - BD Intelliport™ 5-Bay Charger Specifications

### Appendix B Tablet Technical Specifications

The tablet provides the user interface for clinicians interacting with the BD Intelliport™ Medication Management System. It consists of a standard, commercial tablet computer with embedded BD Intelliport™ system software pre-installed, a touch screen, and Radio for a wireless communications with the Injection Site. The tablet also communicates with the gateway on the hospital network. This Appendix provides information for positioning and mounting the tablet for use.

The tablet is positioned near the clinicians work envelope. Typically, it is mounted to the anesthesia machine or anesthesia cart in the operating room, or near the patient bed or computer workstation in perioperative nursing care areas.

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![Figure 77 - Tablet on Mounting Arm](image-url)
Table 7 - Tablet Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frame Length</strong></td>
<td>38 cm (15 in.)</td>
</tr>
<tr>
<td><strong>Frame Width</strong></td>
<td>23 cm (9 in.)</td>
</tr>
<tr>
<td><strong>Frame Depth</strong></td>
<td>3 cm (1.2 in.)</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>1.5 kg (3 lb.)</td>
</tr>
<tr>
<td><strong>Power</strong></td>
<td>100-230 VAC, 50-60 Hz, 0.65-1.0 A, Grounded (3-prong) 8 ft. power cord</td>
</tr>
<tr>
<td><strong>Network</strong></td>
<td>802.11 (a/g/n) Wi-Fi compatible network for communication with gateway.</td>
</tr>
<tr>
<td></td>
<td>100 Mb (or faster) wireless network</td>
</tr>
<tr>
<td><strong>Mounting</strong></td>
<td>VESA² MIS-D 100/75, C, MIS-E, MIS-F compliant</td>
</tr>
<tr>
<td><strong>Antivirus</strong></td>
<td>Windows Defender™</td>
</tr>
<tr>
<td><strong>Wireless Communication with injection site</strong></td>
<td>See Appendix G</td>
</tr>
</tbody>
</table>

1 Mounting not included with the BD™ Intelliport system. To be provided by customer. Available mounting equipment suppliers include:
- GCX™ (WS-0008-15, WS-0008-16, and adapters for specific anesthesia machines, if needed)
- Amico (adjustable height monitor arm)

² Flat Display Mounting Interface (FDMI), also known as VESA Mounting Interface Standard (MIS).

Appendix C Cleaning and Disinfectant Agents

The following disinfectants are suitable for use with the BD Intelliport™ Base.
- PDI Super Sani-Cloth® wipes

The following cleaning agents are suitable for use with the tablet.
- PDI Super Sani-Cloth® wipes
- Clorox® germicidal wipes

Appendix D Unpacking and Setting Up the Tablet

This section describes the steps to unbox and setup a tablet delivered in its shipping box. The activities described in this Appendix should be performed only under the direction of the System Administrator. Contact your System Administrator before beginning.

Section 1. Unpackaging and Powering on the Tablet

Unboxing

1. Open shipping carton and remove the frame accessory materials. Set aside.
2. Remove the tablet from shipping carton. Place tablet on a flat surface.
3. Locate the Radio, and set it aside for later use.
Power on the Tablet

1. Remove the two sections power cable from the shipping carton. Attach the two sections together, and connect to the AC power adapter port on the side of the tablet.

2. Connect the other end of the power cable to a functioning mains outlet.

⚠️ Use only the power cord supplied by the manufacturer for the tablet or charger. Never adapt the plug to fit a nonstandard outlet.

3. Power on the tablet by pressing the power button in the top left corner of the front panel.

Section 2. Updating Configuration Settings at the Tablet

There are two activities when connecting the tablet to the gateway on the hospital network. The first activity involves connecting the tablet to the network either wirelessly. The second activity involves specifying the IP address for the Production gateway.

Get to the Tablet Desktop

1. Power on the new tablet.

2. Connect a USB keyboard with touchpad to the USB port on the tablet.

3. Navigate to the desktop.

Time and Time Zone

Use the following steps to verify the time and time zone:

1. Touch the Change Date and Time Settings from menu bar at the bottom of the desktop.

2. Update the time zone to match the hospital server.

3. Next, synchronize the Tablet time settings with the Gateway.
   
   A. Press the Data Time in the lower right hand corner of the screen to open the window to change the date and time settings.

   B. Press the “Change date and time settings...”
C. Press the “Change settings…” button.

D. Enter the IP address of the Gateway in the Server box, then press the “Update now” button to ensure the tablet time is synced to the Gateway time.

E. Press the “OK” button in the “Internet Time Settings” screen.

F. Press the “OK” button in the “Date and Time” screen to complete the setup.

4. Touch Apply.

5. Return to the Desktop.

Wireless

Use the following steps to get the tablet on the hospital network via a wireless access point:

NOTE: Wireless setup should be performed by an individual with a system administrator role. Contact your System Administrator before continuing.

1. Touch the Start button from menu bar at the bottom of the desktop.

2. Touch the PC Settings icon. Touch the Control Panel option.

3. Touch the Network and Internet icon.

4. Touch the Network and Sharing Center option.

5. Set up and configure access to the hospital wireless network. Touch the “Setup a new connection or network” link. Then, touch the “Manually connect to a wireless network” option. Enter the following information:

   a. Network name
   b. Security type
   c. Encryption type
   d. Security Key (SSID)

   Your network administrator will be able to provide you with this information.

6. Verify the tablet has wireless communications. You can do this by touching and holding (the Touchscreen equivalent to right-clicking) on the network icon in the Notification Area (system tray) on the extreme right of the taskbar and touching the Network and Sharing Center option.

7. Return to the Desktop.

Gateway Address

NOTE: Configuration changes to the gateway IP address should be performed only under the direction of the System Administrator. Contact your System Administrator before making configuration changes.

A configuration setting on the tablet allows a System Administrator or similar role responsible for the tablet inventory to specify the IP address of the gateway with which the tablet communicates. This is performed when setting up the tablet. The tablet cannot communicate with the gateway unless this setting has been configured correctly. Follow these steps to assign the configuration setting.
1. From the desktop, use the Windows Explorer to navigate to the AnesthesiaDemo.exe.config file.
   C:\DPMB\AnesthesiaDemo.exe.config

2. Right click on the file, and open the file in Notepad or Wordpad.

3. Find the setting name “GWDB-DEVVM”. To locate the setting, use Ctrl+F to open a search box and type in the setting name.
   It will display as below
   ```xml
   <add name="GWDB-DEVVM" connectionString="Data Source=10.160.210.240;" />
   ```
   Change the numerical IP value to the IP address for the Production gateway.

4. Save the file and close.

5. Return to the Desktop.

6. Remove the USB keyboard with touchpad from the USB port on the back panel of the tablet.

7. Power off the tablet.

**Install Radio and Launch the Application**

Use the following steps to launch the tablet software for the first time.

**NOTE:** Once the tablet software is launched, the tablet desktop is available only to authorized users having valid technician log in credentials. Do not launch the application without first completing all of the steps above to specify the time, time zone, wireless settings and gateway IP address.

1. Locate the Radio, and insert it in the USB Port on the side of the tablet.

2. From the tablet desktop, press Restart BD Intelliport™ Application.

![Restart BD Intelliport™ Application Button](image)

This launches the tablet software application.

**Section 3. Registering the Tablet with the Gateway**

The gateway centrally manages the tablets used for delivering perioperative care, testing, training and as replacements. The gateway maintains an inventory of the hospital’s tablets, including information on the tablet’s name, serial number, location, status and versions.

A tablet cannot be used until it is first registered on the gateway. An administrator with appropriate access privileges registers a tablet by adding it to the Device Inventory using the gateway software. Refer to the Gateway Manual for information on adding a new tablet.
Section 4. Updating the Device Drug Library and Tablet Configuration Profile

When first connecting to the gateway, the tablet loads the current version of the hospital’s Device Drug Library and the tablet Configuration Profile.

- The Device Drug Library is a data set having information for each medication stocked in the perioperative care areas. It specifies attributes for each medication that the tablet uses to display the medication and print labels. All tablets designated for patient use and connected to the hospital network share the same Device Drug Library. A new tablet requires the hospital’s device drug library to operate.

- The tablet Configuration Profile is a data set having information for each medication stocked in the perioperative care areas. It specifies attributes for each medication that the tablet uses to display and record medications given. All tablets designated for patient use and connected to the hospital network share the same Device Drug Library. A new tablet requires the hospital’s device drug library to operate.

The gateway centrally manages the Device Drug Library and Tablet Configuration Profile. The gateway makes this information available to tablets on the hospital network. After properly setting the gateway IP address and registering the tablet at the gateway, the tablet will periodically communicate with the gateway to check for new versions. Updates are automatically loaded when the tablet is restarted. Upon boot up, the tablet displays a screen indicating whether the Device Drug Library and tablet Configuration Profile are up to date.

Use the following procedure to load the configuration settings from the gateway.

1. Check that the tablet has been registered at the gateway (Refer to the Gateway Manual for information).

2. Check that a Device Drug Library and tablet Configuration Profile has been published by the gateway (Refer to the Gateway Manual for information).

On power up, the tablet automatically retrieves the current version for the configuration settings and displays a message when the settings are current.

3. Confirm “Current” displays next to the Device Drug Library (Library Version) and Tablet Configuration Profile (Configuration Version) on the boot up screen.

Figure 80 - Boot Up Screen
Section 5. Positioning for Use

Typically the tablet is mounted to the anesthesia machine in operating room and adjacent to the treatment space in the perioperative nursing care areas. Follow these instructions to position the tablet for use.

NOTE: Clean the tablet according to the instructions in Section X prior to moving it to a patient care area.

1. Provide mounting for the tablet (to be provided by customer), according to the specifications in Appendix B.

2. Assemble the frame with the tablet seated in frame using the screws and hex key provided.

3. Secure the tablet and frame to the mount using the Flat Display Mounting Interface (FDMI), also known as VESA Mounting Interface Standard (MIS).

⚠️ Be sure the tablet is mounted securely to avoid falling and resulting in patient/clinician injury.

⚠️ Properly secure the tablet prior to use or after positioning. Do not loosely place the tablet on other equipment.

4. Connect to the AC power adapter port on the side of the tablet.

5. Connect the other end of the power cable to a functioning mains outlet.

⚠️ 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 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. Provide an isolated power supply for operation.

⚠️ It is recommended that the tablet AC power adapter be connected to an isolated power supply.

6. Position the tablet to be viewable when administering medications in the treatment space.

7. Power on the tablet by pressing the power button in the top left corner of the front panel.

The tablet is ready for deployment testing.

Section 6. Conducting Deployment Testing

Deployment testing is a check point to confirm that the tablet and network settings are properly configured for operation at the hospital. BD recommends that the applicable set of deployment tests be performed as a final check of the system installation in all environments, both test (not for human use – NFHU) and production environments.

Refer to the Gateway Manual for information on applicable tests to be conducted, depending on the tablet configuration at your organization. In addition, BD recommends the Device Setup Deployment Test be performed for every unit during initial system implementation and whenever a specific Labeler has been added, made inactive, or its location changed.

Appendix E Standards

The BD Intelliport™ system is intended for use under the supervision of healthcare professionals only. This is a Class II medical device. The BD Intelliport™ 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 F Glossary

The following terms are used in these Instructions for Use.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Charger</strong></td>
<td>A device that recharges the battery in the reusable BD Intelliport™ Base, as needed.</td>
</tr>
<tr>
<td><strong>Configuration</strong></td>
<td>The way the BD Intelliport™ System is set up, or the assortment of components that make up the BD Intelliport™ System. The Gateway manages the configuration settings. All Tablets for a care area have the same settings, except for wireless and printers.</td>
</tr>
<tr>
<td><strong>EMR Integrated Mode</strong></td>
<td>System configuration that supports integration with electronic medical records or perioperative information management systems (PIMS). (Requires a software interface. See page 29.)</td>
</tr>
<tr>
<td><strong>Encoded Syringes</strong></td>
<td>Syringes having a special barcode identifier on the BD Luer-Lok™ collar.</td>
</tr>
<tr>
<td><strong>Encoding</strong></td>
<td>A special barcode identifier on the BD Luer-Lok™ collar of syringes.</td>
</tr>
<tr>
<td><strong>Gateway</strong></td>
<td>A software application that enables the BD Intelliport™ System to function as an enterprise device and information system. The Gateway provides a central hub to which all Tablets connect via the hospital network. It also includes an interface engine for the BD Intelliport™ System to exchange data with other networked hospital information systems, along with a suite of utilities for general Gateway implementation, operation, and maintenance.</td>
</tr>
<tr>
<td><strong>Injection Port</strong></td>
<td>The split septum port on the BD Intelliport™ Sensor where the syringe attaches.</td>
</tr>
<tr>
<td><strong>BD Intelliport™ Base</strong></td>
<td>The BD 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 BD Intelliport™ Base as needed.</td>
</tr>
<tr>
<td><strong>BD Intelliport™ Injection Site</strong></td>
<td>An intelligent injection port. It attaches to an injection site (&quot;Y Site&quot; or stopcock) for manually administered IV injections. It comprises a BD Intelliport™ Sensor and a BD Intelliport™ Base, which snap together prior to use.</td>
</tr>
<tr>
<td><strong>BD Intelliport™ Sensor</strong></td>
<td>A BD Intelliport™ Sensor is a sterile disposable device having an injection port and a BD Luer-Lok™ connection. The BD Intelliport™ Sensor is supplied in a sterile package for single patient use.</td>
</tr>
<tr>
<td><strong>BD Luer-Lok™</strong></td>
<td>A Becton Dickenson trademark for its patented fitting used for making leak-free connections. A BD Luer-Lok™ fitting securely locks together using threads.</td>
</tr>
<tr>
<td><strong>Non-encoded Syringes</strong></td>
<td>Syringes that do not have special encoding on the BD Luer-Lok™ collar. The BD Intelliport™ Injection Site cannot identify the drug contents of this type of syringe.</td>
</tr>
<tr>
<td><strong>Perioperative Drug Library</strong></td>
<td>The BD Intelliport™ System operates using the hospital's perioperative drug library. The Gateway manages the drug library. When a non-encoded syringe is attached, the pick list is derived from the perioperative drug library.</td>
</tr>
<tr>
<td><strong>Paper Record Mode</strong></td>
<td>System configuration that supports a paper anesthesia record</td>
</tr>
<tr>
<td><strong>BD Intelliport™ Tablet</strong></td>
<td>A commercial tablet computer with embedded software for the BD Intelliport™ System operation. It continuously captures and displays the medication administration record (MAR) data from the BD Intelliport™ Injection Site 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.</td>
</tr>
<tr>
<td>QUICK REFERENCE – BEFORE CASE</td>
<td></td>
</tr>
<tr>
<td>------------------------------</td>
<td></td>
</tr>
<tr>
<td>MATERIALS:</td>
<td></td>
</tr>
<tr>
<td>• 1 Sensor in its packaging</td>
<td></td>
</tr>
<tr>
<td>• 1 Base, charged and disinfected</td>
<td></td>
</tr>
<tr>
<td>• 3 flush syringes (10mL- purged of air bubbles)</td>
<td></td>
</tr>
<tr>
<td>ASSEMBLE</td>
<td></td>
</tr>
<tr>
<td>1. Keep white Sensor cap in place until connecting to IV line.</td>
<td></td>
</tr>
<tr>
<td>2. Attach the Sensor to the Base. Listen for an audible “snap” sound.</td>
<td></td>
</tr>
<tr>
<td>3. Look for a blinking light. If none, disconnect and retry.</td>
<td></td>
</tr>
<tr>
<td>PREPARE</td>
<td></td>
</tr>
<tr>
<td>4. Push 4mL of Normal Saline with full force.</td>
<td></td>
</tr>
<tr>
<td>5. Wait 5 seconds, then push 5mL with full force.</td>
<td></td>
</tr>
<tr>
<td>6. Look for green lights as you push. If none, repeat with additional flush syringes. The Tablet displays green READY when ready for use.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONNECT TO IV Line</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Remove the white Sensor cap and attached to the patient’s IV line.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ASSIGN SENSOR TO PATIENT RECORD</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Start data collection at the EMR.</td>
</tr>
<tr>
<td>9. Check that the patient information on their wristband matches the information on the Tablet. Press Verify button.</td>
</tr>
</tbody>
</table>

| REMINDER: Verify that the patient wristband matches the information on the Tablet. |

<table>
<thead>
<tr>
<th>CONNECT WIRELESSLY TO TABLET</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. At the Tablet, Press the serial number matching what is printed on the Sensor.</td>
</tr>
<tr>
<td>11. Look for flashing lights at the Base. Press Connect button.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUICK REFERENCE – DURING CASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIVE INJECTIONS</td>
</tr>
<tr>
<td>1. Scrub the hub.</td>
</tr>
<tr>
<td>2. Attach a syringe with barrel label visible on top.</td>
</tr>
<tr>
<td>3. Turn the syringe until it stops (graduations visible on top).</td>
</tr>
<tr>
<td>4. Check the drug announced and displayed at Tablet.</td>
</tr>
<tr>
<td>5. Look at syringe graduations when pushing.</td>
</tr>
<tr>
<td><strong>DO NOT LOOK at the tablet screen while administering a medication. The only accurate way to administer a medication is to look at the graduations on the syringe. Looking at the tablet screen during medication administration can lead to underdose and overdose and the user may not be aware that the incorrect dose was given.</strong></td>
</tr>
<tr>
<td>6. Flush all medication injections with a flush syringe.</td>
</tr>
</tbody>
</table>

**REMINDER: Flush the injection site**
- Unless flushed using a syringe, 0.334 mL of medication will remain in the injection site after each dose. This is different from your current practice. Your IV line will not flush the injection site.
- Failure to flush the injection site with a syringe may result in under-dosing of the patient.
- Flushing ensures medication reaches the IV line and avoids an interaction between incompatible medications in the injection site.

<table>
<thead>
<tr>
<th>DOCUMENT AT TABLET AFTER TREATING PATIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. If a syringe without encoding is used:</td>
</tr>
<tr>
<td>a. Press Select Med button to view the med list. (Press VIEW ALL MEDS button to see entire formulary).</td>
</tr>
<tr>
<td>b. Select the correct drug and concentration. Press Save.</td>
</tr>
</tbody>
</table>

| 8. If there is a message adjust dose if needed. Press Save button. |
| 9. Review each dose for accuracy at EMR. |

**REMINDER: Review each dose at EMR for accuracy.**
- Dose not sent to EMR unless message has been answered.

<table>
<thead>
<tr>
<th>TRANSITION TO PACU</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Stop data collection at the EMR.</td>
</tr>
<tr>
<td>11. Scan dose history at Tablet to answer messages.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONNECT WIRELESSLY TO TABLET IN PACU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doses given outside OR will not go to EMR unless connected to Tablet.</td>
</tr>
<tr>
<td>12. Check the patient information on their wristband matches the information on the Tablet.</td>
</tr>
</tbody>
</table>

**REMINDER: Verify that the patient wristband matches the information on the Tablet.**

| 13. Look for flashing lights at the Base. Press Connect button. |

<table>
<thead>
<tr>
<th>END CASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. Select Power Down Port from menu.</td>
</tr>
<tr>
<td>15. Remove Sensor and discard, recirculate Base for cleaning.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TROUBLESHOOTING</th>
</tr>
</thead>
<tbody>
<tr>
<td>- If stuck, set aside Injection Site and revert to charting at EMR.</td>
</tr>
</tbody>
</table>
Appendix I Radio Frequency Wireless Technology

There are two wireless technologies used in the BD Intelliport™ system as depicted in Figure 49 below.

![Diagram of BD Intelliport™ System Two Wireless Technologies]

The radio frequency (RF) signal power has been limited to a very low level to negate any potential electromagnetic interference (EMI) with other medical devices. Both wireless technologies utilized have been approved for use by the Federal Communications Commission (FCC) and meet Federal electromagnetic compatibility (EMC) and electromagnetic interference guidelines. In the event of a potential signal loss of these RF communications a "lost communications" message is displayed on the tablet to inform the operator. The tablet indicates when communications are resumed. Information on proper set-up, configuration and performance with the Hospital Network is provided at the time of system installation. No set-up is required for BD Intelliport™ Injection Site-to-tablet 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; lost messages will be resent. The tablet computer will indicate when lost communications exist. The BD Intelliport™ Base status indicator will double blink when communication with the tablet is lost.

BD Intelliport™ Base to Tablet

The tablet uses a BD Intelliport™ Radio to wirelessly communicate with the BD Intelliport™ Injection Site using an RF signal at 2.4 GHz to form a local medical device network. A number of BD Intelliport™ Injection Sites and tablets may be used in the same vicinity such as a Pre-operative care area or a post anesthesia care unit (PACU). A license has been issued by the 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 BD Intelliport™ Injection Site and the tablet 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. A lost wireless communication message will display when communication is lost between the base and the tablet. If this happens, check the event history for accuracy.

BD Intelliport™ Injection Sites using proprietary 2.4GHz technology are associated (linked) with specific patients using the tablet IEEE standards based on 802.11a/b/n (2.4GHz-5GHz) Wi-Fi technology. The User identifies the BD Intelliport™ Sensor by serial number and selects a specific patient from the hospital’s patient listing. All medication administration data from the BD Intelliport™ Injection Site 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 BD Intelliport™ Injection Site and transferred to the tablet when communications are resumed.
Tablet to Gateway through the Hospital Network

The tablet 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 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 tablets 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. Actual medication and fluid administration data are sent to the gateway and accompanied database for recordkeeping. Once recorded on the gateway and accompanied database these data are automatically available in other care areas when the patient is transferred and the BD Intelliport™ Injection Site is wirelessly connected to a tablet. In the event of a communication loss, medication administration data will not be sent to the gateway and therefore not available in the next care area. A message will be displayed to inform you that the gateway is down. In this situation, manual transfer of clinical information is recommended.

### Summary of IEC 60601-1-2 Testing and Specifications

<table>
<thead>
<tr>
<th>Technology Type</th>
<th>2.4 GHz proprietary messaging</th>
<th>802.11 a, b, g, n secure wireless connection with the correct quality of service (QoS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective Power</td>
<td>Charger: +5 V dc, 1 A BD Intelliport™ Base Battery: Li Ion cell – 720mAH, 3.7V dc</td>
<td>N/A</td>
</tr>
<tr>
<td>Effective transmission distance</td>
<td>10 meters or less</td>
<td>10 meters to hospital wireless access point (WLAN AP)</td>
</tr>
<tr>
<td>Data throughput and latency</td>
<td>Real-time information, no delays</td>
<td>Subject to hospital network performance</td>
</tr>
</tbody>
</table>

#### Table 8 - Summary of IEC 60601-1-2 Testing and Specifications

### Appendix J Reference Documents

Available documentation and training for the BD Intelliport™ system includes:

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Document Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>10000143030</td>
<td>Essential Prescribing Information and User Manual (This document)</td>
</tr>
<tr>
<td>10000143031</td>
<td>BD Intelliport™ Gateway User Manual</td>
</tr>
<tr>
<td>10000121446</td>
<td>BD Intelliport™ 5-Bay Charger Instructions for Use</td>
</tr>
</tbody>
</table>

#### Table 9 - Reference Documents
Appendix K Description of Symbols

The following symbols are used by the BD Inteliport™ system.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="WARNING" /></td>
<td><strong>WARNING</strong>: Indicates a potential for personal injury or death</td>
</tr>
<tr>
<td><img src="image" alt="PRECAUTION" /></td>
<td><strong>PRECAUTION</strong>: Indicates either potential damage to the hardware or loss of data and instructs how to avoid the problem.</td>
</tr>
<tr>
<td><img src="image" alt="IPX2" /></td>
<td>Ingress Protection from falling water drops</td>
</tr>
<tr>
<td><img src="image" alt="Refer to user operating instructions" /></td>
<td>Refer to user operating instructions</td>
</tr>
<tr>
<td><img src="image" alt="Packaging damage" /></td>
<td>Do not use if package is damaged or protector cap is unattached.</td>
</tr>
<tr>
<td><img src="image" alt="Magnetic Resonance (MR) Unsafe" /></td>
<td>Magnetic Resonance (MR) Unsafe</td>
</tr>
<tr>
<td><img src="image" alt="Type BF/Defibrillation Proof applied part" /></td>
<td>Type BF/Defibrillation Proof applied part</td>
</tr>
<tr>
<td><img src="image" alt="Single Use Only. Do not reuse!" /></td>
<td>Single Use Only. Do not reuse!</td>
</tr>
<tr>
<td><img src="image" alt="Manufacturer" /></td>
<td>Identifies the component manufacturer</td>
</tr>
<tr>
<td><img src="image" alt="Keep dry" /></td>
<td>Keep dry</td>
</tr>
<tr>
<td><img src="image" alt="Upper temperature limit" /></td>
<td>Upper temperature limit</td>
</tr>
<tr>
<td><img src="image" alt="Expiration Date" /></td>
<td>Expiration Date</td>
</tr>
<tr>
<td><img src="image" alt="Lot number" /></td>
<td>Lot number</td>
</tr>
<tr>
<td><img src="image" alt="Supplied Sterile, Ethylene Oxide gas" /></td>
<td>Supplied Sterile, Ethylene Oxide gas</td>
</tr>
<tr>
<td><img src="image" alt="Radio Transmitter" /></td>
<td>Radio Transmitter</td>
</tr>
<tr>
<td><img src="image" alt="Atmospheric Pressure limitation" /></td>
<td>Atmospheric Pressure limitation</td>
</tr>
<tr>
<td><img src="image" alt="Humidity Range" /></td>
<td>Humidity Range</td>
</tr>
</tbody>
</table>

Table 10 - Description of Symbols
### Appendix L ASTM Drug Category Color Schema

Color differentiated by admixture drug class.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Color</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction Agents</td>
<td>Yellow</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Orange</td>
</tr>
<tr>
<td>Benzodiazepines Receptor Antagonists</td>
<td>Orange and White Diagonal Stripes</td>
</tr>
<tr>
<td>Muscle Relaxants (Depolarizer)</td>
<td>Red</td>
</tr>
<tr>
<td>Muscle Relaxants (Non-Depolarizer)</td>
<td>Red</td>
</tr>
<tr>
<td>Relaxant Antagonists (Non-Depolarizer)</td>
<td>Red and White Diagonal Stripes</td>
</tr>
<tr>
<td>Narcotics</td>
<td>Blue has a white diagonal stripes</td>
</tr>
<tr>
<td>Narcotics Antagonists</td>
<td>Blue and White Diagonal Stripes</td>
</tr>
<tr>
<td>Major Tranquilizers</td>
<td>Salmon</td>
</tr>
<tr>
<td>Vasopressors</td>
<td>Violet</td>
</tr>
<tr>
<td>Hypotensive Agents</td>
<td>Violet and White Diagonal Stripes</td>
</tr>
<tr>
<td>Local Anesthetics</td>
<td>Gray</td>
</tr>
<tr>
<td>Anticholinergic Agents</td>
<td>Green</td>
</tr>
<tr>
<td>Beta Blockers</td>
<td>Copper</td>
</tr>
</tbody>
</table>

**Table 11 - Drug Category Color Schema**

---

**TECHNICAL SUPPORT:**

**Dial 866-488-1408 and select option 4**

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Appendix M Measurable Drug List

The following list of drugs are those which meet the +/-10% accuracy specification at room temperature. Using BD Intelliport™ with any other drugs will produce an “Enter Dose” message for volume measurements.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
<th>Concentration Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefazolin</td>
<td>100</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Labatelol</td>
<td>5</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Succinylcholine chloride</td>
<td>20</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Vecuronium bromide</td>
<td>1</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Atropine sulfate</td>
<td>0.4</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Midazolam</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Lidocaine</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Phenylephrine HCl</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Rocuronium bromide</td>
<td>50</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Ketamine</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Saline</td>
<td>1</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Ephedrine Sulfate</td>
<td>5</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Furosemide</td>
<td>10</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Ondansetron</td>
<td>2</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Glycopyrrolate</td>
<td>0.2</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>2</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Neostigmine Methylsulfate</td>
<td>0.5</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Fentanyl Citrate</td>
<td>50</td>
<td>mg/ML</td>
</tr>
<tr>
<td>Propofol</td>
<td>10</td>
<td>mg/ML</td>
</tr>
</tbody>
</table>

Table 12 - Measurable Drug List