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Navigate this Document

Quick Links to Integrated Safety Information:

- Large Volume Pump
- Infusions Dashboard
- Infusate Library
- Infusate Library Browser

Ivenix Infusion System

Integrated Safety Information

The Integrated Safety Information does not include all the information needed to use the Ivenix Infusion System safely and effectively. Please refer to Ivenix Infusion System Instructions for Use for more information.

Product REF #:
LVP-0004, Large Volume Pump (LVP) BKT-0004/ BKT-0005, LVP Charging Bracket LVP-SW-0005 Version 5.9.1, LVP Software IMS-0800 Version 5.1, IMS Software

To report SUSPECTED PRODUCT QUALITY COMPLAINTS AND ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at (855)354-6387, option 2, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

IVENIX
INFUSION SYSTEM

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Indications for Use

[Appears in the LVP IFU 800-0037-06]

The Ivenix Infusion System is indicated for use in a hospital and in outpatient care environments for the controlled administration of fluids through clinically accepted routes of administration: intravenous, intra-arterial, epidural, and subcutaneous. Administered fluids may be pharmaceutical drugs, red blood cells, platelets, plasma, and other mixtures required for patient therapy.

The Ivenix Large Volume Pump (LVP) is indicated for use only with the Ivenix sterile, single use, disposable administration sets, including:

- Primary dual inlet, single outlet, 1 Y-site
- Primary single inlet, single outlet
- Blood Set, dual inlet, single outlet, 1 Y-site, for administration of red blood cells, platelets and plasma
- Microbore single inlet, single outlet, for administration of epidural fluids, with luer connector
- Microbore dual inlet, single outlet, 1 Y-site
- Microbore single inlet, single outlet, for administration of epidural fluids, with NRFit(R) connector
- Primary dual inlet, single outlet, dual Y-site
- Microbore dual inlet, single outlet, dual Y-site
- Microbore single inlet, single outlet

Infusion Management System (IMS)

The IMS provides information to the clinician regarding the use of the Ivenix Large Volume Pump (LVP) by way of a drug library, LVP configurations, and by providing remote information regarding LVP status. It also provides information on pump usage data reports to various functions within an institution.

Exclusions

[Appears in the LVP IFU 800-0037-06]

The LVP and administration sets should not be used for administering an infusion:

- In or near an MRI Suite (MR Unsafe)
- In or across a hyperbaric chamber
- In a vehicle or aircraft
- For patient controlled analgesia (PCA)
- In an X-ray or CT beam
- Within 1 meter (3 feet) of X-ray, CT, or diathermy equipment
- Passing through security systems, such as metal detectors

1 LVP IFU 800-0037-06

Warnings and Cautions

The red triangle represents a warning in this document and on the LVP.
A yellow triangle represents a caution in this document and on the LVP.

Warnings

A Warning describes a situation that could result in death or serious injury, and provides information on how to avoid it. It may also describe potential, serious adverse events and safety hazards.

To avoid the risk of electric shock, the equipment must only be connected to an AC mains power source with protective earth.

Do not bypass or damage the power cord grounding pin. Connect the power cord plug to an AC mains power source with a protective earth ground to avoid possible electric shock.

Do not operative the LVP with the Charging Bracket case open. Contact with exposed electrical components can cause electric shock.

WARNING

Disconnect the power cord from the AC mains power or disconnect the Charging Bracket before servicing the LVP to avoid possible electric shock.

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING

Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Ivenix LVP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING

Do not use the LVP in the presence of flammable anesthetics. A fire or explosion could occur from an internal spark.

WARNING

Do not use the LVP in an oxygen-rich environment, such as a hyperbaric chamber. A fire could occur from an internal spark.

WARNING

MR Unsafe. Do not use the LVP in the presence of strong magnetic fields, such as in an MRI environment. The LVP contains magnetic materials that will be attracted to an MRI machine at a high velocity and might cause significant injury to a patient and/or nearby personnel.

WARNING

The administration set Flow Dial or slide clamp must be closed to prevent uncontrolled flow if a patient-connected administration set is not loaded in an LVP. Use the Flow Dial and monitor flow rate using the drip chamber to administer a controlled gravity infusion.

WARNING Clamp the line using a slide clamp and disconnect the administration set from the patient before using the Cassette Lock Release Button to unload a locked cassette. When the cassette is loaded in the LVP (and the Cassette Loading Lever is locked), the Flow Dial may be in an open position. If the Cassette Release Button is used to unload a locked cassette and the slide clamps have not been properly applied, uncontrolled flow can occur. If the administration set is attached to a patient with the Flow Dial in an open position (and the slide clamps have not been properly clamped), there will be flow to the patient and patient injury can occur.

WARNING Clamp the primary and/or secondary lines when the administration set is not loaded in the LVP. If the clamps have not been properly applied, uncontrolled back flow can occur (diluting the drug), which may result in patient injury.

WARNING Do not use the Power Button during a running infusion. Holding the button down can power off the LVP and stop the infusion. Pause the infusion using the touchscreen Pause button and then power off or place the LVP in standby.

WARNING Connect the LVP to AC mains power if an Extremely Low Battery alarm occurs during an infusion. The LVP battery is depleted and power off is imminent.

WARNING Load only Fresenius Kabi proprietary Ivenix administration sets into the LVP. The risk associated with using any other type of set is unknown.

WARNING Prime all administration sets with fluid to remove air bubbles from the cassette, line (tubing), and injection sites. Infused air bubbles may cause embolisms.

WARNING Do not prime or purge an administration set while attached to a patient. Infused air bubbles may cause embolisms. Disconnect the set from the patient and prime the line to remove the air bubbles.

WARNING

Verify the compatibility of infusates being administered sequentially to the same patient through the same LVP. Incompatible infusates can form precipitates that can occlude the line and, if infused, may cause embolisms and/or vasculitis.

WARNING

Administer only anesthetics/analgesics approved for epidural administration, as indicated by the drug labeling, via the epidural route. Administering drugs not indicated for epidural use may result in significant patient injury.

WARNING

Administer parenteral infusates via a parenteral route only, as indicated by the infusate labeling. Administration of enteral fluids parenterally would likely result in significant patient injury.

WARNING

Infuse blood products at rates below 500 mL/hr. Administration of blood products at rates higher than 500 mL/hr may result in increased hemolysis.

WARNING

No modification of this equipment is allowed.

WARNING

Administer parenteral infusates via a parenteral route only, as indicated by the infusate labeling. Administration of enteral fluids parenterally would likely result in significant patient injury.

WARNING

If the LVP is within approximately six (6) inches of a strong electromagnetic field (such as a fluorescent light or electrosurgical device), interference from the electromagnetic field may cause the touchscreen to actuate on its own without any key presses. Keep the LVP at least six (6) inches away from the source of the electromagnetic field.

Cautions

A Caution is a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the clinician or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

CAUTION Federal (USA) law restricts this device for sale by or on the order of a physician or other licensed health practitioner.

CAUTION The infusion LVP, administration sets, and accessories shall be used by clinicians who have demonstrated competence in the facility's infection control protocols and standard precautions, IV assessment, primary infusion setup, and safe IV medication administration.

CAUTION The infusion LVP shall be used by trained individuals who have demonstrated competence in its safe operation. LVP owners have sole responsibility for operator training and testing even when Fresenius Kabi personnel assist in training processes.

CAUTION Inspect and maintain the LVP on a regular basis. Failure to do so might cause the LVP to operate improperly and prevent use.

CAUTION Dispose of an administration set only per the institution’s disposal policy.

CAUTION Use the remaining battery time reported by the LVP as an estimate. It is subject to change as the power consumed by the LVP changes (such as when changing infusions, using the touchscreen, etc.).

CAUTION Select a care profile to program an infusion that is appropriate for the patient, administered medication, and care environment. Clinicians administering infusions are responsible for familiarizing themselves with care profile medication safety settings that govern LVP operation and infusion programming as customized by the healthcare institution.

CAUTION Use cleaning solutions (recommended by Fresenius Kabi) only as directed by the manufacturer and facility policy.

CAUTION Use only the disinfectants recommended by Fresenius Kabi Others may degrade components or otherwise damage the LVP. Use these disinfectants only as directed by the manufacturer and facility policy.

CAUTION Some disinfectants may be used for the cleaning steps. After cleaning, use a new dampened lint-free cloth or wipe for the disinfecting steps.

CAUTION Do not immerse the LVP in fluid of any kind.

CAUTION When cleaning and disinfecting, pay particular attention to the LCD Touchscreen as well as the Valve Pins and Resistor Drive Coupler in the cassette loading area. Residual cleaning solution/disinfectant may affect LCD Touchscreen readability and may cause binding of Valve Pins and Resistor Drive Coupler components if allowed to build up over time. Thoroughly rinse the LCD Touchscreen as well as the Valve Pins and Resistor Drive Coupler components as part of the cleaning/disinfecting process.

CAUTION Do not sterilize the LVP using heat, steam, Ethylene Oxide (ETO), or radiation.

CAUTION Never use sharp objects or abrasive brushes/scouring pads to clean any part of the LVP.

CAUTION Follow standard precautions for personal protection including the use of personal protection equipment and mechanical ventilation systems, as appropriate. Consult the Material Safety Data Sheets (MSDS) for the cleaning solutions and disinfectants to be used.

CAUTION MR Unsafe. Do not use the LVP in the presence of strong magnetic fields, such as in an MRI environment. Strong magnetic fields can cause the LVP to operate improperly, distort the display screen, and prevent use.

CAUTION Do not use of the LVP within the beam of X-ray and CT equipment. This may cause damage to the LVP or disrupt its operation.

CAUTION Keep the LVP at least 1 to 2 meters (approximately 3 to 6 feet) away from X-ray machines, CT equipment, diathermy equipment, or security systems, including walk-through and hand-held metal detectors. Such equipment may generate powerful electromagnetic emissions.

CAUTION Inspect the power cord and do not use if damaged. A damaged cord with exposed wiring can cause a fire or be an electric shock risk.

CAUTION Check an IV pole for stability after attaching an LVP to prevent inadvertent tipping that could pull out an IV line, injure a patient, or damage the LVP.

CAUTION Arrange the administration set line to avoid entanglement with the line. Entanglement can cause pressure wounds or restrict perfusion.

CAUTION Do not force the Cassette Loading Lever closed. Excessive force can damage the LVP and prevent use.

CAUTION Do not expose the LVP directly to ionizing radiation such as that from a linear accelerator. High energy x-rays can damage internal circuitry and prevent LVP use.

CAUTION Monitor the IV site frequently during an infusion for infiltration or extravasation. The LVP cannot detect infiltrations.

CAUTION Inspect the cassette and downstream line for leaks that indicate a defective set after priming an administration set. Replace a defective set to ensure that the patient receives all of the medication.

CAUTION

Do not pierce a needle-free connector with a needle. A needle damages the connector and causes leakage. Use a luer-lock injection-site adapter for administering medications to a downstream Y-site.

CAUTION

Avoid excessive activations of the needle-free connector. More than 48 activations may compromise its prevention of microbial ingress.

CAUTION

Do not pressurize an administration set with a fluid bag pressure cuff to a pressure greater than 525 mmHg (10 psi). High pressure can damage the cassette and cause leakage.

CAUTION

Do not pressurize an administration set by infusing into a hyperbaric chamber at a pressure greater than 525 mmHg (10 psi). High pressure can damage the cassette and, if connected to a patient, cause blood loss.

CAUTION

Practice aseptic technique (per your facility's policy) when using the administration set fluid-path connections to prevent contamination and reduce the risk of infection. Wear personal protective equipment (e.g., gloves) to avoid microorganism transmission. Sanitize the needle-free connector by applying a 70% isopropyl alcohol wipe for 10 to 15 seconds in a scrubbing motion. Allow to dry for at least 15 seconds.

CAUTION

Do not use an Ivenix administration set for longer than 96 hours. Ivenix administration sets should be changed per the healthcare institution's policy or every 96 hours, whichever is less.

CAUTION

Administration sets are intended for single use only. Reuse or re-sterilization of a set might cause damage, infections, or allergic reactions.

CAUTION

Spike a fluid bag septum carefully and completely. During spiking, the tip can inadvertently pierce the container wall and cause a hand injury, cause leakage, and/or compromise the infusate sterility. An insufficient spike might not permit sufficient flow.

CAUTION Connect the line of a primed administration set to the patient before starting the infusion to ensure all medication is delivered.

CAUTION Back priming from a primary container to a secondary container will mix fluids and dilute the concentration of a drug in the secondary container.

CAUTION Keep an administration set with attached primary and secondary containers loaded in an LVP to prevent fluid mixing between containers. Clamp either the primary or secondary lines attached to the cassette or detach the secondary container before unloading the set to prevent fluid mixing.

CAUTION Dispose of an administration set only per the institution's disposal policy.

CAUTION Double-check calculated and basic infusion programming with a licensed healthcare professional. Inadvertent miscalculations can lead to unintentional over- or under-dosing and patient injury.

CAUTION Use the LVP's drug calculator to administer continuous medications not in the LVP library (rather than using basic programming). Inadvertent miscalculations can lead to unintentional over- or under-dosing and patient injury.

CAUTION Do not use the slide clamp to regulate a gravity infusion. The clamp can become dislodged inadvertently and cause an overdose. Use the Flow Dial.

CAUTION Review infusion programming before starting an infusion to detect any inadvertent programming errors that might cause patient injury.

CAUTION

Review the Occlusion Pressure Setting before starting an infusion. If your institution has enabled your ability to change the occlusion pressure, consult with an infusion therapy professional and set it to a value that is appropriate for the patient and the administration route.

- Setting the Occlusion Pressure overly high increases the time for the LVP to detect an occlusion and might delay therapy. Infusions running at low flow rates will take longer to reach the pressure alarm limit and there might be a period of time during which the patient is without the intended therapy.
- Setting the Occlusion Pressure overly high increases the fluid amount delivered after relieving a downstream occlusion (i.e., post-occlusion bolus) to a maximum of 0.5 mL.
- Setting the Occlusion Pressure overly low might cause an occlusion artifact that produces an alarm, pauses an infusion, and delays therapy.
- The lower the Occlusion Pressure setting, the less time it will take for the infusion pressure to reach the limit and produce an alarm.

CAUTION

Use a recommended syringe that is a size of 60 mL or smaller to administer medications through the cassette's secondary inlet. Loading a cassette with a larger syringe will hinder loading, bend the cassette, and prevent use.

CAUTION

Use a recommended syringe that is a size of 5 mL to 60 mL to administer medications through the cassette’s secondary inlet. Using a smaller syringe size can occlude flow and cause an alarm.

CAUTION

Back prime the administration set cassette’s secondary port to remove a residual air bubble (approximately 100 mcL) after attaching a line or recommended syringe. Otherwise, the air bubble may be detected and stop an infusion.

CAUTION

Remove any residual air bubble (approximately 40 mcL) with a syringe from the downstream Y-site connector before use. The air bubble can cause an embolism.

CAUTION

Due to the wide variation in manufacturing tolerances of commonly available syringes, some resistance may occur when delivering from a syringe and the LVP may alarm for an upstream occlusion. Small volume syringes and low infusion rates increase the likelihood of resistance causing upstream occlusions on the LVP. In the event that occlusions are observed, back prime (as described in the next section) to loosen the plunger. If that does not resolve the upstream occlusion:

1 Remove the syringe from the secondary port.
2 Manually exercise the plunger to free up the resistance.
3 Reconnect the syringe.
4 Restart the infusion.

If upstream occlusions persist, remove the syringe and deliver the medication manually.

CAUTION

Monitor the downstream line during an infusion for air bubbles that can form from normal outgassing, or use a downstream air filter. Air bubbles may cause embolism. Downstream air bubbles are more likely to form if the infusate has been chilled or the infusion rate is slow (e.g., less than 5 mL/hr).

CAUTION

Trace the infusate container to the administration set inlet (e.g., primary or secondary) before making changes to infusion programming during a running infusion. It is possible to deliver an unintended infusion when multiple bags and LVPs are used on the same IV pole.

CAUTION

Do not invert the administration set cassette during priming. Inverting the cassette inhibits air bubble removal. Air bubbles that are retained in the cassette will be detected and may stop an infusion.

CAUTION

The LVP touchscreen must remain dry during use. A fluid droplet on the surface can be perceived as a finger contact. As a result, the touchscreen might appear to malfunction.

CAUTION

Do not power off the LVP during a software update. Doing so may render the LVP inoperable.

2 Infusions Dashboard IFU 800-0039-06

Warnings and Cautions

Warnings A Warning describes a situation that could result in death or serious injury, and provides information on how to avoid it. It may also describe potential serious adverse events and safety hazards.

WARNING The pump cannot be controlled from the Infusions Dashboard. And, there are no audible alarms (a reminder of this is shown on the Dashboard). You must go to the pump to attend to an event.

WARNING Data is not displayed in real time. The display of data is refreshed every 30 seconds.

WARNING If connectivity is lost between the Infusions Dashboard and the Infusion Management System (IMS) or pump(s), infusions will not display on the Dashboard.

Cautions

A Caution is a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the clinician or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

CAUTION

The Infusions Viewer may not display all available patients and/or infusions. Be sure to scroll down to view all information on the screen.

3 Infusate Library IFU 800-0040-06

Warnings and Cautions

Warnings

A Warning describes a situation that could result in death or serious injury, and provides information on how to avoid it. It may also describe potential serious adverse reactions and safety hazards.

WARNING

Verify that the Air Detect Bubble Size setting is appropriate for the expected patient population in each care profile. An unintended high setting would allow an overly large air bubble, if present, to be infused to the patient without detection or awareness by the clinician. Infused air bubbles might cause serious patient injury. A setting greater than the 50 mcL default might not be appropriate for populations such as pediatric and low-weight patients.

Cautions

A Caution is a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the clinician or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

CAUTION

Consistent with good-quality practices, have new Infusate Library content reviewed for accuracy and intent by qualified smart pump Infusate Library stakeholders before updating the pump fleet. Neglecting to have stakeholders verify new library content can allow unintentional settings or inappropriate values to be deployed to the pump fleet that might either restrict intended infusion programming or fail to alert pump users to unsafe pump use or infusion programming.

CAUTION

Consistent with good-quality practices, have new Pump Settings content reviewed for accuracy and intent by qualified Pump Settings stakeholders before updating the pump fleet. Neglecting to have stakeholders verify new content can allow unintentional settings or inappropriate values to be deployed to the pump fleet that might either restrict intended infusion programming or fail to alert clinicians to unsafe pump use or infusion programming.

CAUTION

Configure the system's units/departments with access to the intended care profiles. Neglecting to provide care profile access for a unit/department selected by a clinician might preclude clinicians from using the care profile that provides appropriate safety settings. For example, a clinician might administer the infusate by using an alternative care profile with unintended Dose Error Reduction System (DERS) limits and/or pump safety settings.

CAUTION

Configure an Infusate Library's care profile with all of the infusates being administered in the institution's units/departments that have access to the care profile. Neglecting to include an infusate in an intended care profile might prevent clinicians from:

- Using the care profile that provides appropriate safety settings. For example, a clinician might administer the infusate by using an alternative care profile with unintended pump safety settings.
- Utilizing programming safety settings. For example, a clinician might program the infusate without access to Dose Error Reduction System (DERS) limits by using basic or calculated drug programming.

CAUTION

Label infusates using a generic name and brand name (that is, main label and second label). Unrecognized or unexpected infusate names might be overlooked by clinicians and preclude them from utilizing programming safety settings.

CAUTION

If appropriate, only use commonly accepted abbreviations to label infusates. For example, refrain from concatenating labels with clinical identifiers. Unrecognized, unexpected, or ambiguous infusate names can be overlooked by clinicians and preclude them from utilizing safety settings for programming an infusate.

CAUTION

Verify that library content for each infusate is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, unrecognized labeling, incorrect infusate type, or incorrect admixture units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that library content for each Infusate is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians that delay therapy. For example, unrecognized labeling, incorrect infusate type, or incorrect admixture units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that active ingredients are paired with active ingredients that are intended to indicate y-site incompatibility. An infusate containing an active ingredient that is incorrectly identified as incompatible with another active ingredient can prompt a clinician to unnecessarily establish a second IV access site, obtain a second infusion pump, and therefore, delay therapy.

CAUTION

Enable bolus programming if it is appropriate for the infusate and designated care profile. Neglecting to enable bolus programming can lead to the use of error-prone infusion programming by clinicians. For example, a clinician can program a bolus manually by increasing the dose rate but neglect to lower it after the bolus is delivered.

CAUTION

Verify that library content for each care profile's Care Profile Infusate Settings is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, missing admixtures, unintended Pump Controls settings, or incorrect dosing units, can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Provide soft and/or hard limit values (for example, Soft Min, Soft Max) for all programming performed by clinicians as is appropriate for the infusate, infusion therapy, and care profile. Neglecting to provide a limit precludes clinicians from receiving notifications regarding inadvertent infusion programming that might be unsafe.

CAUTION

Provide soft and/or hard dose and/or concentration limits for medication admixtures that are entered by clinicians at the point of care to draw attention to potentially unsafe concentrations. Medication concentrations programmed incorrectly by clinicians can lead to underdosing or overdosing during an infusion. For example, a hard max concentration limit is recommended to prevent significant overdoses.

CAUTION

Verify that admixtures associated with limits and modifiers, if used, are complete and accurate. Missing admixtures can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, missing admixtures can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that admixtures associated with limits and modifiers, if used, are complete and accurate. Missing admixtures can lead to use of programming workarounds by clinicians that delay therapy. For example, missing admixtures can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that infusates are assigned to the intended active ingredient, and that active ingredients are appropriately paired to indicate incompatibility. An infusate assigned to an unintended active ingredient might be paired with an inappropriate incompatible active ingredient. If this occurs on the same administration set, the LVP will prevent the secondary infusion, which will delay therapy.

CAUTION

Enable 5-Digit Dose Values for intermittent drug type infusate admixtures that are intended to be programmed on the pump with dose values above 9,999 and up to 99,999. The default 4-Digit Dose Values can be inappropriate for some intermittent drug type infusate admixtures and restrict programming that can lead to use of programming workarounds by clinicians and delay therapy.

CAUTION

Enable 5-Digit Bolus Dose Values for continuous infusates that are intended to be programmed on the pump with bolus dose values above 9,999 and up to 99,999. The default 4-Digit Bolus Dose Values can be inappropriate for bolusing some infusates and restrict programming that can lead to use of programming workarounds by clinicians and delay therapy.

CAUTION

Verify that library content for each care profile's Care Profile Infusate Settings is complete and accurate.

- Missing or incorrect library content can lead to use of programming workarounds by clinicians that delay therapy. For example, missing admixtures, unintended Pump Controls settings, or incorrect dosing units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).
- Neglecting to enable the Bag Almost Empty Alarm Pump Control might leave a clinician with insufficient notice to replace a bag before the bag empties. As such, a continuous drug infusion that completes will be paused during the time it takes to replace the bag and resume the infusion.

CAUTION

Enabling the KVO Pump Control for an infusate running at a higher flow rate than the default KVO pump setting will immediately drop to the KVO rate upon completion of the infusion.

CAUTION

Provide Hard Min limits as needed to ensure safe infusate administration. Overly high Hard Min limits will inhibit clinicians from programming an appropriate infusion and may delay therapy.

CAUTION

Provide Hard Max limits as needed to ensure safe infusate administration. Overly low Hard Max limits will inhibit clinicians from programming an appropriate infusion and may delay therapy.

CAUTION

Verify the accuracy of defined formulary admixtures for programmed medications. A clinician selecting an admixture with an incorrect concentration can lead to inadvertently underdosing or overdosing of an infusate.

CAUTION

Verify that the Air Detect Bubble Size setting is appropriate for the expected patient populations in each care profile. An unintended low setting will cause overly small air bubbles to be detected and either pause an infusion or prevent an infusion from being started. Therapy will be delayed until a clinician can clear the air bubble(s) from the fluid path.

CAUTION

Verify that the Occlusion Pressure setting is appropriate for the expected patient populations in each care profile.

- An overly high setting delays the pump's ability to detect and annunciate an alarm if an occlusion occurs. The length of the delay is greater at lower infusion flow rates. If an occlusion is detected, the infusion is paused until a clinician can remove the occlusion and resume therapy.
- An overly low setting might cause inadvertent or temporary pressure artifacts (for example, high flow rates, patient movement) to appear as occlusions and pause an infusion. If the number of attempts to resume an infusion following an occlusion has exceed the Occlusion Retry Attempts setting, the infusion remains paused until a clinician can resume therapy.

CAUTION

Verify that the Rate Hard Max Alert setting, if used, is appropriate for the expected patient populations in each care profile. An overly low setting might inappropriately restrict intended infusion programming rates and delay therapy.

CAUTION

Before deploying content, use the Infusate Library Simulator to verify that the content will appear on the LVP as intended. If the content does not appear correctly in the Infusate Library Simulator, the database may be corrupted and should not be deployed. In this case, contact Fresenius Kabi Ivenix Support.

After deploying content, check the Systems Dashboard to verify that the content was deployed. In addition, use a pump to verify that the content appears consistent with the published changes. If the content does not appear correctly, contact Fresenius Kabi Ivenix Support.

4 Infusate Library Browser IFU 800-0041-06

Warnings and Cautions

Warnings

A Warning describes a situation that could result in death or serious injury, and provides information on how to avoid it. It may also describe potential serious adverse events and safety hazards.

WARNING

Verify that the Air Detect Bubble Size setting is appropriate for the expected patient population in each care profile. An unintended high setting would allow an overly large air bubble, if present, to be infused to the patient without detection or awareness by the clinician. Infused air bubbles might cause serious patient injury. A setting greater than the 50 mcL default might not be appropriate for populations such as pediatric and low-weight patients.

Cautions

A Caution is a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the clinician or patient or damage to the equipment or other property. It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the care necessary to avoid damage to a device that may occur as a result of use or misuse.

CAUTION

Verify that the system's units/departments are configured with access to the intended care profiles. Neglecting to provide care profile access for a unit/department selected by a clinician might preclude clinicians from using the care profile that provides appropriate safety settings. For example, a clinician might administer the infusate by using an alternative care profile with unintended Dose Error Reduction System (DERS) limits and/or pump safety settings.

CAUTION

Verify that an Infusate Library's care profile is configured with all of the infusates being administered in the institution's units/departments that have access to the care profile. Neglecting to include an infusate in an intended care profile might prevent clinicians from:

- Using the care profile that provides appropriate safety settings. For example, a clinician might administer the infusate by using an alternative care profile with unintended pump safety settings.
- Utilizing programming safety settings. For example, a clinician might program the infusate without access to Dose Error Reduction System (DERS) limits by using basic or calculated drug programming.

CAUTION

Verify that infusates are labeled using a generic name and brand name (that is, main label and second label). Unrecognized or unexpected infusate names might be overlooked by clinicians and preclude them from utilizing programming safety settings.

CAUTION

Verify that, if appropriate, only commonly accepted abbreviations are used to label infusates. For example, refrain from concatenating labels with clinical identifiers. Unrecognized, unexpected, or ambiguous infusate names can be overlooked by clinicians and preclude them from utilizing safety settings for programming an infusate.

CAUTION

Verify that library content for each infusate is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, unrecognized labeling, incorrect infusate type, or incorrect admixture units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that bolus programming is enabled if it is appropriate for the infusate and designated care profile. Neglecting to enable bolus programming can lead to the use of error-prone infusion programming by clinicians. For example, a clinician can program a bolus manually by increasing the dose rate but neglect to lower it after the bolus is delivered.

CAUTION

Verify that library content for each care profile's Care Profile Infusate Settings is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, missing admixtures, unintended Pump Controls settings, or incorrect dosing units, can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that soft and/or hard limit values (for example, Soft Min, Soft Max) are provided for all programming performed by clinicians as is appropriate for the infusate, infusion therapy, and care profile. Neglecting to provide a limit precludes clinicians from receiving notifications regarding inadvertent infusion programming that might be unsafe.

CAUTION

Verify that soft and/or hard dose and/or concentration limits for medication admixtures that are entered by clinicians are provided at the point of care to draw attention to potentially unsafe concentrations. Medication concentrations programmed incorrectly by clinicians can lead to underdosing or overdosing during an infusion. For example, a hard max concentration limit is recommended to prevent significant overdoses.

CAUTION

Verify that admixtures associated with limits and modifiers, if used, are complete and accurate. Missing admixtures can lead to use of programming workarounds by clinicians and preclude them from utilizing infusion programming safety settings. For example, missing admixtures can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that admixtures associated with limits and modifiers, if used, are complete and accurate. Missing admixtures can lead to use of programming workarounds by clinicians that delay therapy. For example, missing admixtures can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that infusates are assigned to the intended active ingredient, and that active ingredients are appropriately paired to indicate incompatibility. An infusate assigned to an unintended active ingredient might be paired with an inappropriate incompatible active ingredient. If this occurs on the same administration set, the LVP will prevent the secondary infusion, which will delay therapy.

CAUTION

Verify that library content for each Infusate is complete and accurate. Missing or incorrect library content can lead to use of programming workarounds by clinicians that delay therapy. For example, unrecognized labeling, incorrect infusate type, or incorrect admixture units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).

CAUTION

Verify that the 5-Digit Dose Values option is enabled for intermittent drug type infusate admixtures that are intended to be programmed on the pump with dose values above 9,999 and up to 99,999. The default 4-Digit Dose Values can be inappropriate for some intermittent drug type infusate admixtures and restrict programming that can lead to use of programming workarounds by clinicians and delay therapy.

CAUTION

Verify that the 5-Digit Bolus Dose Values option is enabled for continuous infusates that are intended to be programmed on the pump with bolus dose values above 9,999 and up to 99,999. The default 4-Digit Bolus Dose Values can be inappropriate for bolusing some infusates and restrict programming that can lead to use of programming workarounds by clinicians and delay therapy.

CAUTION

Verify that library content for each care profile's Care Profile Infusate Settings is complete and accurate.

- Missing or incorrect library content can lead to use of programming workarounds by clinicians that delay therapy. For example, missing admixtures, unintended Pump Controls settings, or incorrect dosing units can lead to a clinician's unsafe use of a Basic Infusion or more time-consuming programming of a Calculated Infusion (Drug Calculator).
- Neglecting to enable the Bag Almost Empty Alarm Pump Control might leave a clinician with insufficient notice to replace a bag before the bag empties. As such, a continuous drug infusion that completes will be paused during the time it takes to replace the bag and resume the infusion.

CAUTION

Verify that the KVO Pump Control option is enabled, if appropriate. Enabling the KVO Pump Control for an infusate running at a higher flow rate than the default KVO pump setting will immediately drop to the KVO rate upon completion of the infusion.

CAUTION

Verify that Hard Min limits are provided as needed to ensure safe infusate administration. Overly high Hard Min limits will inhibit clinicians from programming an appropriate infusion and may delay therapy.

CAUTION

Verify that Hard Max limits are provided as needed to ensure safe infusate administration. Overly low Hard Max limits will inhibit clinicians from programming an appropriate infusion and may delay therapy.

CAUTION

Verify the accuracy of defined formulary admixtures for programmed medications. A clinician selecting an admixture with an incorrect concentration can lead to inadvertently underdosing or overdosing of an infusate.

CAUTION

Verify that the Air Detect Bubble Size setting is appropriate for the expected patient populations in each care profile. An unintended low setting will cause overly small air bubbles to be detected and either pause an infusion or prevent an infusion from being started. Therapy will be delayed until a clinician can clear the air bubble(s) from the fluid path.

CAUTION

Verify that the Occlusion Pressure setting is appropriate for the expected patient populations in each care profile.

- An overly high setting delays the pump's ability to detect and annunciate an alarm if an occlusion occurs. The length of the delay is greater at lower infusion flow rates. If an occlusion is detected, the infusion is paused until a clinician can remove the occlusion and resume therapy.
- An overly low setting might cause inadvertent or temporary pressure artifacts (for example, high flow rates, patient movement) to appear as occlusions and pause an infusion. If the number of attempts to resume an infusion following an occlusion has exceed the Occlusion Retry Attempts setting, the infusion remains paused until a clinician can resume therapy.