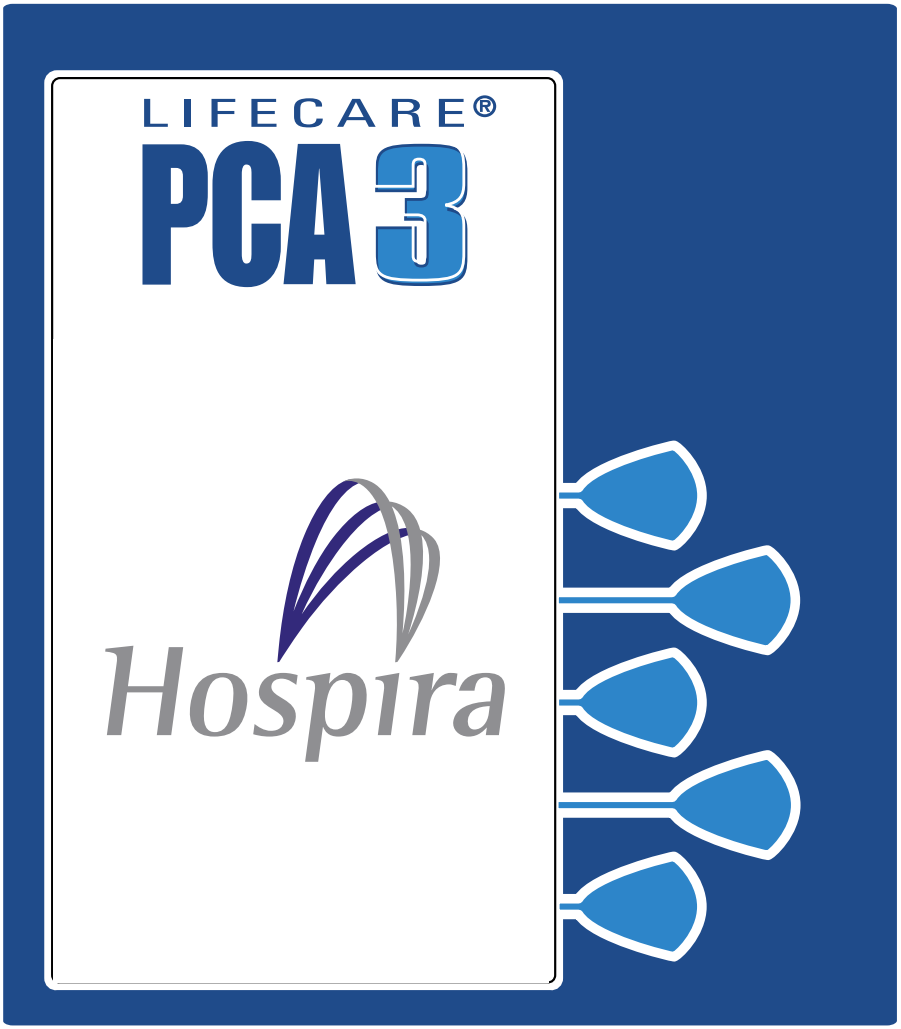
System Operating Manual



Hospira, Inc., Lake Forest, IL 60045, USA

430-04684-002 (Rev. 01/06)

Change History

Title	Description of Change	Pages Affected
430-04684-001 (Rev. 1/05)	Initial Release	All
430-04684-002 (Rev. 01/06)	Second Release	All

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1) Descriptive Information

The LifeCare® PCA 3™ Infusion System is the newest Hospira LifeCare® PCA device. Like its predecessor, the PCA Plus II, the PCA 3 system can be used in a wide range of clinical settings, including but not limited to:

General Floor	***Labor/Delivery/ Post Partum***	***Burn Unit***
Medical/Surgical	***Operating Room***	***Oncology***
Critical Care Units	***Post Anesthesia Care Unit (PACU)***	***Pediatrics***

The PCA 3 Infusion pump allows clinicians to administer or patients to self-administer, analgesia safely and effectively within clinician programmed limits. The epidural route can be used to provide anesthesia or analgesia.

1.1 Product Description

The primary feature of the PCA 3 is the bar code reader, which is designed to automate drug identification. Other enhancements include new programming features, a numeric keypad to directly enter programming values, and a device weight of less than 12 pounds.

The PCA 3 system includes a microprocessor based infusion device with keypad controls, patient pendant, a bar coded drug vial, and a compatible administration set *(see Section 2.3 for list of compatible sets)*. The pump has a serial port for connection to a computer or printer, and the software is field upgradeable. It is intended to operate on AC power, but an internal battery is provided to maintain operation for short periods of time when AC power is not available.

The vials are single-use, bar coded and prefilled with a prescription drug by Hospira, or sterile and empty to be custom-filled by the hospital pharmacy.

The PCA 3 system is capable of the following modes of delivery:

- **PCA ONLY**
- **CONTINUOUS ONLY**
- **PCA+CONTINUOUS**

The PCA 3 system also provides the ability to store frequently used prescriptions called Protocols. The protocols are only available for Hospira pre-filled vials and must be set up through the service mode by a hospital-designated authority.

1.2 Indications for Use

PCA is a method of pain management that permits patients to treat their pain by self-administering doses of analgesics. PCA can be used to manage all types of pain, but is most commonly used to manage acute pain.

PATIENT SELECTION

Patients selected for use of PCA should be able to understand the relationship between pain, pushing the PCA patient pendant and pain relief, and can physically self-administer a PCA dose using the patient pendant.

WARNING

FOR EPIDURAL USE, ADMINISTER ONLY ANESTHETICS/ANALGESICS APPROVED FOR EPIDURAL ADMINISTRATION (AS INDICATED OR ALLOWED BY THE DRUGS' FDA APPROVED LABELING). EPIDURAL ADMINISTRATION OF DRUGS OTHER THAN THOSE INDICATED FOR EPIDURAL USE COULD RESULT IN SERIOUS INJURY TO THE PATIENT.

USER QUALIFICATIONS

All clinicians should be appropriately trained on programming of the PCA 3 pump prior to use.

The PCA 3 is intended for use at the direction or under the supervision of licensed physicians or certified healthcare professionals. They must be trained in the use of the pump, administration of parenteral and epidural fluids and drugs, and the prevention of related IV complication and precautions to prevent accidental infusion of air. Training should emphasize the assessment and monitoring of patients receiving potent analgesic medications, and the appropriate treatment for possible adverse reactions.

1.3 Contraindications For Use

The PCA 3 should not be used for patient controlled analgesia by patients who do not have the cognitive ability to understand the use of self-administered pain medication nor have the physical capacity to operate the patient pendant, if required.

Drugs not compatible with silicone rubber or PVC plastic, or not stable under infusion conditions, should not be used with this system.

1.4 Conventions

This section describes the conventions used throughout this manual, as follows:

CONVENTION	APPLICATION	EXAMPLE
Italic	Reference to a section, figure, or table Function or mode specific instructions	(*See Section 3-1, Components*) *Primary Only: Attach an empty container.*
[BRACKETED ALL-CAPS]	Keys or buttons on the device are displayed in [BRACKETED ALL-CAPS] or with a graphic.	[START/PAUSE] or 
ItalicSmallcaps>	Softkey Options	*CHOOSE>*
Initial Caps lowercase	Screen displays and device labels (as appropriate)	Therapy Dose Calculation
Bold	Emphasis	...sets are supplied **Sterile** and are for....

WARNINGS, CAUTIONS, AND NOTES

Alert messages used throughout this manual are described below. Pay particular attention to these messages.

WARNING

A WARNING MESSAGE CONTAINS SPECIAL SAFETY EMPHASIS AND MUST BE OBSERVED AT ALL TIMES. FAILURE TO OBSERVE A WARNING MESSAGE IS POTENTIALLY LIFE THREATENING.

CAUTION: A CAUTION USUALLY APPEARS IN FRONT OF A PROCEDURE OR STATEMENT. IT CONTAINS INFORMATION THAT COULD PREVENT IRREVERSIBLE PRODUCT DAMAGE OR HARDWARE FAILURE. FAILURE TO OBSERVE A CAUTION COULD RESULT IN SERIOUS PATIENT OR USER INJURY.

NOTE: A Note highlights information that helps explain a concept or procedure.

This symbol directs the user to consult accompanying documents.

NOTE: Figures are rendered as graphic representations to approximate the actual product. Therefore, figures may not exactly reflect the product.

1.5 Definitions (General and Clinical)

TERM	DEFINITION
1 Hour Dose Limit	*Programmed parameter specifying the maximum amount of drug that can be administered in a rolling (continuously advancing) one hour time period.*
4 Hour Dose Limit	*Programmed parameter specifying the maximum amount of drug that can be administered in a rolling (continuously advancing) four hour time period.*
Accuracy	*The degree to which the instrument is capable of delivering the volume of analgesic drug that is displayed or targeted to be delivered. Accuracy shall be specified as the maximum allowable delivery error from a targeted or displayed value (see product specification, Section 9).*
Continuous	*Infusion therapy characterized by a constant fixed-rate dose.*
Custom Syringe or Vial	*Bar coded Hospira sterile empty vial which is custom-filled by a licensed pharmacy.*
Default	*Generally refers to the factory setting for parameters or options.*
History	*Displays Parameter Settings, Dose History and Event Log. Also provides access to Print History softkey.*

TERM	DEFINITION
Lockout Interval	*Programmed time interval specifying the minimum time that must pass after a PCA dose or Loading Dose is administered before the next PCA dose can be infused. The bolus requests made during this period are not delivered.*
Loading Dose	*An optional dose delivered before starting normal function of the pump (or thereafter by unlocking the door).*
Occlusion	*Inability of the instrument to infuse fluid to the patient. Possible causes of occlusions include kinked tubing, plugged tubing, etc.*
Maximum Occlusion Pressure	*The maximum pressure observed in response to a patient line occlusion.*
Patient Pendant	*Hand-held pendant connected to the instrument that allows the patient to request a bolus PCA dose by pressing a button.*
PCA mode	*Infusion therapy characterized by bolus doses administered on patient demand subject to a lockout interval and, optionally, a 1 or 4 hour dose limit.*
PCA 3 *Vial*	*Bar coded vial compatible with the* **PCA 3** *instrument that is either prefilled or custom filled with a drug.*
PCA 3 *Instrument*	*Programmable patient controlled infusion pump.*
PCA 3 *Set*	*Tubing which connects the* **PCA 3** *Vial to the patient.*

TERM	DEFINITION
Prime	*Manually removing air from the syringe and line.*
Purge	*Running the mechanism to remove system slack when a new vial/ injector is installed. (The system must be primed first and disconnected from the patient.)*
Warning	*An indication to advise the clinician:* *A) of a possible dangerous condition such as a low battery* *B) that an attempt has been made to use a function in the wrong sequence, wrong time, or with the wrong values, such as an invalid key attempt*

1.6 Precautions

- **Product damage may occur unless proper care is exercised during the unpacking and setup process. The battery may not be fully charged upon receipt.**

ARTIFACTS

- **Nonhazardous, low-level electrical potentials are commonly observed when fluids are administered using infusion devices. These potentials are well within accepted safety standards, but may create artifacts on voltage-sensing equipment such as ECG, EMG, and EEG machines. These artifacts vary at a rate that is associated with the infusion rate. If the monitoring machine is not operating correctly or has loose or defective connections to its sensing electrodes, these artifacts may be accentuated so as to simulate actual**

physiological signals. To determine if the abnormality in the monitoring equipment is caused by the infusion device instead of some other source in the environment, set the infusion device so that it is temporarily not delivering fluid. Disappearance of the abnormality indicates that it was probably caused by the electronic noise generated by the infusion device. Proper setup and maintenance of the monitoring equipment should eliminate the artifact. Refer to the appropriate monitoring equipment system documentation for setup and maintenance instructions.

- **The PCA 3 system is designed to operate normally in the presence of most encountered electromagnetic interference (EMI) conditions. In the event of extreme levels of interference, such as those encountered next to an electrosurgical generator, it is possible that the normal operation of a sensor or microcomputer might be disrupted. Even in this event, the outcome would likely be a false alarm or detected system malfunction and would not result in a hazard to patient or clinician.**
- **Use of radio frequency emitting devices such as cellular telephones and 2-way radios in close proximity of this device may affect its operation.**

GENERAL

- **Possible explosion hazard exists if used in the presence of flammable anesthetics.**
- **Potent analgesic medications are used with this device. Refer to drug package insert for precautions and possible adverse reactions.**
- **Refer to analgesic package enclosure for possible incompatibility with fluid or drug being delivered through the IV line.**
- **Coupling together of more than one pump into one patient line may significantly affect the infusion rate of at least one of the pumps.**

- **Do not use sharp objects such as pens, scissors, or fingernails to press keys. Such objects may damage keys and cause a malfunction.**
- **Arrange tubing, cords, and cables to minimize the risk of patient strangulation or entanglement.**
- **Failure to use Hospira vials and Hospira PCA sets with integral anti-siphon valve may cause an inaccurate dose delivery to the patient.**
- **The system must be primed prior to purging. Remove all air from vial before placing into pump.**
- **Always close slide clamp on PCA administration set before removing or replacing syringe, and before discontinuing infusion.**
- **Patient must be disconnected from the PCA set before the purge cycle.**
- **Vial and injector must be securely locked into the infuser before beginning delivery.**

PROGRAMMING

WARNING

FOR CUSTOM SYRINGES, CONFIRM THAT THE DISPLAYED CONCENTRATION (MG/ML) OR (MCG/ML) EXACTLY MATCHES THE CONCENTRATION VALUE AND DRUG NAME ON THE SYRINGE. IF THEY DO NOT MATCH, UNDER/OVERDOSAGE MAY RESULT.

- **In the CONTINUOUS and PCA+CONTINUOUS modes, if a purge is not performed after a syringe change, the pump automatically performs a small system compliance step to remove slack when the [START/PAUSE] key is pressed (with door locked). Although fluid is not normally delivered to the patient during the compliance step, under some conditions up to 0.3 mL of fluid may be delivered. If 0.3 mL of fluid represents a hazard to the patient, the set should be disconnected during this operation.**

- **At flow rates less than 0.5 mL/hr, there may be a significant delay before flow is established if system is not purged.**
- **Selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values.**

LOADING DOSE/DOSE LIMITS

- **A loading dose is included in the 4-hour (or 1) dose limit calculation ONLY if administered after the 4-hour dose limit has been programmed. If the loading dose is administered prior to setting the 4-hour dose limit, it will NOT be included in the 4-hour dose limit calculation. The loading dose is always included in the total dose delivered.**
- **A supplemental "booster" dose can be delivered at any time during setup or operation, even if the 4-hour dose limit is already reached or will be exceeded after delivery.**
- **Setting a new 4-hour dose limit will not erase the previous 4-hour dose history.**
- **The concentration can only be changed by removing and re-inserting a custom vial or by turning the pump OFF then ON again. Once the concentration is programmed and confirmed, it cannot be changed without performing one of these two actions. If the concentration is changed, the current settings and consequently the dose limit accumulation are cleared.**
- **Partial boluses can be the result of interrupting delivery by pressing [START/STOP] (PCA + Cont.), opening the door (PCA Only), loss of power, reaching the dose limit, emptying the vial, or a malfunction alarm.**
- **If the loading or supplemental "booster" dose causes the 4-hour dose limit to be exceeded, the complete dose will still be delivered. The volume beyond the 4-hour dose limit will count towards the "next" rolling 4-hour dose limit.**

- **Always monitor the PCA 3 when delivering medication with the door open.**
- **Patient Pendant is only to be pressed by the intended patient.**

OPERATION

- **Perform close assessment and monitoring of patients receiving potent analgesic medication for possible adverse reactions.**
- **The PCA 3 is not intended to be used for frequent, long-term portable operation. Keep plugged into a properly grounded AC receptacle whenever possible, and reserve battery power for temporary portable operation and emergency backup. If the AC receptacle is in doubt, use battery power.**

MAINTENANCE

- **Always confirm bar code reader window is clean. Blood, fingerprints, condensation, and other elements may obstruct the view of the bar code reader. Elements on the window (other than scratches) can be cleaned by using one of the recommended cleaning solutions in the *Section 7, Maintenance.***
- **Window scratches cannot be wiped clean and will probably lead to window replacement.**
- **To avoid mechanical or electrical damage, do not immerse the pump in any fluids or cleaning solutions.**
- **Some cleaning and sanitizing compounds may slowly degrade components made from some plastic materials. Using abrasive cleaners or cleaning solutions not recommended by Hospira may result in product damage. Do not use compounds containing combinations of isopropyl alcohol and dimethyl benzyl ammonium chloride.**
- **Do not sterilize by heat, steam, ETO, or radiation.**
- **Do not place the PCA 3 in service if it fails the self-test.**

- **Hospira will be responsible for the effect on safety, reliability, and performance of this device only if: adjustments, modifications, or repairs are performed by persons authorized by Hospira; the electrical setup at the point of use complies with appropriate local requirements; and the device is used in accordance with the instructions for use identified in this operating manual.**

ALARMS

- **If the MALFUNCTION alarm sounds, press the [ON/OFF] key to turn the pump off. Then turn the pump back on. If the malfunction alarm repeats, remove the pump from service.**

EPIDURAL ADMINISTRATION

- **Recommended use of the epidural route is to provide anesthesia or analgesia for periods up to 96 hours.**
- **It is strongly recommended that the epidural infusion system be prominently identified as EPIDURAL. Failure to identify the infusion system as epidural could result in incorrect administration of intravenous rather than epidural formulations. In addition, failure to identify the epidural infusion system could result in confusion with other infusion systems delivering concomitant intravenous formulations.**
- **This device can be used to administer only those anesthetics/analgesics approved for epidural administration (as indicated or allowed by the drugs' FDA approved labeling). Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient.**
- **For epidural administration, the use of pump sets without Y-sites, and "epidural" stickers indicating ongoing epidural administration are recommended.**
- **Administration of drugs via the epidural route should be limited to personnel familiar with associated techniques**

and patient management problems. Proper epidural placement of the catheter is essential since catheter migration could result in intravascular or intrathecal administration. Facilities practicing epidural administration must be equipped with resuscitative equipment, oxygen, naloxone, and other resuscitative drugs. Adequate monitoring equipment (e.g., Oximetry) is recommended for continuous monitoring of the patient during epidural administration. Patients must be observed frequently for side effects in a fully-equipped and staffed environment for at least 24 hours following completion of drug administration by the epidural route. DELAYED RESPIRATORY DEPRESSION FOLLOWING CONTINUOUS EPIDURAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE HAS BEEN REPORTED.

- **The epidural space has 58 openings through which fluid can exit. Pressure buildup during administration is transient. However, if a large volume of fluid is administered over a short time period, the pressure will take longer to return to normal. If overdelivery occurs during administration, observe the patient closely for signs of spinal cord compression (disorientation, headache, transient neuralgias) and drug overdose.**

BATTERY OPERATION

WARNING

DISCONNECT AC POWER CORD BEFORE REMOVING BATTERY DOOR.

CAUTION: DO NOT OPERATE THE PCA 3 WITH THE BATTERY REMOVED ON PATIENTS. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS ENSURE PROPER OPERATION.

- **The battery may not be fully charged upon receipt. Connect the PCA 3 to AC power for at least 16 hours.**

- **Use AC power whenever possible. Connect to AC power during storage to ensure a fully charged battery for emergencies.**
- **Always connect the pump to a properly grounded receptacle unless battery operation is desired. If quality earth grounding source is in doubt, use battery power.**
- **If the low-battery alarm sounds, connect to AC power immediately.**

SETS AND ACCESSORIES

Use Hospira Lifecare PCA Set List 6517 whenever the pump is in CONTINUOUS or PCA+CONTINUOUS modes.

- **When using PCA or PCA+CONTINUOUS mode, another fluid line may be attached to the distal backcheck "Y" site. Use Hospira Lifecare PCA Set, List 3559, 6516, or a combination of List 6514 and 6517.**
- **It is recommended that highly viscous solutions and drugs, colloidal suspensions and emulsions should not be delivered through the inline backcheck valve of the PCA set. Valve functionality may be compromised by the presence of residue.**
- **Refer to vial and set package inserts for precautions and information on proper handling.**

NOTES

2) Principles of Operation

The PCA 3 Infuser is a portable infusion pump that allows a patient to self-administer analgesia within programmed limits as well as providing continuous infusion of desired drug. Generally, a nurse following a physician's order programs the infuser with operating parameters, which may include the following:

- **Loading Dose**
- **Delivery Mode Setting, i.e., PCA, CONTINUOUS, or PCA+CONTINUOUS**
- **PCA Dose**
- **Lockout Interval**
- **Rate of Continuous Flow**
- **1 or 4 Hour Dose Limit (*factory setting 4-hour*)**
- **Protocols (Hospital configured settings for prefilled vials)**

Available operating parameters and their allowed ranges are determined based on the confirmed vial and the delivery mode selected. The loading dose and dose limits are optional. This programmed flexibility allows the physician to tailor an effective pain management program unique to each patient.

The PCA 3 can be programmed to deliver either PCA doses (PCA mode), to deliver only a continuous background infusion with no PCA doses permitted (CONTINUOUS mode), or to deliver a continuous rate and allow PCA doses (PCA+CONTINUOUS mode).

Analgesic drugs may be delivered through the PCA 3 intravenously by any of the three modes mentioned above. In addition, Preservative-Free Morphine Sulfate Injection, USP, or other approved analgesic drugs can be administered epidurally through a recommended Low Priming Volume PCA Set without a Y-adapter. The epidural route can be used to provide analgesia by any of the three modes of infuser operation.

A “lockout” interval controls the frequency with which a patient may receive a PCA dose of analgesic. If the pump is set in the PCA or PCA+CONTINUOUS mode, the patient may request a bolus of analgesic during therapy by pressing a button on the patient pendant, causing the pump to release the specified bolus of analgesic into the IV line. After a Loading or Supplemental “booster” Dose delivery, the patient cannot receive any additional patient requested boluses until the lockout interval has elapsed, assuming the dose limit has not been exceeded *(see Section 5.4 for a detailed description of Dose Limits).*

The PCA 3 records therapy settings and up to 400 “events” that may occur during the therapy regimen. Events recorded include opening or closing of the security door, start or stop of continuous infusion, an alarm condition, and so on. All event descriptions are preceded with time of occurrence.

The PCA 3 operates on AC or back-up battery power. It attaches and locks to an IV pole and also has a locking security door to prevent tampering.

The alarm system sounds an audible alarm to alert the user to various conditions or a malfunction (*see Section 6.3 for a detailed description of alarm messages*).

2.1 Features

DRUG RECOGNITION

- **Bar code reader identifies drug name and concentration in the vial (prefilled Hospira vials only)**
- **Bar code reader identifies custom-filled vials when pharmacy-filled vial is used**

MODES OF DELIVERY

- **PCA Only**

- **Continuous**
- **PCA + Continuous**

PROGRAMMING

- **Keypad with large numbers, decimal point & icons for ease of use**
- **Prompting alphanumeric display**

BATTERY

- **8 V Battery**
- **Long battery life (4 hours) for emergency backup and temporary portable operation**

BIO MEDICAL

- **Serial Communication**
- **Upgradability (Field)**
- **Diagnostics Setup Options**
- **Alarm History**
- **Ability to store protocols for Hospira prefilled vials**

OPTIONS

- **Infusion History**

OTHER FEATURES

- **Microprocessor control**
- **Liquid crystal display (LCD) and Light-Emitting Diode (LED) display**
- **Panel back illumination**
- **Security Features**
- **Prefilled and Sterile empty vials**

2.2 Administration Equipment

The following sets and catheters are supplied sterile and are for single use only.

ADMINISTRATION SETS

List 3559: ***PCA Set, Mini-Bore with Integral Anti-Siphon Valve-SL 170 cm. Approximate Priming Volume 2.3 mL. For use in PCA mode via Intravenous route.***

List 6514: ***PCA Extension Set with Backcheck Valve-SL 25 cm. Approximate Priming Volume 1.1 mL. For use in conjunction with set 6517 to convert from Continuous to PCA mode via Intravenous route.***

List 6516: ***PCA Set-Long, Mini-Bore with Integral Anti-Siphon Valve-SL 218 cm. Approximate Priming Volume 2.6 mL. For use in PCA mode when extra length needed via Intravenous route.***

List 6517: ***PCA Continuous Infusion Set, Mini-Bore with Integral Anti-Siphon Valve-SL 203 cm. Approximate Priming Volume 1.5 mL.***

For use in Continuous and PCA+Continuous modes via Intravenous route.

For use in PCA, Continuous, and PCA+Continuous modes via Epidural route.

2.3 Printer Kits

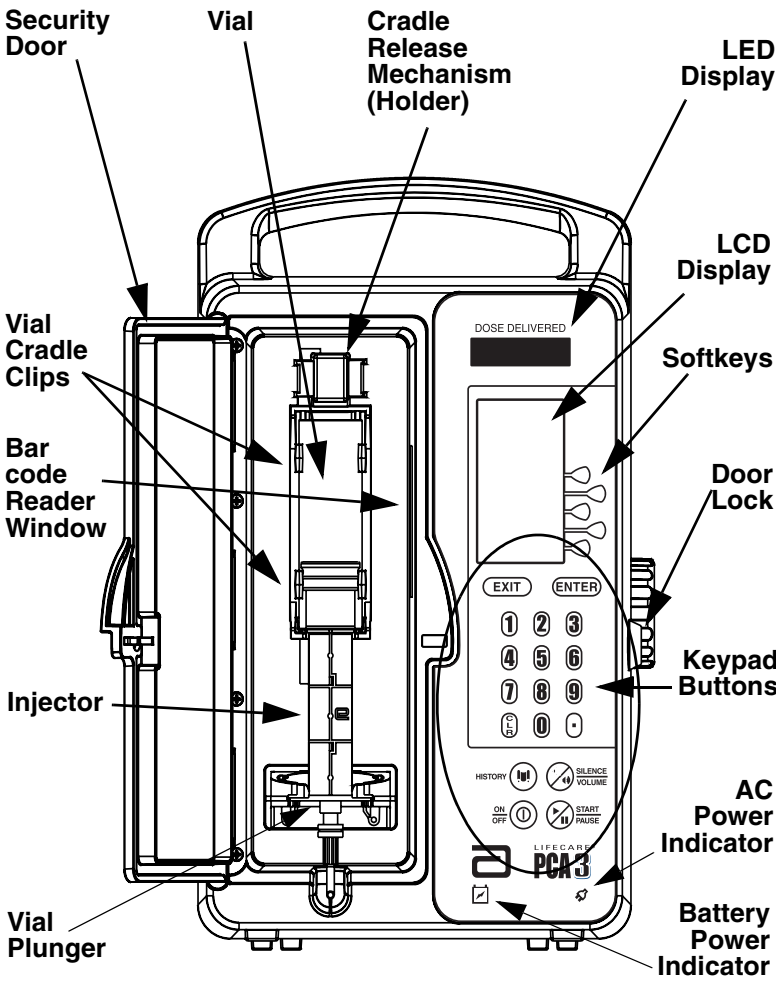
List 12406-01:	***Complete thermal printer kit includes: printer, connector cable, battery pack, AC adaptor, & paper pack.***
List 12406-02:	***Connector cable only***

***** See current product sales catalog for available drugs *****

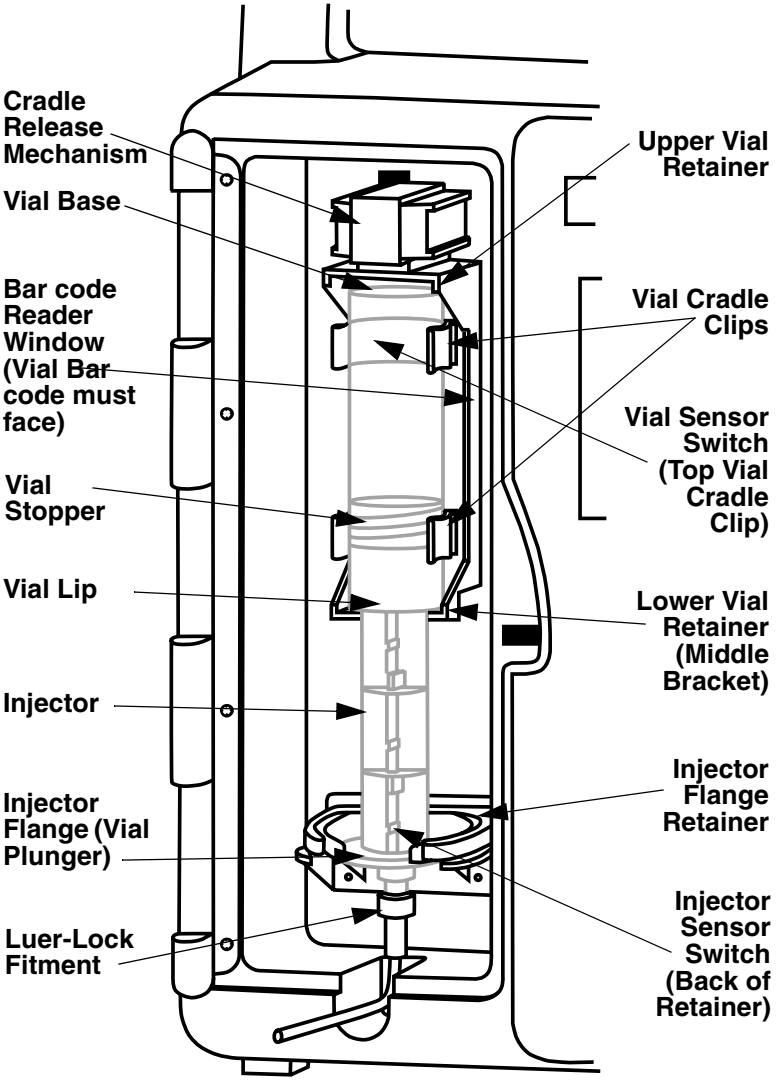
NOTES

3) Equipment Description

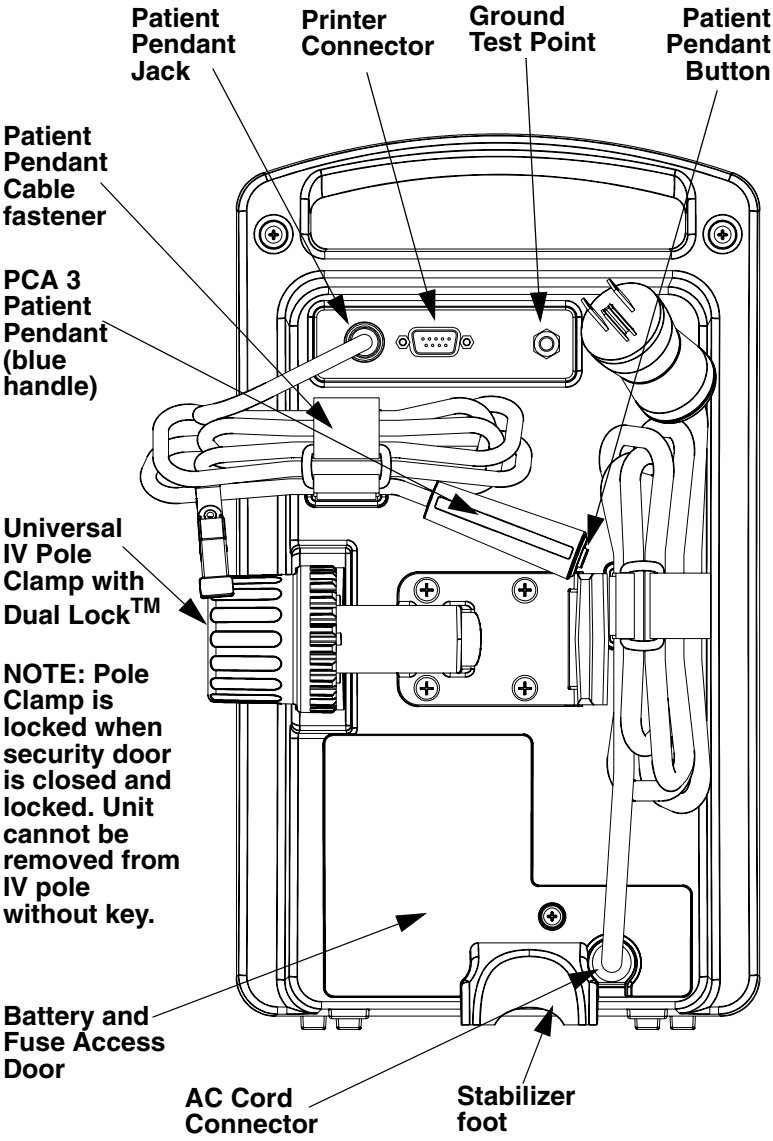
3.1 Components



Basic Layout of Front Panel and Keypad



Vial Cradle Assembly

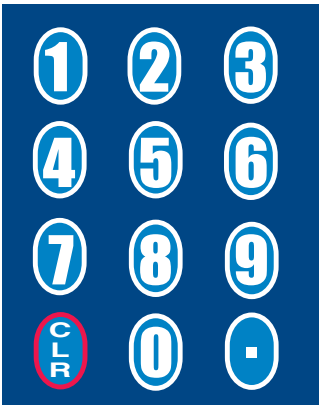

Patient Pendant Jack
Printer Connector
Ground Test Point
Patient Pendant Button
Patient Pendant Cable fastener
PCA 3 Patient Pendant (blue handle)
Universal IV Pole Clamp with Dual Lock™
NOTE: Pole Clamp is locked when security door is closed and locked. Unit cannot be removed from IV pole without key.
Battery and Fuse Access Door
AC Cord Connector
Stabilizer foot

Rear Panel

3.2 Operating Buttons & Keys

	The [ON/OFF] button is used to control the power of the PCA 3 instrument.
	The [CLEAR] button is used to clear an entry.
	The [ENTER] button is used to select and accept various screen options.
	The [EXIT] button is used to return to the main display from non-programming screens.

	**The [SILENCE/ VOLUME] button is used to temporarily silence an alarm while correcting a condition or to adjust alarm volume when the pump is in run mode.**
	**The [START/PAUSE] button is used to start or pause a continuous infusion.**
	**The [HISTORY] button is used to display parameter settings, dose history, and event log. It also provides access to the Print History softkey.**



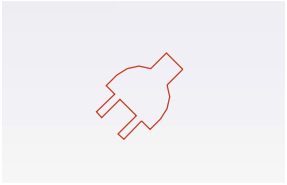
The numeric buttons are used to enter values for any field requiring numeric data.

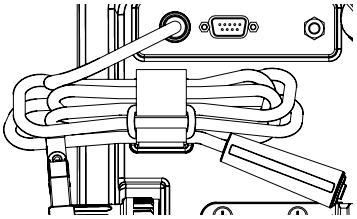
The [DECIMAL POINT] button is used for entering numbers with a decimal point. An example would be 10.5 mL.

Keys (or Softkeys) are touchkeys which are located to the right of the main display. They perform a variety of functions correlating to the description displayed on the screen.

An example of a softkey in this manual is *PCA ONLY>*

Battery indicator illuminates continuously when pump is running on battery power.

	**AC (mains) power indicator illuminates when pump is plugged into AC power.**
	**LED displays the dose delivered.** **When displaying dose delivery in micrograms, a vertical "walking stick" appears on the right side of the display.** **When displaying dose delivering in milligrams, the "walking stick" appears on the left side of the display.**



PCA 3 Patient Pendant is used by the patient to deliver the drug upon the press of the button.

WARNING

PATIENT PENDANT IS ONLY TO BE PRESSED BY THE INTENDED PATIENT.

If Patient Pendant is partially pressed, a Pendant Fault message will appear. This can be corrected by releasing the button. A PCA bolus will not be delivered during a Pendant Fault condition.

4) Basic Operation

4.1 GETTING STARTED

This section details the PCA 3 instrument setup procedures.

UNPACKING

CAUTION: PRODUCT DAMAGE MAY OCCUR UNLESS PROPER CARE IS EXERCISED DURING UNPACKING AND SETUP. DO NOT USE THE PCA 3 IF IT APPEARS DAMAGED IN ANY WAY. THE BATTERY MAY NOT BE CHARGED UPON RECEIPT.

Inspect the PCA 3 packaging for possible shipping damage. If damage is found, contact the delivery company immediately.

Use care when unpacking the PCA 3. Retain the packing slip and save all packing material in case the PCA 3 is damaged or fails the pump self-test and has to be returned to Hospira.

Inspect the PCA 3 thoroughly for damage.

CAUTION: IF THE PCA 3 APPEARS TO BE DAMAGED, CONTACT HOSPIRA.

CONNECTING THE PATIENT PENDANT

The Patient Pendant should be plugged into the unit prior to programming.

1) Connect Patient Pendant plug into back of unit opening labeled *Patient Control*.

2) Tighten connector ring snugly to confirm proper attachment.

SYSTEM SELF-TESTS

Connect the AC power (mains) cord to an AC power receptacle, then confirm that the power plug icon is illuminated on the front of the pump.

A systematic self-testing of the processing, delivery, and safety systems is performed whenever the PCA 3 is turned on, to verify readiness for operation.

> **CAUTION: DO NOT PLACE THE PCA 3 IN SERVICE IF IT FAILS THE SYSTEM SELF-TESTS.**
>
> **NOTE:** If the quality of earth grounding source is in doubt, use battery power.

Failure during the Self-Tests will be reported in the Malfunction Log as a Malfunction Condition.

Unlock door and press the [ON/OFF] button, or insert the vial, to turn the power on. Check screen display and listen for a beep to indicate the audio is working. Wait for the self-tests to complete. If successful, put a vial (with a fully primed set) into the pump.

When operating on battery power, a Low Battery message will be displayed informing you of the condition, and prompting you to connect to AC power.

> **CAUTION: DO NOT OPERATE THE PCA3 WITH THE BATTERY REMOVED. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS ENSURE PROPER OPERATION.**

To ensure battery is fully charged, connect the PCA 3 to AC power for a minimum of 16 hours while in the OFF mode.

If an alarm occurs during the power on self-test, identify the alarm message, then take corrective action (see *Section 6*, *Alarms and Troubleshooting*).

Power the pump ON. If the alarm recurs, remove the PCA 3 from service and contact the hospital biomedical department or your local Hospira representative.

DATA RETENTION

Delivery program settings and programming option selections are retained in memory.

If the PCA 3 has been turned OFF for more than one hour, all delivery settings are cleared and programming option selections are returned to zero and new programming must be entered.

4.2 Operating the PCA 3

INTRAVENOUS PCA ADMINISTRATION

1) Connect the syringe to the set and manually prime set.

2) Attach primary IV set line to recommended PCA set, list #'s 3559, 6516, or 6517 attached to list 6514 via backcheck valve port.

3) Prime IV set and the lower portion of the PCA set, and close the manual clamp on the IV set.

EPIDURAL PCA ADMINISTRATION

NOTE: The administration of drugs is restricted to those analgesic drugs approved for continuous epidural administration.

Recommended use of the epidural route is for labor and delivery, acute pain control, or post-operative analgesia for periods up to 96 hours.

WARNING

IT IS STRONGLY RECOMMENDED THAT THE EPIDURAL INFUSION SYSTEM BE PROMINENTLY IDENTIFIED AS "EPIDURAL". FAILURE TO IDENTIFY IT AS EPIDURAL MAY RESULT IN INCORRECT ADMINISTRATION OF INTRAVENOUS RATHER THAN EPIDURAL FORMULATIONS. IN ADDITION, FAILURE TO IDENTIFY THE EPIDURAL INFUSION COULD RESULT IN CONFUSION WITH OTHER INFUSION SYSTEMS DELIVERING CONCOMITANT INTRAVENOUS FORMULATIONS.

FOR EPIDURAL USE, ADMINISTER ONLY ANESTHETICS/ANALGESICS APPROVED FOR EPIDURAL ADMINISTRATION (AS INDICATED OR ALLOWED BY THE DRUGS' FDA APPROVED LABELING). EPIDURAL ADMINISTRATION OF DRUGS OTHER THAN THOSE INDICATED FOR EPIDURAL USE COULD RESULT IN SERIOUS INJURY TO THE PATIENT.

If patient access device is not indwelling, prime and establish epidurally. Confirm proper placement. Attach recommended low priming volume pump set, without Y-injection sites, to patient access device.

CAUTION: EPIDURAL ADMINISTRATION OF DRUGS BY PCA AND/OR CONTINUOUS MODES SHOULD BE LIMITED TO PERSONNEL FAMILIAR WITH ASSOCIATED TECHNIQUES AND PATIENT MANAGEMENT PROBLEMS. PROPER EPIDURAL PLACEMENT OF THE CATHETER IS ESSENTIAL SINCE CATHETER MIGRATION COULD RESULT IN INTRAVASCULAR AND INTRATHECAL ADMINISTRATION. FACILITIES PRACTICING CONTINUOUS EPIDURAL ADMINISTRATION MUST BE EQUIPPED WITH RESUSCITATIVE EQUIPMENT, OXYGEN, NALOXONE AND OTHER RESUSCITATIVE DRUGS. ADEQUATE MONITORING EQUIPMENT (E.G., OXIMETRY) IS RECOMMENDED FOR CONTINUOUS MONITORING OF THE PATIENT DURING EPIDURAL ADMINISTRATION. PATIENTS MUST BE OBSERVED FOR SIDE-EFFECTS FREQUENTLY IN A FULLY EQUIPPED AND STAFFED ENVIRONMENT FOR AT LEAST 24 HOURS FOLLOWING COMPLETION OF EPIDURAL DRUG ADMINISTRATION.

CAUTION: DELAYED RESPIRATORY DEPRESSION FOLLOWING CONTINUOUS EPIDURAL ADMINISTRATION OF PRESERVATIVE-FREE MORPHINE SULFATE HAS BEEN REPORTED.

If overdelivery occurs during administration, observe the patient carefully for signs of the following:

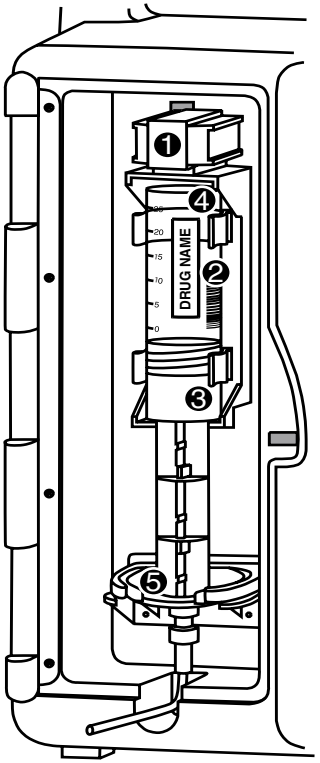
- **Compression on spinal cord (disorientation, headache, or transient neuralgia)**
- **Drug overdose**

The epidural space has 58 openings through which fluid can exit. Pressure build-up during administration is transient. However, if a large volume of fluid is administered over a short period, the pressure will take longer to return to normal.

4.3 Loading Vial

WARNING

FAILURE TO USE COMPATIBLE HOSPIRA VIAL/ INJECTOR AND HOSPIRA PCA SETS WITH INTEGRAL ANTI-SIPHON VALVE MAY CAUSE AN INACCURATE DOSE DELIVERY TO THE PATIENT.



1. Squeeze Cradle Release Mechanism together at the top of the holder and move to the uppermost position.

NOTE: Always confirm bar code reader window is clean before inserting vial.

2. Hold the vial with the graduated markings facing the clinician. This will ensure the vial bar code label faces the bar code reader on the right side of the vial compartment.

CAUTION: DO NOT LOAD VIAL INTO UPPER VIAL CLIP FIRST. VIAL LIP MAY CRACK OR CHIP.

3. Insert bottom of glass vial into the middle black bracket.

4. Gently press upper end of glass vial into upper black bracket.

5. Squeeze the top of the Cradle Release Mechanism and move down until the vial injector snaps into the bottom bracket.

6. Select *CONTINUE>*.

7. If vial bar code is not read by pump, slowly rotate the vial and position with the bar code on the right until bar code has been read.

CAUTION: VIAL AND INJECTOR MUST BE SECURELY LOCKED INTO THE INFUSER BEFORE BEGINNING DELIVERY.

WARNING

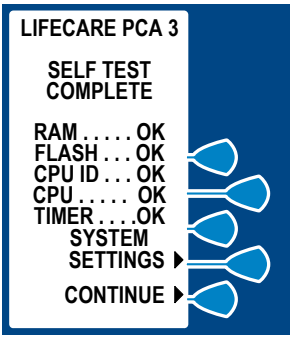
CRACKED VIALS MAY NOT SHOW EVIDENCE OF LEAKAGE UNTIL DELIVERY PRESSURE IS APPLIED.

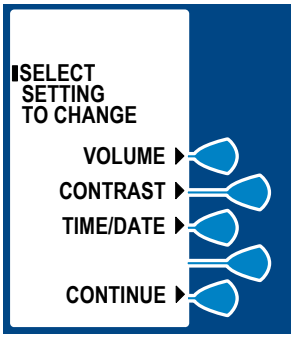
NOTE: If the device is OFF, improper loading of syringe will turn ON the device and activate a non-silenceable CHECK SYRINGE alarm within 30 seconds after ***CONTINUE>*** is selected. Proper loading (engaging injector flange) will silence the alarm.

4.4 Adjusting Settings

1) Press ⏻ button to power on the pump. Upon initial start-up, the self-test begins.

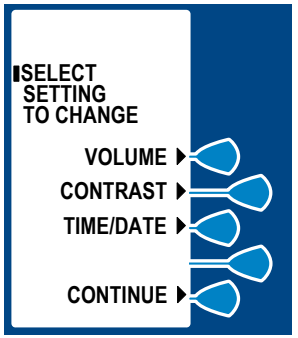
2) Select *SYSTEM SETTINGS>* to view the Change Settings menu.



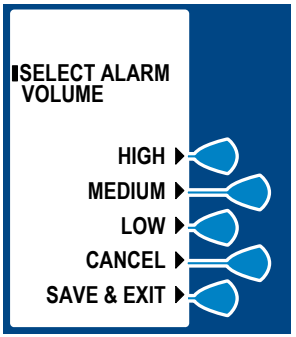


3) Choose the setting to change by selecting the appropriate softkey.

CHANGING ALARM VOLUME



1) Select *VOLUME>*.

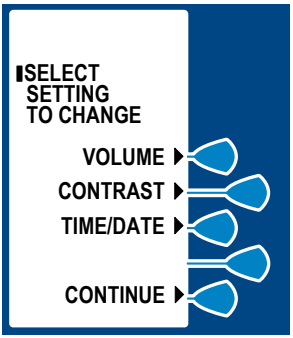


2) Select desired volume, then *SAVE & EXIT>*.

The current setting will flash at this screen.

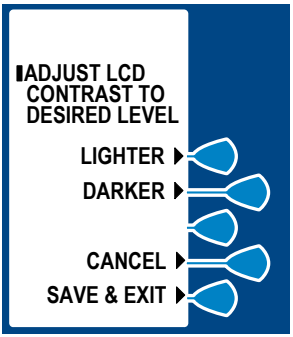
CHANGING CONTRAST OF MAIN DISPLAY

1) Select *CONTRAST>*.



2) Select desired adjustment softkey repeatedly until contrast is optimized for viewing.

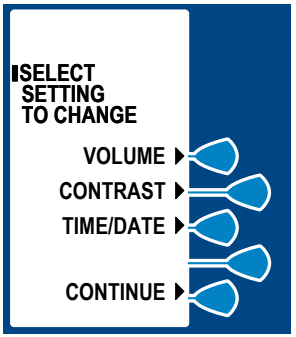
3) Select *SAVE & EXIT>*.



CHANGING OR CONFIRMING TIME AND DATE

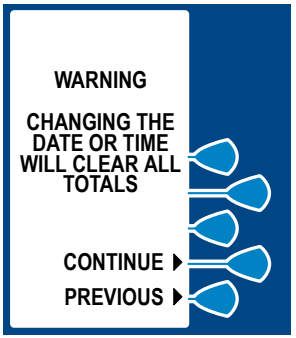
WARNING

CHANGING THE DATE OR TIME WILL CLEAR ALL TOTALS. THE CURRENT PROGRAM WILL REMAIN INTACT WHEN THE TIME/DATE FUNCTION IS ACCESSED. LOCKOUTS OR LIMITS IN PLACE WHEN THE TIME/DATE IS CHANGED WILL REMAIN IN EFFECT.

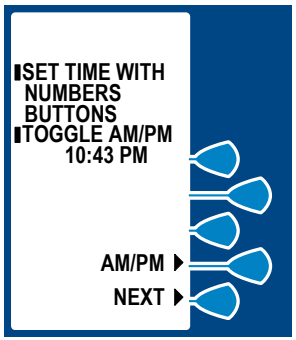


1) Select *TIME/DATE>*.

After selecting ***TIME/DATE>***, a warning screen appears to inform you that changing the date or time will clear all totals. The current program will remain intact when the time/date function is accessed. Lockouts or limits in place when the time/date is changed will remain in effect.



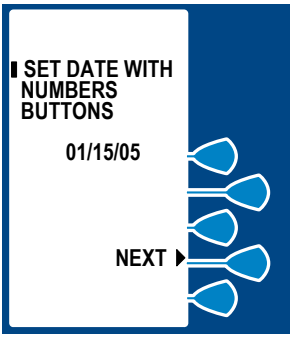
2) Warning Screen appears, select *CONTINUE>*.



3) Set Time with number buttons. Enter hour as two digits (*01*:00) and minutes as two digits (01:*07* PM). Select *AM/PM>* to alternate between AM and PM.

NOTE: Time can be displayed as 12 or 24 hour clock. The default setting is 12 hour.

4) After changing time, select *NEXT>* to change Date. Set date with numbers buttons.

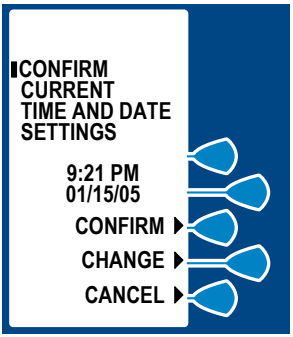


Current setting for Date will flash.

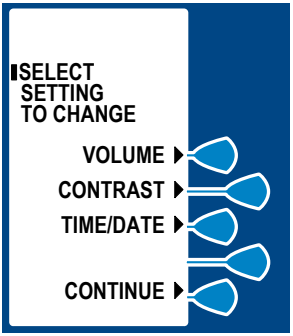
NOTE: Date must be entered in MM/DD/YY sequence.

5) Select *NEXT>* again after changing to desired date. This will advance you to the confirmation screen.

6) Select *CONFIRM>* to confirm the changed settings.



7) Then select *CONTINUE>* to exit the Change System Settings menu and display the Vial Confirmation screen (if vial is loaded properly).

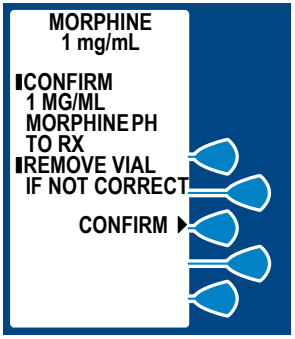


4.5 Guided Start-Up for Prefilled vials

1) Press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins. *(See Section 4.3)*

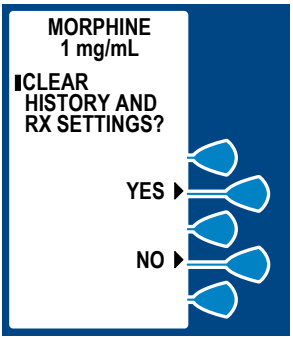
This screen will be followed by another displaying all self-test information, including time, date, software version and copyright information. It lasts about 2 seconds. During the self-test, the pump will read the bar code label.

2) Select *CONTINUE>* to advance to the next screen.



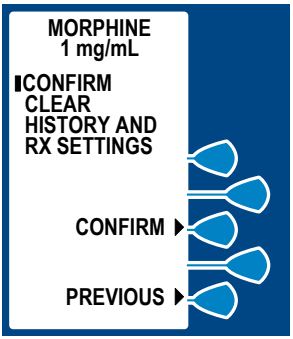
3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.

4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF for 1 hour or less.

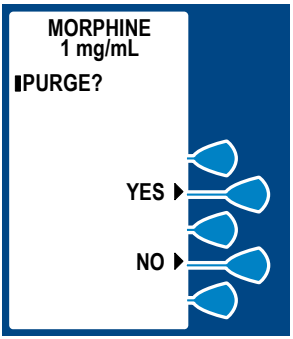


5) Select *CONFIRM>* to confirm choice and continue.

A screen will appear confirming History has been cleared.



6) Select either *YES>* or *NO>* to purge the system.



PURGING THE SYSTEM

WARNING

PATIENT MUST BE DISCONNECTED FROM THE PCA SET BEFORE THE PURGE CYCLE.

After the pump is turned on, and the self-tests complete, you are prompted to purge the system. Confirm the PCA set is disconnected from the patient's IV line before pressing ***YES>*** to initiate the purge cycle.

Press and hold the ***PURGE>*** key. The flow rate during purging is approximately 250 mL/hr. As soon as fluid is seen at the end of the administration set, and no air remains in the set, release the key. After the ***PURGE>*** key is released, the purge cycle will stop and the pump will prompt you to respond if flow was seen. If flow was not seen, the cycle may be repeated until a total of 3 mL has been delivered.

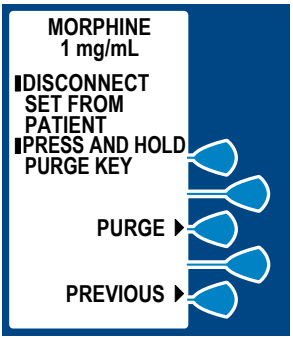
To remove system slack when a new syringe is installed, it is recommended that the pump be purged before beginning operation.

NOTE: The system must be primed before purging. Remove all air from the syringe before putting it into the pump.

NOTE: Drug delivered during the purge cycle is not stored in system memory and will not be displayed.

CAUTION: IN CONTINUOUS AND PCA+CONTINUOUS MODES, IF A PURGE IS NOT PERFORMED AFTER A SYRINGE CHANGE, THE PUMP AUTOMATICALLY PERFORMS A SMALL SYSTEM COMPLIANCE STEP TO REMOVE SLACK WHEN [START] IS PRESSED (WITH DOOR LOCKED). ALTHOUGH FLUID IS NOT NORMALLY DELIVERED TO THE PATIENT DURING THE COMPLIANCE STEP, UNDER SOME CONDITIONS UP TO 0.3 ML OF FLUID MAY BE DELIVERED. IF 0.3 ML OF FLUID REPRESENTS A HAZARD TO THE PATIENT, THE SET SHOULD BE DISCONNECTED DURING THIS OPERATION.

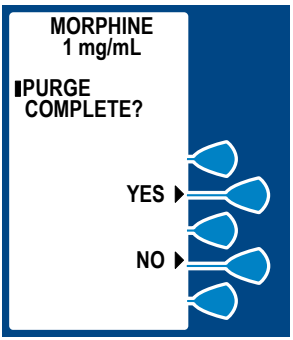
7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.



While purging is occurring, the word PURGING will be displayed.

> **NOTE:** Purging is recommended to remove system slack when a new vial is inserted. The maximum volume delivered during a purge is 3 mL.

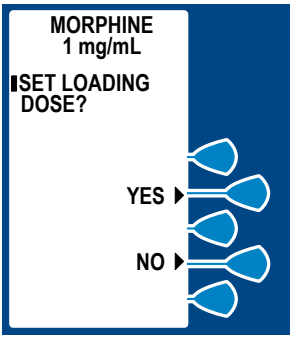
Upon release of the ***PURGE>*** softkey, the display will ask if the purge is complete.



8) Select *YES>* to continue, or select *NO>* to purge again until complete.

9) Reconnect Set to patient.

10) Set Loading Dose (if desired) by selecting *YES>*.

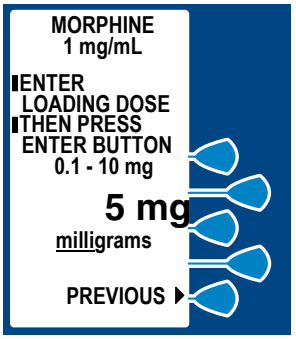


If ***NO>*** is selected, you will go directly to the Select Mode screen. Information on modes can be found in *Section 5*.

LOADING DOSE

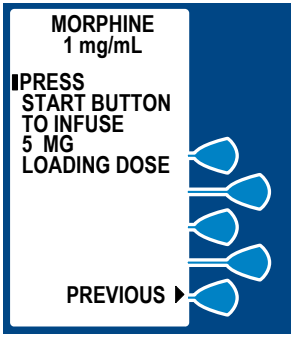
After the drug concentration has been confirmed, an optional loading dose may be programmed to provide an immediate bolus to the patient.

NOTE: A supplemental (booster) dose can be delivered at any time during operation by opening the door and selecting the ***LOADING DOSE>*** key. If the 4 (1) Hr Dose Limit is set and has been reached, using the loading dose function may result in exceeding the dose limit.



11) Enter a Loading Dose within the displayed range.

12) Then press ENTER.

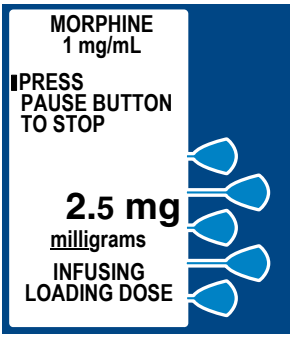


13) Press button to infuse programmed Loading Dose.

NOTE: If an occlusion condition is detected, the delivery will stop for 10 seconds. If the occlusion condition still exists at the 10-second mark, then the Occlusion Alarm occurs. Otherwise, the delivery is automatically resumed.

Example screen displaying Loading Dose Value as it infuses. Bottom of screen displays text confirming Loading Dose is active. Upon completion, Red LED (above LCD) displays Dose Delivered.

This will bring you to the Select Mode screen which is described in the next section.

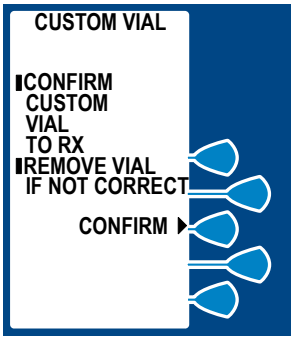


4.6 Guided Start-Up for Custom Vials

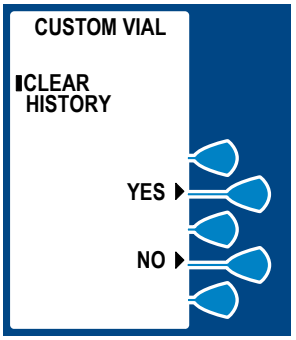
1) Press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins.

This screen will be followed by another displaying all self-test information, including time, date, software version and copyright information. It lasts about 2 seconds. During the self-test, the pump will read the bar code label.

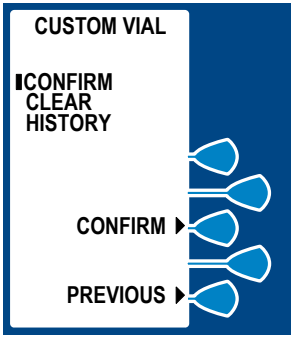
2) Select *CONTINUE>* to advance to the next screen.



3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.



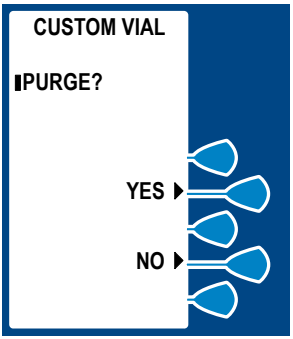
4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF one hour or less.



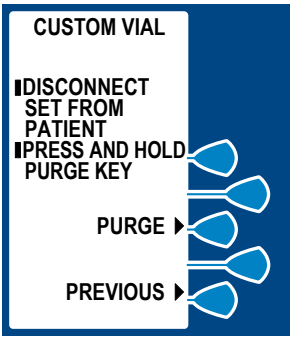
5) Select *CONFIRM>* to confirm choice and continue.

A screen will appear confirming History has been cleared.

6) Select either *YES>* or *NO>* to purge the system.



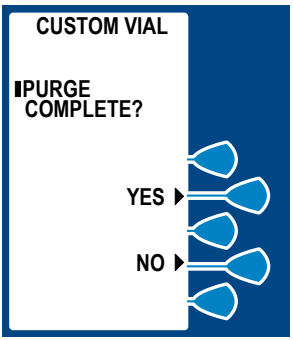
7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.



While purging is occurring, the word PURGING will be displayed.

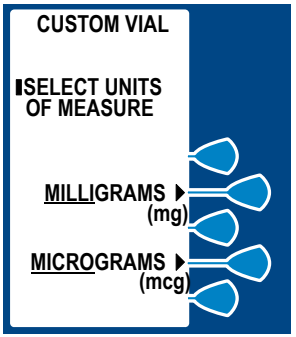
> **NOTE:** Purging is recommended to remove system slack when a new vial is inserted. The maximum volume delivered during a purge is 3mL.

Upon release of the ***PURGE>*** softkey, the display will ask if the purge is complete.



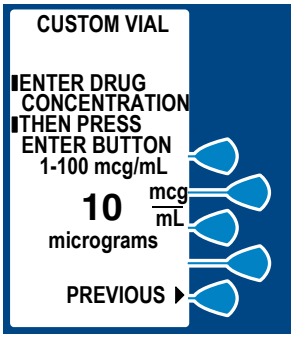
8) Select *YES>* to continue, or select *NO>* to purge again until complete.

9) Reconnect Set to patient.



10) Select desired Units of Measure.

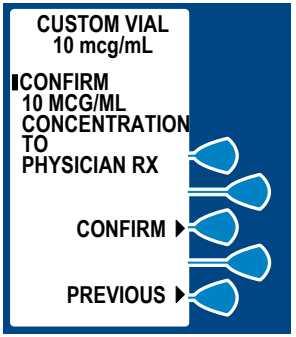
For the purposes of this instruction, Micrograms is selected.



11) Enter desired Drug Concentration within the displayed range.

NOTE: Only whole numbers may be entered when using micrograms (mcg). If a decimal entry is attempted, the display will inform the user that decimals are not allowed. Press [CLEAR] to zero the value. Then enter a value within the displayed range.

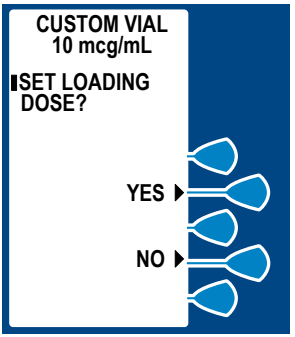
12) Then press ENTER.



13) Confirm Concentration by selecting *CONFIRM>*.

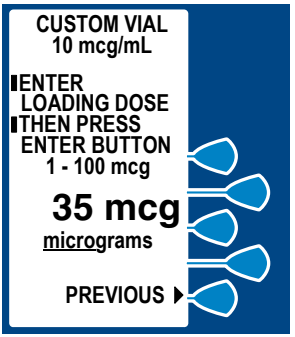
14) Set Loading Dose (if desired) by selecting *YES>*.

If ***No>*** is selected, you will go directly to the Select Mode screen. Information on modes can be found in Section 5.



15) Enter a Loading Dose within the displayed range.

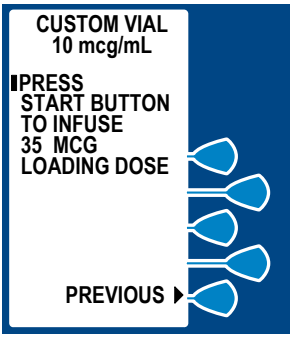
16) Then press ENTER.

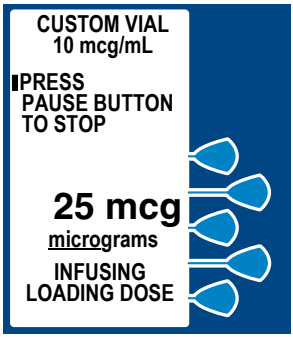


17) Press button to infuse programmed Loading Dose.

WARNING

ALWAYS MONITOR THE PCA 3 WHEN DELIVERING MEDICATION WITH THE DOOR OPEN.





Example screen displaying Loading Dose Value as it infuses. Bottom of screen displays text confirming Loading Dose is active. Upon completion, Red LED (above LCD) displays Dose Delivered.

This will bring you to the Select Mode screen which is described in the next section.

5) Select Mode

5.1 Modes of Delivery

The PCA 3 delivers analgesia in one of three modes:

- **PCA ONLY**
- **CONTINUOUS**
- **PCA+CONTINUOUS**

PROTOCOLS

Pre-programmed settings for the 3 delivery modes, created in the Service Mode for Hospira prefilled drug vials. For information on using the Service Mode, contact Hospira Technical Support Operations at 1-800-241-4002.

NOTE: Protocols not available for Custom Vials.

PCA ONLY

A patient initiated dose can be administered using the patient pendant when the PCA AVAILABLE message appears. After completing the dose, the pump enters either the preset LOCKOUT interval or the DOSE LIMIT REACHED state (if a dose limit has been entered); further delivery is prohibited in both of these conditions.

Partial doses can be the result of interrupting delivery by pressing [START/STOP] (PCA + Cont.), opening the door (PCA Only), loss of power, reaching the dose limit, emptying the vial, or a malfunction alarm.

The screen message will alert the user that PCA is not available and a different audible tone will occur if patient pendant button is pressed (unless deactivated in Service Mode).

CONTINUOUS

A programmed continuous infusion is started by pressing the **[START/PAUSE]** button after the door is closed and locked. The patient pendant is disabled in CONTINUOUS mode. Upon reaching the DOSE LIMIT, if entered, the pump stops drug delivery and the 4 (or 1)-HR LIMIT REACHED message is displayed.

PCA+CONTINUOUS

Infusion is started by pressing the **[START/PAUSE]** button after the door is closed and locked. A patient initiated PCA dose can be administered using the patient pendant when the PCA AVAILABLE message appears. When the patient-initiated dose is activated, the PCA dose is delivered prior to the CONTINUOUS infusion rate. After the PCA dose is completed, the pump enters the LOCKOUT interval. While in the lockout period, the CONTINUOUS infusion remains in progress, but the patient initiated dose cannot be activated. **If a Dose limit state has been reached, the pump stops drug delivery.**

> **NOTE:** In CONTINUOUS or PCA+CONTINUOUS mode, The **[START/PAUSE]** button must be pressed within 30 seconds of locking the door or the pump will alarm.

5.2 Programming PCA Only

For detailed Startup information including Vial Insertion, Clearing Settings, Purging, and setting a Loading Dose, *see Section 4*.

Also refer to *Section 4* for information on adjusting system settings such as contrast and volume.

1) Unlock door and press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins.

2) Select *CONTINUE>* to advance to next programming screen.

3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.

4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF for one hour or less.

5) Select *CONFIRM>* to confirm choice and continue.

6) Select either *YES>* or *NO>* to purge the system.

7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.

8) Select *YES>* to continue, or select *NO>* to purge again until complete.

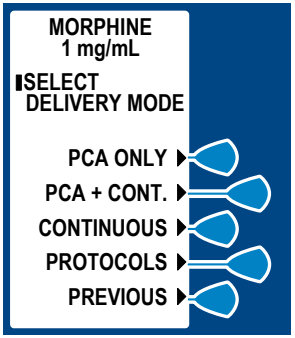
9) Reconnect Set to patient.

10) Set Loading Dose (if desired) by selecting *YES>*.

11) Enter a Loading Dose within the displayed range.

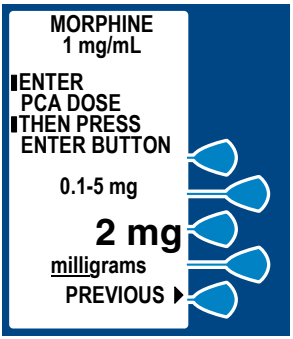
12) Then press ENTER.

13) Press button to infuse programmed Loading Dose.



14) From the Select Delivery Mode screen, select *PCA ONLY>*.

15) Enter the desired PCA dose using the numeric keypad. (Value range is displayed on screen)

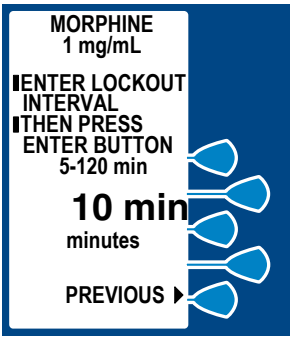


If value is entered incorrectly, press CLR to change value.

16) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

17) Enter a lockout Interval value. (Value range is displayed on the screen)



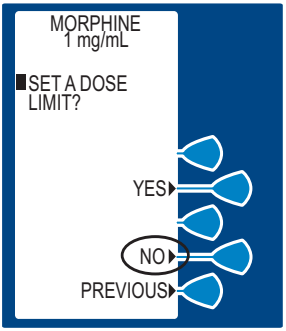
If value is entered incorrectly, press CLR to change value.

18) Then press ENTER.

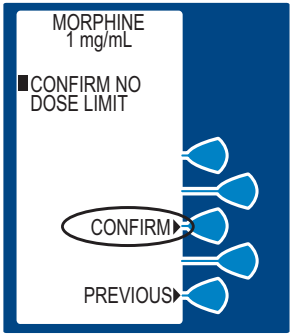
If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

19) Set a specific dose limit by selecting *YES>* and advancing to the Dose Limit Enter Value screen. Or select *NO>* to choose No Dose Limit.

No Dose Limit will be selected for this example.

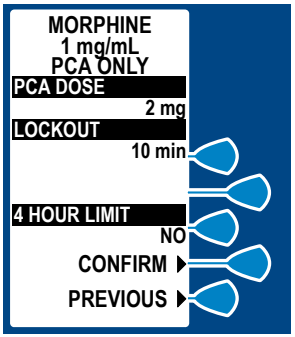


NOTE: *See Section 5.6 Dose Limit (1 or 4 hour)* for complete information on this feature.



20) Select *CONFIRM>* to confirm No Dose Limit selection.

Select ***PREVIOUS>*** to return to the previous screen.



21) Select *CONFIRM>* to confirm settings. Or, select *PREVIOUS>* to return to the previous screen.

22) Close and lock door. Place key in a secure location. Upon door lock, PCA is available.

23) Patient presses pendant to initiate PCA dose.

NOTE: If an occlusion condition is detected, the delivery will stop for 10 seconds. If the occlusion condition still exists at the 10-second mark, then the Occlusion Alarm occurs. Otherwise, the delivery is automatically resumed.

Approximately 10 seconds after door is locked, “Door Locked” message will disappear. After delivery of PCA dose, PCA LOCKOUT message appears indicating PCA is locked out.

If Patient Pendant is partially pressed, a Pendant Fault message will appear. This could be corrected by releasing the button.

When Dose Limit is reached, a message will be displayed indicating Dose Limit has been reached.

5.3 Continuous Mode

For detailed Startup information including Vial Insertion, Clearing Settings, Purging, and setting a Loading Dose, see Section 4.

Also refer to Section 4 for information on adjusting system settings such as contrast and volume.

1) Unlock door and press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins.

2) Select *CONTINUE>* to advance to next programming screen.

3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.

4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF one hour or less.

5) Select *CONFIRM>* to confirm choice and continue.

6) Select either *YES>* or *NO>* to purge the system.

7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.

8) Select *YES>* to continue, or select *NO>* to purge again until complete.

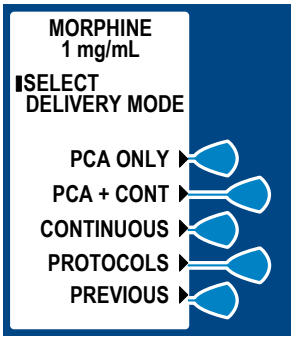
9) Reconnect Set to patient.

10) Set Loading Dose (if desired) by selecting *YES>*.

11) Enter a Loading Dose within the displayed range.

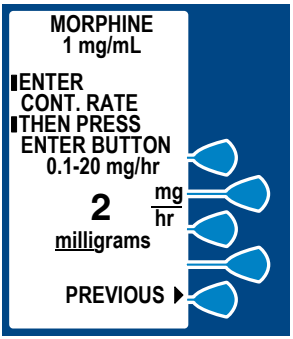
12) Then press ENTER.

13) Press button to infuse programmed Loading Dose.



14) From the Select Mode screen, select *CONTINUOUS>*.

15) Enter a value using the keypad. (Value range is displayed on screen)

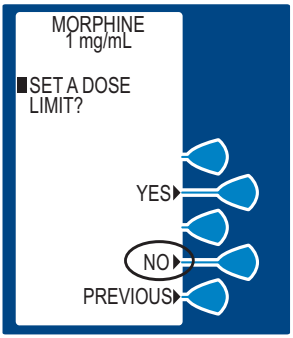


If value is entered incorrectly, press CLR to change value.

16) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

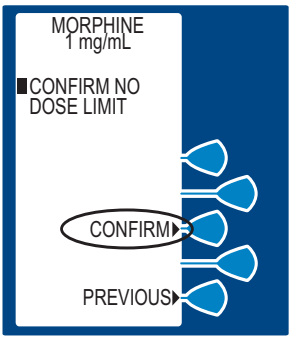
17) Set a specific dose limit by selecting *YES>* and advancing to the Dose Limit Enter Value screen. Or select *NO>* to choose No Dose Limit.



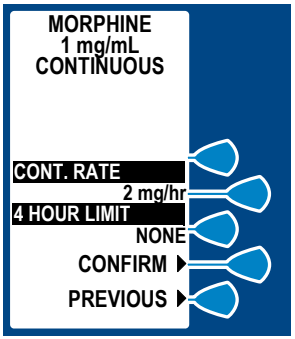
No Dose Limit will be selected for this example.

> **NOTE:** *See Section 5.6 Dose Limit (1 or 4 hour)* for complete information on this feature.

18) Select *CONFIRM>* to confirm No Dose Limit selection.



Select ***PREVIOUS>*** to return to the previous screen.



19) Select *CONFIRM>* to confirm settings.

Or, select ***PREVIOUS>*** to return to the previous screen.

20) Close and lock door. Place key in a secure location.

21) Press to begin therapy.

Approximately 10 seconds after door is locked and is pressed, “Door Locked” message will disappear.

When Dose Limit is reached, a message will be displayed indicating Dose Limit has been reached.

5.4 PCA + Continuous Mode

For detailed Startup information including Vial Insertion, Clearing Settings, Purging, and setting a Loading Dose, see Section 4.

Also refer to Section 4 for information on adjusting system settings such as contrast and volume.

1) Unlock door and press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins.

2) Select *CONTINUE>* to advance to next programming screen.

3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.

4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF one hour or less.

5) Select *CONFIRM>* to confirm choice and continue.

6) Select either *YES>* or *NO>* to purge the system.

7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.

8) Select *YES>* to continue, or select *NO>* to purge again until complete.

9) Reconnect Set to patient.

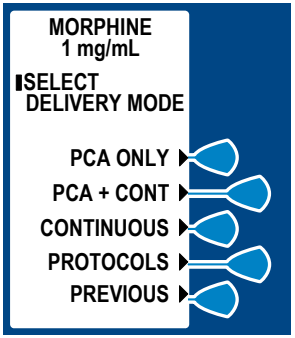
10) Set Loading Dose (if desired) by selecting *YES>*.

11) Enter a Loading Dose within the displayed

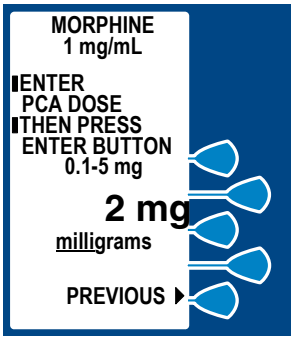
range.

12) Then press ENTER.

13) Press button to infuse programmed Loading Dose.



14) From the Select Mode screen, select *PCA + CONT.>*.



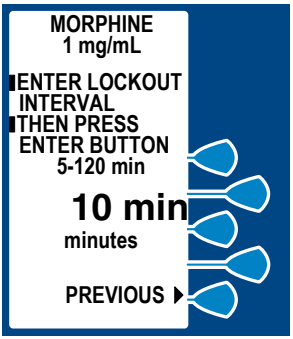
15) Enter PCA dose value using the keypad. (Value range is displayed on screen)

If value is entered incorrectly, press CLR to change value.

16) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

17) Enter a Lockout Interval value. (Value range is displayed on screen)

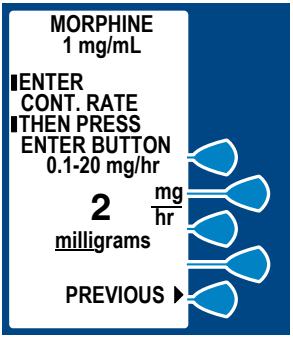


If value is entered incorrectly, press CLR to change value.

18) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

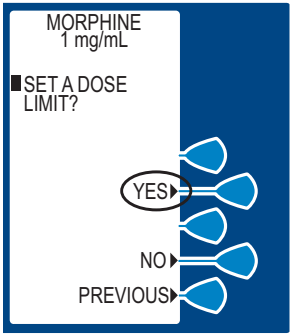
19) Enter a Continuous Rate. (Value range is displayed on screen)



If value is entered incorrectly, press CLR to change value.

20) Then press ENTER.

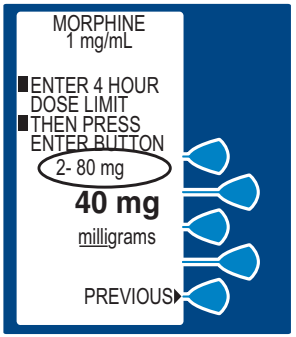
If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.



21) Set a specific dose limit by selecting *YES>* and advancing to the Dose Limit Enter Value screen. Or select *NO>* to choose No Dose Limit.

Setting a specific Dose Limit will be selected for this example.

NOTE: *See Section 5.6 Dose Limit (1 or 4 hour)* for complete information on this feature.



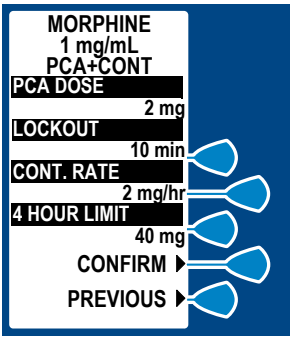
22) Enter the Dose Limit value using the numeric keypad (the range is displayed on the screen).

If value is entered incorrectly, press CLR to change value.

23) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

24) Select *CONFIRM>* to confirm settings.



Or, select ***PREVIOUS>*** to return to the previous screen.

25) Close and lock door. Place key in a secure location.

26) Press to begin therapy.

Approximately 10 seconds after door is locked and is pressed, “Door Locked” message will disappear.

5.5 Protocols

NOTE: Standard Protocols must be established by hospital through the Service Mode. Protocols can only be established for Hospira prefilled vials. Only Protocols associated with the inserted drug vial will be available.

For detailed Startup information including Vial Insertion, Clearing Settings, Purging, and setting a Loading Dose, *see Section 4*.

Also refer to Section 4 for information on adjusting system settings such as contrast and volume.

1) Unlock door and press ⏻ button, or load drug vial into cradle, to power on the pump. Upon initial start-up, the self-test begins.

2) Select *CONTINUE>* to advance to next programming screen.

3) Select *CONFIRM>* to accept the inserted drug or remove the vial if not correct.

4) Select either *YES>* or *NO>* to clear history and dose settings if pump has been OFF one hour or less.

5) Select *CONFIRM>* to confirm choice and continue.

6) Select either *YES>* or *NO>* to purge the system.

7) If *YES>* is selected, disconnect the set from the patient, and press and hold the *PURGE>* softkey.

8) Select *YES>* to continue, or select *NO>* to purge again until complete.

9) Reconnect Set to patient.

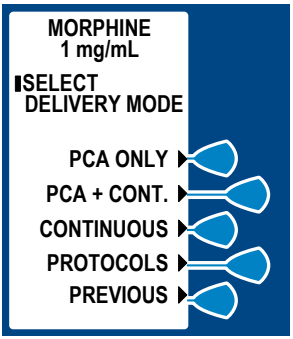
10) Set Loading Dose (if desired) by selecting *YES>*.

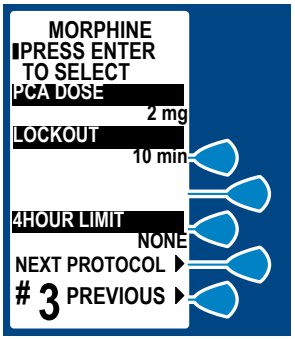
11) Enter a Loading Dose within the displayed range.

12) Then press ENTER.

13) Press button to infuse programmed Loading Dose.

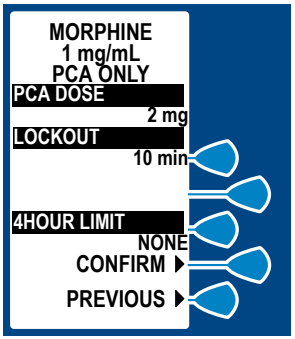
14) From the Select Mode screen, select *PROTOCOLS>*.





15) Press ENTER to accept protocol, or select *NEXT PROTOCOL>* and *PREVIOUS>* to view other stored protocols if available.

Press ***PREVIOUS>*** to return to the previous display.



16) Select *CONFIRM>* to accept settings of chosen protocol.

17) Close and lock door.

18) Press button to begin chosen Protocol.

5.6 Dose Limit (1 or 4 hour)

DOSE LIMIT CALCULATION

The dose limit is a physician prescribed value that serves to limit the total dosage that can be delivered in any 4 hr (or 1 hr) period. This optional feature provides added safety to limit the total drug delivered in all delivery modes.

> **NOTE:** The PCA 3 is factory set for programming a 4 hr dose limit. However, it can be changed to a 1 hr dose limit setting by a qualified biomedical person. For the purpose of simplifying this section, it will be written for 4 hr dose limit programming.

NOTE: A loading or supplemental loading dose is included in the 4 hr dose limit calculation ONLY if it is administered AFTER the 4 hr dose limit has been programmed. If a loading or supplemental loading dose is administered BEFORE a 4 hr dose limit has been programmed, it will NOT be included in the 4 hr dose limit calculation. The loading and/or supplemental loading dose(s) is always included in the total for dose delivered.

When the sum of all doses (PCA dose, CONTINUOUS dose, and any applicable loading or supplemental loading dose) in the rolling 4 hour period equals or exceeds the 4 hr dose limit, patient requests for doses are unsuccessful and a "4 HR LIMIT REACHED" message appears. In all modes, the pump stops delivery when the 4 hr dose limit is reached, except during administration and delivery of a supplemental loading dose. A supplemental loading dose can be delivered anytime during setup or operation, even if the dose limit has already been reached (as indicated by a “4 HR LIMIT REACHED” message) or will be exceeded after delivery.

As the oldest dose (either PCA dose, CONTINUOUS dose, or a supplemental loading dose) ages out of the 4 hour dose record, the “4 HR LIMIT REACHED” message will disappear. The pump will again accept patient initiated dose requests in PCA Only and PCA+CONTINUOUS modes (assuming the programmed PCA lockout interval has also elapsed) and resumes infusion at the continuous rate in the CONTINUOUS and PCA+CONTINUOUS modes.

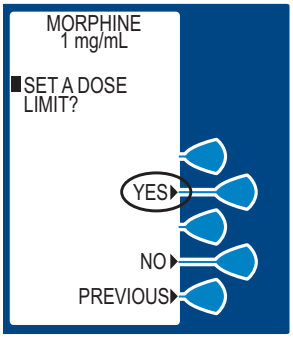
NOTE: A loading dose or supplemental loading dose can be delivered anytime during setup or operation, even if the dose limit has already been reached or will be exceeded after delivery.

NOTE: Setting a new dose limit will not erase the previous dose history.

PROGRAMMING THE 4 (OR 1) HR DOSE LIMIT

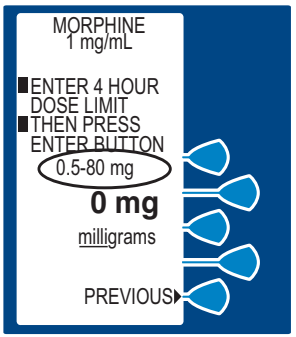
The opportunity to program this feature is presented in two entry screens. The first screen prompts the clinician to choose whether or not to set a Dose Limit. Selecting ***NO>*** will bring up the Confirm No Dose Limit screen. Selecting ***YES>*** will bring up the Dose Limit Enter Value screen, requiring the clinician to enter a value within the displayed range.

TO PROGRAM A DOSE LIMIT:



1) Select *YES>* at the Dose Limit Selection screen.

The display will advance to the Dose Limit Enter Value screen.



2) Enter the 4 HR Dose Limit value using the numeric keypad (the value range is displayed on the screen).

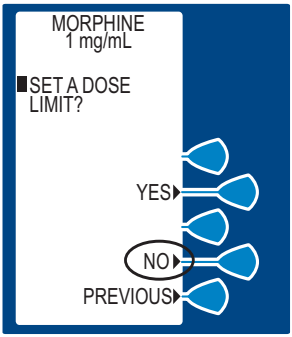
NOTE: Entry of "0" for the 4 HR Dose Limit, using the numeric keypad, is NOT accepted by the PCA 3. If appropriate, *see instructions for programming NO Dose Limit on the following page.*

3) Then press ENTER.

TO PROGRAM NO DOSE LIMIT:

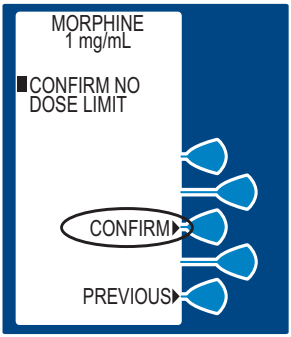
1) Select *NO>* at the Dose Limit Selection screen.

The display will advance to the Confirm No Dose Limit screen.

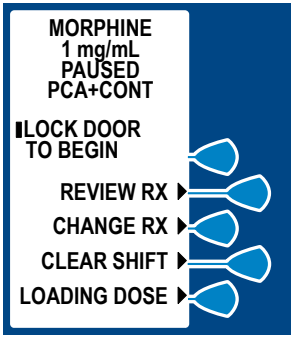


2) Select *CONFIRM>* to confirm the selection of No Dose limit.

NOTE: When NO LIMIT has been programmed, the message “NO 4 HR LIMIT” will be displayed after the door has been locked.



TO CLEAR OR CHANGE DOSE LIMIT



1) Unlock door while pump is running.

2) Select *CHANGE RX>*.

3) Select *NEXT>* to display more change options.

4) Select *DOSE LIMIT>*.

5) Set a specific dose limit by selecting *YES>* and advancing to the Dose Limit Enter Value screen.

Or, select ***NO>*** to choose No Dose Limit.

No Dose Limit will be selected for this example.

6) Select *CONFIRM>* to confirm the No Dose Limit selection.

Or, select ***PREVIOUS>*** to return to the previous screen.

7) Press *SAVE & EXIT>* at the next screen. This will bring up the Program Review screen.

8) Press *CONFIRM>* to accept new program.

CLEARING THE HISTORY & RX SETTINGS

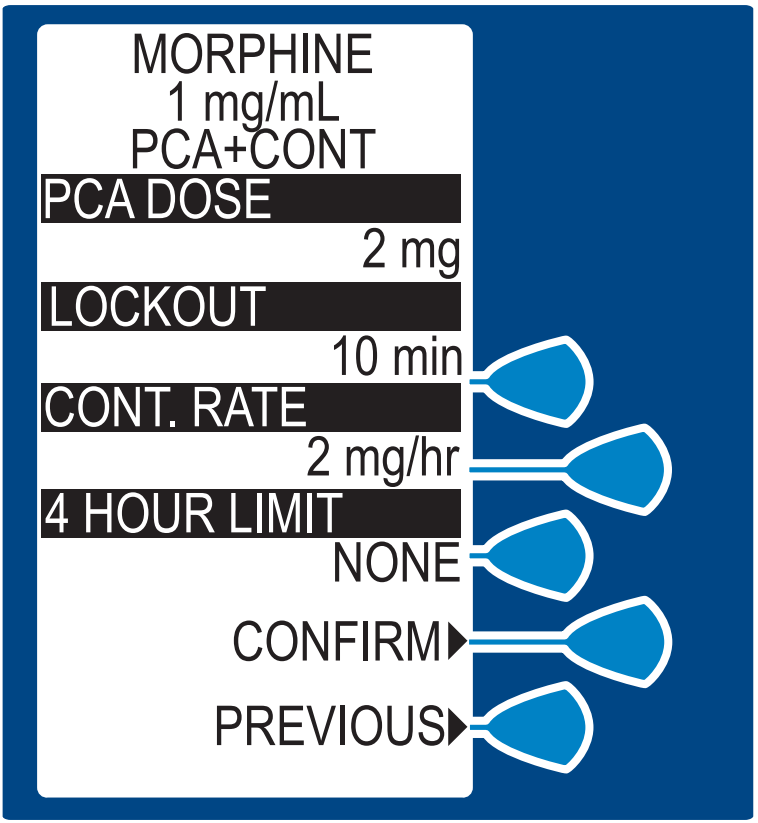
To clear the dose limit history, turn the pump off and on, and press ***CONFIRM>*** when the "CONFIRM TO CLEAR HISTORY AND Rx" screen appears.

5.7 Using Review Screens

REVIEW SCREENS

Prior to locking the pump and removing the key, a review screen will appear as shown below. As determined by the programmed mode of delivery, the screen will display the current settings for the applicable parameters (including PCA Dose, Lockout Interval, Continuous Rate, and 4 (1) Hr Dose Limit)

.



- **Clinicians should review each programmed parameter and ensure that the displayed program agrees with the physician's order.**
- **If all of the programmed parameters AGREE with the physician's order, the clinician can confirm the settings by selecting *CONFIRM>*.**
- **If one or more of the programmed parameters do not agree with the physician's order, the clinician should select *PREVIOUS>* until the incorrectly programmed parameter(s) is displayed. Depending on the parameter(s) that is incorrect, the programmed values can be changed by either entering the new value by using the numeric keypad and pressing [ENTER] or selecting the new setting using the appropriate *SOFTKEY>*. Once the appropriate parameters have been changed, the review screen will be presented again. The clinician should review each setting to ensure agreement with the physician's order.**
- **Once *CONFIRM>* has been selected, the clinician should close and lock the door.**
- **Place the key in a secure location.**
- **Upon locking the door, PCA is available if the mode is set on either PCA ONLY or PCA + CONTINUOUS. If mode is set for PCA + CONTINUOUS or CONTINUOUS, therapy will begin after pressing [START/PAUSE].**

5.8 Changing Settings During Setup

During setup, select ***PREVIOUS>*** to return to the previous display and enter desired setting. Each time ***PREVIOUS>*** is selected, the message display will revert to the previous setting, until the first setting is displayed.

5.9 Stopping Infusion or Turning Pump OFF

STOPPING INFUSION

1) Close slide clamp on PCA administration set.

WARNING

ALWAYS CLOSE SLIDE CLAMP ON PCA ADMINISTRATION SET BEFORE REMOVING OR REPLACING SYRINGE, AND BEFORE DISCONTINUING INFUSION

2) Unlock door.

3) Or, press for Continuous or PCA + Continuous.

NOTE: If paused longer than two minutes without pressing an appropriate key, the pump will alarm.

TO TURN PUMP OFF

1) Close slide clamp on PCA administration set.

2) Unlock door.

3) Press button

5.10 Making Changes After Setup

TO REVIEW CURRENT SETTINGS

WHILE INFUSION IS RUNNING

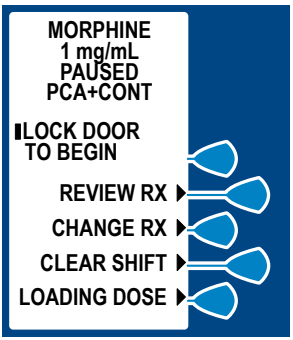
1) Press button twice.

2) Press EXIT to return to main menu.

WHILE INFUSION IS STOPPED

1) Unlock door.

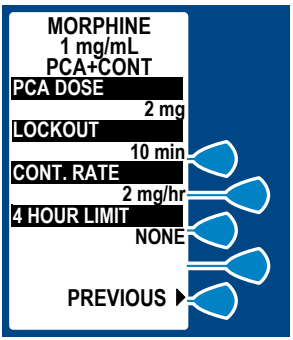
2) Select *REVIEW RX>* to review all current settings.



3) Press EXIT to return to main menu.

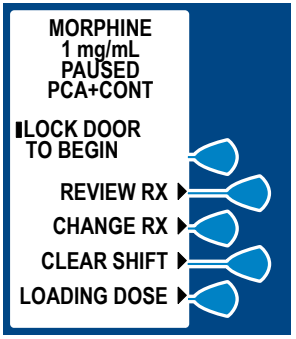
4) Close and lock door and place key in a secure spot.

5) Press to begin infusion.



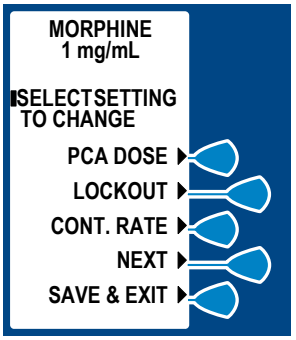
Or, select ***PREVIOUS>*** to return previous display.

TO CHANGE SETTINGS



1) Unlock door while pump is running.

2) Select *CHANGE RX>* to change individual settings.

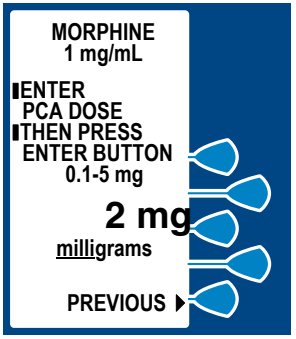


3) Select desired field to change. *(EXAMPLE PCA DOSE>)*

Or, select ***NEXT>*** to display more change options, such as Mode of delivery and Dose Limit.

If Mode of delivery is changed, the display will prompt you to reprogram using the same steps as outlined in the beginning of this section.

The value previously set for the PCA dose will be flashing.



4) Enter the desired PCA dose using the numeric keypad. (Value range is displayed on screen)

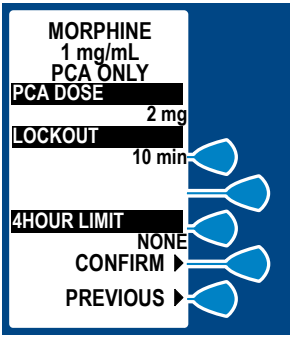
If value is entered incorrectly, press CLR to change value.

5) Then press ENTER.

If programming changes need to be made, select ***PREVIOUS>*** to return to the previous screen.

6) Select *SAVE & EXIT>* at next screen to confirm desired changes.

7) Select *CONFIRM>* to accept new program.

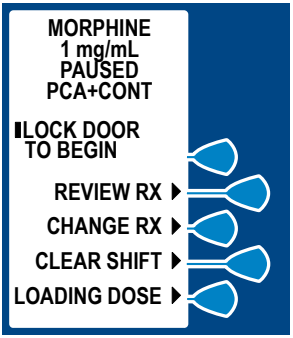


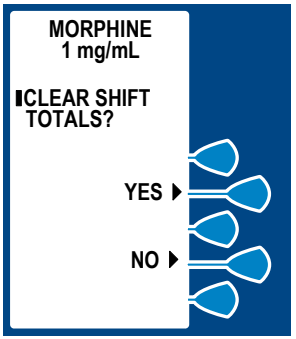
TO CLEAR SHIFT TOTALS

1) Review & record shift totals using the button before clearing.

2) Unlock door while pump is running.

3) Select *CLEAR SHIFT>* to display option to clear total dose delivered.





4) Select *YES>* to clear dose delivered and return to previous screen.

NOTE: Selecting ***YES>*** will clear PCA Summary data but does not clear 4HR dose limit data

5) Or, select *NO>* to return to previous screen.

TO CHANGE A VIAL

1) The alarm message "EMPTY SYRINGE" appears along with the statement "REPLACE SYRINGE".

2) Close slide clamp on PCA administration set.

3) Press button.

4) Insert key and lock door.

Screen displays infuser is "PAUSED".

5) Remove old vial by firmly grasping glass vial on both sides and pulling straight out.

6) Load in new vial as shown before. *(See Section 4.3)*

The Review Confirmation Screen appears.

7) Select *CONFIRM>*.

8) Select *NO>* when *"Clear History and Rx Settings"* is displayed.

9) Select *YES>* when *"Purge"* is displayed.

WARNING

PATIENT MUST BE DISCONNECTED FROM THE PCA SET BEFORE THE PURGE CYCLE.

10) At this point, you must:

- **disconnect the set from the patient**
- **release the slide clamp on the PCA administration set**
- **select & hold the Purge> key until fluid is seen at the end of the set and no air remains inside the set**

NOTE: Purging is recommended to remove slack when a new vial is inserted. The system must be primed before purging. The maximum volume delivered during a purge is 3 mL.

NOTE: Drug delivered during purge cycle is NOT stored in system memory and will not be displayed.

CAUTION: IN CONTINUOUS AND PCA+CONTINUOUS MODES, IF A PURGE IS NOT PERFORMED AFTER A SYRINGE CHANGE, THE PUMP AUTOMATICALLY PERFORMS A SMALL SYSTEM COMPLIANCE STEP TO REMOVE SLACK WHEN [START] IS PRESSED (WITH DOORS LOCKED). ALTHOUGH FLUID IS NOT NORMALLY DELIVERED TO THE PATIENT DURING THE COMPLIANCE STEP, IT IS RECOMMENDED THAT THE SET BE DISCONNECTED FROM THE PATIENT DURING THIS OPERATION.

Upon release of the ***PURGE>*** softkey, the display will ask if the purge is complete.

11) Select *YES>* to continue, or select *NO>* to purge again until complete.

12) Reconnect the set to the patient.

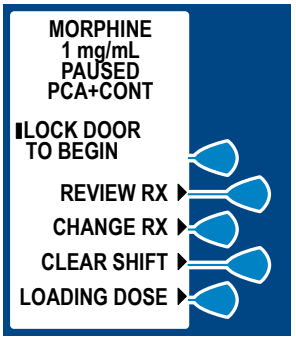
13) Select *YES>* to retain the current Rx settings (unless you are changing the Rx settings).

The Review Confirmation Screen appears.

14) Review the entered parameters, and if correct, select *CONFIRM>*.

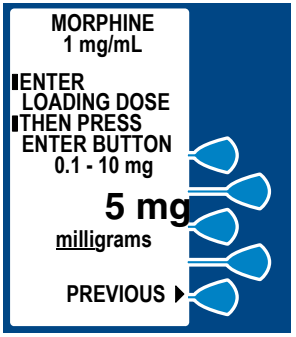
15) Close and lock door to begin infusion. Press the button if in the Continuous or PCA+Continuous mode.

TO ADD A SUPPLEMENTAL LOADING DOSE



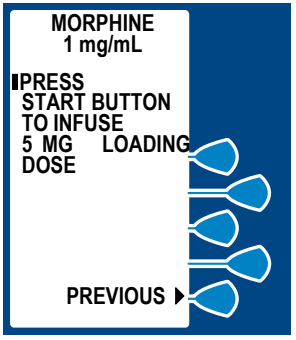
1) Unlock door while pump is running.

2) Select *LOADING DOSE>*.



3) Enter a Loading Dose within the displayed range.

4) Then press ENTER.



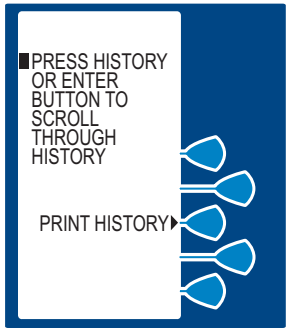
5) Press to infuse loading dose.

5.11 Checking History & Settings

1) To Check History or Settings, press button at any time.

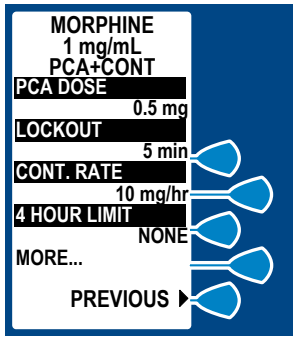
NOTE: Partial boluses can be the result of interrupting delivery by pressing [START/STOP] (PCA + Cont.), opening the door (PCA Only), loss of power, reaching the dose limit, emptying the vial, or a malfunction alarm.

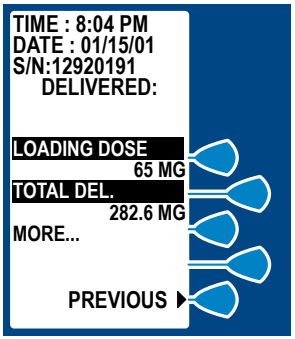
2) Press or ENTER button to scroll through history. Or select *PRINT HISTORY>* to print (if connected to printer).



3) Press or ENTER button a second time for more information.

When MORE is displayed, more information is stored in pump history.





4) Continue to press or ENTER button for more information such as:

- **Last Hour Only information**
- **Last 24-Hour information**
- **Event Log**

Event Log allows you to view all events since last Clear History. Up to 400 events may be logged.

5) Press EXIT to return to the Main Delivery screen.

5.12 Printer Setup

The PCA3 is configured to communicate with a serial printer or communications link. The required serial settings are:

- **9600 baud**
- **8 bit data**
- **no parity.**

To configure a Seiko Instruments SII DPU-414 Thermal Printer, the settings are controlled on power-up using two panel control switches:

- **[PAPER FEED]= OFF**
- **[ON LINE]= ON).**

The Seiko printer also has other configuration settings that relate to the control and formatting of the printer. To set any one feature, all the features need to be set in a series of yes/no/continue inputs using just the two controls. This may be a little tedious, but once set, the printer is ready for use.

To program the Seiko printer, hold the "ONLINE" button while turning on the power. The printer will then display (on the paper tape output) the configuration it has stored in memory, and prompt the user for input. The print-out of the user settings should look like the following:

```
[DIP SW setting mode]

Dip SW-1
1 (OFF) : Input = Serial
2 (ON ) : Printing Speed = High
3 (ON ) : Auto Loading = ON
4 (OFF) : Auto LF = OFF
5 (ON ) : Setting Command = Enable
6 (OFF) : Printing
7 (ON ) :   Density
8 (ON ) :   = 100 %
Dip SW-2
1 (ON ) : Printing Columns = 40
2 (ON ) : User Font Back-up = ON
3 (ON ) : Character Select = Normal
4 (ON ) : Zero = Normal
5 (ON ) : International
6 (ON ) :   Character
7 (ON ) :   Set
8 (OFF) :   = U.S.A.
Dip SW-3
1 (ON ) : Data Length = 8 bits
2 (ON ) : Parity Setting = No
3 (ON ) : Parity Condition = Odd
4 (ON ) : Busy Control = H/W Busy
5 (OFF) : Buad
6 (ON ) :   Rate
7 (ON ) :   Select
8 (ON ) :   = 9600 bps

Continue ? : Push 'On-line SW'
Write ?    : Push 'Paper feed SW"
```

If the above is already configured, press the [PAPER FEED], and the printer will display :

```
DIP SW settings complete !!
```

If the above is not displayed, the printer may not communicate correctly with the PCA3, or may print gibberish. To make any change, all the settings for that DIP SW need to be made as a block of entries using the [ONLINE] button for ON, and [PAPER FEED] button for OFF. Pressing the [ONLINE button at this point begins the entry process for the first DIP SW. To access DIP SW 2 or 3, all the entries for the earlier settings need to be duplicated in sequence. Once the desired DIP SW has a complete set, pressing the [PAPER FEED] button when prompted, finishes the process.

From power-up, to setup as shown above, required user input is:

1. Press and hold [ONLINE] while turning on power.

Wait for user prompt.

2. Press [ONLINE] to begin setup

The printout should read:

```
Dip SW-1
```

The printer is now waiting for a entry for the first position (Input Method: Serial). This functional setting should be OFF, so:

3. Press [PAPER FEED] button

The printout should then read:

```
DIP SW-1

1 (OFF) : Input = Serial
```

4. The remainder of the settings are then entered, pressing [ONLINE] for ON, and [PAPER FEED] for OFF. This is done sequentially for ALL 24 fields [DIP SW-1(8), 2(8), & 3(8)].
The remainder of settings should be set as follows, continuing with SW1-2:

REQUIRED PRINTER SETTINGS TO OPERATE WITH PCA 3

Switch	Function	Setting	Button to Press	
SW1-1	Input Method: Serial	Off		Feed
SW1-2	Printing Speed: High	On	On line	
SW1-3	Auto loading: On	On	On line	
SW1-4	Auto LF: Off	Off		Feed
SW1-5	DIP SW setting command: Enabled	On	On line	
SW1-6	Printing density: 100%	Off		Feed
SW1-7	Printing density: 100%	On	On line	
SW1-8	Printing density: 100%	On	On line	
SW2-1	Print Mode: 40 columns	On	On line	
SW2-2	User font back-up: On	On	On line	
SW2-3	Character select: Normal	On	On line	
SW2-4	Zero font: Normal	On	On line	
SW2-5	Int'l Character Set: American	On	On line	
SW2-6	Int'l Character Set: American	On	On line	
SW2-7	Int'l Character Set: American	On	On line	
SW2-8	Int'l Character Set: American	Off		Feed
SW3-1	Data bit length: 8 bits	On	On line	
SW3-2	Parity: No parity	On	On line	
SW3-3	Parity condition: Odd	On	On line	
SW3-4	Flow control: H/S busy	On	On line	
SW3-5	Baud rate: 9600 bps	Off		Feed
SW3-6	Baud rate: 9600 bps	On	On line	
SW3-7	Baud rate: 9600 bps	On	On line	
SW3-8	Baud rate: 9600 bps	On	On line	

```
Continue ? : Push 'On-line SW'

Write ?    : Push 'Paper feed SW"
```

5. Press FEED

```
DIP SW setting complete !!
```

5.13 Printing Event History Log

The history event log can be printed by connecting the pump to a Seiko Instruments SII DPU-414 thermal printer, using the previous instructions. Two custom printer cables are available. They are not interchangeable.

WARNING

DISCONNECT THE PUMP FROM THE PATIENT BEFORE CONNECTING THE PUMP TO A PRINTER OR COMPUTER.

To print from the PCA 3, complete the following steps:

1. **Load printer with test paper.**
2. **Plug in AC adapter.**
3. **Press and hold ONLINE while turning ON power.**
4. **Review the printout of configured settings against the previous table. If they match, you're ready to print. If they do not match, reconfigure as explained in the previous section.**
5. **Connect the printer to the PCA 3 using a 9-pin male to 9-pin female cable. *Contact Customer Service for information on printer connector cables.***
6. **Print whenever the PCA 3 offers the *PRINT>* softkey option.**

5.14 Downloading to a PC

EQUIPMENT NEEDED

- Pump
- Computer with Windows 3.1 or Windows 95/98/ NT/2000
- Standard Printing Cable
- 25-pin to 9-pin converter
- Null Modem Adapter

PUMP TO WINDOWS 95, 98, NT OR 2000

INITIAL HYPER TERMINAL ACCESS- CREATING A NEW CONNECTION

1. Select the *Start* menu.
2. Select *Programs*.
3. Select *Accessories*.
4. Select *HyperTerminal*.
5. Double-click on the HyperTerminal icon.
6. If a message box appears indicating that a modem is necessary for a connection, click NO.
7. In the Connection Description box, enter the name which to save the settings.
8. Click OK.
9. In the Phone Number box, select *Direct to Com 2* from the *Connect Using Drop Down* list.
10. Click OK.
11. In the COM Port properties window, set the Bits Per Second to 9600 and Flow Control to None.
12. Click OK.
13. Select the Propertied icon. (farthest to right)
14. Select the Settings tab.
15. Select the ASCII setup button.
16. Make sure ‘Append line feeds to incoming line ends’ is not checked.

17. Click OK in the ASCII setup window.
18. Click OK in the properties window.
19. Select *File* from the menu bar.
20. Select *Save* from the file menu.

HyperTerminal Access- Using an Existing Connection

1. Select the Start Menu.
2. Select *Programs*.
3. Select *Accessories*.
4. Select *HyperTerminal*.
5. Double-click on the icon with the name entered in step #7 above.

Printing the File

1. Select *Call* from the menu bar.
2. Select *Connect* from the Call menu.
3. Select *Transfer* from the menu bar.
4. Select *Capture Test* from the Transfer menu.
5. Type the *Path To* and *the name of the file* in which to save the printout. If the file name already exists, the newly transferred data will be appended to the end of the already existing file.
6. Click *Start*.
7. Select the desired print function from the group.
8. When the transmission of the data has completed, select *Transfer* from the menu bar.
9. Select *Capture Text* from the Transfer menu.
10. Select *Stop* from the Capture Text menu.
11. Select *Call* from the menu bar.
12. Select *Disconnect* from the Call menu.
13. Exit HyperTerminal
14. Pull up the file in your word processor of choice and print or view as desired.

PRINT TO WINDOWS 3.1

INITIAL TERMINAL ACCESS- CREATING A NEW CONNECTION

1. Open the *Accessories* group.
2. Select *Terminal* from the Accessories group.
3. Select *Settings* from the menu bar.
4. Select *Terminal Preferences* from the Settings menu.
5. Make sure *CR->CR/LF Inbound* is not selected.
6. Click OK.
7. Select *Settings* from the menu bar.
8. Select *Communications* from the Settings menu.
9. Make sure Baud Rate is 9600, Data Bits are 8, Stop Bits 1, Parity is none, Xon/Xoff is selected, and COM 1 or 2 is selected.
10. Click OK.
11. Select *File* from the menu bar.
12. Select *Save* from the File menu.
13. Enter the name under which to save the settings.
14. Click OK.

TERMINAL ACCESS- USING AN EXISTING CONNECTION

1. Select the *Accessories group*.
2. Select *Terminal*
3. From File menu, select *Open*.
4. Select name of *Connection Saved*, click OK.

PRINTING THE FILE

1. Select *Transfers* from the menu bar.
2. Select *Receive Text File* from the Tranfers menu.
3. Type the *Path To* and *the name of the file* in which to save the printout.
4. Click OK.
5. Select the desired print function from the pump.
6. When the transmission of the data has completed, select *Transfer* from the menu bar.
7. Select *Stop* from the Transfers menu.

8. Exit Terminal.
9. Pull up the file in your word processor of choice and print or view as desired.

5.15 History and Event Log

The infuser stores data on therapy settings, quantity and/or number of doses delivered, and chronological record of approximately 400 most recent events occurring during infusion. These events include: PCA doses requested, the amount delivered, the change of any settings, the opening or closing of the security door, start or stop of continuous infusion, and alarm conditions. Pressing the [HISTORY] touchswitch displays this data on the LCD. Pressing the ***PRINT HISTORY>*** softkey generates a hard copy printout of the data if a compatible printer (Centronics interface) is properly connected (*see FRONT PANEL TOUCHSWITCHES, Section 3*).

When the infuser is configured for HOUR-BY-HOUR history format, the number of PCA injections, partial doses, and patient demands occurring in each one-hour period during the last 24 hours can be displayed or printed. Only the one-hour periods with PCA activity are displayed and printed. When the Infuser is configured for LAST 1 & 24 HOUR history format, PCA activity totals in the last hour and in the last 24 hours are displayed and printed.

Note: The HOUR-BY-HOUR and the LAST 1 & 24 HOUR history totals represent a dynamic summation of past delivery of drugs and events. Data is accumulated in 10 minute time slots. At any given time, the last 10 minute time slot may represent anywhere from 0 to 10 minutes of data. Therefore, the hour and 24-hour periods are approximate only and may, in fact, represent as small as 50 minutes of data for the LAST HOUR total and 23 hours 50 minutes for the LAST 24 HOUR total.

Note: PCA requested doses (patient demands) as recorded in the history display and event log may not reflect the total number of demands. (Maximum of 100 patient demands per 10 minute interval.)

Note: Events occurring while printing is in progress are stored in memory, but not included in the current printout.

Note: If the lithium battery, the MCU PWA, or the electronics assembly have been replaced, the serial number will NOT display on printouts.

See the following pages for a sample history printout (in the PCA+CONTINUOUS mode).

```
****************************************
*            LIFECARE PCA 3            *
*            PATIENT RECORD            *
****************************************

SERIAL NUMBER:

PATIENT NAME:

_____________________________________________

DRUG ADMINISTERED:

_____________________________________________

PM 03:09 JUN 25 2002

MODE: PCA + CONTINUOUS

                SETTINGS:
CUSTOM VIAL                      1.0 mg/mL
PCA DOSE                         0.5 mg
PCA LOCKOUT                        5 min
CONTINUOUS RATE                  0.5 mg/hr
4 HOUR LIMIT                    NONE

                DELIVERED:

LOADING DOSE                     0.0 mg
TOTAL                            2.3 mg

              LAST 1 HOUR:

PCA COMPLETED                      4
PCA PARTIAL                        0
PCA DENIED                         0

LOADING DOSE                     0.0 mg
TOTAL                            2.3 mg
```

```
             LAST 24 HOURS:

PCA COMPLETED                        4
PCA PARTIAL                          0
PCA DENIED                           0

LOADING DOSE                     0.0 mg
TOTAL                            2.3 mg

HOUR-BY-HOUR:

03:00P-03:09P
PCA COMPLETED                        2
PCA PARTIAL                          0
PCA DENIED                           0

02:24P-03:00P
PCA COMPLETED                        2
PCA PARTIAL                          0
PCA DENIED                           0

                EVENT LOG:

03:07P PCA END                   0.5 mg
03:01P PCA END                   0.5 mg
02:54P PCA END                   0.5 mg
02:25P PCA END                   0.5 mg
02:25P START INFUSION
02:25P DOOR LOCKED
02:25P DOSE LIMIT NOT SELECTED
02:25P SET CONT. RATE            0.5 mg/hr
02:25P SET PCA LOCKOUT             5 min
02:25P SET PCA DOSE              0.5 mg
02:25P SET PCA + CONT. MODE
02:25P CUSTOM VIAL               1.0 mg/mL
02:24P SET DRUG CONC.            1.0 mg/mL
02:24P HISTORY CLEARED

****************************************
VERIFIED BY:
****************************************

****************************************
*             END OF RECORD            *
****************************************
```

6) Troubleshooting

The PCA 3 is programmed to display status and alarm messages and to sound an audible tone for most alarm conditions. These messages and alarm conditions are described in the following sections.

6.1 Status Messages

Displayed status messages are defined in the following table:

MESSAGE	DEFINITION
DOOR LOCKED	**Message indicates the security door is closed and locked. It displays for 10 seconds and disappears.**
PCA LOCKOUT	**Message appears only when the security door is locked in the PCA or PCA+CONTINUOUS mode. The message remains until the lockout interval elapses and is displayed after a successful patient-originated dose delivery.**
4 (1) HR LIMIT REACHED	**Message displayed if 4 (or 1) hour dose limit has been selected and reached with security door locked.**
PCA AVAILABLE	**Message indicates patient can initiate a dose in PCA or PCA+CONTINUOUS mode.**
PCA	**Message displayed when pump is in PCA mode.**
CONTINUOUS	**Message displayed when pump is in CONTINUOUS mode.**

MESSAGE	DEFINITION
PCA+CONT.	Message displayed when pump is in PCA+CONTINUOUS mode.
PAUSED	Message displayed when pump is stopped, but door is locked. Or, if door is opened.

6.2 Pump Alarm System

During an Alarm condition, the system performs the following actions:

- **The current display message is saved.**
- **A flashing alarm message appears on the display *(see following table)*.**
- **A repetitive, audible tone sounds with all MALFUNCTION alarms except PENDANT FAULT, which is a single tone with continuous visual flashing. The audible tone volume is adjustable to low, medium, or high by accessing system settings during self-test at Start-up. It can also be accessed by pressing [SILENCE/VOLUME] when pump is in RUN Mode. Select desired volume of alarm, then press *SAVE AND EXIT>* softkey.**

NOTE: The pump stops delivery when any of these alarms occur: CHECK INJECTOR, CHECK VIAL, CHECK SYRINGE, EMPTY SYRINGE, OCCLUSION, DEAD BATTERY or MALFUNCTION.

6.3 Silencing an Alarm

To silence an alarm, press the [SILENCE] key, then follow the displayed messages. All alarms except the MALFUNCTION, CHECK VIAL, CHECK INJECTOR, and CHECK SYRINGE, alarms can be muted.

Clear the cause of the alarm, if possible, and press the [START/PAUSE] key to resume operation for Continuous or PCA + Continuous modes. The original display message will be restored.

> **NOTE:** If the MALFUNCTION alarm sounds, press the [ON/OFF] key to turn the pump off. Turn the pump on. If the malfunction repeats, remove pump from service. Refer pump to the hospital's technical support or contact Hospira Technical Support Operations.
>
> **NOTE:** In the event two or more alarms conditions simultaneously occur, the alarm with shortest muting period will take priority and be displayed first.

If the alarm is muted and a second alarm condition occurs during the muting period, an audible alarm signaling the new condition will immediately occur.

6.4 Alarms and Messages

Message	Muting Times	Possible Cause	Corrective Action
Bar Code Not Read	1 minute	Vial not loaded properly	• Position vial correctly • Clean bar code reader window
Check Settings	1 minute	Door locked without appropriate therapy settings	• Open the door. Complete settings.
Occlusion	1 minute	Occlusion detected	• Open security door if closed. Remove back pressure by squeezing and releasing the cradle release handles. Identify and correct the cause of the occlusion. Alarm will self correct.
Check Syringe	None	Syringe (Vial and Injector) not properly loaded	• Properly insert syringe into holder assembly
Check Vial	None	Injector detected and vial not properly loaded	• Properly insert vial into holder assembly or removal of injector
Check Injector	None	Vial is detected and injector not properly loaded	• Properly insert injector into holder assembly or removal of vial

Message	Muting Times	Possible Cause	Corrective Action
Empty Syringe	15 minutes	Empty vial detected	• Press [Silence] to silence the alarm. Unlock and open the security door and squeeze and release handles in order to replace vial. May turn infuser OFF while preparing new vial.
Door Open	N/A	Door left open or unlocked for more than 2 minutes	• Close door and Lock
Infuser Paused	5 minutes	Infusion paused for more than 2 minutes	• Press [START/ PAUSE] key again, or unlock door
Low Battery	10 minutes	Battery life has less than thirty minutes remaining and currently operating on battery power	• Apply AC power
Dead Battery	None	Battery life has expired	• Apply AC power

Message	Muting Times	Possible Cause	Corrective Action
Pendant Fault - 0	Visible Flashing Occurs	Pendant not secured into port Faulty Connection or pendant Partial Pendant press Using PCA Plus II Patient Pendant (white handle)	• Secure pendant into port • Replace pendant or pump • Release pendant button • Confirm use of PCA 3 Patient Pendant (blue handle)
Pendant Fault - S	Visible Flashing Occurs	Electrical Short in pendant	• Replace pendant

7) Maintenance

7.1 Pump Storage

To prolong the life of the PCA 3, observe the following storage precautions:

- **Store away from excessive heat, cold, and humidity**
- **Store the PCA 3 connected to AC (mains) power**
- **Switch off using the [ON/OFF] key**

7.2 Cleaning and Sanitizing

Establish a routine schedule for cleaning the pump to keep it free of contamination.

CAUTION: ALWAYS CONFIRM BAR CODE READER WINDOW IS CLEAN. BLOOD, FINGERPRINTS, CONDENSATION, AND OTHER ELEMENTS MAY OBSTRUCT THE VIEW OF THE BAR CODE READER. ELEMENTS ON THE WINDOW (OTHER THAN SCRATCHES) CAN BE CLEANED BY USING ONE OF THE RECOMMENDED CLEANING SOLUTIONS IN THIS SECTION.

CAUTION: TO AVOID MECHANICAL OR ELECTRONIC DAMAGE, DO NOT IMMERSE THE PCA 3 IN ANY FLUIDS OR CLEANING SOLUTIONS.

CAUTION: SOME CLEANING AND SANITIZING COMPOUNDS MAY SLOWLY DEGRADE COMPONENTS MADE FROM SOME PLASTIC MATERIALS. DO NOT USE COMPOUNDS CONTAINING COMBINATIONS OF ISOPROPYL ALCOHOL AND DIMETHYL BENZYL AMMONIUM CHLORIDE.

CAUTION: DO NOT STERILIZE BY HEAT, STEAM, ETHYLENE OXIDE (ETO), OR RADIATION. APPLY DISINFECTANTS TO THE

OUTSIDE SURFACE OF THE PUMP ONLY. USING ABRASIVE CLEANERS OR CLEANING SOLUTIONS NOT RECOMMENDED BY HOSPIRA MAY RESULT IN PRODUCT DAMAGE.

CAUTION: TO AVOID PUMP DAMAGE, CLEANING SOLUTIONS SHOULD ONLY BE USED AS DIRECTED. THE DISINFECTING PROPERTIES OF CLEANING SOLUTIONS VARY; CONSULT THE MANUFACTURER FOR SPECIFIC INFORMATION.

CAUTION: NEVER USE SHARP OBJECTS SUCH AS FINGERNAILS, PAPER CLIPS, OR NEEDLES TO CLEAN ANY PART OF THE PCA 3.

Establish a routine weekly schedule for cleaning the pump case, front panel, and patient pendant. To clean, proceed as follows:

Turn the PCA 3 off with the [ON/OFF] switch, then disconnect from AC power.

The exposed surfaces of the PCA 3 may be cleaned with a lint-free cloth dampened by one of the recommended cleaning solutions in the following list or mild, nonabrasive soapy water.

Cleaning Solution	Manufacturer	Preparation
Manu-Klenz®	*Calgon Vestal Laboratories*	*Per manufacturer's recommendation*
Formula C ™	*Diversey Corporation*	*Per manufacturer's recommendation*
Coverage™HBV	*Steris Corporation, A division of Calgon Vestal Laboratories*	*Per manufacturer's recommendation*

Cleaning Solution	Manufacturer	Preparation
Sporicidin®	*Sporicidin International*	*Per manufacturer's recommendation*
Dispatch®	*Caltech Industries*	*Per manufacturer's recommendation*
Precise®	*Caltech Industries*	*Per manufacturer's recommendation*
Household bleach	*Various*	*Per hospital procedures; do not exceed one part bleach in ten parts water*

On a routine basis, clean all of the elements behind the syringe door using cotton-tipped swabs saturated with cleaning solution. The door may be unlatched from the door handle to facilitate cleaning.

No other routine maintenance is required; the pump has no other user serviceable parts. All service must be carried out by Hospira qualified technical personnel. A technical service manual may be ordered from Hospira Technical Service.

7.3 Battery Maintenance

WARNING

DISCONNECT AC POWER CORD BEFORE REMOVING BATTERY DOOR.

CAUTION: DO NOT OPERATE THE PCA 3 ON PATIENTS WITH THE BATTERY REMOVED. USE OF A PROPERLY MAINTAINED AND CHARGED BATTERY HELPS ENSURE PROPER OPERATION.

CAUTION: IF THE LOW-BATTERY ALARM SOUNDS, CONNECT THE PCA 3 TO AC (MAINS) POWER IMMEDIATELY.

The PCA 3 is battery powered for emergency backup and temporary portable operation. A fully charged, new battery provides four hours of continuous operation and will deliver at least 30 mL of solution before the low battery alarm sounds (at least 30 minutes prior to shutdown).

The battery charges whenever the PCA 3 is connected to AC (mains) power. If the PCA 3 is switched off, recharge takes approximately 16 hours. Recharge takes longer if the PCA 3 is turned on.

When the PCA 3 Infuser is not in use and not connected to an AC line, a fully charged battery will retain at least 20% of its initial charge after six months storage at 20 degrees Centigrade.

As a general rule, the more often the battery is partially discharged and recharged, the sooner it will need to be replaced. Consult a qualified biomedical technician for battery replacement if necessary.

To maintain maximum battery charge and to prolong battery life, connect the PCA 3 to AC (mains) power whenever possible.

SERVICE

All servicing or adjustments to the PCA 3 should be referred to qualified technical personnel. A technical service manual may be ordered from the local Hospira sales office.

8) Specifications

Dimensions:	***Approximately 8"W 13"H 6"D, excluding pole clamp protrusion and power cord storage.***
Weight:	***Approximately 10 lbs. with battery.***
Casing:	***High-impact plastic***
Drug Concentration Settings:	***See Section 9***
Delivery Rate:	***See Section 9***
PCA Mode:	***Approximately 1 mL in 35 seconds***
CONTINUOUS Mode:	***Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr)***
PCA+CONTINUOUS Mode:	***Variable from 0.1 x concentration (mg/hr or mcg/hr) to 20 x concentration (mg/hr or mcg/hr), + PCA dose (mg)***
Lockout Interval Range:	***5 to 120 minutes in 1- minute increments***
Maximum Infusion Pressure:	***45 psig***
Occlusion Alarm Pressure:	***15 psig ± 5psig***
Occlusion Bolus Volume:	***2 mL for fully primed set (max)***
Operating Temperature:	***5° to 40° C, 10% - 90% relative humidity***
Storage Temperature:	***-20° to 60° C, 10% - 90% relative humidity***

Atmospheric Pressure:	***0 - 10,000 feet (0 - 3,000m) or equivalent pressure***
Power Requirements:	***105-130 Volts, 57 - 63 Hz, <50 W.***
Power Cord:	***Hospital-grade AC cord. 10 ft long, with transparent plug and retainer plate.***
Fuses:	***1.0 A, 250 V, Slow Blowing.***
Battery:	***One sealed, lead-acid, rechargeable 8 V battery, internal to device. Accessible for ease of field replacement, with color-coded leads and polarized connector.***
Battery Life:	***A new battery at full charge should operate for at least 4 hours of continuous operation and deliver at least 30 mL of solution before LOW BATTERY alarm. PCA3 should provide a LOW BATTERY warning at least 30 minutes prior to shutdown.***
Recharge:	***After discharge to the LOW BATTERY operative limit, the battery will recharge to at least 80% of its charge capacity in 16 hours, provided it is plugged into rated AC power. The infuser will operate on AC power in the event the battery is open or shorted.***

Self-Discharge:	***50% of charge retained for at least one month when unit is neither plugged-in nor operating.***
Electrical Leakage:	***Risk current limits meet AAMI/ANSI SCL (ungrounded) 12/78 standard.***
Administration Sets:	***Use only compatible Hospira PCA sets with Integral Anti-Siphon Valve***
Electrical Safety:	***Meets IEC 60601-1 standards for:***
Class 1:	***AC (mains) supply equipment using protective earth***
Type CF:	***Equipment providing***
Drip Proof IPX1:	***Protected against dripping water.***
	Disinfectable
	Note: Not to be used in the presence of flammable anesthesics
Electromagnetic Interference (EMI) and Radio Frequency Interference (RFI):	***The LifeCare PCA 3 is designed to perform in the typical hospital environment***
	A qualified service technician should verify performance in any environment where EMI or RFI levels are excessive
Attention: 	***Consult accompanying documents***

Equipotential Post: ***Terminal for connection of an equipotential conductor***

Printer Port: ***Maximum nondestruct voltage is 5 V***

Maximum Overinfusion: ***The maximum overinfusion under single fault conditions is 25%***

8.1 Stored Occlusion Volume

DELIVERY RATE	PRESSURE LIMIT (Average)	STORED VOLUME (Average)
0.1 mL/H	***12.8 psig***	***0.92 mL***
5 mL/H	***12.6 psig***	***0.94 mL***
20 mL/H	***12.7 psig***	***0.96 mL***

8.2 Time from Occlusion to Alarm

DELIVERY RATE	PRESSURE LIMIT (Average)	TIME TO OCCLUDE (Average)
0.1 mL/H	***12.8 psig***	***12 hours***
5 mL/H	***12.6 psig***	***11 minutes***
20 mL/H	***12.7 psig***	***3 minutes***

8.3 Delivery Rate Accuracy

Delivery accuracy is ± 5% at a flow rate of 1 mL/hr or higher. For accuracy data at other flow rates, see the following typical trumpet curves. The underdelivery that may occur at rates less

than 0.5 mL/hr or bolus volumes less than 0.5 mL may be substantially greater than 5%, and is due primarily to the variability of friction between the syringe plunger and barrel. This underdelivery may include periods of no delivery.

If multiple, partial PCA doses are delivered, the accumulated total reflected in the history totals may be more than the sum of the PCA doses logged in the event log. This is due to the fact that only a portion of the next 0.1 mg (or 1 mcg) may have been delivered at the time any of the PCA doses were interrupted. As these portions accumulate, their combined total may account for 0.1 mg (or 1 mcg).

TRUMPET CURVES

The typical trumpet curve graphs following the example show representative maximum and minimum percent flow rate deviation from the programmed rate over time. This information was developed in accordance with IEC 60601-2-24: 1998, Sub-Clause 50.102. Refer to this standard for detailed information.

How to read a Trumpet Curve Graph (Refer to example on the following page): The graphs following the Example plot flow rates at 30 second intervals for the first 2 hours and for the 96th hour of delivery. The graph plots mean delivery rate error (Average of 3 pumps) for the 2nd hour and the 96th hour as a straight line. The graph also presents maximum and minimum average delivery rate error for this interval plotted by averaging delivery errors over intervals of 2, 5, 11, 19 and 31 minutes (“Trumpet Curve”).

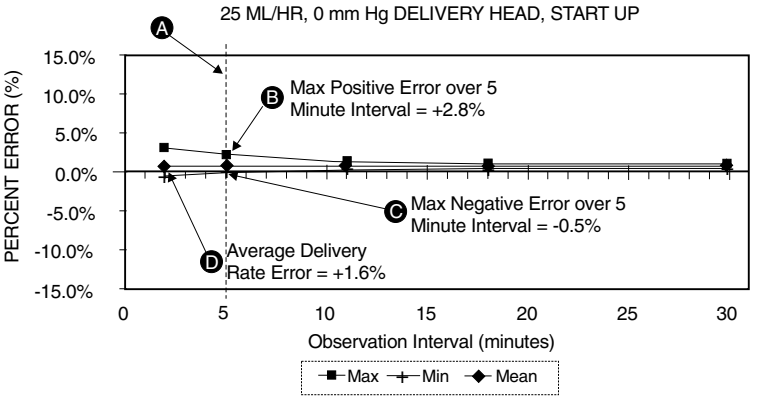
EXAMPLE

From the Trumpet Curve Graph sample that follows, find the 5 minute interval (A) at the horizontal axis and read the corresponding points (B) and (C) on the vertical axis. The values are approximately +2.8% and -0.5%.

This means that at the rate of 25 mL/hr the average maximum flow rate fluctuation for any 5 minute time interval during the 2nd

hour of operation was within the limits of +2.8% and -0.5% from the nominal rate. The average delivery rate error over the entire 2nd hour was +1.6% (D).

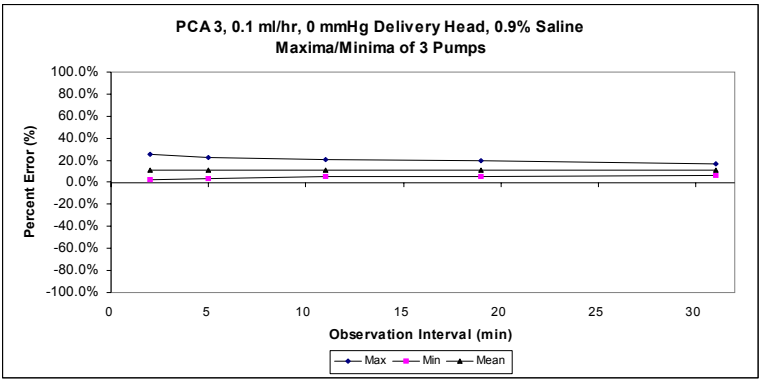
For other time intervals look at other points at the horizontal axis and determine corresponding limits as above.

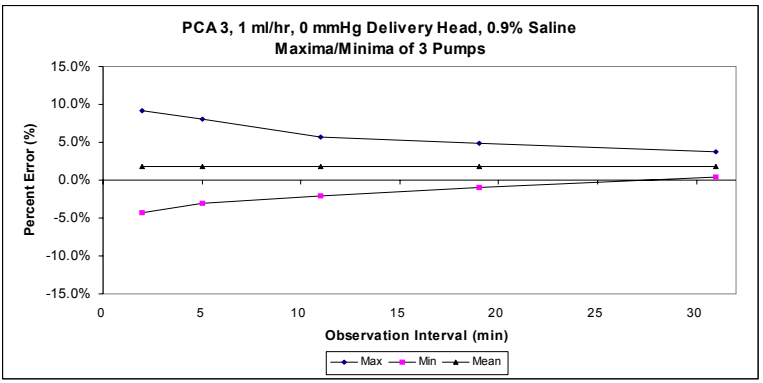


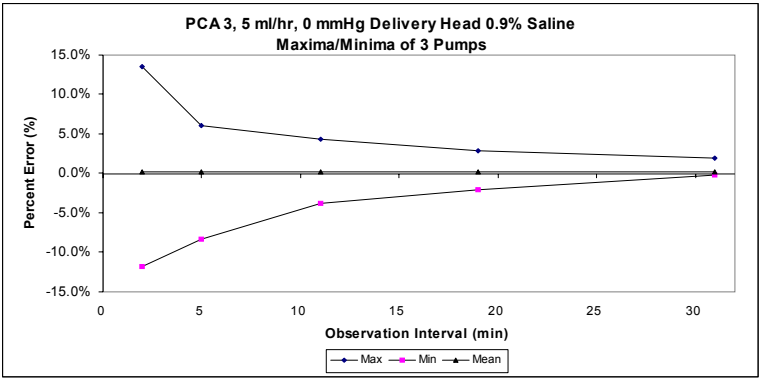
A trained professional can use the resulting graphs to select a pump with the appropriate startup and flow characteristics to suit the clinical application.

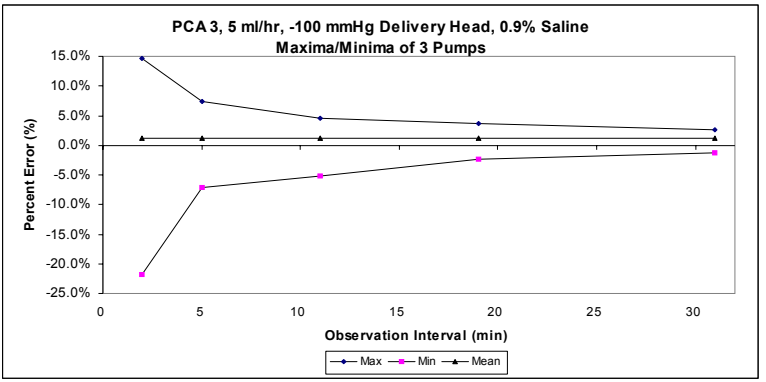
NOTE: As an example of how the trumpet curves can be used, consider the maximum and minimum deviations at the 5 minute average interval. The upper curve provides the maximum expected delivery rate error over a 5 minute interval, the lower curve provides the minimum expected delivery rate error over a 5 minute interval. An example would be Morphine administered at 5 mL/mg. At 5 minutes, the average drug delivery error would be within the range of +2.8% and -0.5% of the expected nominal rate.

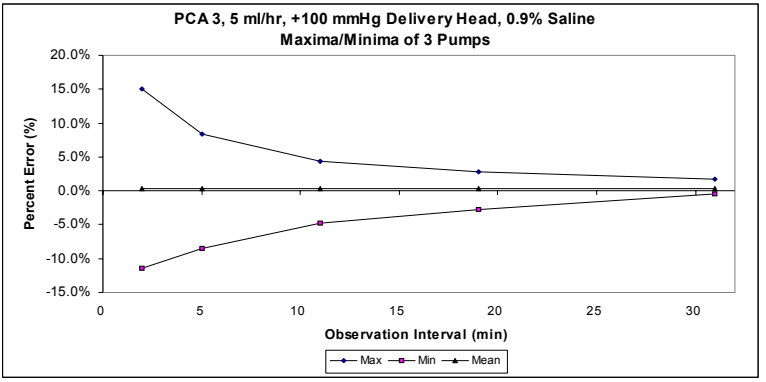
8.4 Trumpet Curves

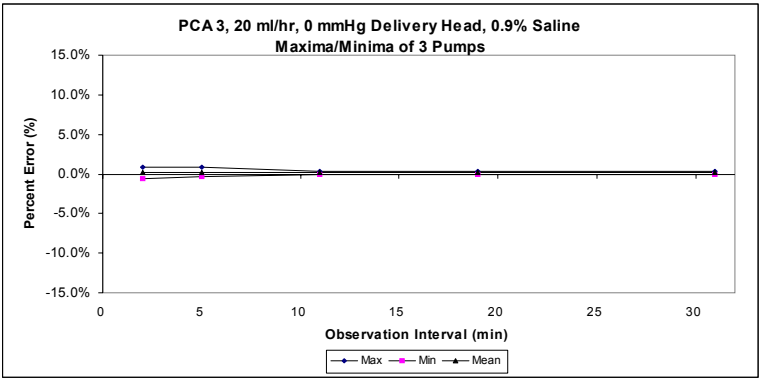







PCA 3, 5 ml/hr, -100 mmHg Delivery Head, 0.9% Saline
Maxima/Minima of 3 Pumps
Percent Error (%)
15.0%
10.0%
5.0%
0.0%
-5.0%
-10.0%
-15.0%
-20.0%
-25.0%
0
5
10
15
20
25
30
Observation Interval (min)
Max
Min
Mean


PCA 3, 5 ml/hr, +100 mmHg Delivery Head, 0.9% Saline
Maxima/Minima of 3 Pumps
Percent Error (%)
20.0%
15.0%
10.0%
5.0%
0.0%
-5.0%
-10.0%
-15.0%
0
5
10
15
20
25
30
Observation Interval (min)
Max
Min
Mean


PCA 3, 20 ml/hr, 0 mmHg Delivery Head, 0.9% Saline
Maxima/Minima of 3 Pumps
Percent Error (%)
15.0%
10.0%
5.0%
0.0%
-5.0%
-10.0%
-15.0%
0
5
10
15
20
25
30
Observation Interval (min)
Max
Min
Mean

9) Prescription Delivery Limits

Prescription Delivery limits for loading dose, PCA dose, 4-hour dose limit, and continuous delivery rate parameters will vary with the drug and concentration selected.

See the following table for listings of the lower and upper limits.

NOTE: Drug and concentration selections are rounded up to the nearest tenth of a digit for mg/mL values or to the nearest digit for mcg/mL values. Minimum delivery rate is 0.1 mL/hr for concentrations between 0.1 and 1 mg/mL.

PCA Drugs and Dose Limits

Drug/ Bar code HRI	Conc. mg/mL	Loading Dose (mg) min - max	PCA Dose (mg) min - max	Cont. Rate (mg/hr) min - max	4 hr Limit (mg) min - max	1 hr Limit (mg) min - max
Morphine Sulfate (p-f)	1	0.1 - 10	0.1 - 5	0.1 - 20	0.1 - 80	0.1 - 20
Morphine Sulfate	5	0.5 - 50	0.5 - 25	0.5 - 100	0.5 - 400	0.5 - 100
Meperidine HCl	10	1 - 100	1 - 50	1 - 200	1 - 800	1 - 200
Other Drug (Sterile Empty Vial)	mg/mL	mcg	mcg	mcg/hr	mcg	mcg
mg units	0.1 - 10	+- **	+- *	+- ***	+- ****	+- ***
mcg units	1 - 100	+- **	+- *	+- ***	+- ****	+- ***

(p-f = preservative free)

NOTES: a) Lockout interval range is 5 to 120 minutes (increments of 1 minute).

b) Parenthesis symbols in bar code HRI are NOT output by bar code reader, they are part of human-readable information only.

c) Symbols used for low and high dose values:
+ = 0.1 X concentration value (but not less than 0.1 mg or 1 mcg)
* = 5 X concentration value
** = 10 X concentration value
*** = 20 X concentration value
**** = 80 X concentration value

NOTES

10) Warranty

Subject to the terms and conditions herein, Hospira, Inc., herein referred to as Hospira, warrants that (a) the product shall conform to Hospira's standard specifications and be free from defects in material and workmanship under normal use and service for a period of one year after purchase, and (b) the replaceable battery shall be free from defects in material and workmanship under normal use and service for a period of 90 days after purchase. Hospira makes no other warranties, express or implied, as to merchantability, fitness for a particular purpose, or any other matter.

Purchaser's exclusive remedy shall be, at Hospira's option, the repair or replacement of the product. In no event shall Hospira's liability arising out of any cause whatsoever (whether such cause be based in contract, negligence, strict liability, other tort, or otherwise) exceed the price of such product, and in no event shall Hospira be liable for incidental, consequential, or special damages or losses or for lost business, revenues, or profits. Warranty product returned to Hospira must be properly packaged and sent freight prepaid.

The foregoing warranty shall be void in the event the product has been misused, damaged, altered, or used other than in accordance with product manuals so as, in Hospira's judgment, to affect its stability or reliability, or in the event the serial number or lot number has been altered, effaced, or removed.

The foregoing warranty shall also be void in the event any person, including the Purchaser, performs or attempts to perform any major repair or other service on the product without having been trained by an authorized representative of Hospira and using Hospira documentation and approved spare parts. For purposes of the preceding sentence, "major repair or other service" means any repair or service other than the replacement of accessory items such as batteries and detachable mains power cords.

In providing any parts for repair or service of the product, Hospira shall have no responsibility or liability for the actions or inactions of the person performing such repair or service, regardless of whether such person has been trained to perform such repair or service. It is understood and acknowledged that any person other than a Hospira representative performing repair or service is not an authorized agent of Hospira.

For customer service within the United States, contact:

1-877-9-HOSPIRA (1-877-946-7747)

For technical assistance, product return authorization, and to order parts, accessories, or manuals within the United States, contact Hospira Technical Support Operations.

1-800-241-4002

To order parts using the online eCatalog, download technical publications, technical training courses, and additional services, visit the website at:

WWW.HOSPIRAPARTS.COM

After authorization, ship prepaid product returns to the following address:

Hospira
Technical Support Operations
755 Jarvis Drive
Morgan Hill, CA 95037

NOTE: Outside the U.S., contact your local Hospira sales office.

CAUTION: FEDERAL (USA) LAW RESTRICTS THIS PUMP TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER LICENSED PRACTITIONER.

WARNING

POSSIBLE EXPLOSION HAZARD EXISTS IF THE PUMP IS USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

Type CF	Equipment providing adequate degree of protection against electrical shock and suitable for application to patient
IPX1 Drip Proof Medical Equipment	Protected against dripping water
Class 1	Mains supply equipment using protective earth
C SA US UL 60601-1 CSA 601.1	CSA is a registered trademark of the Canadian Standards Association. The use of NRTL/C adjacent to the CSA mark indicates that the product has been certified by CSA to U.S. And Canadian standards. CSA has been accredited by the U.S. Occupational Safety and Health Administration (OSHA), as a Nationally Recognized Test Laboratory (NRTL).