



Body Guard 545

Epidural Infusion Pump

OPERATIONS MANUAL

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1.0 BODYGUARD PUMP OVERVIEW

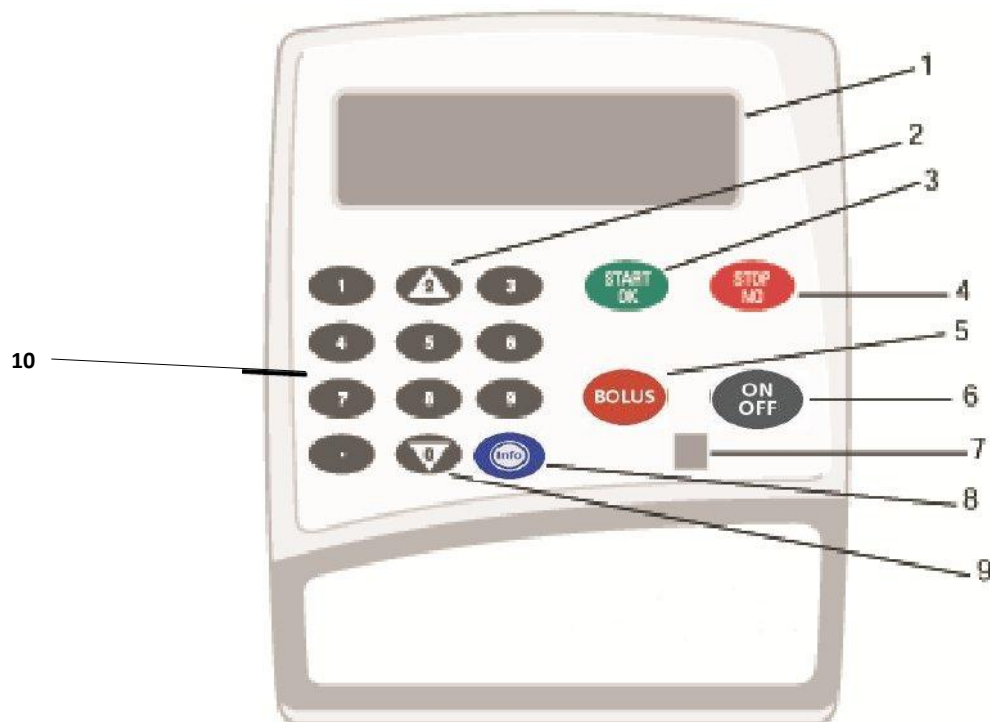
The BodyGuard Epidural System provides the following :

- Multiple programmes:
 - Bolus only (Patient Controlled) - 0.1-25.5ml @ 100-1000ml/h
 - Continuous (basal) plus patient controlled bolus (PCEA)
 - Continuous only (Epidural Analgesia (EA))- infuse 0.1-1000ml @ 0.1-30ml/h
- Used for ambulatory care, can be pole mounted or used with a carrying pouch
- A small, light & compact pump with quiet operation
- +/- 5% accuracy, even at low infusion rates
- Rechargeable Li-Polymer internal battery & mains operations
- Battery charged in a pole mount charging cradle or with an A/C adaptor
- Free-flow protection integral to all administration sets (anti-siphon/reflux)
- Prevents false occlusion alarms when delivering boluses through an epidural catheter by automatically varying bolus delivery rate
- Post-Occlusion Bolus Prevention System
- MediGuard protection ensures protocol is appropriate to patients weight
- 512 Event Log plus detailed patient history (1024 events log is optional)
- Ability to output history to PC (printer or file) using BodyComm software (optional)



2.0 PUMP DESCRIPTION AND FUNCTIONS

FRONT OF BODYGUARD AMBULATORY INFUSION PUMP



1. DISPLAY SCREEN

- a. Displays pump/infusion status
- b. Displays programming choices & instructions

2. UP ARROW

- a. Scrolls up through options on menu screens



3. START/OK

- a. Confirms parameter selection
- b. Starts infusion



4. STOP/NO

- a. Stops infusion/bolus
- b. Silences an alarm condition
- c. Stops priming
- d. Zeroes the displayed value during programming
- e. Erases the last digit during programming
- f. Returns to previous screen.
- g. Returns to main menu when held down for 2 seconds after stopping infusion delivery



5. BOLUS

- a. Administers bolus dose during PCA regimes (this function is normally performed using the remote bolus cable)
- b. Activates clinician (CA) bolus when pump in STOP mode. (Can only be activated under code conditions)



6. POWER ON/OFF

- Turns the pump on by pressing and holding the key until the software version confirmation screen appears and a beep is heard
- Turns the system off by pressing and holding the key until the graph is black and a beep is generated



7. LED window (beneath the bolus and on/off keys)



- Green Indicator
 - Lights during system self-test
 - Intermittent green light indicates infusion delivery






- Red Indicator
 - Indicates an alarm state with a continuous red light
 - Lights when the pump is in a stand-by mode during programming



8. INFO

- When pressed during infusion displays:
 - Infused Volume & Total to be Infused
 - Battery Status
 - Bolus Attempts, Given & Clinician Bolus volume
 - Protocol review screen
 - Date & Time

- Press  and then  to access:
 - Volume & boluses given in the last 24 hours
 - Hour-by-hour utilisation data
 - Hour-by-hour chart of bolus demand in last 24 hours
 - Hour-by-hour chart of volume infused in last 24 hours

- Holding the  key down whilst the pump is infusing (until the graph displayed turns black), locks and unlocks the keypad to prevent accidental or deliberate changes to pump operation.

9. DOWN ARROW:

- Scrolls down through options on menu screens

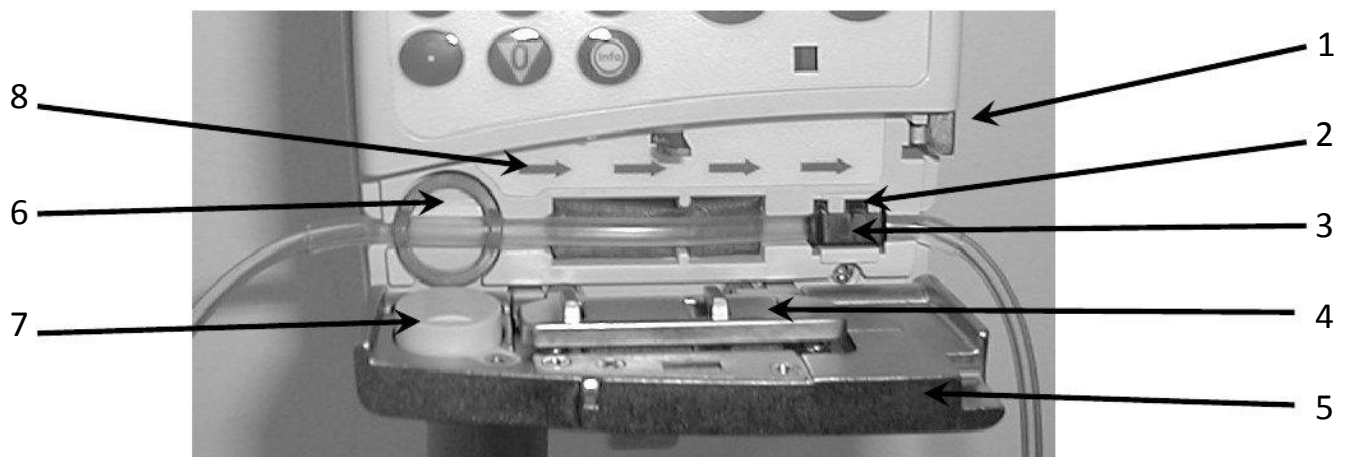


10. NUMERICAL KEYS:

- Enters numeric parameters during programming



BODYGUARD PUMP WITH DOOR OPEN



No.	Area	Function
1	Door latch	Opens the door & holds it closed when latch is in vertical position
2	Pressure sensor (behind keyway)	Detects downstream tubing restriction and occlusion Alarm level adjustable to suit patient/infusion type.
3	Keyway	Guides the administration set into correct position and ensures only dedicated administration sets are used
4	Pressing Plate	Connected to the door by two springs
5	Pump door	Covers the pressing plate
6	Air sensor - front	Ultrasonic air detector mounted on the front housing.
7	Air sensor- door	Mounted on the door
8	Flow Direction	Shows direction of fluid flow

BODYGUARD PUMP IN CHARGING UNIT

Charger display

Displays major pump messages & operation values

Release handle

Push to release the pump from the charging unit



3.0 SYSTEM SAFETY CHECKS

The following details outline the safety checks designed into the BodyGuard pump to minimise the possibility of under or over infusions.

FREE FLOW PROTECTION

When the set is installed in the pump and the door closed, two ridges on the door clamp the set so only the movement of the motor pistons can allow fluid to pass. With the door open, protection is afforded by a check valve, present in all BodyGuard sets, that prevents free flow towards the patient when the set is not attached to the pump. When the pump is attached to the set and delivering fluid, the pressure delivered by the pump opens the valve. The check valve also prevents reflux. The design of the check valve means that although a pressure of 2-3psi can open the check valve in the direction of the patient reflux cannot occur regardless of the pressure that builds up in the set.

POST OCCLUSION BOLUS REDUCTION SYSTEM

During an occlusion, pressure in the downstream section of the line can build up to 21psi (depending on user defined settings). When the pump alarms the user will check the line and attempt to clear the occlusion. In the absence of Post Occlusion Bolus Reduction System the pressure build up could cause a surge of fluid into the patient. This feature works by reversing the operation of the motor until pressure in the downstream line is returned to neutral (usually within 15 seconds).

AIR-IN-LINE DETECTION

BodyGuard utilises two modalities to detect air-in-line. The ultrasonic detector can be configured between 0.0 (OFF) & 1.0ml on the BodyGuard 545 pump for single bubble detection whilst a cumulative check triggers the alarm if an accumulation of smaller bubbles totals 1.0ml (non-configurable) in any 15 minute period. Although a single bubble may not exceed the user defined threshold (e.g. 0.5ml) if the cumulative volume of smaller bubbles exceeds 1ml (e.g. if three 0.4ml bubbles pass the sensor within a 15 minute period) an 'Air/Up Occlusion' alarm is activated. This accumulation feature is particularly useful when infusing products that create a significant number of small air bubbles (out-gas) to a patient who is highly sensitive to air, i.e. infants, neonates, children. If off (0.0ml) there is a 3ml volume for air in line detection.

PROGRAMME LIMITS (including MediGuard toxicity settings)

Under 'Change Set Up' users can choose from a number of options to limit protocol parameters and set safe ceilings on drugs infused. When the MediGuard feature is on users are asked to set the patients weight (kg) and a toxicity ceiling in either ml, mg or mcg (depending on pump configuration) per kilogram bodyweight per hour. If users try to set a protocol where the component elements (basal rate and boluses) exceeds the MediGuard limit the pump will alert the user to this and request they re-confirm their intentions, amend or revise the toxicity ceiling. Level One users will not be able to change the protocol or ceiling under Select Protocol and will have to select an alternative appropriate protocol or consult senior clinical staff with Level Three authority. Alternatively you can choose to simply limit either the rate or number of boluses delivered over either a 0, 1, 4, or 24 hour period according to local practice.

4.0 SYMBOLS

SYMBOLS & LABELS

The following symbols are used on the BodyGuard pump, accessories and consumables. Labels on the pump or statements in this manual preceded by any of the following words and/or symbols are of special significance, intended to help you to operate the pump in a safe and successful manner.



Attention, consult accompanying Instructions



CE mark indicates conformance to Medical Device Directive 93/42/EEC



Do not dispose of in municipal waste. Symbol indicates separate collection for electrical and electronic equipment. (WEEE Directive 2002/96/EEC).

NOTE: Does not apply to the battery.



Do not dispose of battery in municipal waste. Symbol indicates separate collection for battery is required.



The use of single-use disposable components on more than one patient is a biological hazard. Do not reuse single-use disposable components.



Type CF applied part



Date of Manufacture

SN

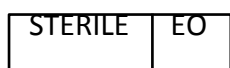
Serial Number



Expiry Date of disposable

LOT

Lot Number



Sterilized with Ethylene Oxide

5.0 INTENDED USE. WARNINGS & NOTES. OPERATING PRECAUTIONS

INTENDED USE

The BodyGuard 545 Epidural Infusion System is intended to be used only for administration via the epidural or intrathecal route (collectively referred to as neuraxial). BodyGuard 545 fully complies with the recommendations of the NHS National Patient Safety Agency (NPSA) that colour-coded epidural administration sets & dedicated epidural pumps should be used for application via this route so as to clearly distinguish them from equipment used for delivery via other routes (e.g. I.V.)

To minimize risk when administering neuraxial infusions the BodyGuard 545 Infusion pump & the dedicated administration sets are yellow colour-coded to clearly denote the intended route of administration.

Please ask your local representative or contact us direct for further details. Please ensure the pumps are only used by, or under the supervision of, trained medical staff.

WARNING: Drugs must not be administered to the epidural space unless the drugs are indicated for this purpose and are administered in accordance with the indications included in the manufacture's package. Epidural administration of drugs other than those indicated for epidural use could result in serious injury to the patient. For epidural administration of drugs use the BodyGuard dedicated MicroSet only.

WARNINGS & NOTES

Warnings & notes will be seen throughout this manual. These are described as:

WARNING: Warnings advise of circumstances that could result in injury or death to the user/operator or circumstances that could result in damage to the device. Read and understand this manual and all warnings before operating the BodyGuard Ambulatory Infusion Pump.

NOTE: Indicates that the information that follows is additional important information or a tip that will help you recover from an error.

PRECAUTIONS

ABOUT THIS MANUAL

The operator must be thoroughly familiar with the BodyGuard 545 Ambulatory Infusion pump described in this manual prior to use, and in particular must read and understand any precautions stated herein. If a software change occurs and the operation/specification for the pump changes, new or additional operating instructions will be issued, if needed.

All illustrations used in this manual show typical settings and values that may be used in setting up the functions of the pump. These settings and values are for illustrative use only. The complete range of settings and values are specified in the Specifications section of this manual.

This operating manual document has been developed with consideration to the requirements in relevant Harmonised Standards. Data presented in the Technical Specifications reflect specific test conditions defined in this standard. Other external factors such as varying back pressure, temperature, head height, set usage, fluid restrictions, solution viscosity or combinations of these factors, may result in deviations from the performance data enclosed.

OPERATING PRECAUTIONS

Although the BodyGuard infusion pump has been designed and manufactured to exact specifications, it is not intended to replace trained personnel in the supervision of neuraxial infusions.

CME will assume no responsibility for incidents which may occur if the product is not used, stored or transported in accordance with the environmental conditions stipulated in this document and on the package labelling.

This infusion pump is designed for ambulatory use, and should withstand everyday handling. If the pump is dropped onto a hard surface, or is suspected of being dropped, the operation and calibration should be checked by a qualified technician.

Do not bathe or shower whilst using the pump. The pump is resistant to a limited amount of splashing, but its construction does not make it resistant to large amounts of spraying or immersion in liquids. Damage to the internal components may result.

INFUSION PRECAUTIONS

Always read and follow the instructions which accompany the administration sets. Carefully follow the instructions for priming the set, as well as the recommended set change interval.

The fluid bag & administration set should be disposed of in an appropriate manner, considering the nature of the residual fluid that may be contained within, in accordance with the hospital/homecare provider's disposal practices.

Drugs for infusion by use of the pump may only be prescribed by a qualified medical practitioner.

Caution must be exercised in the selection of drugs and the amount and rate intended to be delivered via any infusion pump. If the drug contained in the fluid bag will be exposed to extreme environmental conditions for prolonged time periods, it is important to select drugs that will not change pharmacologically upon such exposure. As with all automatic infusion devices, whenever a toxic or dangerous level of drug is stored in the reservoir, constant monitoring of the infusion is required.

In all applications, time to alarm under occlusion or other fault conditions will depend on the infusion rate and levels of alarm settings. It is recommended to consider these parameters when using drugs requiring infusion stability or low flow rates, and therefore a quick time to alarm.

GENERAL PRECAUTIONS

Do not use hard or sharp objects on the keypad.

The specified accuracy of the pump can only be maintained if the pump is used, maintained and serviced in accordance with the instructions given in this manual. If the pump has failed to calibrate during the servicing procedure, it must be returned for repair or disposal.

If the pump is dropped, subjected to excessive moisture, humidity or high temperature, or otherwise suspected to have been damaged, remove it from service for inspection by qualified personnel.

The pump has been designed to be as safe as possible to handle; however, care should be exercised to avoid trapping of fingers or other body parts in the mechanism.

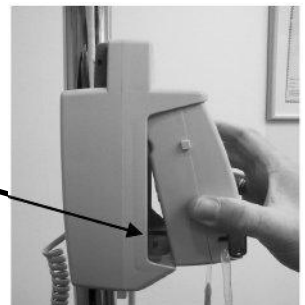
6.0 INSTALLATION & SET-UP

PLACING & REMOVING THE PUMP FROM THE CHARGING UNIT

NOTE: Before using the BodyGuard ensure the battery is fully charged.

PLACING THE PUMP INTO THE CHARGING UNIT

Put the pump into the charger top first until it clicks into place.



REMOVING THE PUMP FROM THE CHARGING UNIT

Press the pump release button to lift the pump out of the charger bottom first.



CHARGING THE PUMP

AC power indicator:

Connect the charger unit to AC power, verify the indicator is lit

Green light = connected to mains

Red light = on battery power

Battery charging status Indicator:

Verify that the indicator is lit

Green light = fully charged battery

Red light = battery charging



BATTERY & CHARGING PRECAUTIONS

Be sure that the battery is fully charged at all times.

Replace the battery once every four years.

When the pump is not in use store the pump in the charger.

After the "End Battery" signal has been activated or following long periods of storage, wait 2 minutes after the pump has been connected to an AC power supply before operating.

Do not operate the pump on AC power if the battery is not loaded in the pump for back up.

Whenever possible, use the pump connected to an AC power supply via the charging unit. This preserves the battery power supply for emergency use or for situations where the AC power is not available.

The pump is protected against overcharging. In order to keep your battery fully charged, connect the pump to the mains via the charger whenever possible.

Blown fuses could cause a fire hazard. Replace blown fuses on the Charger only with fuses of the same type and rating (see fuse values on the Charger PCB).

WARNING: Voltage present on internal components may cause severe shock or death upon contact. Disconnect the Charger from the mains, prior to opening the casing. Only trained service personnel should open the pump cover.

7.0 OPERATING THE BODYGUARD PUMP

7.1 SECURITY

Before performing any of the set-up & period tests or to operate, programme or configure the pump you will need to access the pump using the security codes. As the BodyGuard 545 is designed for pain management therapies the pump has several levels of security to ensure safe set up and administration of pain protocols and to prevent idle or malicious tampering.

ACCESS CODES

To operate, programme and configure the BodyGuard Ambulatory Infusion Pump three Access Codes are required.

Level One	700	Allows user to run pre-set protocols and titrate infusion rate (within pre-set protocol limits).
Level Two	*	Allows authorised users to deliver Clinician Activated Bolus or loading dose.
Level Three	**	Allows users to set up or modify standard infusion protocols & change pump configuration parameters in 'Change Set Up'.

** / ** refer to senior clinical or lead service personnel for relevant code*

A further code is used to access the technicians menu but this is only provided to fully trained (by CME) & authorised Electro-Biomedical Engineering departments.

Codes can be changed from the pump defaults and the code level applied can be changed if required. This is carried out via the technician's menu.

KEYPAD LOCK

As a further, simple security feature you can also lock the keypad.

1. Whilst the pump is infusing press and hold  until the Lock Mode chart which the pump displays goes from OFF to ON.
2. This now prevents the operation of all keys except ,  & .
3. To unlock the keypad press and hold  again until the chart goes from ON to OFF.

NOTE: To prevent unauthorised individuals accessing the main menu a technique is required to return to the menu code screen when the pump is in STOP mode.

To return to the menu during infusion: press STOP (to stop delivery and enter the STOP state). Press & hold STOP until the 'Resume or Menu' choice prompt appears.

NOTE: When keypad lock is on, entering the stop state & holding down STOP will not return you to the main menu. Press START (to restart the infusion), press & hold INFO (to remove keypad lock), then press & hold STOP until prompted for the access code to return to the main menu.

7.2 SETTING UP & MODIFYING PROTOCOLS

When you receive your BodyGuard 545 pump and go to 'Modify Protocol' on the main menu for the first time you will see that all protocols are blank. You can edit, add or delete up to a maximum of 26 infusion protocols to tailor the protocols to your service. (CME can pre-programme if requested).

From the main menu you access "Review Set up" and "Change set-up" to set local preferences for device configuration from the options available. Some initial settings may need to be activated from the Technicians menu.

This section is probably the most complex of the manual but remember you should only have to perform this function once for each protocol with each pump whilst you are setting it up for use on the first few patients. You may also ask CME representatives or service personnel to assist with the set up of the pump which can be done prior to delivery.

Each protocol requires the following data (depending on initial set up):

- A. Drug/Protocol name (up to 18 characters)
- B. Volume to be infused (VTBI)
- C. Initial Infusion rate in ml, mg or mcg per hour. This step and the protocol maximum rate step will be hidden if the pump has been set to 0ml maximum basal rate by the technical staff.
- D. Protocol Maximum rate (to allow titration within protocol)
- E. Bolus volume (if applicable)
- F. Maximum bolus
- G. Lock Out between boluses (if applicable) Drug concentration (optional)
- H. Programme limits: MediGuard and volume/bolus limit (choice of 0, 1, 4 or 24h limit of either volume boluses set up) Set under "Change Set Up" as applicable.

NOTE: You can use protocols to set up several commonly used treatment regimes in your service i.e. same bag, drug name, basal rate but different bolus volumes or lockout times.

NOTE: Each protocols parameters are unique to that protocol. For example if you use both Ropivacaine and Bupivacaine in your service and one commonly comes in a 100ml bag whilst the other is in a 250ml bag then you can set these bag sizes as standard for each.

NOTE: After setting up your most common regimes as a protocol set up the next or last protocol letter as a 'Tailored' or one off regime that you can modify for individual patients who don't fall within the pre-set protocols. Once the infusion has been administered for a particular patient you can go back in and change this for the next or a future patient.

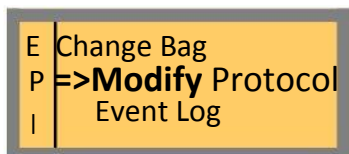
NOTE: Entry of all parameters is via the numeric keypad. Only the protocol selection is a scroll option menu using the UP & DOWN arrows. The previous value will be displayed. Enter the new value, which will automatically delete the previous value. If you make an error whilst entering, pressing STOP will delete the previous digit. Repeat as necessary.

NOTE: At certain screens, if you delay for a period of time between key presses the pump will revert to the previous screen.

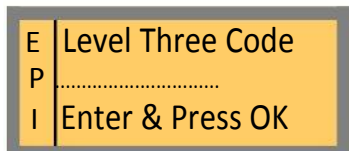
PROGRAMMING DRUG/REGIME PROTOCOLS

NOTE: The BodyGuard has a system called MediGuard which can be activated under 'Change Set Up', program Limits'. When this feature is set to 'ON' the pump will ask for the patients weight at the stage of entering the protocol. If disabled you will skip this stage. Refer to Appendices for instructions for setting up protocols with MediGuard enabled.

1. From the main menu select "Modify Protocol" and press



2. Enter Access Code and press



3. Scroll to select the protocol for adding/modifying, (A to Z) press



If setting up protocols for the first time, the protocol initial only will be visible.



A. DRUG/PROTOCOL NAME

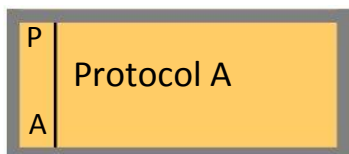
4. To enter the edit mode and add a protocol name press



If you need to delete a protocol name previously entered press continuously until the cursor is at the left side of the display.



Even if the name appears empty you must still perform this step as the line is full of blank spaces.



5. Use numeric keys 2 (up), 4 (left), 6 (right) & 0 (down) as cursor keys to navigate around the letter, number and symbol choices.

To select a character, position the white cursor over the target letter/number/symbol, press




Repeat the last step as required to build your protocol name.

To add a space, position the cursor in the top left blank space of the grid and press




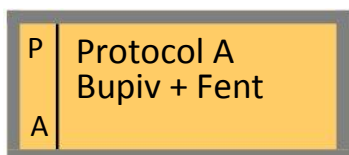
The maximum name size is 18 letters/digits including spaces.


6. When you have finished building your protocol name position the cursor in the top right side,

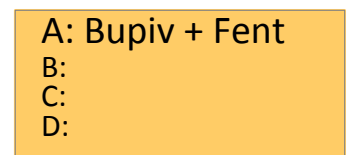
press  to confirm your new Protocol name:

Then either:

Press  to accept your new name and return to protocol selection or



press  to return to edit mode.



9. By returning to edit the protocol list (A to Z) displays:

Select the protocol to edit, press



B. VTBI

10. Enter bag volume in ml, press



To change any numeric programme parameter just enter the numbers which will replace the previous value and this will overwrite the previous value.

11. If you make a mistake whilst entering, press



to delete the last digit entered.

Press



when correct value is entered.

C. INITIAL INFUSION RATE (ml/h)

12. Enter the initial rate using the numeric keypad, press



If the rate step does not appear then the Maximal Rate under 'Change Set Up' has been set to 0ml/h to prevent users from delivering regimes with a continuous element. If you have the authority to change this go to 'Change Set Up' (see later section).

D. PROTOCOL MAXIMUM RATE

13. This will have defaulted to the initial rate you have just set. Enter the maximum rate you will allow for

this protocol, press



For example, you may wish to start an epidural with 6ml/h but allow users to titrate up to 12ml/h.

NOTE: To programme in mg/h or mcg/h:

Press STOP 4 times respectively (first press clears the previous rate, second asks if you want to accept "ml only" and third takes you to concentration mg/ml screen. A further press takes you to mcg/ml). To specify the concentration in mg or mcg/ml of the drug regime you are programming, use the numeric keypad to enter the value (i.e. 1mg/ml). Press when done.

NOTE: BodyGuard 545 is capable of continuous (basal) rates of up to 30ml/h. Users can fix a maximum basal rate in 'Change Set Up' using the Level three Access Code to ensure other users cannot accidentally programme the pump to deliver above the safe ceiling for your commonly used drugs.

E. BOLUS VOLUME (If applicable)

14. Change or accept the bolus volume using the numeric keypad, press



F. MAXIMUM BOLUS

15. Enter the maximum bolus, press



G. LOCK OUT BETWEEN BOLUSES

16. Change or accept the Lock Out (bolus lockout interval) in minutes, press



H. PROGRAM LIMITS

NOTE: If the screen does not appear, then the option is set to off (zero hour limit under "Change set up" - this is the default).

17. Change or accept the 0, 1, 4 or 24 hour limit. To turn the limit off enter '0', press



Depending on how this has been configured under 'Change Set Up' in 'Program Limits' the pump will ask you to set the limit in either volume (ml), concentration (mg or mcg) or number of boluses.

If MediGuard is enabled, refer to Appendices for MediGuard Set Up.

18. You can now confirm or review the settings entered

If satisfied with protocol settings, press



This will return you to the main menu screen, "Select Protocol"

If you wish to review or change your settings, press



This will return you to the Protocol list (A to Z) selection screen to continuously run through and check/change your entries before arriving back at the 'Confirm' or 'Review' screen.

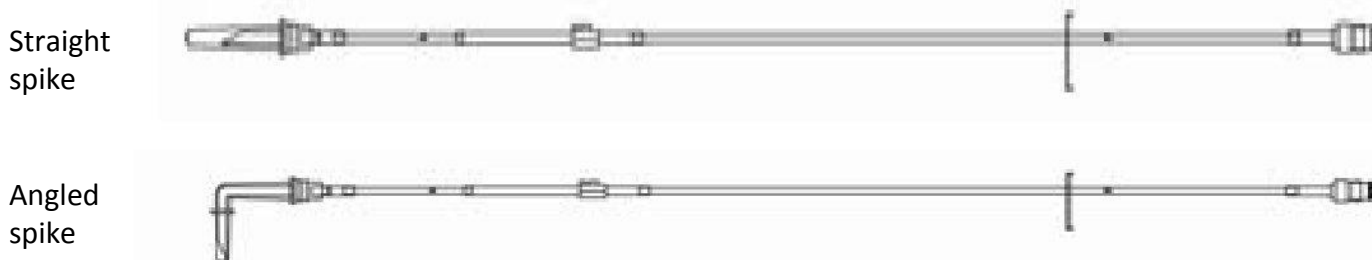
Confirm: Press OK
Review: Press NO

WARNING: Before the pump is put into use check the defaults (by selecting 'Review Set Up' from the main menu) are appropriate for your intended use. Settings can be changed in 'Change Set Up' using the relevant Code. CME suggests this is done only by the lead clinical person or your local electronic engineering department. Please see the later section on 'Change Set Up' for further information.

7.3 DEDICATED BODYGUARD ADMINISTRATION SETS

Only dedicated BodyGuard administration sets should be used with BodyGuard pumps. All BodyGuard microsets incorporate the following features: -

- Latex-free, microbore anti-kink tubing to prevent occlusion particularly in ambulatory configuration.
- Colour-coded (yellow-epidural) to aid identification of administration route.
- Pumping segment- non-colour coded, section containing the key block, visible on the pumping segment ensures set can only be installed correctly (for direction of flow) and that only dedicated sets (calibrated to the pump to ensure accuracy) are used.
- Check valve (anti-siphon/anti-reflux) at the distal end of the set.
- Choice of straight or angled spikes.



230 cm, color coded (yellow), epidural administration spike set with approximate 5 ml priming capacity.

Anti-Free Flow valve

The Anti-Free Flow valve enhances pump functioning by:

- Preventing free-flow in the event the set is detached from the pump.
- Preventing back-flow (reflux) in the event several infusion pumps are connected simultaneously to the same patient.
- Preventing free-flow in the event of a mechanical malfunction.
- The mechanism along the inner door side of the pump maintains optimal accuracy even if the line is used over several days.

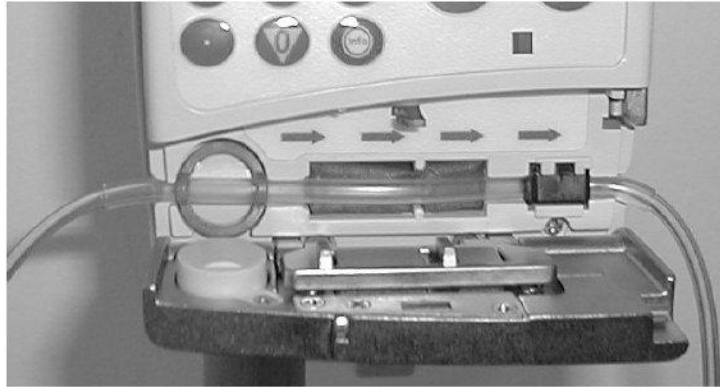
WARNING: BodyGuard sets are designed specifically for ambulatory epidural use. They have a set capacity of c.5ml for safety reasons. Normal hospital lines can hold up to 16ml of fluid which is not appropriate when administering potent agents such as morphine. Non-colour coded sets are available on request.

WARNING: Use of administration sets other than dedicated sets may impair the operation of the pump and accuracy of infusion. Do not operate the BodyGuard Ambulatory Infusion Pump with any set other than those supplied by CME.

WARNING: All BodyGuard dedicated administration sets incorporate sections of PVC tubing and the pumping segment is polyurethane/silicone. Do not use pharmaceuticals with this device that are not compatible with either PVC or polyurethane administration sets.

NOTE: A kinked/occluded administration set may impair operation of the pump and the accuracy of the infusion. Before operation, verify that the set is not kinked or occluded. BodyGuard epidural sets are manufactured from kink resistant tubing.

7.4 LOADING THE ADMINISTRATION SET



1. Prepare fluid bag & attach to administration set . Open the BodyGuard pump door (using latch on right side of door).
2. The clear, silicone section of the administration line fits into the pump. Hold this section of tubing with the key (small plastic block) on the right & make sure the flow direction is in line with the flow direction arrows inside the pump door.
3. Insert the BodyGuard administration set into the pump by placing the key into the keyway as shown by the arrow in the diagram above. Close the pump door until the catch clicks.

WARNING: Use aseptic technique. Patient infection may result from the use of non-sterile components. Maintain sterility of all disposable components and only use single use consumables marked ②, once only.

WARNING: Do not attach the set to the patient's access device before priming the administration set.

WARNING: The key can only be fitted into the keyway one way. If you are having trouble fitting it do not force it in. Check to ensure you have correctly lined up the tubing with the direction of flow.

7.5 POWERING UP & PRIMING A SET

WARNING: Do not attach the set to the patient's access device before priming the administration set.

1. Once the set is loaded turn on the BodyGuard pump by pressing

ON
OFF

2. During power up these screens display automatically to confirm pump software version and pre-set limits .

BodyGuard
EPI28A

Limit OFF
Air Alarm 0.5 ml
Occlusion 21 psi

3. Press

START
OK

to resume a previous infusion (retain patient history) or

Press

STOP
NO

to take you to the main menu

E P I | Press OK to Resume
Press NO for Menu

4. Enter Level One Access Code, press

START
OK

E P I | Level One Code
.....
Enter & Press OK

5 Scroll to "Prime" (if necessary), ensure the cursor is pointing to "Prime" &

the text appears in a larger font, press

START
OK


E P I | =>Prime
Select Protocol
Change Bag

6. BodyGuard prompts you to ensure the pump is disconnected from the patient, to commence priming press

START
OK

WARNING !!
Disconnect Patient
Press OK to Prime

7. The chart now displaying shows the progress versus total pre-set priming volume. *You may stop priming at any time or repeat the last two steps if the line is not completely primed after first priming function.*

PRIME
0  6
(Press NO to Stop)

8. On completion of priming the screen displays the main menu.

E P I | Prime
=>Select Protocol
Change Bag

NOTE: Priming volume is user configurable depending on the capacity of the administration sets in regular use in your service. For epidural sets, a 6ml prime volume is suggested.

NOTE: All BodyGuard administration sets contain a check valve which means the line cannot be primed using gravity. Sets must be primed using the infusion pumps priming function.

NOTE: The priming volume and rate can be changed in via the "Change Set Up" option in the main menu. Increasing the priming rate may cause excessive turbulence in the set on priming and make it difficult to purge all air from the system. CME recommend a priming rate of <425ml/h.

7.6 SELECTING A PROTOCOL

Under normal, everyday circumstances most users of dedicated infusion pumps use the pumps to perform the same or a limited number of infusion protocols for the majority of patients. For example, in pain management it is common for patients to be on a regime consisting of bolus only delivery of a concentration of 1-2mg/ml morphine supplied by pharmacy in a fixed infusion bag volume. The service may occasionally use different bolus volumes or lockout times depending on individual patient needs.

This means once you have set up these protocols, using the Level 2 Access Code in 'Modify Protocol' as described in the previous section, Level 1 code users can access the pump and run the standard protocols for a patient without having to enter or change any infusion parameters. This reduces the risk of inadvertent changes of key parameters during set up. *This is achieved as follows:*


Load an administration set, close the pump door & turn the power on (refer to page 18 "Powering up & priming" for full instructions) Following completion of priming, the pump returns to the main menu.

1. Ensure the curser points to "Select Protocol", (larger font denotes


the option selected), press 

Prime
=> Select Protocol
Change Bag

2. To confirm set up is for a new patient, press 

To resume press  (this carries forward patient totals)

New Patient?
Answer OK or NO

3. Select the Protocol required by using / 

(larger font denotes the option selected), press 

A: Bupiv + Fent
B: Bupiv
C: Labour 100ml
D:

4. The Infusion summary screens displays to confirm, press 

VTBI Initial 480 ml
VTBI Current 480 ml
Volume Infused 0
Press OK to Continue

5. The protocol summary screen displays, to confirm, press 

*Review the summary screen carefully to ensure the parameters match
The prescription*

Rate 6ml/h
Max. Rate 15ml/h
PCEA 2ml/ 5min
OH Limit OFF

6. Start the infusion when ready to do so by pressing 

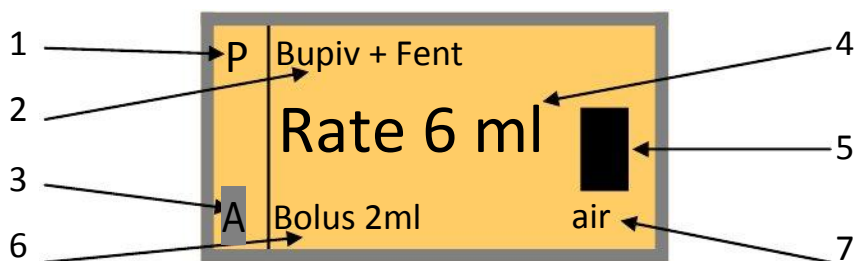
Start Infusion?

7. The infusion summary screen now displays
(See over the page for interpretation of this screen)

P Bupiv + Fent
Rate 6 ml
A Bolus 2ml

NOTE: If MediGuard feature is turned on user is prompted for patients weight. Enter in kilograms then press START. Refer to Appendices for MediGuard set up.

7.7 INTERPRETING THE SCREEN WHILST INFUSING



1. "P" for Protocol
2. Protocol selected (the name that is assigned to that protocol displays).
3. The currently selected protocol letter displays in the left hand margin of the display
4. Programmed infusion rate (mg or ml/hour) - displays the current infusion rate in the units configured for that protocol, (i.e. ml/h, mg/h or mcg/h). If the maximum basal rate has been set to 0ml/h in 'Change Set Up', or the protocol does not contain a continuous infusion element, the infusion rate line will be replaced with Bolus Volume.
5. Battery Status indicator—the battery symbol will be visible if the pump is not connected to the mains charger and the level of charge can be checked by monitoring the black fill inside the symbol (i.e. A completely black symbol indicates a fully charged battery).
6. Displays the bolus volume for the current protocol. As with infusion rate this will be displayed in mls, mgs or mcg depending on how the current protocol is set up. If the maximum basal rate has been set to 0ml/h in 'Change Set Up' then this line is replaced with the lock out time for the bolus in minutes.
7. Air detector indicator: if the single bubble air detection has been disabled then the display will indicate this with the word "air" (scored through) to warn the user.

NOTE: Users can confirm the pump is infusing by checking the LED is blinking green. The LED can be disabled under 'Change Set Up' to enhance battery operating time.

7.8 RATE CHANGE DURING DELIVERY (Rate Titration)

If the protocol selected contains an initial infusion rate and a maximal rate that allows titration (ask senior medical staff) then this rate can be titrated as follows:

1. Whilst the infusion is running, enter the new infusion rate required using

the numerical keypad, press  (change not available if keypad locked)

Rate 8 ml/h
Enter & Press OK

NOTE: If the rate selected is above the protocol maximum range the pump will not accept the entry & will display a message notifying the maximum rate allowed.

2. Enter the relevant access code , press



E | Level One Code
P |
I | Enter & Press OK

3. The pump beeps to confirm acceptance of the change and the new rate is confirmed on the display.

P | Bupiv + Fent
Rate 8 ml
Bolus 2ml

7.9 BOLUS DOSE DELIVERY

The BodyGuard can be configured to deliver a patient-controlled bolus or an auto-bolus. In addition there is the option of a Clinician activated bolus.

BodyGuard has a feature which optimises bolus delivery speed and prevents false occlusion alarms when infusing through narrow epidural catheters. The pump attempts the bolus at the pre-set bolus rate. If a back pressure above the pre-set occlusion pressure level is detected during delivery it reduces the delivery speed until a pressure below the occlusion alarm level is achieved. If it cannot achieve this even at the minimum bolus delivery rate the pump will then alarm 'Down Occlusion'. This feature prevents false occlusion alarms during bolus delivery through narrow catheters.

NOTE: BodyGuard is capable of delivering the bolus dose up to a maximum rate of 1000ml/h. The default setting is 300ml/h. The user can adjust bolus delivery rate down to a minimum of 100ml/h in 'Change Set Up' Mode.

NOTE: Patient-controlled bolus and Clinician activated bolus will be covered in the following sections. For information on Auto-bolus refer to Appendices, page 41.

PATIENT CONTROLLED BOLUS

The BodyGuard Epidural can be programmed to allow the patient to administer bolus doses of medication on demand, either with or without a continuous background (basal) infusion. A patient-controlled bolus can only be activated via the remote bolus button.

If a bolus has been programmed into the current regimen it will always include the following parameters:

1. Bolus volume – the volume of drug to be delivered in each bolus event. When the bolus button is pressed the pump will beep to confirm acceptance and a bar chart will appear on the display confirming bolus volume to be delivered and progress as the pump delivers it.
2. Lock Out – the lockout time which must elapse after a bolus dose has been delivered before the pump will allow another bolus dose. If the patient presses the bolus button during the Lock Out the pump will beep to confirm the press but no chart is displayed and the pump continues with the background Infusion (if programmed).
User can check the time until the next bolus dose will be available for the patient by using the INFO key to view the Bolus Summary screen where the countdown is shown beside the Boluses Given count. Every minute, the infusion running screen will display when the next bolus is available.

If an occlusion is experienced or the pump is stopped during bolus administration the pump will allow the remainder of the partially delivered bolus dose to be requested and delivered, once the occlusion has been cleared and/or the pump restarted, without the patient having to wait another full lockout period. If the patient does not take the residual within the lockout time the amount available resets to the programmed dose.

NOTE: Every press of the bolus button, whether a dose is given or just attempted, enters a record in the patient history and 512 event log. Using the information key (see next section). It allows the user to check boluses given vs. attempts in order to check patient's current regime is sufficient for their pain status.

CLINICIAN ACTIVATED (CA) BOLUS

During certain pain management protocols it may be necessary for the clinician to administer loading or top up bolus outside of the parameters of the standard protocol. A Clinician activated bolus can be given prior to, or during an infusion.

A loading dose delivered before the user goes to 'Select Protocol', using the Clinician Bolus' option from the main menu, will not show in the patient history as all counters are cleared when you select 'New Patient?' during protocol selection. If you wish the loading dose to be recorded then deliver it immediately after the infusion has commenced using the steps described over the page.

CA boluses delivered after the start of a protocol are recorded in the current patient history and the number of doses and total volume can be seen on the Bolus Summary screen.

WARNING: CA Bolus overrides programme limits. Take care to ensure only trained, authorised personnel have the relevant code and understand the function of this feature.

NOTE: Lead personnel can limit the maximum clinician dose under 'Change Set Up' to prevent accidental overdosing. Default setting is 0ml for a single dose but this can be configured between 0ml (disabled) to 20ml (maximum).

NOTE: If an occlusion occurs or the pump is stopped during clinician bolus delivery the user will have to repeat steps to deliver the balance of the CA bolus.

To administer a clinician activated bolus/loading dose before therapy commences:

(i.e. immediately after the set has been primed and connected to the patient but before selecting a protocol):

1. Scroll down the main menu to 'Clinician Bolus' then press



2. Enter the relevant access code (if authorised) then press



3. Enter the desired volume of the bolus in mg or ml (depending on the units in use in the current Protocol), press



NOTE: If the user requests a dose above the default or configured maximum clinician dose the pump will display the maximum single dose available and the user should then re-enter within this limit.

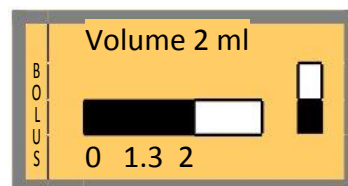
4. Confirm volume to be delivered & press



to commence delivery

Bolus delivery status displays:

(On completion of bolus delivery the screen reverts to the main menu)



5. In the main menu, scroll to Select Protocol and proceed with set up

To administer a clinician activated bolus during an infusion:

1. To stop infusion delivery, press



2. Press



3. Enter Clinician access code, press

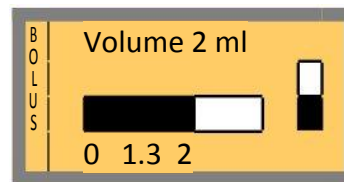


4. Enter the desired volume of the bolus in mg or ml (depending on the units in use in the current Protocol), to immediately deliver the bolus press



NOTE: If the user requests a dose above the default or configured maximum clinician dose the pump will display the maximum single dose available and the user should then re-enter within this limit.

Bolus delivery status displays:



Once BodyGuard has delivered the CA Bolus the infusion continues running the current protocol.

7.10 END OF INFUSION & BAG CHANGE

When the end of infusion is reached (pump has delivered the pre-set bag volume) the alarm sounds and the screen displays:

End of Infusion
Press STOP for Menu

1. To confirm end of infusion and to return to the main menu, press

STOP
NO

2NOTE: If Keep vein open (KVO) has been set, after four beeps of the end of infusion alarm the alarm stops and the pump goes to the pre-set KVO rate. In KVO mode, the alarm will sound again every 4 minutes until the user changes the bag or stops the pump. If the KVO is set to 0ml/h then the pump will continue to alarm until attended to.

2. Enter Level 1 Access Code, press

START
OK

E Level One Code
P
I Enter & Press OK

3. Ensure the cursor points to "Change Bag", press

START
OK

E Select Protocol
P =>Change Bag
I Modify Protocol

NOTE: If you have set the pump up with identical protocols except for the bag size and intend to switch the user to a different bag size for the remainder of their therapy then Select Protocol, choose the protocol containing the alternate bag size but answer NO to 'New Patient?' prompt to retain history.

4. Attach the new bag to the line or change both line and bag, depending on local practice guidelines

Change Bag

5. When bag change is complete, press

START
OK

Press OK when done

NOTE: If necessary select 'Prime' and press twice to initiate priming. Repeat until fluid appears at the distal end of the set if all air is purged from the set. Press STOP to stop priming at any time.

WARNING: Always detach the distal end of the set from the patient before priming the new line.

6. To confirm bag volume, press

START
OK

The new bag volume should display in addition to the total of all volume infused to date out of previous bag (s)

VTBI Initial 480 ml
VTBI Current 480 ml
Volume Infused 480
Press OK to Continue

7. To confirm protocol, press

START
OK

Rate 8ml/h
Max. Rate 10ml/h
PCEA 2ml/ 5min
OH Limit OFF

8. To continue the current patient's infusion., press

START
OK

Start Infusion?

9. The infusion is now running and the summary screen will display


P Bupiv + Fent
A Rate 8 ml
Bolus 2ml

7.11 USING HISTORY FUNCTIONS

CURRENT PATIENT HISTORY






The BodyGuard keeps a rolling 24 hour history of the current patient's infusion delivery. In this section we will address how this can be used. There is also a 512 event log keeping track of the last 512 user actions in a date and time stamped record.

ACCESSING INFORMATION WHILST INFUSING:

1. Pressing the  key repeatedly will scroll through:
 - Press 1: Infused vs. volume to be infused
- Since current protocol started
 - Press 2: Battery Level
 - Press 3: Boluses attempted, given & Clinician boluses
- For the last 24 hours
- Includes countdown showing time to next patient bolus availability
 - Press 4: Protocol review screen
- Allows user to check details of current protocol parameters without having to stop the infusion.
 - Press 5: Date & Time

NOTE: The default duration for information screens to display is 8 seconds. If no key presses take place the screen will revert to the infusion running screen. The default duration can be changed in "Change Set Up" if required.

ACCESSING INFORMATION WHEN ON HOLD/PAUSED:

1. Press  to stop infusion delivery then press  repeatedly to scroll through:
 - Press 1: Volume and boluses given in 24 hours (↓ for 8 hours)
 - Press 2: Bolus attempts, given and volume infused hour-by-hour for the last 24 hours
(use the  and  keys to navigate through the hours)
 - Press 3: Chart of bolus delivery during the last 24 hours, hour-by-hour.
 - Press 4: Chart of Volume (incl. Boluses) delivered during the last 24 hours, hour-by-hour.
2. Press  to resume infusion when you return to the 'STOP' screen

EVENT LOG

The Event log carries the last 512 user events (i.e. changes to programmes, pump started, stopped, etc) and the status of the pump (i.e. battery charge, pressure levels, etc). It is not patient specific (i.e. the 512 events are likely to span many patients recently treated with that particular pump).

The Event Log is only accessed via the main menu & when the pump is stopped.

1. From the main menu scroll to 'Event Log' and press





2. Enter the Level 1 Access Code, press




3. The screen will now show the most current user event, date, time, etc, for example:

Event Num: 450
20:10:08 15.59
Switched OFF
Press INFO - Details

4. Use   to scroll through events to find a specific event you wish to view

5. When you find an event of interest:

Pressing  will display further data, relevant to this event, on the status of the Protocol and pump at the time of this event. The user can scroll through the information shown here to check what the pump was set up for, whether it was operating on battery or mains, whether it was locked out and what the pressure settings and readings were at that time.

Rate	8ml/h
Vol. Left	478ml
Infused	2 ml
Epidural Program	
Battery Operation	
Battery Level-Normal	
Pressure Level Taken	
Lock Level 2	
Vol. Cal for 25ml/h:	540
Occlusion Pressure	HIGH
Pressure DELTA:	15
Pressure CAP:	255
Pressure Baseline:	121
Actual Pressure	81

NOTE: To return to previous screen, press STOP.

7.12 ELIMINATING AIR DURING OPERATION

WARNING: Using the pump with air in line detector off may cause an embolism resulting death or paralysis. Switching the air detector off is not recommended and should be used only when absolutely necessary. Please contact your technician in order to enable the air sensor if disabled with no need.

When either a single bubble of air above the user-defined alarm level (see 'Change Set Up') or an accumulation of smaller bubbles exceeding 1ml/15 minute period is detected in the line (providing the air-in-line alarm has not been disabled), the screen shows AIR/UP OCCLUSION, and the LED indicator turns from green to red. The screen displays:

Air/Up Occlusion
Check for air/occl
Press NO to mute

To eliminate air in the line during pump operation:

1. Press  to cancel the alarm

2. Check and resolve the cause of air detected in the line. If it is necessary to prime the line disconnect the line from patient access device as per local policy.

WARNING: Ensure the line is disconnected from the patient before priming. failure to do so could result in the patient receiving a large bolus.


3. Press & hold 


4. When screen visible: "YES to Resume, No for Menu, press



5. Enter the relevant access code, press



6. Scroll & select "Prime", press . (Follow screen prompts to complete priming)

7. Once all air is eliminated from the line and fluid is seen at the distal end of the set, press  to return to the main menu

8. Scroll to Select Protocol, press




9. The screen displays "Press OK to Resume, Press NO for Menu", press



(to retain pt history)

10. Enter the relevant access, press



11. Check the Infusion Summary screens, if correct then press  each time to confirm settings for each screen to restart delivery.

NOTE: The air detection system monitors and records air passing the sensors. If the total volume of a single bubble exceeds the user defined limit configured, or smaller bubbles accumulate to 1ml over a 15 minute period, an alarm is activated.

NOTE: In the case of an UPSTREAM OCCLUSION, the AIR/UP OCCLUSION alarm will activate as the tubing collapses upstream of the pumping mechanism giving the sensors the impression of air in the line. After an air alarm always check the set for the visible presence of air. If no air is visible exclude the possibility of the set being occluded/pinched/ clamped between the pump and the fluid reservoir.

7.13 ALARMS & ALERTS

ALARM ACTIVATION

The conditions listed will cause the BodyGuard to activate an alarm:

- Air in line/Upstream occlusion
- Downstream occlusion
- Pump Paused too long
- End Battery
- End of infusion
- Missing Key
- System Error

ALARM CONDITIONS

When the infusion pump detects a problem, four things occur: -

1. Infusion delivery stops
2. An audible alarm is activated
3. An alarm message appears on the display indicating the cause
4. The LED indicator will change from green to red

NOTE: Pressing STOP during an alarm, mutes the alarm for two minutes.

NOTE: End of battery indicates that the battery power requires immediate charging. The pump will cease operating. the battery must be charged at this stage to restart the pump.

ALERT ACTIVATION

The conditions listed will cause the BodyGuard to activate an alert:

- Near end of infusion
- Low Battery

ALERT CONDITIONS

During an infusion, when the infusion pump reaches the “Near End” state, the user is alerted and the following occurs:

1. Pump beeps x 3 (The infusion will continue to run until the end)
2. Every 3/4 minutes until the end, a screen alert will be visible which states the reason for the alert. (This alert alternates with the infusion running screen).
3. The LED will blink red.


NOTE: Near end of infusion alert commences when there is approximately 5ml volume to be infused (VTBI).


TROUBLESHOOTING

DESCRIPTION	RESULT	POSSIBLE CAUSE	POSSIBLE
Air/Up Occlusion Check for air/occl. Press NO to mute	Alarm sounds. Infusion stops. LED blinks red.	Air in administration set. The set is occluded between the infusion bag and pump (Upstream Occlusion).	If air is visibly present disconnect set from patient and prime air. If no air is present check for upstream occlusion (for kinked or trapped set).
Down Occlusion Check Set/Access Press NO to mute	Alarm sounds. Infusion stops. LED blinks red.	Administration set is kinked or clamp is closed downstream of the pump. Patient access device is locked. Administration set is loaded incorrectly.	Straighten the set and/or remove or open any clamp or clip. Change/flush the access device. Reload the set correctly.
Missing Key	Alarm sounds. Infusion stops. LED blinks red. Pump will not start.	Administration set loaded incorrectly or user trying to load anon-proprietary set.	Load administration set with key in keyway. Check set is the correct dedicated BodyGuard set.
STOPPED Press OK to Re-start	Alarm sounds. infusion stops. LED blinks red.	2 minutes have elapsed without a key press. Pump left in the STOP state for more than 2 minutes.	Press START/OK to resume the infusion. Press STOP/NO to continue pause.
Near End	Alert sounds. 3 beeps are heard. Infusion continues.	Approximately 5ml VTBI.	Prepare new bag, if applicable.
End of Infusion Press OK	Alarm sounds. Infusion stops. LED blinks red.	Current infusion programme has completed.	Either turn off the pump, enter a new programme or start a new bag.
Low Battery	Alert sounds. 3 beeps are heard. Infusion continues.	30 minutes of battery life remaining.	Place the pump in the charger or use the connection lead to connect it to the charger.
End Battery Press STOP	Alarm sounds. Infusion stops. LED blinks red.	Battery is depleted.	Immediately place the pump in the charger or use the connection lead to connect it to the charger.
Door Open Close Door	Alarm sounds. Infusion stops. LED blinks red.	The pump door has opened during infusion.	Close door, re-start infusion.
LOCK MODE	Settings cannot be changed, keys do not function.	Keypad lock is turned on.	Press and hold the INFO key until the lock is off.
System Malfunction			
System Error Press INFO	Alarm sounds. Infusion stops. LED blinks red.	Internal malfunction has occurred.	When INFO pressed, will advise to power off & restart which may rectify the error. If error recurs:
Error (Number) Send for Service			Take pump out of use. Press INFO to obtain error message. Record error code & summary of fault & return pump to Service Centre.

7.14 REVIEW SET UP

You can view any of the default parameters from the main menu:

1. When the main menu is accessible, scroll to “Review Set-up” press 

2. Scroll to a parameter you wish to view and press 


NOTE: In this mode you can only view the parameters but cannot change any of values.


NOTE: Review screen is displayed showing infusion parameters for the protocol you selected. ALWAYS check the review screen carefully to ensure the parameters match the prescription. If MediGuard is enabled the programme limit will show the max rate allowed for the weight of the current patient.


7.15 CHANGE SET UP

For users to configure the variable default settings they must use the Level three Access Code. To change default settings follow these steps:

1. From the main menu select ‘Change Set Up’ and press 


2. Enter the level 3 access code & press 

3. Scroll through the parameters to the one you wish to change, press 

- If it is a numeric value simply key in the new value and press 

- If it is an optional value, scroll through the options and to confirm your choice, press 

4. Once the user has changed or confirmed a parameter the pump returns to the main menu ‘Exit’ option.

5. Press  to exit or scroll down to view/change another parameter repeating from step 3 above.

NOTE: Not all the default parameters can be configured by the user. *Refer to Appendices for Default parameters.*

7.15 KEEP VEIN OPEN MODE (KVO)

A Keep Vein Open (KVO) mode can be configured to run at the end of a protocol if desired. The KVO rate can be set from 0.1 to 5 ml/hr. If the programmed infusion rate is lower than the KVO rate, the KVO will run at the programmed infusion rate. To use the automatic KVO at the end of a protocol, make sure that the fluid bag contains overfill beyond the volume to be infused.

7.17 MAINTENANCE & SERVICE

CLEANING

Before connecting the pump to a new patient, and periodically during use, clean the unit using a lint-free cloth lightly dampened with warm water and a mild detergent or disinfectant.

WARNING: Always turn the pump off, and remove the battery before cleaning. Allow drying time before replacing battery and turning the pump on again.

WARNING: Ensure all equipment is disconnected from mains power supply before cleaning.

WARNING: Do not clean the pump or charger with chemical such as Xylene, Acetone or similar solvents. These chemicals could cause damage to plastic components & paint.

WARNING: Do not soak or immerse any part of the pump or charger in water or any cleaning solution.

STORAGE

If the pump is to be stored for an extended period it should be clean and the battery charged. Remove the battery from the pump and store in a clean, dry atmosphere at room temperature. Ensure that the battery is fully charged once every three months.

WARRANTY

Refer to the warranty certificate packaged with your pump.

SERVICING

CME recommends that the BodyGuard pump should be calibrated once a year by a CME Service representative or by your local engineers if they have been trained and certified to carry out this work by CME personnel.

For service on your BodyGuard pump, to order service parts or for Technician/technical enquiries contact the service facility at sales@cme-infusion.com or phone Head Office on +800-323-57-500

WARNING: Any adjustments, maintenance, or repair of the uncovered pump may impair the operation of the *BodyGuard* Infusion System and/or the accuracy of the infusion. Any adjustments, maintenance, or repair of the uncovered pump or charger should be performed by authorized skilled technicians. Any adjustments, maintenance, or repair of the uncovered pump or charger while connected to the power should be avoided.

8.0 APPENDICES

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A. CME CONTACT DETAILS

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Lichtenstein, Germany

WEBSITE: www.cme-infusion.com

SERVICE DEPARMENT EMAIL: sales@cme-infusion.com

PHONE +800-323-57-500

B. PUMP SPECIFICATIONS

545 BodyGuard Ambulatory Infusion Pump	
Pumping Mechanism	Piston Pump
Flow Rate:	0.0 to 30.0 ml/h in 0.1ml increments
Priming Rate	Range 300-425 ml/h (default 400ml/h)
Total Infused Volume	0.1 to 1,000 ml
Accuracy	± 5 %.
KVO rate	0 to 5 ml/h
Air Sensor	Ultrasonic, adjustable air bubble size
Maximum Pressure	21 psi adjustable (High = 21psi, Normal = 14psi, Low = 7psi)
Power Supply	110-240 VAC, 50/60 Hz. 0.3A max.
Battery	Rechargeable Li-Polymer 7.2V, 1800mAh
Battery operation	20 hours @ 125ml/h (Rechargeable)
Battery Charging	Automatic when clicked into the Charger connected to an AC power source. 6 hours needed to charge a fully depleted battery.
Alarms	When a problem is detected, the BodyGuard displays the following alarms: Air in line Down Occlusion Pump Unattended End Program Low Battery End Battery Door Open Error (followed by error code, see table p36) Lock Mode Missing Key
BodyGuard Dimensions	112mm x 89mm x 32mm. (L x W x H)
Classification	Type CF Equipment (degree of protection against electrical shock)
Housing	ABS (fire retardant)
Weight:	280 grams without battery 390 grams with battery
Electrical Safety	Complies with IEC 60601-1 (Medical Electrical Equipment Safety), IEC601-2-24 (Infusion pumps and controllers), IEC 601-1-4 (Programmable Electrical Medical System)
Standards	Manufactured in accordance to ISO 9001:2000 & ISO 13485:2003. CE marked in accordance with the Medical Devices Directive 93/42/EEC.
EMC	The BodyGuard infusion system is designed to be in compliance with EN60601 -1 (safety) and IEC 601-1-2 (EMC)
Environmental Specifications	Non Operating Conditions (Transportation and Storage): Temperature: - 25°C to 50°C (-13°F to +122°F) Humidity: 5% to 100% R.H., non-condensing Air Pressure: 48kPa to 110kPa Operating Conditions The system may not meet all performance specifications if operated outside of the following conditions: Temperature: +18°C to +45°C (+59°F to +113°F) Humidity: 20% to 90% R.H. at +40°C, non- condensing Air Pressure 70kPa to 110kPa
Administration set	Dedicated administration set with anti-siphon valve and key

C. LIMITED WARRANTY

The *BodyGuard* Infusion Pump has been carefully manufactured from the highest quality components.

Caesarea Medical Electronics Ltd. (CME) guarantees the pump against defects in material and workmanship for twelve (12) months from date of purchase by the original purchaser.

CME's obligation, or that of its designated representative under this Limited Warranty, shall be limited, at CME's option, or that of its designated representative, to repairing or replacing pumps, which upon examination, are found to be defective in material or workmanship. The repair or replacement of any product under this Limited Warranty shall not extend the above-mentioned Warranty period.

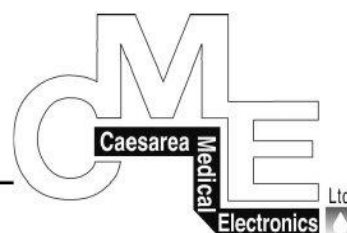
All repairs under this Limited Warranty should be undertaken only by qualified, trained service personnel. In the event that a pump is found to be defective during the warranty period, the purchaser shall notify CME or its designated representative within thirty (30) days after such defect is discovered.

The defective pump should be sent immediately to CME or its designated representative for inspection, repair or replacement. Shipping costs are the purchaser's responsibility. *Material returned to CME or its designated representative should be properly packaged using CME shipping cartons and inserts. Inadequate packaging may result in severe pump damage.*

This Limited Warranty shall not apply to defects or damage caused, wholly or in part, by negligence, spilt fluids, dropping of the pump, misuse, abuse, improper installation or alteration by anyone other than qualified, trained personnel; or to damage resulting from inadequate packaging in shipping the pump to CME or its designated representative.

If, after inspection, CME or its designated representative is unable to identify a problem, CME or its designated representative reserves the right to invoice purchaser for such inspection.

This Limited Warranty is the sole and entire warranty pertaining to CME's products and is in lieu of and excludes all other warranties of any nature whatsoever, whether stated, or implied or arising by operation of law, trade, usage or course of dealing, including but not limited to, warranties of merchantability and warranties of fitness for a particular purpose. Purchaser expressly agrees that the remedies granted to it under this limited warranty are purchaser's sole and exclusive remedies with respect to any claim of purchaser arising under this Limited Warranty.



Manufacturer:

European address:

Caesarea Medical Electronics GMmbH.

International Toll Free: +800-323-575-00

Staufenburgstr. 23 Lichtenstein

P.O.B. 1248 Lichtenstein 72805 Germany

www.cme-infusion.com

D. BODYGUARD DEFAULT SETTINGS

The pump comes programmed with a number of default parameters that can be viewed using 'Review Set Up' from the main menu and changed using the designated Access Code in 'Change Set Up' mode or via the Technician Menu.

NOTE: * Denotes that the parameter can be reviewed via the "Review Set Up" menu.

** Denotes that the parameter is changed via the Technician Menu.

NOTE: For safety reasons default access code are not contained within this manual. Refer to senior clinical or lead service personnel for relevant codes.

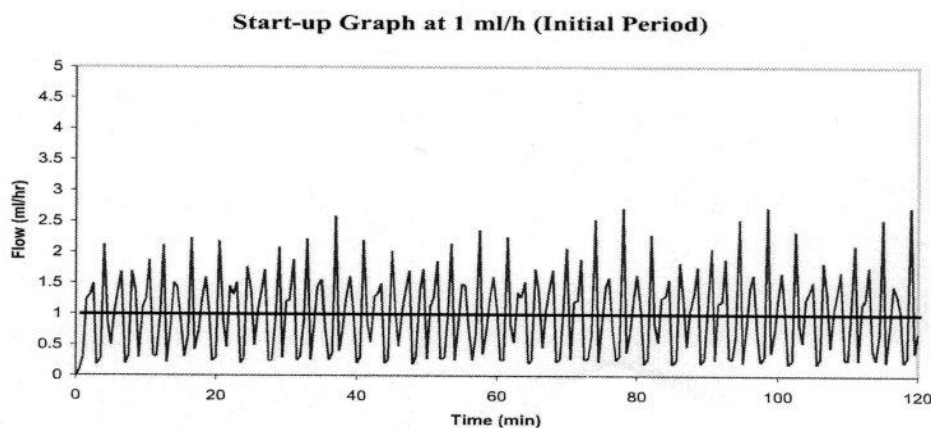
PARAMETER	PURPOSE	DEFAULT	RANGE
Keystroke Volume*	Changes keystroke volume	3	0 - 7
Alarm Sound Volume	Changes alarm volume	7	2 - 7
Occlusion Pressure*	Occlusion Pressure setting	21psi	High: 21psi. Normal: 14 psi. Low: 7psi
Priming Volume*	Pre-set priming volume	5ml	0 – 20ml (Recommend 6 ml)
Priming Rate*	Rate at which priming occurs	400ml/h	300 – 1200ml/h (425ml/h recommended)
Maximum CA Bolus*	Disable or Limit maximum clinician single dose	0ml	0ml (disabled) – 25ml
Bolus Rate*	Pre-set bolus delivery rate	300ml/h	100 – 1000ml/h
Maximum Basal Rate*	Maximum continuous (basal) infusion rate	30ml/h	0.0 – 30ml/h
KVO Rate*	Keep Vein Open rate	0ml	0.0 – 5.0ml/h
Program limits*	Set limits for body weight (ml/kg/h) or for volume or boluses over a range of time periods	OFF OFF 0 HOURS	MediGuard ON/OFF, volume/boluses & 0, 1, 4 or 24 hour periods
Minimum Lock-out*	Minimum time to set	15 mins	1 – 240 min
Air-in-line limit*	Sets volume of single air bubble needed to trigger air-in-line alert	0.5ml	0.0 – 1.0ml (if set to zero ((disabled)) alarms at 3ml to prevent upstream occlusion)
LED Indicator*	Switches the indicator On/Off	ON	ON/OFF
Bolus titration*	Allows titration of bolus dose volume	OFF	ON/OFF (If ON, max volume 20mls)
Backlight Duration	Length of time for screen backlight illumination following key press	20 seconds	1 - 255 seconds
Info Duration	Length of time for the Info screen to be displayed	8 seconds	1 - 255 seconds
Set time & date*	Set current time/date		dd/mm/yy 00/00/00
**Access Codes	Changing code numbers & level	See NOTE above	
**Auto bolus	Delivers fixed bolus (time/volume)	Off	
Battery level*	Current battery charge		Empty >> Full
Serial number*	Unique Pump serial no.		Fixed data
Production date*	Date of manufacture		Fixed data
Operating hours*	Hours since last service		Fixed data
Software version*	Pump software version		Fixed data
Volume Calibration*	Calibration value		Fixed data
Pressure Delta*	Calibration value		Fixed data
Pressure CAP*	Calibration value		Fixed data

E. PUMP ACCURACY & TRUMPET CURVES

START UP CURVES

The following graphs and curves were derived from testing described in IEC60601-2-24. Testing was performed under normal conditions at room temperature (72 °F). Any deviations from normal conditions and room temperature may cause changes in the accuracy of the pump.

Start-up curves represent continuous flow versus operating time for two hours from the start of the infusion. They exhibit the delay in onset of delivery due to mechanical compliance and provide a visual representation of uniformity. Trumpet curves are derived from the second hour of this data. Test performed according to IEC 60601-2-24 standard.



TRUMPET & FLOW RATE

With the BodyGuard Ambulatory Infusion Pump, as with all infusion systems, the action of the pumping mechanism and variations cause short-term fluctuations in rate accuracy.

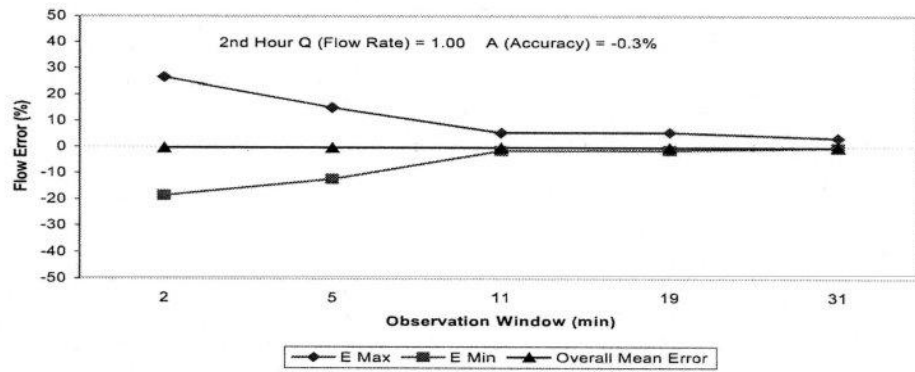
The following curves show typical performance of the system in two ways:

- The accuracy of fluid delivery over various time periods is measured (trumpet curves).
- The delay in onset of fluid flow when infusion commences (start up curves).

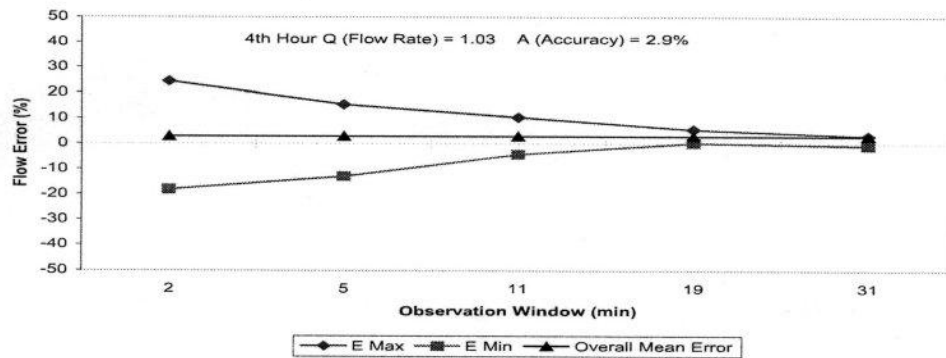
Trumpet curves are named for their characteristic shape. They display discrete data averaged over particular time periods or "observation windows", not continuous data versus operating time. Over long observation windows, short-term fluctuation has little effect on accuracy as represented by the flat part of the curve. As the observation window is reduced, short-term fluctuations have greater effects as represented by the "mouth" of the trumpet.

Knowledge of system accuracy over various observation windows may be of interest when certain drugs are being administered. Short-term fluctuations in rate accuracy may have clinical impact depending on the shelf-life of the drug being infused and the degree of inter-vascular integration, the clinical effect cannot be determined from the trumpet curves alone.

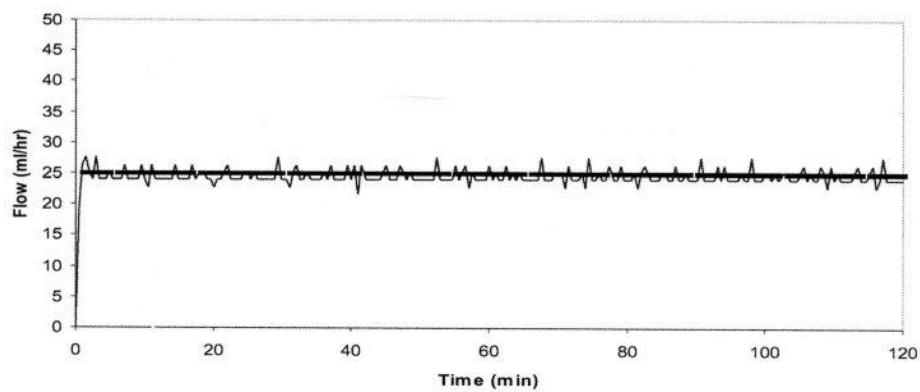
Trumpet Graph at 1 ml/h (2nd hour of delivery)



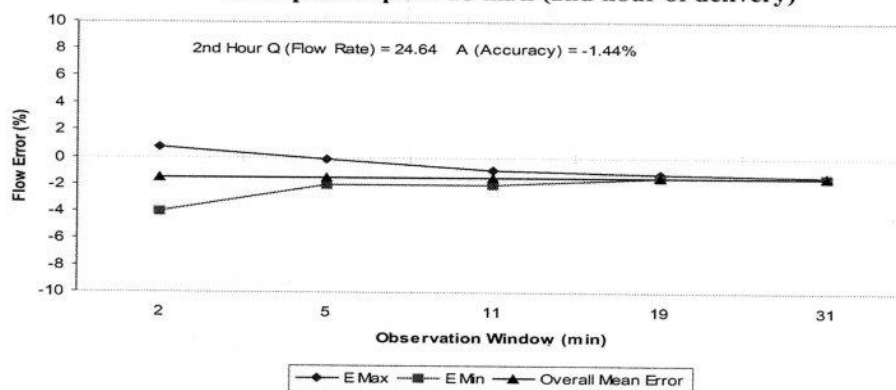
Trumpet Graph at 1 ml/h (4th hour of delivery)



Start-up Graph at 25 ml/h (Initial Period)



Trumpet Graph at 25 ml/h (2nd hour of delivery)



F. MEDIGUARD SET-UP

The MediGuard feature is used to control a protocol where the main feature in the calculations is based on the patient weight, it is mainly used in the field of paediatric medicine.

It is enabled or disabled in the Program Limits selection within Change Set Up. The patient's weight is entered in kilograms and the drug concentration can be set in mls, mgs or mcgs. Thus a toxicity ceiling in ml, mg or mcg (depending on pump configuration) per kilogram bodyweight per hour is created. If users try to set a protocol where the component elements (basal rate and boluses) exceeds the MediGuard limit. The pump will alert the user to this and request they re-confirm their intentions, amend or revise the toxicity ceiling. Level One users will not be able to change the protocol or ceiling under Select Protocol and will have to select an alternative appropriate protocol or consult senior clinical staff with Level Three authority.

RUNNING A MEDIGUARD PROTOCOL:

1. Turn the pump on and PRIME the dedicated epidural set

2. Go to main menu

3. Scroll down to "Select Protocol"

4. Confirm for New Patient

6. Scroll to select the appropriate protocol

7. Enter Patient Weight

You will now see a summary of the VTBI, followed by a summary of the Rate, Max. Rate, PCEA and Drug Limit as calculated by the pump based on the bodyweight of the patient.

8. Follow screen prompts, the pump will then prompt Start Infusion?

9. Press  when ready to do so

SETTING UP A MEDIGUARD PROTOCOL:

To enable this option, enter "Change Set Up" option and scroll to Program Limits. Press start/ok to access and set MediGuard on. Press the OK key to approve.

When MediGuard option is on, the user will be required to set the maximal approved MediGuard rate. Maximal MediGuard rate will be defined as ml (mg, microgram)/hour per 1 kg. of patient weight

When selecting a protocol, either by Select Protocol or by Modify Protocol, the user will be required to set the patient weight in kg. The software will calculate the maximal rate allowed for the specific patient based on his weight (multiplied by the maximal MediGuard rate). The calculated values will be displayed as "drug limit" in programmed accumulation screen and during programme operation.

G. SETTING A PROTOCOL BASED ON RATE WHEN THE BOLUS IS SET TO ZERO

The pump will enable programmed operation only if the basal rate set is equal or less than maximal MediGuard rate (If rate is out of limits, pressing start/ok from accumulation screen will display “drug limit overflow” message). In case the programmed basal rate is less than MediGuard maximal allowed rate, the pump will count the difference between the two different rates. The difference between the actual rate and the maximal MediGuard rate will be stored in a buffer called “credit buffer “. Maximum volume saved in the credit buffer is volume of 10 minutes delivery of the MediGuard maximal rate. The credit is used to enable delivering of clinician bolus. If Clinician bolus volume is less than the volume in the buffer, the bolus will be delivered at maximal bolus rate. If Clinician bolus volume is higher than the volume in the buffer, the volume in the buffer will be delivered at maximal bolus rate and the remaining bolus volume will be delivered at MediGuard maximal rate (if there is no volume in the credit buffer all bolus will be delivered at MediGuard maximal rate).

H. SETTING A PROTOCOL BASED ON A COMBINATION OF BOLUSES AND BASAL RATE (OR BOLUS ONLY)

Pump will enable programmed operation only if the basal rate set is equal or less than maximal MediGuard rate (If rate is out of limits, pressing start/ok from accumulation screen will display “drug limit overflow” message). In case the programmed basal rate is less than MediGuard maximal allowed rate, the pump will count the difference between the two different rates. The difference between the actual rate and the maximal MediGuard rate will be stored in the credit buffer. As programme begins, the credit buffer will automatically include volume for one bolus. Maximum volume saved in the credit buffer is bolus volume. The credit is used to enable delivering of patient and clinician boluses. Whenever a bolus is required (either by the patient or by the clinician): If the bolus volume is less than the volume in the buffer, the bolus will be delivered at maximal bolus rate; If the bolus volume is higher than the volume in the buffer, the volume in the buffer will be delivered at maximal bolus rate and the remaining bolus volume will be delivered at MediGuard maximal rate.


NOTE:

1. Setting MediGuard option ON shall disable the Clinician bolus option from the menu. Any attempt to give a clinician bolus from the Menu will display the following message:
“MediGuard set ON Clinician boluses can be given from protocol only “
2. The MediGuard option is replacing the 4 hour limit, therefore setting MediGuard ON, the 4 hours limit will be disabled and not shown in the parameters settings.

I. AUTO-BOLUS SET UP

Auto-bolus is the facility to set an automatic (intermittent) bolus, this is an *alternative* to a patient controlled bolus. Auto-bolus is not available on pump default settings, it can only be activated via the technician menu.

Once activated in the Technician’s area, it allows the operator to set an automatic (intermittent) bolus during the Modify Protocol process. It is set by means of bolus volume and interval time. (Prompts will appear to enter the relevant data).

- When a protocol is selected with the auto-bolus feature activated the pump will deliver the predetermined dose at a pre-determined time without the need for a remote bolus request from the patient.
- The bolus delivery can be stopped at any time by pressing 

J. ACCESSORIES

The most common used accessories are shown below,
For full, up-to-date information of all accessories, codes & pricing, view the website
www.cme-infusion.com.

LOCK BOX



(250ml ambulatory lockbox also available)



PATIENT BOLUS CABLE



EXTERNAL BATTERY CHARGER



The external charger allows charging an additional battery while the main battery is used for operating the pump. The battery can either be clicked into the charger or connected through a DC cable. The external batteries charger can be connected to the mains to charge the battery.

BODYGUARD COMMUNICATIONS SOFTWARE



All BodyGuard infusion pumps are capable of communication with a PC. Easy download of patient history, protocols and settings is achieved with one click connecting the pump into the communication charger. All is needed is a communication charger and the BodyComm software (supplied with the communication charger).

WARNING: Unsafe operation may result from using improper accessories. Use only accessories provided by CME and designed for use with the BodyGuard Ambulatory Infusion Pump.

CME BodyGuard 545 Ambulatory Syringe Pump Operations Manual
CME BG545-1.1 (28F/Dec 09)

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