B | BRAUN
SHARING EXPERTISE

Space^plus Perfusor® Syringe Pump and Infusomat® Space^plus Volumetric Pump

SUPER USER TRAINING RECORD

HOSPITAL: ....

WARD: ....

ROLE: ....

NAME: ....

We
PROTECT
and
IMPROVE
the
HEALTH
of people

around the world.

CONTENT

SUPER USER TRAINING GUIDE

INTENDED USE

Adults, children and neonatal for the intermittent or continuous administration of parenteral and enteral solutions through standard medical access routes.
The pump is to be used to deliver drugs, fluids, blood and blood components that are infused via intravenous, intra-arterial, subcutaneous, epidural, or enteral access routes.
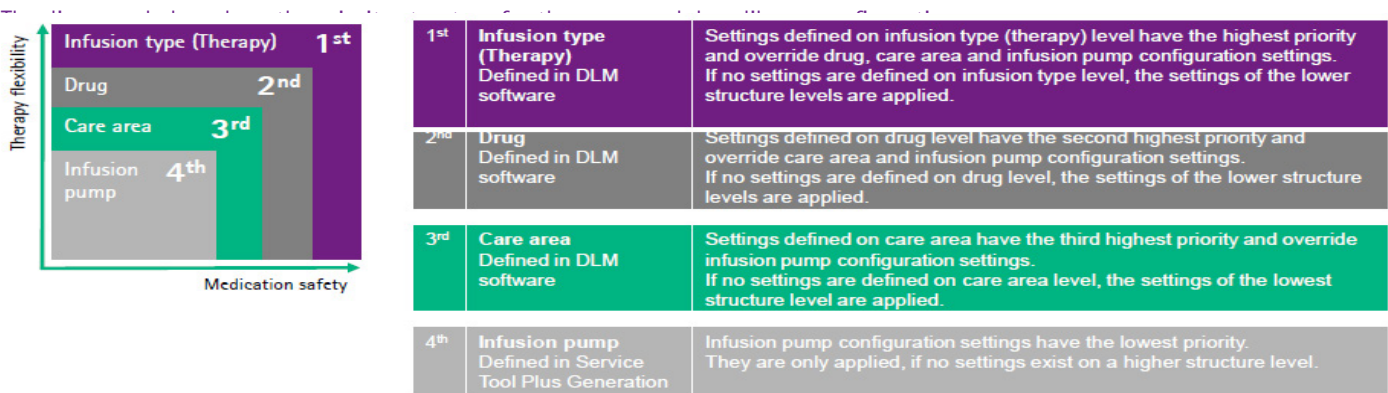
SETTING UP AND MAINTAINING AN INFUSION

Self-Test

When the pump is switched on it will automatically conduct a self-test. If this self-test is unsuccessful the pump will need to be returned for servicing.

Inserting Disposable

- If further instruction is needed, press the home button and select help.
- Automatic priming via pump can be enabled via service tool.

Drug Library

- The pump can be configured to mandate the use of a drug library.
- Drug Library delivers pre-defined drugs with concentrations, colour labels, limits, loading dose, bolus, pressure settings, etc.
- Drugs can be grouped into categories.
- There are two ways to select a drug from the library:
  - either via keypad
  - or in the footer all drugs

The Drug Library Is Constructed Using The Following Data:

- care area
- drug name
- patient profile
- concentration
- patient data
- infusion parameter

It is possible to activate a drug library review screen in order to view all programmed data before starting an infusion.

Changing Parameters While An Infusion Is Running

Select the infusion parameter on the right of the run screen to edit or select home - change parameter button.

Selecting A Different Variable Run Screen Parameter

In order to see more or different parameters of the running infusion (e.g. downstream pressure, infused volume, remaining time/syringe time/volume, care area etc.), a selection of those are provided by clicking on the parameter that you wish to alter, underneath the drug name on one of the smaller parameters.

Syringe View

In order to see the status of the syringe on the run screen select - change view. A visual of the live syringe will be displayed, showing fill status, brand and size of syringe.

Entering Values

- If soft limits are defined in the drug library they are displayed at the top of the screen when entering infusion parameters.
- If It is not possible to enter values outside the defined ranges, you cannot confirm the value (the confirm button is greyed out).
- Values within editor should be entered from left to right in order to have no value limitations within the keyboard.

The keyboard automatically greys out values which are outside the defined ranges, either per drug library or via mechanical limitations.

Delivering A Bolus

There are three options for administering a bolus:

- Programming a bolus
- Reusing a programmed bolus
- Manually administering a bolus

Whether all three options are available to you or not depends on the configuration of your pump and the situation.

- Programming a bolus: In the bolus menu, press the 'programme bolus' button. Enter the bolus amount followed by the bolus duration. Start the programmed bolus from the overview menu.
- Reusing a programmed bolus: In the bolus menu, press the 'last bolus' button. The pump displays an overview menu that allows you to view and change the values of the last programmed bolus. Start the programmed bolus from the overview menu.
- Press and hold the 'Manual bolus' button in the bolus menu. The pump infuses the bolus for as long as the button is pressed. The manual bolus is interrupted after 10 seconds and an audible signal sounds.

After delivery of programmed bolus: pump displays hint which summarises given bolus vs programmed bolus.

Totals And Info

- Infused volumes and infusion status available
- Infused volumes and the infusion status is available via the home menu and selecting totals and info.
  - infused volumes are configurable within the service tool. (intermittent volume can be deactivated).
  - total volume counts all infused volume administered to the patient (if you clear total volume, also the intermittent volume is cleared)

All volumes (intermittent and total) are cleared as soon a new patient is selected.

- Infusion Status: Sums up all data about the running infusion: infusion parameter, patient data, selected drug data incl. clinical advisory, syringe data, remaining battery capacity, KVO settings.

SUPER USER TRAINING GUIDE

SETTING UP AND MAINTAINING AN INFUSION

Battery

- The battery symbol is shown in the left part of the display on the run screen or on the headline of the display in the programming screens.
- The battery charges as soon as a pump is inserted into the Station or when it is connected to the mains.
- Pre-alarm occurs when nearly empty.
- Operating alarm occurs 3 minutes before battery has completely depleted.

Pressure Settings

- To change the pressure settings access the home button and select pressure settings or device settings.
- Pressure settings can be pre-defined per drug within the drug library settings.
- While selecting a pressure level the respective mm Hg is shown.
- On the run screen, the manometer pointer shows the current pressure in the infusion system. The lower the selected pressure level, the bigger the grey area on the manometer. As soon as the pointer enters this grey area, a pressure alarm is triggered.

It may be necessary to change the pressure level due to various influencing factors, e.g. fluctuations in syringe friction, line length and inner diameter, fluid viscosity, and the filter used in the system.
As a general rule, the pressure level should always be set higher than the pressure in the infusion system. Start with a low pressure level and adjust it if necessary to ensure short alarm times.

Standby

Only possible when disposable is inserted

- To activate standby hold on/off button for 1.5 seconds.
- Standby time can be changed once standby is activated.
- If standby has elapsed, pump gives notification.

If an infusion has been programmed and the pump is in standby, the programmed infusion will be shown in the headline of the display

Display Lock

- Display locks automatically activates following a pre determined time frame. This is to ensure no accidental presses can occur.
- In order to change a parameter on the run screen, deactivate the display lock by pressing unlock. No code is required.
- By pressing the home button, the display lock is automatically disabled.

Data Lock

- Available via home – device settings.
- The pump can be protected against unauthorised use using the code lock.
- Various codes can be stored in the pump.

Alarms and Troubleshooting

Information to user via notification and reminder

- Pre-alarm (yellow alarm): infusion still runs.
- Operating alarm (red alarm): infusion stops.
- Device alarm: disconnect the pump from the patient, remove the disposable syringe and switch the device off and on again. If the alarm persists contact the service department.

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Barcode

Shows data matrix with article code and serial number (e.g. for inventory reasons).

Help Menu

- Available in the home menu.
- The help menu displays disposable change, to access this function select the home button and help.

TRANSPORT / ATTACHMENT OF SPACE^PLUS PUMPS

Only carry via integrated handle, with a maximum of 3 pumps to be carried via handle. The pump clamp can be positioned vertical or horizontal.

Handling Together With Space^plus Station

- A maximum of 24 pumps can be stacked in one system using six stations.
- Close pump handle before inserting pump into the Station.
- When inserting device into the station ensure the 'click' occurs to ensure devices are securely placed.
- If the pump is correctly locked in, the release button on the left side of the pump is flush with the pump housing.
- Use tube guides (left side on the Station) in order to organise lines.
- The Station only provides power when pump is properly inserted.
- Cover shows pump status (running and alarming).

Cover Can Run On Battery During Transport

- Alarm volume can be changed on the Cover.
- Brightness sensor adapts to environment.

DISINFECTION AND CLEANING

Do not spray disinfectant directly onto the mains power connections, interfaces or pump openings. This can lead to short circuits, corrosion or malfunction of sensitive electronic components and/or to electric shocks.

- Do not immerse the pump in liquid.
- Observe the exposure times required according to the manufacturer's instructions before usage. The pump must be completely dry before use.
- Do not use sharp objects for cleaning.
- Disinfect the pump/accessories with damp cloths from all angles.

COMPETENCY ASSESSMENT OF THE SUPER USER

DURING THE DEMONSTRATION SESSION PROVIDED BY A B. BRAUN SPECIALIST, THE SUPER USER:	YES	NO
1. Stated the clinical application of the Pump		
2. Explained the safety checks and precautions to be taken prior to use		

3. Securely fastened the pump by
   a. mounting in the Station, or
   b. using the pump clamp and attaching to an IV pole		

4. Stated the functions of the keys and indicators on the front panel		
5. Demonstrated the correct insertion of the disposable		

6. Initiated and started a prescribed infusion
   a. mL/h
   b. drug per drug library with patient data		

7. Explained the information displayed on the screen whilst the pump is running		
8. Demonstrated the ability to change the rate once the infusion has started		

9. Demonstrated the correct administration of a prescribed bolus (if applicable) by
   a. delivering a manual bolus
   b. delivering a programmed bolus		

10. Demonstrated how to check the pumps battery status		
11. Explained why the pressure indicator is important and demonstrated how to check and adjust the pressure level		
12. Demonstrated how to activate standby mode		
13. Demonstrated the ability to activate and de-activate data lock (if applicable)		
14. Demonstrated the correct way to remove the disposable from the pump		
15. Turned the pump off and discussed the correct cleaning and storage procedures		

WRITTEN ASSESSMENT

1. How many pumps can be attached to one pump clamp?

2. What do you do if the pump has a Device Alarm?

3. Can you deliver a bolus whilst the infusion is stopped?

4. Write down the steps involved in giving a bolus, using one of the three possible methods.

WRITTEN ASSESSMENT

5. Where do you locate the pumps' battery capacity?

6. Where would you go if you needed to change the pumps' Occlusion Pressure Alarm Limits?

7. a) Explain the difference between a Yellow 'pre-' and Red 'operational' alarm.

   b) Give an example of each.

8. What is the intended use of the Space^{plus} pumps?

9. How to clean the devices?

CERTIFICATION

This is to certify that:

Trainees Name: .... Date: ....

Signed: ....

has successfully completed the super user training session, and has been assessed by:

Assessors Name: .... Date: ....

Signed: ....

of B. Braun Medical to be competent on using the Space^{plus} Perfusor® and/or Space^{plus} Infusomat®, with the software version:

.... in delivering cascade training sessions and assessing user competence.

This space is designed for your Trainer to note any action points, (if required) for further practice following your assessment. Your Trainer may also set a date that you may be required to attend an annual update or complete further training.

Review Date	Notes/Training Update Required