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This Supplemental Directions for Use contains supporting information for use of the Delay Options and Multidose Mode features in the MEDLEY™ Pump Module. This Supplemental Directions for Use is intended to be used in conjunction with the Pump Module and Programming Module Directions for Use. Please read and understand all instructions prior to using the MEDLEY™ System.

About This Directions for Use

For a complete listing of Warnings and Cautions for the MEDLEY™ Medication Safety System, refer to the Pump Module and Programming Module Directions for Use.

Feature Descriptions

Delay Options  When enabled, Delay Options permits a clinician to program the delay of an infusion for up to 120 minutes, or for a specific start time up to 23 hours 59 minutes into the future. A Callback for a programmed delay can be scheduled to give an alert Before an infusion is to be initiated, After an infusion is completed, Before and After an infusion, or no (None) alert.

Multidose Mode  When enabled, the Multidose Mode allows 2 - 24 doses to be programmed at equally spaced intervals on the same Pump Module over a 24 hour period. The Multidose Mode is designed to allow delivery of multiple, equal doses from the same IV container at regularly scheduled intervals.
Setting Delay Options

Delay Options can be enabled at the time the MEDLEY™ System is configured for use. If Delay Options is not enabled, the PAUSE function (described in “Pausing an Infusion” in the Pump Module Directions for Use) will still be available. If Delay Options is enabled, the following options are available.

**NOTE:** Since by definition, an infusion with Delay Options will not be infusing for a programmed period of time, it is assumed that another infusing IV line will keep the vein open until the delayed infusion begins.

Pausing an Infusion

1. Press **DELAY OPTIONS** soft key.

2. Press **Pause** soft key.

   **NOTES:**
   - *Using the Pause function in the Delay Options screen is the same as pressing the PAUSE key on the Pump Module.*
   - *The time displayed in the upper right corner of the screen is the time of day in a 24-hour clock format (military time).*

3. Press **CONFIRM** soft key.
   - PAUSE scrolls in Channel Message Display.
   - PAUSED appears next to appropriate channel in Main Display.
   - Yellow Standby Status Indicator illuminates.
   - After two minutes, PAUSE - RESTART CHANNEL visual and audio prompts begin. Yellow Standby Status Indicator flashes.
Setting Delay Options (Continued)

Pausing an Infusion (Continued)

4. To reinitiate infusion:
   • Press **RESTART** key on Pump Module.
   OR
   • Press **CHANNEL SELECT** key on Pump Module and **START** soft key.

Delaying an Infusion (Specified by Minutes)

The **Delay For** option is used to program an infusion delay for a minimum of one minute and up to 120 minutes. An infusion delay can be programmed prior to or after an infusion is initiated.

1. Press **DELAY OPTIONS** soft key.

2. Press **Delay For** soft key.
3. Use numeric keypad entry keys to enter number of minutes (up to 120) infusion is to be delayed for.

4. Press CONFIRM soft key. Delay period counts down on Main Display.

5. If a Callback has not been scheduled, infusion automatically initiates at end of delay period.

6. At completion of infusion, INFUSION COMPLETE scrolls in Channel Message display.

**Delaying an Infusion (Specified by Time of Day)**

The Delay Until option is used to program an infusion delay for a minimum of one minute and up to 23 hours 59 minutes. An infusion delay can be programmed prior to or after an infusion is initiated.

1. Press DELAY OPTIONS soft key.
Setting Delay Options (Continued)

Delaying an Infusion (Specified by Time of Day) (Continued)

2. Press **Delay Until** soft key.

3. If **Current time** displayed is correct, press **CONFIRM** soft key; otherwise, press **Change Time** and enter correct time. (Reference “Setting Up Time of Day” procedure in MEDLEY™ Programming Module Directions for Use.)

4. Use numeric keypad entry keys to enter time of day infusion is to be initiated (up to 23 hours 59 minutes).

5. Press **CONFIRM** soft key.

6. Time that infusion initiates appears next to appropriate channel in Main Display. If a Callback has not been scheduled, infusion automatically initiates at end of delay period.
Setting Delay Options  (Continued)

Scheduling a Callback

When programming a Delay For or Delay Until infusion, a Callback can be scheduled for that infusion. There are three types of Callback:

- **Before** - gives an alert when delay is completed and infusion needs to be initiated.
- **After** - gives an alert when delayed infusion has completed.
- **Before and After** - gives an alert when delay is completed and infusion needs to be initiated and when delayed infusion has completed.

The default Callback (None) will appear on the Main Display. To schedule a different Callback:

1. During the Delay For or Delay Until programming process, press **CALL BACK** soft key prior to pressing **CONFIRM** soft key and initiating delay.

2. Press soft key corresponding to desired Callback option.

3. Press **CONFIRM** soft key to initiate delay. Scheduled Callback appears on Main Display.
NOTES:

- Since, by definition, a multidose infusion will not be infusing for a programmed period of time, it is assumed that another infusing IV line will keep the vein open until the beginning of the first dose and between subsequent doses. There is no keep vein open (KVO) infusion at the completion of a programmed Delay Until infusion.
- The Delay Options function for multidose infusions is similar to Delay Options for continuous drug infusions, with the following differences:
  - Delay For option is not available in Multidose Mode.
  - Maximum allowable delay on a multidose infusion is 8 hours.

WARNING

The Multidose feature is to be used only by personnel properly trained in using multidose infusions.

- Caution labels, which clearly differentiate single dose and multidose containers, must be utilized.
- Single dose piggybacking systems employing check valve sets are not designed for use with multidose containers.

Multidose Infusion with Volume/Time Enabled

If Volume/Time was enabled at the time the MEDLEY™ System was configured for use, use the following procedure to program a multidose infusion.

1. Prime and load primary administration set (refer to “Loading Primary Administration Set”).
2. Press CHANNEL SELECT key on Pump Module.
4. Press Multidose soft key.
5. If Current time displayed is correct, press CONFIRM soft key; otherwise, press Change Time and enter correct time.
   (Reference “Setting Up Time of Day” procedure in MEDLEY™ Programming Module Directions for Use.)

   NOTE: If the current time has been previously confirmed, this screen will not be displayed.
### Multidose Mode (Continued)

#### Multidose Infusion with Volume/Time Enabled (Continued)

6. Press **VOLUME DURATION** soft key.

7. Use numeric data entry keys to enter volume to be infused for each dose.

8. Press **DURATION** soft key and use numeric data entry keys to enter desired duration for each dose.

   **NOTE:** *RATE* is recalculated with **DURATION** input.

9. Press **DOSE INTERVAL** soft key and use numeric data entry keys to enter desired time interval (1 to 24 hours) between doses.
10. Press #OF DOSES soft key and use numeric data entry keys to enter desired number of doses.

**NOTE:** The DELAY OPTIONS soft key will appear in this screen if that option has been enabled. Refer to “Setting Delay Options” to program an infusion delay.

11. Press START to begin multidose infusion. Main Display shows remaining VTBI for that dose.

12. During infusion, press CHANNEL SELECT key on Pump Module to see detail screen.

13. When infusion is complete, display indicates number of doses completed and when next dose starts.
If Volume/Time was not enabled at the time the MEDLEY™ System was configured for use, use the following procedure to program a multidose infusion.

1. Prime and load primary administration set (refer to “Loading Primary Administration Set”).
2. Press CHANNEL SELECT key on Pump Module.
4. Press Multidose soft key.
5. Use numeric keypad entry keys to enter desired rate.
6. Press VOLUME/DOSE soft key and use numeric data entry keys to enter volume to be infused for each dose.
7. Press DOSE INTERVAL soft key and use numeric data entry keys to enter desired time interval (1 to 24 hours) between doses.
8. Press #OF DOSES soft key and use numeric data entry keys to enter desired number of doses.

9. Press START to begin multidose infusion. Main Display shows remaining VTBI for that dose.

10. During infusion, press CHANNEL SELECT key on Pump Module to see detail screen.

11. When infusion is complete, display indicates number of doses completed and when next dose starts.
### Advisories

<table>
<thead>
<tr>
<th>Advisory</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay Complete</td>
<td>Delay time has completed.</td>
<td>Press <strong>RESTART</strong> key on Pump Module or press <strong>CHANNEL SELECT</strong> on Pump Module and <strong>START</strong> soft key.</td>
</tr>
<tr>
<td>Infusion Complete</td>
<td>Current infusion has completed.</td>
<td>Press <strong>CONFIRM</strong> soft key.</td>
</tr>
<tr>
<td>Start time for next dose</td>
<td>Start of next dose has passed.</td>
<td>Press <strong>CONFIRM</strong> soft key.</td>
</tr>
<tr>
<td>has passed.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Alarms

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Meaning</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pump Chamber Occluded</td>
<td>Blocked pump chamber has been detected.</td>
<td>Open door and inspect pump chamber. Massage tubing to open blockage, as required. Press <strong>reset</strong> soft key and <strong>RESTART</strong> key on Pump Module to continue infusion.</td>
</tr>
</tbody>
</table>
Specifications

For a complete listing of the specifications for the MEDLEY™ Medication Safety System, refer to the Pump Module and Programming Module Directions for Use.

Configurable Settings

**NOTE:** With the Profiles™ Feature enabled, the settings are configured independently for each Profile. A hospital-defined, best practice Guardrails™ Data–set must be uploaded to enable the Profiles™ Feature.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Default Setting</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delay Options</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Callback Delay Options</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
<tr>
<td>Multidose Mode</td>
<td>Disabled</td>
<td>Enabled - Disabled</td>
</tr>
<tr>
<td>Callback Multidose</td>
<td>None</td>
<td>None, Before, After, Before and After</td>
</tr>
</tbody>
</table>

Specifications

For a complete listing of the specifications for the MEDLEY™ Medication Safety System, refer to the Pump Module and Programming Module Directions for Use.