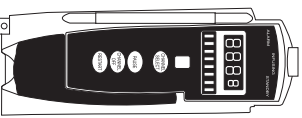


MEDLEY™
MEDICATION SAFETY SYSTEM
INFUSION PUMP MODULE - MODEL 8100
Delay Options and Multidose Mode Features



DIRECTIONS FOR USE

INFUSION PUMP MODULE
MODEL 8100 - SUPPLEMENT

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INTRODUCTION

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About This Directions for Use

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.

Warnings and Cautions

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. |

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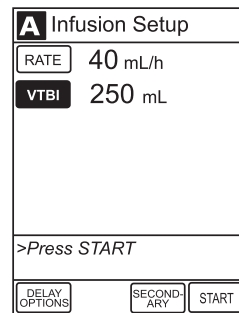
Setting Delay Options

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

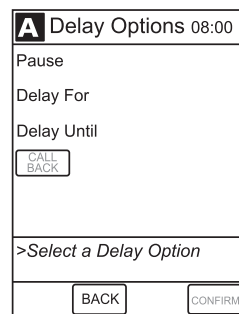
1. Press **DELAY OPTIONS** soft key.



2. Press **Pause** soft key.

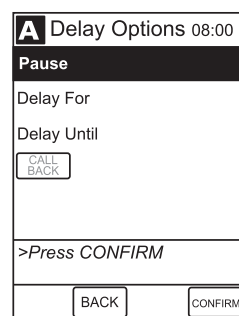
NOTES:

- 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)

- 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.

- Press **DELAY OPTIONS** soft key.

A Infusion Setup

RATE 40 mL/h

VTBI 250 mL

>Press START

DELAY OPTIONS SECONDARY START

- Press **Delay For** soft key.

A Delay Options 08:00

Pause

Delay For

Delay Until

CALL BACK

>Select a Delay Option

BACK CONFIRM

A Delay Options 08:00

Pause

Delay For _ _ _ minutes

Delay Until

CALL BACK

>Enter Delay Time
(1 - 120 min)

BACK CONFIRM

Setting Delay Options (Continued)

Delaying an Infusion (Specified by Minutes) (Continued)

- Use numeric keypad entry keys to enter number of minutes (up to 120) infusion is to be delayed for.

A Delay Options 08:00	
Pause	
Delay For	_20 minutes
Delay Until	
<input type="button" value="CALL BACK"/>	None
>Select Callback or Press CONFIRM	
<input type="button" value="BACK"/>	<input type="button" value="CONFIRM"/>

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

Midtown Hospital Adult ICU	
A	Start in 20 min
B	VTBI = 497.0 mL
C	VTBI = 57.0 mL
D	VTBI = 249.0 mL
<input type="button" value="VOLUME INFUSED"/> <input type="button" value="AUDIO ADJUST"/>	

- If a Callback has not been scheduled, infusion automatically initiates at end of delay period.
- At completion of infusion, **INFUSION COMPLETE** scrolls in Channel Message display.

Midtown Hospital Adult ICU	
A	VTBI = 249.0 mL
B	VTBI = 497.0 mL
C	VTBI = 57.0 mL
D	VTBI = 249.0 mL
<input type="button" value="VOLUME INFUSED"/> <input type="button" value="AUDIO ADJUST"/>	

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.

- Press **DELAY OPTIONS** soft key.

A Infusion Setup	
<input type="button" value="RATE"/>	40 mL/h
<input type="button" value="VTBI"/>	250 mL
>Press START	
<input type="button" value="DELAY OPTIONS"/>	<input type="button" value="SECONDARY"/> <input type="button" value="START"/>

Setting Delay Options (Continued)

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

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

A Delay Options 08:00

Pause

Delay For

Delay Until

CALL BACK

>Select a Delay Option

BACK CONFIRM

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.)

A Delayed Options

Time of Day

Current time: 08:00 Change Time

CONFIRM

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.

A Delay Options 08:00

Pause

Delay For

Delay Until 9:00

CALL BACK None

>Select Callback or Press CONFIRM

BACK CONFIRM

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.

Midtown Hospital Adult ICU 08:00

A Start at 09:00

B VTBI = 497.0 mL

C VTBI = 57.0 mL

D VTBI = 249.0 mL

VOLUME INFUSED AUDIO ADJUST

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.

A Delay Options 08:00
Pause
Delay For **_20** minutes
Delay Until
CALL BACK None
>Select Callback or Press CONFIRM
BACK CONFIRM

2. Press soft key corresponding to desired Callback option.

A Delay Options 08:00
Pause
Delay For 20 m
Delay Until
CALL BACK >>>>>
Before
Before & After
After
None
>Select a Callback Option
BACK CONFIRM

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

A Delay Options 08:00
Pause
DelayFor **_20** minutes
Delay Until
CALL BACK Before
>Select Callback or Press CONFIRM
BACK CONFIRM

Multidose Mode

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.
3. Press **OPTIONS** key on Programming Module.
4. Press **Multidose** soft key.

A Channel Options 1 of 1
Drug Calculation Setup
Multidose
Pressure Limit - P
Channel Labels
>Select an Option or EXIT
EXIT

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.

A Multidose
Time of Day
Current time: 13:00 Change Time
>Press CONFIRM
CONFIRM

Multidose Mode (Continued)

Multidose Infusion with Volume/Time Enabled (Continued)

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

A Multidose	13:00
RATE	___ mL/h
VOLUME/DOSE	
DOSE INTERVAL	
# OF DOSES	
>Enter Rate	
VOLUME DURATION	

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

A Multidose	13:00
RATE =	___ mL/h
VOLUME/DOSE	___ mL
DURATION	
DOSE INTERVAL	
# OF DOSES	
>Enter Volume/Dose	
RATE VOLUME	

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.*

A Multidose	13:00
RATE =	___ mL/h
VOLUME/DOSE	50 mL
DURATION	___ h ___ min
DOSE INTERVAL	
# OF DOSES	
>Enter Duration	
RATE VOLUME	

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

A Multidose	13:00
RATE =	100 mL/h
VOLUME/DOSE	50 mL
DURATION	00 h 30 min
DOSE INTERVAL	every ___ h
# OF DOSES	
>Enter Dose Interval	
RATE VOLUME	

USING ADDED FEATURES

Multidose Mode (Continued)

Multidose Infusion with Volume/Time Enabled (Continued)

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.

A Multidose		13:00
RATE = 100 mL/h		
VOLUME/DOSE	50 mL	
DURATION	00 h 30 min	
DOSE INTERVAL	every 06 h	
# OF DOSES	_4 doses	
>Press START		
DELAY OPTIONS	RATE VOLUME	START

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

Midtown Hospital		13:00
Adult ICU		
A VTBI = 50.0 mL		
VOLUME INFUSED	AUDIO ADJUST	

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

A Multidose		13:00
Rate = 100 mL/h		
Volume/ Dose	= 50 mL	
Duration =	00 h 30 min	
every 06 h x	04 doses	
Doses completed =	0	
Volume remaining =	50 mL	
>Press START		
DELAY OPTIONS	START	

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

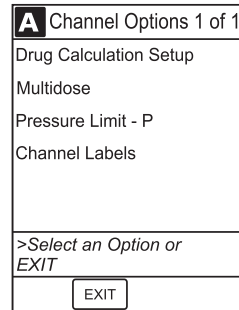
A Multidose		13:30
Rate = 100 mL/h		
Volume/ Dose	= 50 mL	
every 06 h x	04 doses	
Doses completed =	1	
Dose 2 Starts	19:00	
>Press START		
DELAY OPTIONS	SETUP	START

Multidose Mode (Continued)

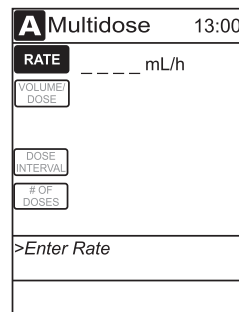
Multidose Infusion with Volume/Time Disabled

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.

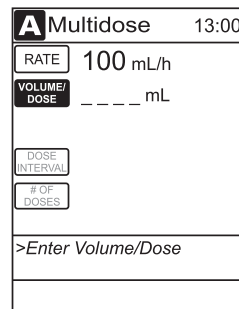
1. Prime and load primary administration set (refer to “Loading Primary Administration Set”).
2. Press **CHANNEL SELECT** key on Pump Module.
3. Press **OPTIONS** key on Programming Module.
4. Press **Multidose** soft key.



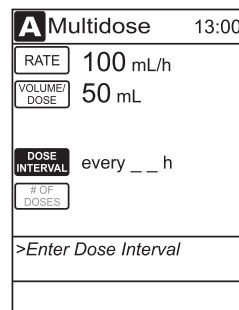
5. Use numeric keypad entry keys to enter desired rate.



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.



USING ADDED FEATURES

Multidose Mode (Continued)

Multidose Infusion with Volume/Time Disabled (Continued)

8. Press **#OF DOSES** soft key and use numeric data entry keys to enter desired number of doses.

A Multidose	13:00
RATE	100 mL/h
VOLUME/DOSE	50 mL
DOSE INTERVAL	every 06 h
# OF DOSES	_4 doses
>Press START	
DELAY OPTIONS	START

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

Midtown Hospital	13:00
Adult ICU	
A VTBI = 50.0 mL	
VOLUME INFUSED	AUDIO ADJUST

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

A Multidose	13:00
Rate =	100 mL/h
Volume/ Dose =	50 mL
every 06 h x 04 doses	
Doses completed =	0
Volume remaining =	50 mL
>Press START	
DELAY OPTIONS	START

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

A Multidose	13:30	
Rate =	100 mL/h	
Volume/ Dose =	50 mL	
every 06 h x 04 doses		
Doses completed =	1	
Dose 2 Starts	19:00	
>Press START		
DELAY OPTIONS	SETUP	START

ADVISORIES AND ALARMS

Advisories

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

Alarms

Alarm	Meaning	Response
Pump Chamber Occluded	Blocked pump chamber has been detected.	Open door and inspect pump chamber. Massage tubing to open blockage, as required. Press reset soft key and RESTART key on Pump Module to continue infusion.

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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.

System Settings

Feature	Default Setting	Options
Delay Options	Disabled	Enabled - Disabled
Callback Delay Options	None	None, Before, After, Before and After
Multidose Mode	Disabled	Enabled - Disabled
Callback Multidose	None	None, Before, After, Before and After

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