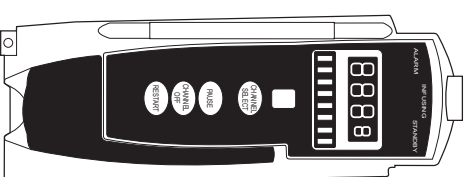# MEDLEY™

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

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.
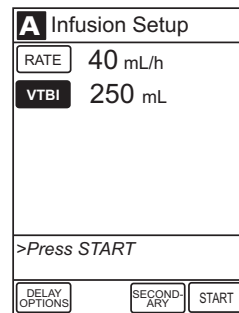
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Setting Delay Options

Delay Options can be enabled at the time the MEDLEY™ System is configured for use. If Delay Options is <u>not</u> 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.
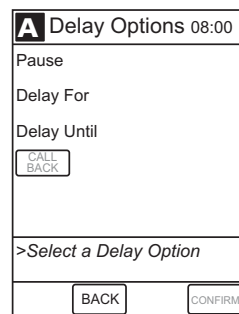
Pausing an Infusion

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

```
┌─────────────────────┐
│ [A] Infusion Setup  │
│ [RATE]  40 mL/h     │
│ [VTBI]  250 mL      │
│                     │
│                     │
│                     │
│ >Press START        │
│ ┌─────┐ ┌──────┐ ┌─────┐ │
│ │DELAY│ │SECOND│ │START│ │
│ │OPTNS│ │-ARY  │ │     │ │
│ └─────┘ └──────┘ └─────┘ │
└─────────────────────┘
```

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).*

```
┌─────────────────────┐
│ [A] Delay Options 08:00 │
│ Pause               │
│ Delay For           │
│ Delay Until         │
│ ┌────┐              │
│ │CALL│              │
│ │BACK│              │
│ └────┘              │
│ >Select a Delay Option │
│   ┌────┐    ┌──────┐ │
│   │BACK│    │CONFIRM│ │
│   └────┘    └──────┘ │
└─────────────────────┘
```

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.

```
┌─────────────────────┐
│ [A] Delay Options 08:00 │
│ ▓Pause▓             │
│ Delay For           │
│ Delay Until         │
│ ┌────┐              │
│ │CALL│              │
│ │BACK│              │
│ └────┘              │
│ >Press CONFIRM      │
│   ┌────┐    ┌──────┐ │
│   │BACK│    │CONFIRM│ │
│   └────┘    └──────┘ │
└─────────────────────┘
```
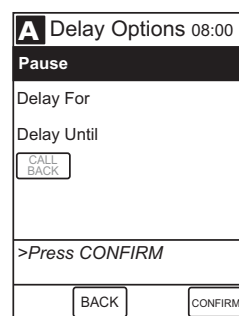
Pausing an Infusion (Continued)

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.

```
┌─────────────────────────┐
│ [A] Infusion Setup      │
│ ┌──────┐                │
│ │ RATE │   40 mL/h      │
│ └──────┘                │
│ ┌──────┐                │
│ │ VTBI │  250 mL        │
│ └──────┘                │
│                         │
│                         │
│                         │
│ >Press START            │
│ ┌──────┐ ┌──────┐┌─────┐│
│ │DELAY │ │SECOND││START││
│ │OPTIONS│ │-ARY ││     ││
│ └──────┘ └──────┘└─────┘│
└─────────────────────────┘
```

2.   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││
│       └──────┘ └───────┘│
└─────────────────────────┘
```

Delaying an Infusion (Specified by Minutes) (Continued)

3. 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               |
| [CALL                     |
|  BACK]   None             |
|                           |
| >Select Callback or Press |
| CONFIRM                   |
|        [BACK]  [CONFIRM]   |
+---------------------------+
```

4. 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      |
|                           |
|                           |
| [VOLUME]      [AUDIO      |
|  INFUSED]      ADJUST]    |
+---------------------------+
```

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.

```
+---------------------------+
| Midtown Hospital          |
| Adult ICU                 |
| [A]  VTBI = 249.0 mL      |
| [B]  VTBI = 497.0 mL      |
| [C]  VTBI =  57.0 mL      |
| [D]  VTBI = 249.0 mL      |
|                           |
|                           |
| [VOLUME]      [AUDIO      |
|  INFUSED]      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.

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

```
+---------------------------+
| [A] Infusion Setup        |
| [RATE]   40 mL/h          |
| [VTBI]  250 mL            |
|                           |
|                           |
|                           |
| >Press START              |
| [DELAY    [SECOND-[START] |
|  OPTIONS]  ARY]           |
+---------------------------+
```

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 │  None          │
│ │ BACK │                │
│ └──────┘                │
│ >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   08:00 │
│ Adult ICU               │
├─────────────────────────┤
│ [A] Start at 09:00      │
│                         │
│ [B] VTBI = 497.0 mL     │
│                         │
│ [C] VTBI =  57.0 mL     │
│                         │
│ [D] VTBI = 249.0 mL     │
│                         │
│ ┌──────┐      ┌────────┐│
│ │VOLUME│      │ AUDIO  ││
│ │INFUSED│     │ ADJUST ││
│ └──────┘      └────────┘│
└─────────────────────────┘
```

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 <u>and</u> 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 <u>prior to</u> 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   Before
Delay Until   Before & After
CALL BACK > > > > >   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

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 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 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         every 06 h     │
│ INTERVAL                     │
│ # OF        _4 doses        │
│ DOSES                        │
│                             │
│ >Press START                │
│                             │
│ DELAY  RATE          START  │
│ OPTIONS VOLUME              │
└─────────────────────────────┘
```

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        AUDIO         │
│ INFUSED       ADJUST        │
└─────────────────────────────┘
```

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

```
┌─────────────────────────────┐
│ A Multidose          13:00  │
├─────────────────────────────┤
│ Rate = 100 mL/h             │
│ Volume/ = 50 mL             │
│ Dose                         │
│ Duration = 00 h 30 min      │
│ every 06 h x 04 doses       │
│ Doses completed = 0         │
│ Volume remaining = 50 mL    │
│ >Press START                │
│ DELAY                START  │
│ OPTIONS                      │
└─────────────────────────────┘
```

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/ = 50 mL             │
│ Dose                         │
│ every 06 h x 04 doses       │
│ Doses completed = 1         │
│ Dose 2 Starts 19:00         │
│                             │
│ >Press START                │
│ DELAY  SETUP         START  │
│ OPTIONS                      │
└─────────────────────────────┘
```

Multidose Infusion with Volume/Time Disabled

If Volume/Time was <u>not</u> 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").

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

2. Press **CHANNEL SELECT** key on Pump Module.

3. Press **OPTIONS** key on Programming Module.

4. Press **Multidose** soft key.

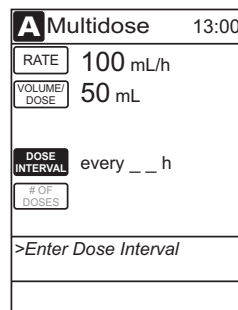5. Use numeric keypad entry keys to enter desired rate.
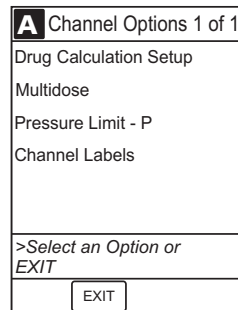
A Multidose   13:00
RATE _ _ _ _ mL/h
VOLUME/DOSE
DOSE INTERVAL
OF DOSES
>*Enter Rate*
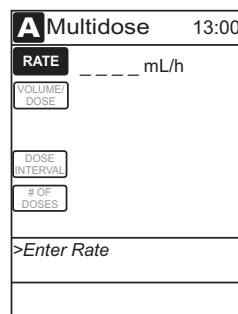
6. Press **VOLUME/DOSE** soft key and use numeric data entry keys to enter volume to be infused for each dose.
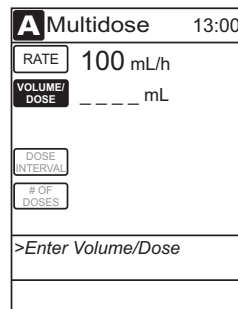
A Multidose   13:00
RATE 100 mL/h
VOLUME/DOSE _ _ _ _ mL
DOSE INTERVAL
OF DOSES
>*Enter Volume/Dose*

7. 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
DOSE INTERVAL every _ _ h
OF DOSES
>*Enter Dose Interval*

USING ADDED FEATURES

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 Adult ICU	13:00
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

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.

ADVISORIES AND ALARMS

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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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