PEA ALMEIS 8120

Installation

Instruments are tested and calibrated before they are packaged for shipment. To ensure proper operation after shipment, it is recommended that an incoming inspection be performed before placing the instrument in use.

Prior to placing the Medley[™] System in use:

- Perform check-in procedure per Medley[™] Maintenance Software/User Manual (Model 8970C, or later).
- 2. Verify whether or not Profiles feature has been enabled. Reference "Reviewing System Configuration" section in "Getting Started" chapter.

NOTE: To enable the Profiles feature, a hospital-defined best-practice data set must be uploaded to the Point-of-Care Unit.

Attaching and Detaching Modules

Modules can be attached to either side of the Point-of-Care Unit or to either side of another module. The process to attach or detach is the same for either side, whether attaching/detaching to/from a Point-of-Care Unit or another module.

Attaching Module(s)

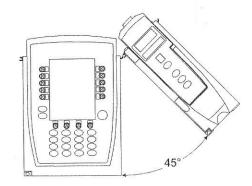
- Position free module at a 45° angle, aligning IUI connectors.
- 2. Rotate free module down against Point-of-Care Unit or attached module, until bottom latch snaps in place.

NOTES:

- Individual hospital/facility may choose to permanently attach modules. To remove permanently attached modules, contact qualified service personnel.
- Application of adhesive tape or other materials to the sides of the Point-of-Care Unit and modules may prevent proper latching.

WARNING

When properly secured/snapped, the bottom latch provides a very secure connection between modules. If not properly latched, a module can be dislodged during operation.

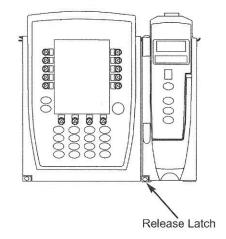


Attaching and Detaching Modules (Continued)

Detaching Module(s)

- 1. Ensure module(s) is powered off before detaching.
- Push module release latch (located directly below IUI connectors) and then rotate module(s) up and away from Point-of-Care Unit or attached module (opposite to motion shown above) to disengage connectors.
 - Medley[™] System reidentifies and shows appropriate module identification (A, B, C or D), from left to right.
 - Appropriate module position(s) (A, B or C) for remaining module(s) appear on Main Display.

NOTE: The Medley™ Medication Safety System is designed to operate a maximum of 4 infusion or monitoring modules. Modules added in excess of 4 will not be recognized by the system. The module(s) can be attached in any position; however, when mounted on an IV pole, it is recommended that a balanced configuration be maintained.



Adding Module(s) While System is Powered On

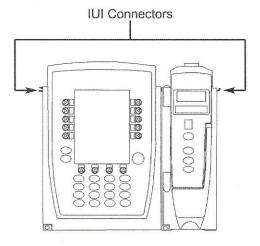
Add module as described in "Attaching Module(s)".

- System tests module, causing all LED segments and indicator lights of displays to illuminate briefly.
- Appropriate module identification display (A, B, C or D) illuminates. Modules are always labeled left to right, so if a module is added to left of other modules, all modules will be reidentified. Module reidentification does NOT interrupt or affect infusion or monitoring on active modules.
- Module positions (A, B, C or D) appear on Main Display.

NOTE: If any of the following conditions are observed, the affected module must be removed from use and inspected by qualified personnel:

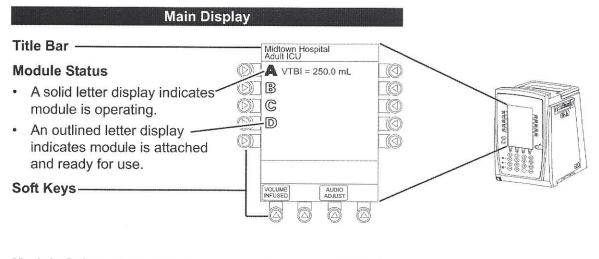
- LED segments are not illuminated on displays during poweron test
- Indicator lights do not illuminate.
- Appropriate module identification (A, B, C or D) is not displayed.

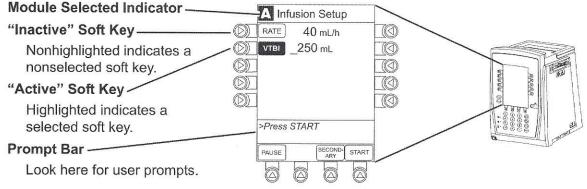
If the affected module operates normally when it is attached via the alternate IUI connector, it may be used until a replacement module can be substituted.



Displays

The displays illustrated throughout this document are for illustration purposes only. The display content will vary, depending on configuration settings, hospital-defined data set uploaded using the Guardrails® Safety Software, and many other variables.

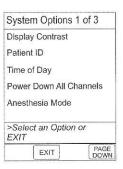




Displays (Continued)

Adjusting Display Contrast

- Press OPTIONS key.
- Select Display Contrast soft key.



- To adjust display for optimum viewing, use Lighter/Darker soft keys.
- 4. To return to main screen, press MAIN SCREEN soft key.



Start-Up

Powering On System

- Connect Point-of-Care Unit to an external AC power source.
- 2. Press SYSTEM ON.
- 3. System self test begins:
 - Diagnostics test causes all LED display segments and Status Indicator lights of attached module(s) to illuminate briefly.
 - · Power Indicator illuminates.
 - Appropriate module identification (A, B, C or D) displays on attached module(s).
 - · An Audio tone sounds.
- -- Continued on Next Page --

Powering On System (Continued)

- At completion of system-on test, New Patient? screen appears.
- If PM Reminder option is enabled and scheduled preventive maintenance is due, MAINTENANCE REMINDER screen appears.

NOTES:

- Previous infusion parameters are automatically cleared after 8 hours.
- If any of the following conditions are observed, the Point-of-Care Unit or the affected attached module must be removed from use and inspected by qualified personnel:
 - LED segments are not illuminated during system-on test.
 - · Indicator lights do not illuminate.
 - Appropriate module identification (A, B, C or D) is not displayed.
 - · Audio tone does not sound.
 - Main Display does not appear backlit, appears irregular, or has evidence of a row of pixels not functioning properly.

If the affected module operates normally when it is attached via an alternate IUI connector, it may be used until a replacement module can be substituted.

Responding to Maintenance Reminder

If the Preventive Maintenance (PM) Reminder option is enabled and the Point-of-Care Unit or an attached module is due for preventive maintenance, a **MAINTENANCE REMINDER** message appears at power up.

NOTES:

- If necessary, the reminder can be temporarily bypassed by pressing the CONFIRM soft key.
- Notify the appropriate facility personnel when a MAINTENANCE REMINDER occurs.
- Remove and, if needed, replace module requiring maintenance with a new module (reference "Attaching and Detaching Modules" section).

MAINTENA	NCE REMINDER
Module(s) du preventive m	
Module A:	YYYY-MM-DD
-	

Responding to Maintenance Reminder (Continued)

If "system" (Point-of-Care Unit and attached modules)
was powered off to replace Point-of-Care Unit, reinitiate
start-up process.

OR

If an "attached module" (such as, a Pump Module) was powered off and removed, **MAINTENANCE REMINDER** display reflects removal of that module. To continue start—up process, press **CONFIRM** soft key.

MAINTENANCE REMINDER
Module(s) due for routine preventive maintenance:
CONFIRM

Selecting New Patient and Profile Options

The option to enter and display a 16-character alphanumeric patient identifier is always available. The instrument may be configured to automatically display the **Patient ID Entry** screen during start up or to provide access only through the **Systems Options** menu.

The following procedures assume the Profiles feature is enabled.

NOTE: The display contrast can be adjusted at this time by pressing the **DISPLAY CONTRST** soft key and following the directions on the screen (also reference "Displays", "Adjusting Display Contrast" section).

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Disabled

1. Select required **NEW PATIENT?** option.

To indicate programming is for a new patient and clear all stored patient parameters from memory, press **Yes** soft key.

OR

To confirm programming is for same patient and retain all stored patient parameters, press **No** soft key.

· Last used profile displays.

NOTE: If the Profiles feature is disabled, the main menu appears.

NEW PATIENT?	Yes
"Yes" Clears Previous Patient Data	No
	-1
>Select Yes or No	

Midtown Hospital

Select correct profile.

To accept current profile, press **Yes** soft key and proceed to step 5.

· Main screen appears.

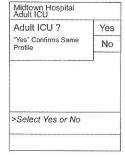
OR

To change profile, press **No** soft key and continue with next step.

- · Profile selection screen appears.
- To select a profile, press corresponding left soft key.

NOTE: To view additional choices, press **PAGE DOWN** soft key.

- 4. To confirm profile selection, press **CONFIRM** soft key.
 - Main screen appears.
- 5. To enter Patient ID, if desired, reference "Entering Patient ID" section.



Midtown Hospital Profiles	1 of 2
Adult ICU	
Adult General Care	
Neonatal	
Peds ICU	
Neonatal ICU	
>Select a Profile an	d
	PAGE

Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Enabled

- 1. Select required NEW PATIENT? option.
 - To indicate programming is for a new patient and clear all stored patient parameters from memory:
 - a. Press Yes soft key.
 - · Patient ID Entry screen appears.
 - b. If patient identifier is not required, press CONFIRM or EXIT soft key.

OR

Enter patient identifier (reference "Entering Patient ID" section).

- · Last used profile displays.
- -- OR --
- To confirm programming is for same patient and retain all stored patient parameters, press No soft key.
 - · Last used profile displays.

NOTE: If the Profiles feature is disabled, the main menu appears.

2. Select correct profile.

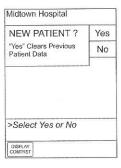
To accept current profile, press Yes soft key.

Main screen appears.

OR

To change profile, press \mbox{No} soft key and continue with next step.

Profile selection screen appears.



Patien	t ID Entry	
A		A-E
В		F-J
С		K-0
D		P-T
E		U-Y
>Enter	Patient ID a	nd Press
	EXIT CON	RM PAGE DOWN



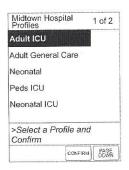
Selecting New Patient and Profile Options (Continued)

Patient ID Entry Feature Enabled (Continued)

3. To select a profile, press corresponding left soft key.

NOTE: To view additional choices, press **PAGE DOWN** soft key.

- 4. To confirm profile selection, press CONFIRM soft key.
 - · Main screen appears.



Entering Patient ID

When the Patient ID Entry feature is disabled, the **Patient ID Entry** screen can only be accessed through the **Systems Options** menu. To enter a patient ID, begin with step 1 of the following procedure.

When the Patient ID Entry feature is enabled, the **Patient ID Entry** screen appears after responding **Yes** to **New Patient?** prompt. To enter a patient ID, begin with step 2 of the following procedure.

- To access Patient ID Entry screen:
 - Press OPTIONS key.
 - System Options menu appears.
 - b. Press Patient ID soft key.
 - · Patient ID Entry screen appears.

	EXIT	PAGE DOWN
>Sele EXIT	ct an Optio	n or
Anesti	nesia Mode	
Power	Down All C	hannels
Time o	of Day	
Patien	t ID	
Displa	y Contrast	Market State
Syste	m Options	1 of 3

Entering Patient ID (Continued)

To enter patient identifier, use numeric data entry keys and/or alpha speed keys.

NOTES:

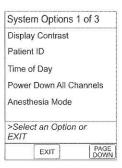
- An alphanumeric identifier, of up to 16 characters, can be entered.
- Press the soft key next to a letter group to list letters in that group. Press the soft key next to an individual letter to enter that letter.
- To access the letter "Z" and special characters (hyphen, underscore, space), press the PAGE DOWN soft key.
- · To clear an entire entry, press CLEAR key.
- To back up a single character at a time, press CANCEL key.

Α		A-E
В		F-J
С		K-C
D		P-T
E		U-Y
>Enter	 Patient ID a	nd Press

- To verify correct entry, press CONFIRM soft key.
 - If accessed from New Patient? screen, last used profile appears.
 - If accessed from Systems Options menu, main screen appears.
 - Patient ID appears on main screen, current profile screen, and New Patient? screen.

Modifying Patient ID

- Press OPTIONS key.
 - · System Options menu appears.
- Press Patient ID soft key.
 - · Patient ID Entry screen appears.



Modifying Patient ID (Continued)

3. To clear entire entry, press CLEAR key.

OR

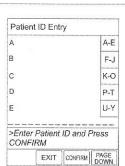
To back up a single character at a time, press **CANCEL** key.



4. To enter modified patient identifier, use numeric data entry keys and/or alpha speed keys.

NOTES:

- An alphanumeric identifier, of up to 16 characters, can be entered.
- Press the soft key next to a letter group to list letters in that group. Press the soft key next to an individual letter to enter that letter.
- To access the letter "Z" and special characters (hyphen, underscore, space), press the PAGE DOWN soft key.



- 5. To verify correct entry, press CONFIRM soft key.
 - · Patient ID Entry verification screen appears.



- 6. To accept modified Patient ID, press Yes soft key.
 - Main screen appears with new Patient ID.

OR

To retain original (old) Patient ID, press No soft key.

· Main screen appears with old Patient ID.

Patient ID	Yes
123456789CD will be changed to 234567891EF	No
Is this correct?	