

# VIALMIX™

ACTIVATION DEVICE FOR  
DEFINITY® Vial for (Perflutren Lipid Microsphere)



USER'S GUIDE



Technical Service Reference:

If you need technical assistance or have questions about Vialmix™, call Lantheus Medical Imaging, Inc. Technical Services at 1-800-635-2683.

Customer Service Reference:

For customer orders, please call Lantheus Medical Imaging, Inc. Customer Services at 1-888-550-7981.

**CAUTION:** The only intended use of Vialmix™ is for the activation of DEFINITY® Vial for (Perflutren Lipid Microsphere).

**CAUTION:** US Federal law restricts this device to sale by or on the order of a licensed medical practitioner.

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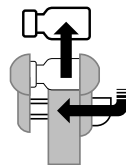
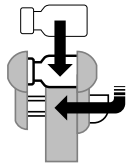
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**NOTE:**

*Vialmix™ will not operate with cover open.*

*Do not open cover while Vialmix™ is operating.*

*Wait 3 minutes between activations.*



*If the cycle is interrupted for any reason, the DEFINITY® vial is unusable. Retain vial and contact Lantheus Technical Services at 1-800-653-2683 for assistance.*

*Keep cover closed when not in use.*

**SET-UP**

- Remove packaging, including red transport collar from base of vial carrier.
- Place Vialmix™ on a flat surface and verify voltage compatibility.
- Connect Vialmix™ to the main power source using enclosed power cord. Non-grounded plug adaptors should never be used.
- Power on Vialmix™ by moving switch to “I.”
- LED display briefly shows “88,” then “45.”

**OPERATION**

**INSERTING VIAL AND ACTIVATING DEFINITY® Vial for (Perflutren Lipid Microsphere):**

- 1 Press lever downward and to the left to open the carrier.
- 2 Hold DEFINITY® vial between thumb and fingers and load vial by first placing the top of the vial in the left cup of carrier; position vial between the two cups.
- 3 Release the lever; then close the Vialmix™ cover.
- 4 Press START and countdown from “45” to “00” will begin.

**REMOVING VIAL:**

- 1 When the full 45-second cycle is complete, open Vialmix™ cover.
- 2 Press lever downward and to the left to open the carrier.
- 3 Remove vial.
- 4 Close the cover.

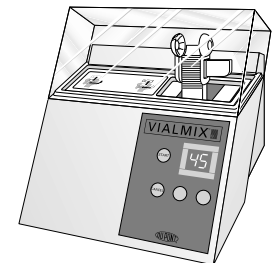
**POWERING OFF VIALMIX**

Vialmix™ should be powered off at the end of the day by moving the switch on the back of the unit to “0.”

**SAFETY PRECAUTIONS**

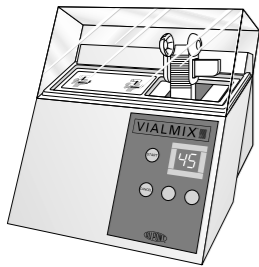
- Before the unit is put into operation, make sure that the operating voltage indicated on the type plate is the same as the supply voltage available. Incorrect voltage may damage the unit.
- This unit must only be operated with the lid closed and intact.
- During operation, the DEFINITY® vial must be the only object placed under the cover.
- The unit must be placed on a level surface.
- A dangerous condition can result from condensation build-up. Before using the unit, allow the unit to reach room temperature, particularly when moving it from a colder to a warmer environment.
- To safely operate the unit, insert the main plug only into an appropriate outlet with a grounded conductor. If an extension cord is used, make sure that the grounded conductor is not broken.
- Turn off and unplug the unit from the power outlet before changing fuses.
- Use only correct fuses. Do not use repaired fuses or bypass the fuse holder.
- In order to avoid electrical shock, DO NOT INSERT ANY OBJECTS INTO THE UNIT.
- If, for any reason, it is possible that the safety of a unit has been compromised, that unit must be removed from operation and identified in such a way that it is not inadvertently operated again by a third party. For example, do not use unit if it does not work as specified or is visibly damaged.
- Keep solvents, inflammable liquids and powerful heat sources away from unit.
- Do not allow cleansers to get into unit during cleaning; an electrical short or a dangerous malfunction may occur. Do not immerse unit in any liquid.
- Except for fuse replacement, all repairs should only be done by Lantheus Medical Imaging, Inc. approved personnel. Do not open unit housing.

**IMPORTANT:** *Read this section carefully before plugging in and operating the unit. The unit must be used in strict accordance with these instructions. We have no liability for any damage arising from any other use of this unit.*



**IMPORTANT:**  
Shaking the **DEFINITY®** vial by hand will not activate the agent adequately. Using **Vialmix™** to shake **DEFINITY®** will ensure proper activation of the agent and consistent product performance.

**Cycle Duration:**  
45 seconds



## SYSTEM FEATURES OVERVIEW

Vialmix™ is the activation device designed specifically for **DEFINITY®** Vial for (Perflutren Lipid Microsphere), an intravenous ultrasound contrast agent. **DEFINITY®** is supplied as a liquid-filled glass vial and requires shaking in order to create the lipid-encapsulated microbubbles. The shaking rate and duration are controlled by Vialmix™ to ensure reproducible activation of **DEFINITY®**.

### FEATURES OF VIALMIX™ INCLUDE:

#### ■ Proper Activation of **DEFINITY®**

A number of LED messages inform the user of successful activation. In the event that the activation cycle is stopped short of the 45 seconds of required shaking time, or the shaking rate deviates from the acceptable range, the user is alerted via LED messages and an audible alarm.

#### ■ Simple Operation

Vialmix™ has only two operational buttons, one for starting the cycle, and another for canceling the cycle, if necessary. Vialmix™ allows for easy loading of the **DEFINITY®** vial into the vial carrier. Vialmix™ has a fixed shaking rate and cycle time. Only one possible activation cycle is available. The cycle duration (45 seconds) is displayed as the default value after turning the power on.

#### ■ Safe Operation

Vialmix™ contains features that ensure safe operation. These include:

- An automatic shut-off switch which is activated if the cover is opened during operation.
- A CANCEL button to allow the user to terminate shaking and a thermal sensor shut-off to prevent the motor from overheating.

## SET-UP

Vialmix™ is packaged with a power cord and this *User's Guide*. Upon receipt of Vialmix™, and prior to use with **DEFINITY®**, the user must perform the following steps.

- 1 Remove Vialmix™ from the package, and remove the styrofoam inserts.
- 2 Remove the red transport collar from the base of the vial carrier.
- 3 Before plugging Vialmix™ into an electrical outlet, verify that the voltage on the type plate on the back of Vialmix™ corresponds to the local power line voltage.
- 4 Place Vialmix™ on a flat surface.
- 5 Connect Vialmix™ to the main power source using the enclosed power cord.

**IMPORTANT:**  
**Vialmix™** must be at room temperature before use.



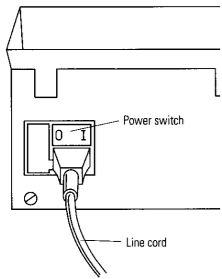
#### POWERING ON VIALMIX™

With Vialmix™ properly connected to the main power, the unit can be powered on by moving the switch on the back of the unit to the “1” position.

During power-on, the LED will display “88” briefly. This will change to “45,” representing the cycle time in seconds. The display will remain at “45” until an activation cycle is initiated.

#### POWERING OFF VIALMIX™

Vialmix™ should be powered off at the end of the day. This is done by moving the switch on the back of the unit to the “0” position.

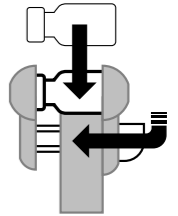


#### LOADING THE VIAL

With the cover open, the vial carrier is easily accessed for vial loading. Complete the following steps to load the DEFINITY® vial:\*

- 1 The vial carrier is spring loaded and opens to accommodate the DEFINITY® vial by means of the release lever. Press the lever downward to unlatch the vial carrier; then press the lever to the left to open the carrier for vial loading.
- 2 Holding the DEFINITY® vial between your thumb and fingers, load the vial by placing the top of the vial in the left cup of the carrier. The cups of the vial carrier are molded to best accommodate the vial when the top of the vial is placed in the left cup. Either position (ie, the top of the vial in either cup) is possible and will allow for acceptable activation of DEFINITY®.
- 3 Release the lever and the spring action of the carrier will hold the vial securely. Make sure that the vial is evenly supported by both cups of the carrier.
- 4 Close the Vialmix™ cover.

**IMPORTANT:** To ensure cleanliness of the DEFINITY® vial septa, load the vial with the flip-top seal in place.



**IMPORTANT:** Do not operate Vialmix™ without a vial in the carrier.

\* NOTE: Refer to the illustration on the Vialmix™ unit, to the left of the vial carrier for the loading procedure.

**IMPORTANT:**

*Vialmix™ will not start the activation cycle with the cover in the open position.*

**IMPORTANT:** *Unless there is a safety concern, do not open the Vialmix™ cover during the shaking cycle. Doing so will render the DEFINITY® vial unusable since acceptable activation is achieved only with an uninterrupted shaking cycle.*

**ACTIVATING THE VIAL**

With Vialmix™ powered on, the vial in place, and the cover closed, the user is ready to activate DEFINITY®. The cycle time of 45 seconds appears on the Vialmix™ LED display. If it does not appear, see Section 6, “Troubleshooting.” Press the START button to begin the activation cycle.

DEFINITY®™ is ready for use if:

- Vialmix™ shakes the vial for the full 45-second activation cycle.
- Vialmix™ stops shaking when the LED display shows “00” seconds remaining.

If the vial is not shaken for the full duration or at the acceptable rate, activation is not considered successful; an LED message will be displayed and an audible alarm will sound to alert the user. Refer to Section 5 for a list of LED messages and the conditions they indicate.

NOTE: After completion of an activation cycle, allow a minimum of 3 minutes before beginning another cycle. This allows the Vialmix™ motor to cool.

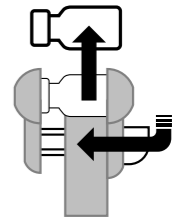
**REMOVING THE VIAL**

After successful activation of the DEFINITY® vial (as indicated by the LED display of “00”), the vial can be removed for use. To remove the vial, open the cover and follow these steps\*:

- 1 Press the lever down to unlatch the vial carrier, then press the lever to the left to fully open the carrier.
- 2 Remove the vial from the carrier.
- 3 Release the lever and the spring action will close the carrier.
- 4 Close the cover.

NOTE: The LED display changes from “00” to “45” when the cover is opened.

**IMPORTANT:** *For safety and maintenance reasons, the cover should be closed when Vialmix™ is not in use.*



\*NOTE: Refer to the illustration to the left of the vial carrier for the removal procedure.



### COVER SHUT-OFF SWITCH

Vialmix™ is equipped with an automatic shut-off switch that prevents the user from coming into contact with the rapidly moving shaking arm. The shut-off switch is triggered in the following situations:

- When the cover is open, the shut-off switch will prevent the activation cycle from beginning. Should the START button be pressed while the cover is open, the motor will not start; consequently, the activation cycle will not begin.
- If the cover is lifted during operation, the shut-off switch will cause the activation cycle to stop.

The following table shows the LED message for each of the above situations, the associated Vialmix™ response, likely cause of the message, and the action required of the user:

LED Message	Associated Vialmix™ Response	Likely Cause of Message	Action Required by User
"CO" for 5 seconds	Emits a brief audible alarm	Cycle initiation attempted while cover is open	Close the cover and re-start the cycle.
"EE" alternating with "CO"	Stops shaking, emits an audible alarm	Opening the cover during the activation cycle	Power off the unit. Do not use the DEFINITY® vial since it was not acceptably activated. Retain the vial and call Technical Services.



### CANCEL BUTTON

Vialmix™ is equipped with a button that allows the user to terminate the activation cycle. By pressing the CANCEL button after the shaking cycle is initiated, the motor shuts down and the shaking cycle stops.

The CANCEL button is available in the unlikely event that the activation cycle must be stopped for safety reasons (for example, should the vial become dislodged or a mechanical failure of Vialmix™ occur).

The following table shows the LED message when the CANCEL button is pressed, the associated Vialmix™ response, the likely cause of the message and the action required of the user:

LED Message	Associated Vialmix™ Response	Likely Cause of Message	Action Required by User
"EE" alternating with "CL"	Stops shaking, emits an audible alarm	CANCEL button was pressed during operation.	Power off the unit. Do not use the DEFINITY® vial since it was not acceptably activated. Retain the vial and call Technical Services.

**IMPORTANT: Pressing the CANCEL button will terminate the activation cycle and render DEFINITY® unacceptable for use. Retain the vial and call Technical Services for assistance.**





**THERMAL SENSOR SHUT-OFF SWITCH**

Vialmix™ is equipped with a sensor that monitors the motor temperature. In the unlikely event that the motor overheats, the sensor triggers the motor to shut down. The LED message (“EE” alternating with “LO”) and an audible alarm alert the user that the motor has overheated.

Under this condition, Vialmix™ will not allow a cycle to begin until the motor has cooled. Should the START button be pressed prior to sufficient cooling, the user is alerted by the LED message, “CO,” and an audible alarm.



In order to ensure acceptable activation of DEFINITY®, Vialmix™ is programmed to display LED messages that alert the user in the event that the shaking cycle is outside the required duration or rate.

The table on the following page shows the LED message, the associated Vialmix™ response, the likely cause(s) of the message, and the action required of the user.

*See table on following page.*



<b>LED Message</b>	<b>Associated Vialmix™ Response</b>	<b>Likely Cause of Message</b>	<b>Action Required by User</b>
<p><b>“LO” alternating with seconds remaining in cycle.</b></p> <p>Shaking is acceptable.</p>	Continues shaking and counting down to “00”	<ul style="list-style-type: none"> <li>■ Low line voltage</li> <li>■ The shaking rate is approaching the lower limit.</li> </ul>	DEFINITY® vial is ready for use, since activation is acceptable. Contact Technical Services for assistance.
<p><b>“EE” alternating with “LO.”</b></p> <p>The shaking rate is unacceptable since it is below the lower limit.</p>	Stops shaking, emits an audible alarm	<ul style="list-style-type: none"> <li>■ Mechanical failure of Vialmix™ affecting the shaking rate</li> <li>■ Low line voltage</li> <li>■ The motor has overheated.</li> </ul>	Power off the unit. Do not use the DEFINITY® vial, since it was not acceptably activated. Retain the vial and call Technical Services for assistance.
<p><b>“EE” alternating with “HI.”</b></p> <p>The shaking rate is unacceptable since it is above the upper limit.</p>	Stops shaking, emits an audible alarm	Mechanical problem with Vialmix™	Power off the unit. Do not use the DEFINITY® vial, since it was not acceptably activated. Retain the vial and call Technical Services for assistance.

In the event that Vialmix™ does not respond as expected, the guide on the following page is given to aid the user in troubleshooting the problem. If the guide does not cover a particular problem, please call Technical Services for assistance.

Do not use the unit if it does not work as specified or is visibly damaged. Contact Technical Services for a Vialmix™ replacement.

**IMPORTANT:**  
Do not attempt to repair Vialmix™. All repairs to Vialmix™ must be performed by Lantheus Medical Imaging, Inc. approved technical personnel. Contact Technical Services if there are any problems with the unit. Do not open the Vialmix™ housing. To avoid electrical shock, do not insert any objects into the main body of Vialmix™.



**IMPORTANT:**  
If you need assistance, or have technical questions about Vialmix™, call Technical Services.

LED Message	Likely Cause	Corrective Action Required
LED display does not operate when power switch is on.	No main power	Check power supply and power cord connection.
	Fuse is blown.	Contact Technical Services for assistance, or refer to page 8.1 for instructions to change the fuse.
Motor does not operate after START button is pressed.	Cover is open.	Close the cover.
	Motor is overheated.	Allow the motor to cool down.
Vialmix™ stops shaking during a cycle.	Cover has been opened.	Do not attempt to use DEFINITY® vial since it was not acceptably activated. Retain the vial and call Technical Services. Do not open the cover during activation.
	Unit deviated from acceptable shaking rate.	Do not use the DEFINITY® vial since it was not properly activated. Retain the vial and call Technical Services.
	Fuse is blown.	Do not use the DEFINITY® vial since it was not properly activated. Retain vial and call Technical Services for assistance. See page 8.1 for instructions to change fuse.
	Motor is overheated.	Allow motor to cool down. Do not use the DEFINITY® vial since it was not properly activated. Retain vial and call Technical Services for assistance.



All plastic parts of Vialmix™ should be cleaned with a soft cloth and, if necessary, with a mild cleanser. Under no circumstances should any solvents or abrasive detergents be used since these can damage the plastic.

The use of isopropanol to clean Vialmix™ is not recommended since over time it may cause the plastic housing to become brittle.

**IMPORTANT:**  
Do not allow cleansers to get into Vialmix™ during cleaning; an electrical short or a dangerous malfunction may occur. Do not immerse Vialmix™ in any liquid.

**SAFETY PRECAUTIONS:**  
**Prior to changing the fuse, power off Vialmix™ and disconnect the power cord from the back of the unit.**

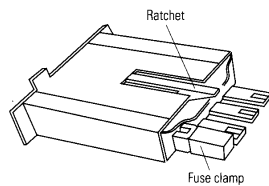
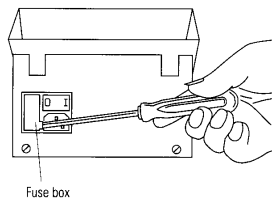
All bearings in Vialmix™ are maintenance-free. Therefore, maintenance of any internal components of the unit is not required.

**CHANGING THE FUSE**

- Use only the correctly-rated fuse to replace the blown fuse (**3AG Slo Blo fuse, Littelfuse, or equivalent**).
- Do not use repaired fuses or bypass the fuse holder.
- To avoid electrical shock, do not insert objects into the main body of the unit.

If the fuse blows, take these steps to change the fuse:

- 1 Turn the power off. Disconnect the power cord.
- 2 The fuse is located on the back of the unit next to the power switch. Place a screwdriver behind the small flap of the fuse box and gently pry it open.
- 3 Slide the fuse box out of the unit.
- 4 Lift the ratchet upward and pull the fuse clamp out of the fuse box. Remove the fuse and replace it with a new one.
- 5 Press the fuse clamp back into the fuse box until you hear the ratchet snap into place. Put the fuse box back into the unit.



**IMPORTANT:** The fuse is the only part of Vialmix™ which may be replaced by the user. All other repairs must be performed by Lantheus Medical Imaging, Inc. approved technical personnel. Contact Technical Services if there are any problems with Vialmix™.

Drive:	Ball-bearing mounted motor with built-in overheating protection and automatic reset
Control System:	Microprocessor-controlled, high-precision shaking time
Vial Carrier:	Self-retaining
Construction:	Steel base and frame; casing and cover made of high impact-resistant plastic
Shaking Frequency:	4530 ±100 oscillations per minute
Shaking Duration:	45-second cycle (3-minute pause between cycles)
Recommended Working Temperature:	18-30° C
Line Voltage:	120V/60 Hz
Power Input:	330 VA
Dimensions:	Height: 160 mm Depth: 195 mm Width: 195 mm
Weight:	3750 g

## TECHNICAL SERVICE



If you need technical assistance, or have questions concerning Vialmix™, please call Lantheus Medical Imaging, Inc. Technical Services at:

**1-800-653-2683**

For customer orders, please call Lantheus Medical Imaging, Inc. Customer Services at:

**1-888-550-7981**

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