



VIALMIX®*RFID*

Activation Device for DEFINITY® Vial for (Perflutren
Lipid Microsphere) Injectable Suspension

User's Guide/ Instructions for Use



516041-1118

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SAFETY PRECAUTIONS



IMPORTANT: Read this section carefully before plugging in and operating the unit. VIALMIX®RFID must be used in strict accordance with these instructions. Lantheus Medical Imaging has no liability for any damage arising from any other use of this unit.

WARNING: Do not operate VIALMIX®RFID and RFID-tagged vials within 6 inches (15cm) of a pacemaker and/or defibrillator.

WARNING: Use of VIALMIX®RFID adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the VIALMIX®RFID, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

- VIALMIX®RFID must only be operated with the lid closed and intact.
- Do not store vials under the lid. Only the DEFINITY® vial placed in the cradle intended for immediate activation should be in the enclosure.
- VIALMIX®RFID must be placed on a level surface and away from the edge of the surface.
- A dangerous condition can result from condensation build-up. Before using VIALMIX®RFID, allow the unit to reach room temperature, particularly when moving it from a colder to a warmer environment.
- To safely operate VIALMIX®RFID, insert the main plug only into an appropriate outlet with a grounded conductor. VIALMIX®RFID can operate using 120 to 240 volts, 50 to 60 Hz power. If an extension cord is used, make sure that the ground conductor is not broken.
- 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 VIALMIX®RFID has been compromised, that unit must be removed from operation and identified in such a way that it is not inadvertently operated again. For example, do not attempt to use VIALMIX®RFID if it does not work as specified or is visibly damaged.
- Keep solvents, inflammable liquids, and 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.
- If the unit is not operating as expected, please contact Lantheus Medical Imaging (see page 15). **Do not open unit housing or attempt to perform any maintenance or repair.**
- VIALMIX®RFID must be properly disposed of at the end of its service life. To dispose of VIALMIX®RFID, contact Lantheus Medical Imaging (see page 15).

MEANING OF SAFETY SYMBOLS

SYMBOL	MEANING
	Signifies that the instruction/manual booklet must be read
	Signifies a mandatory action
	Alerts the user to important information and/or warnings

SYSTEM FEATURES OVERVIEW

VIALMIX®*RFID* is the activation unit designed specifically for DEFINITY® Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an intravenous ultrasound contrast agent. DEFINITY® is supplied as a liquid-filled glass vial and requires activation in order to create the lipid-encapsulated microbubbles. The activation rate and duration are controlled by VIALMIX®*RFID* through the use of Radio-Frequency Identification (RFID) technology to ensure reproducible activation of DEFINITY®.

FEATURES OF VIALMIX®*RFID* INCLUDE:

- **Proper Activation of DEFINITY®**

A number of digital messages inform the user of an unsuccessful activation. In the event the activation cycle stopped short of the required activation time or the activation rate deviated from the acceptable range, the user is alerted via digital messages on the display and an audible alarm. See page 9 for a list of error messages.



IMPORTANT: Shaking the DEFINITY® vial by hand will not activate the agent adequately. Using VIALMIX®*RFID* to activate DEFINITY® will ensure proper activation of the agent and consistent product performance. DO NOT use a DEFINITY® vial if it is not properly activated in VIALMIX®*RFID*

- **Simple Operation**

VIALMIX®*RFID* has two operational buttons on the front panel.

1. ▶ A START button for starting the cycle
2. □ A STOP button for canceling the cycle if needed

VIALMIX®*RFID* allows for easy loading of the DEFINITY® vial into the vial carrier.

VIALMIX®*RFID* is equipped with an RFID reader. Once the DEFINITY® vial is loaded in the vial carrier and the cover is closed, the VIALMIX®*RFID* will read the RFID tag embedded in the DEFINITY® vial label and will automatically set the required activation rate and activation time. The appropriate activation time of 45 seconds will appear on the display. The addition of RFID capability to the VIALMIX®*RFID* is completely transparent to the user and does not require any additional actions to activate DEFINITY®.

- **Safe operation**

VIALMIX®*RFID* contains features that ensure safe operation. These include:

- An automatic shut-off switch that is activated if the cover is opened during operation.
- A STOP button to allow the user to terminate the activation cycle.
- A thermal sensor shut-off to prevent overheating.

SET-UP

VIALMIX®*RFID* is packaged with a power cord and a Quick Reference Guide. Upon receipt of VIALMIX®*RFID* and prior to use with DEFINITY®, the user must perform the following steps.

1. Remove VIALMIX®*RFID* and its power cord from the package.
2. Remove all packing materials from the unit.
3. Place VIALMIX®*RFID* on a flat surface.
4. Open the cover and remove the shipping restraint from the arm.
5. Connect VIALMIX®*RFID* to the main power source using the enclosed power cord.

OPERATION

Powering On VIALMIX®*RFID*

With VIALMIX®*RFID* properly connected to the main power supply, the unit can be powered on by moving the switch on the back of the unit to the "I" position. Once powered on, VIALMIX®*RFID* will display the following when ready for use:



Loading the DEFINITY® Vial

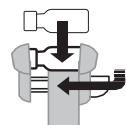
With the cover open, the vial carrier is easily accessed for vial loading. The following screen will be displayed after the cover is opened:



Perform 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 (see diagram below). The cups of the carrier are molded to best accommodate the vial when the top of the vial is placed in the left cup. Either position (i.e. top of the vial in either cup) is possible and will allow for acceptable activation of DEFINITY®.

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



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®RFID cover.

Activating the DEFINITY® Vial

With VIALMIX®RFID powered on, the vial in place, and the cover closed, the following will be displayed when the user is ready to activate DEFINITY®.



The activation time of "45", representing 45 seconds, will appear on the VIALMIX®RFID display. If it does not display, refer to the "Troubleshooting" section located on page 12.

Press the START ▶ button located under the display to begin the activation cycle. The cycle time on the VIALMIX®RFID display will begin to count down to zero.

IMPORTANT: VIALMIX®RFID will not start the activation cycle with the cover in the open position. Do not open the VIALMIX®RFID cover during the activation cycle. Doing so will render the vial unusable. Acceptable activation is achieved only with an uninterrupted activation cycle.

DEFINITY® is ready for use if VIALMIX®RFID shakes the vial uninterrupted for the full activation cycle with no error messages displayed. The following screen will be displayed indicating a successful activation:

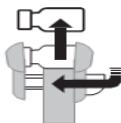


If the DEFINITY® vial does not shake for the full 45 second duration or at the acceptable rate, activation is not considered successful and the vial must not be used. An error message will be displayed and an audible alarm will sound to alert the user. Refer to page 9 for a list of error messages and the conditions they indicate.

Removing the DEFINITY® Vial

After successful activation of DEFINITY®, 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 DEFINITY® vial from the carrier.



3. Release the lever and the spring action will close the carrier.
4. Close the cover.

Powering Off VIALMIX®RFID

VIALMIX®RFID 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 "O" position.

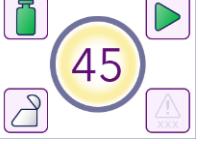
USAGE COUNTER

VIALMIX®RFID is equipped with an internal usage counter which counts the total number of activation cycles performed. A Usage Count Alert will be displayed on the VIALMIX®RFID main display (see page 11) when > 95% of the programmed limit of activation cycles has been reached. **Please contact Lantheus Medical Imaging Customer Service IMMEDIATELY upon receiving this alert to request a new VIALMIX®RFID. Once the usage counter reaches 100% of the programmed limit of activation cycles, a Usage Count Error message will be displayed on the VIALMIX®RFID main display (see page 11) and VIALMIX®RFID will cease to operate.**

ERROR MESSAGES

In order to ensure acceptable activation of DEFINITY®, VIALMIX®RFID is programmed to display error messages that alert the user in the event that the activation cycle is outside the required duration or rate. The table below shows a complete list of error messages, the associated VIALMIX®RFID response, the likely cause(s) of the error, and the action required of the user.

Error	Associated VIALMIX®RFID Response	Likely Cause of Message	Action Required by User
High Oscillation Rate Error	High Oscillation Rate error message on main screen (HE) Audible alert 	DEFINITY® vial has shaken at higher than acceptable shake rate.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Press the STOP (red square) button to clear the error.
Low Oscillation Rate Error	Low Oscillation Rate error message on main screen (LE) Audible alert 	DEFINITY® vial has shaken at lower than acceptable shake rate.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Press the STOP (red square) button to clear the error.
Motor Overcurrent	Motor Overcurrent error message on main screen (MC) Audible alert 	Excess mechanical loading or motor failure.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Power cycle the unit using the power switch on the back of the unit to clear the error.
Thermal Fault	Thermal Fault error message on main screen (OH) Audible alert 	Unit is overheating.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Power the unit off and allow to cool. Once cooled, power the unit on using the power switch on the back of the unit.

Error	Associated VIALMIX®RFID Response	Likely Cause of Message	Action Required by User
Motor Overvoltage	Motor Overvoltage error message on main screen (MO) Audible alert 	Motor is operating higher than standard voltage condition indicating potential future failure.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Power cycle the unit using the power switch on the back of the unit to clear the error.
Motor Under voltage	Motor Under voltage error message on main screen (MU) Audible alert 	Motor is operating lower than standard voltage condition indicating potential future failure.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15). Power cycle the unit using the power switch on the back of the unit to clear the error.
RFID Read Error	RFID Read error message on main screen (RE) Audible alert 	<ol style="list-style-type: none"> 1. RFID Tag does not have correct string of data. 2. RFID Tag is unreadable. 3. No DEFINITY® vial in the cradle. 	Re-position the DEFINITY® vial in the carrier. If the error reoccurs, remove the vial and place a new DEFINITY® vial in the carrier. Do not use the DEFINITY® vial. Retain the vial and call Lantheus Medical Imaging (see page 15).
Cover Open (before start button pressed or pressed and doesn't work)	Cover open icon displayed 	Cover not closed prior to start of activation cycle.	Close the cover and press the START ▶ button

Error	Likely Cause of Message	Action Required by User	
Interrupted Cycle – STOP  button pushed	Interrupted Cycle error message on main screen (IC) Audible alert 	User pushed STOP  button mid-cycle, creates partially activated vial.	Do not use the DEFINITY® vial. Vial was not acceptably activated. The error will clear once the cover is opened, a new DEFINITY® vial is placed in the carrier, and the cover is closed.
Interrupted Cycle – Cover opened	Interrupted Cycle error message on main screen (IC) with cover open icon Audible alert 	User lifted cover mid-cycle, creates partially activated vial.	Do not use the DEFINITY® vial. Vial was not acceptably activated. Press the STOP  button to clear the error Place a new DEFINITY® vial in the carrier and initiate activation cycle by pressing the START  button.
Usage Count Alert	Usage Count Alert message on main screen (>95%) 	VIALMIX®RFID has exceeded 95% but less than 100% of the programmed limit of activation cycles.	Contact Customer Service immediately for a replacement VIALMIX®RFID (see page 15). VIALMIX®RFID will cease to operate once 100% of programmed limit of activation cycles has been reached.
Usage Count Error	Usage Count error message on main screen (100%) 	VIALMIX®RFID has reached the programmed limit of activation cycles and is no longer operational.	VIALMIX®RFID is no longer operational. Call Customer Service for a replacement VIALMIX®RFID (see page 15). VIALMIX®RFID must be properly disposed of at the end of its service life. Please contact Lantheus Medical Imaging for proper disposal.

TROUBLESHOOTING

Observed Issue	Likely Cause	Corrective Action Required
Display does not operate when power switch is on.	No main power	Check power supply and power cord connection
	Fuse is blown	Contact Lantheus Medical Imaging for assistance (see page 15).
Motor does not operate after START button is pressed.	Cover is open	Close the cover
VIALMIX®RFID stops during activation cycle.	Cover has been opened or STOP  button has been pressed during activation cycle.	Do not attempt to use the DEFINITY® vial since it was not acceptably activated. Do not open the cover during activation. Only press the STOP  button if needed.
	An error occurred during the activation cycle.	Do not use the DEFINITY® vial since it was not acceptably activated. Please refer to page 9 for a list of errors. Retain the vial and call Lantheus Medical Imaging (see page 15).
	Fuse is blown	Do not use the DEFINITY® vial since it was not acceptably activated. Retain the vial and call Lantheus Medical Imaging (see page 15).

MAINTENANCE

All internal components in VIALMIX®RFID are maintenance-free. Therefore, maintenance of any internal components of the unit is not required. If the unit is not operating as expected, please contact Lantheus Medical Imaging (See page 15). **Do not open unit housing or attempt to perform any maintenance or repair.**

CLEANING

All external surfaces of VIALMIX®RFID should be cleaned with a soft cloth and, if necessary, with 70% Isopropyl Alcohol, 3% Ammonia, or 1:500 dilution Sodium Hypochlorite. 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. Under no circumstances should any solvents or abrasive detergents be used since these can damage the plastic.

VIALMIX®RFID CALIBRATION AND REPLACEMENT PROCEDURES

No calibration is required for VIALMIX®RFID. Once powered on, VIALMIX®RFID will display the following when ready for use:



If VIALMIX®RFID is not functioning properly, contact Lantheus Medical Imaging (see page 15) to determine if a replacement unit is required.

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC)

VIALMIX®RFID has been tested for electrical safety and Electromagnetic Compatibility and found to be in compliance with the following standards:

IEC 60601-1 – General Safety

IEC 60601-1-2 – Electromagnetic Compatibility

FCC Part 15B – Unintentional Radiator

FCC Part 15C – Intentional Radiator

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

EMC CLASSIFICATION

VIALMIX®RFID is classified as Class A equipment as defined by FCC, CISPR-11, and 60601-1-2. VIALMIX®RFID is intended for professional use only in a hospital or clinical setting.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Specifications

Drive:	Ball-bearing brushless DC motor
Control System:	Microprocessor-controlled, high-precision shaking time and frequency
Vial Carrier:	Self-retaining
Construction:	Aluminum base and die cast zinc shaker frame; casing and cover made of high impact-resistant plastic
Shaking Frequency:	4530 rotations per minute
Shaking Duration:	45-second cycle
Recommended Operating Temperature/Humidity:	15 to 30° C / 20 to 55% Non-Condensing Relative Humidity
Storage Temperature/Humidity:	-20 to 55° C / 10 to 95% Non-Condensing Relative Humidity
Line Voltage:	100-240 V, 2 A, 50-60 Hz Voltage (V)/Amp (A)/Hertz (Hz) ratings are listed on the type plate on the back of the VIALMIX® RFID
Power Input:	330VA
Dimensions:	Height: 165 mm Depth: 195 mm Width: 195 mm
Weight:	3759 g
Fuses:	Time-lag fuses with amperage rating as listed on the type plate on the back of the VIALMIX® RFID
RFID Transceiver	
Frequency:	13.56 MHz per ISO 15693
Effective Radiated Power:	1.1mW
Modulation:	Amplitude Shift Keying (ASK/OOK), 100% Modulation Depth
FCC ID:	XXXXX-XXXXXXXX

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Commented [LPD1]: Place holder for when we receive the actual ID number. FCC is currently off-line due to government shutdown

CONTACT LANTHEUS MEDICAL IMAGING

If you are experiencing issues with VIALMIX®*RFID*, please call Lantheus Medical Imaging at:

(U.S.) 1-800-362-2668

For customer orders or for requesting a printed copy of the Instructions for Use, please call Lantheus Medical Imaging Customer Services at:

(U.S.) 1-800-299-3431

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