LANTHEUS™

VIALMIX® RFID

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

User's Guide/ Instructions for Use

516041-0723

Table of Contents

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* with RFID-tagged vials within 6 inches (15cm) of a pacemaker and/or defibrillator or any other implantable or body worn devices such as neurostimulators and insulin pumps.

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 both are operating normally. If any abnormalities in VIALMIX®*RFID* operation are observed (i.e. display screen distortion, unusual or unexpected noises, incomplete countdown, or power disruption) DO NOT use the DEFINITY® or DEFINITY® RT vial being activated as the vial may not have been properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18).

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. If any degradation of VIALMIX®*RFID* performance is observed (i.e. display screen distortion or power disruption) DO NOT use the DEFINITY® or DEFINITY® RT vial being activated. Vial may not have been properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Remove any possible source of RF emissions from area of operation of VIALMIX®*RFID* before attempting to activate another DEFINITY® or DEFINITY® RT vial. If the issue continues, please contact Lantheus Medical Imaging (see page 18).

- VIALMIX®*RFID* must only be operated with the lid closed and intact.
- Do not store vials under the lid. Only the DEFINITY® or DEFINITY® RT vial placed in the carrier 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 18). **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 18).

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® or DEFINITY® RT Vial for (Perflutren Lipid Microsphere) Injectable Suspension, an intravenous ultrasound contrast agent. DEFINITY® is supplied as a single use 2-mL clear glass Radio Frequency Identification (RFID)-tagged vial containing clear liquid. DEFINITY® RT is supplied as a single use 2-mL clear glass Radio Frequency Identification (RFID)-tagged vial containing a colorless, uniformly clear to translucent (hazy) viscous solution. Both products require 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® and DEFINITY® RT.

FEATURES OF VIALMIX®*RFID* INCLUDE:

- **Proper Activation of DEFINITY® and DEFINITY® RT**
  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® or DEFINITY® RT vial by hand will not activate the agent properly. Using VIALMIX®*RFID* to activate DEFINITY® or DEFINITY® RT will ensure proper activation of the agent and consistent product performance. DO NOT use a DEFINITY® or DEFINITY® RT 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 activation cycle
  2. ■ A STOP button for canceling the activation cycle if needed

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

  VIALMIX®*RFID* is equipped with an RFID reader. Once the DEFINITY® or DEFINITY® RT vial is loaded in the vial carrier and the cover is closed, VIALMIX®*RFID* will read the RFID tag embedded in the DEFINITY® or DEFINITY® RT 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® or DEFINITY® RT.

- **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

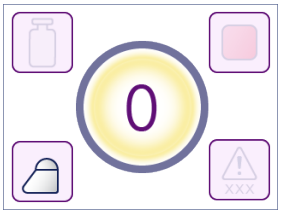
VIALMIX®*RFID* is packaged with a power cord and a Quick Reference Guide. Upon receipt of VIALMIX®*RFID* and prior to use with DEFINITY® or DEFINITY® RT, the user must perform the following steps.

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

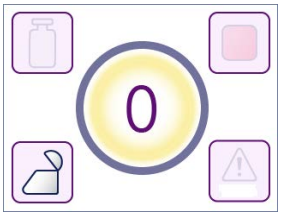
Powering On VIALMIX®*RFID*

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® or DEFINITY® RT Vial

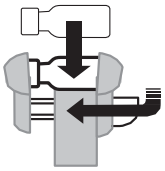
With the cover open, the vial carrier is easily accessed for vial loading. The following screen will be displayed after the cover is opened:



Perform the following steps to load the DEFINITY® or DEFINITY® RT vial.

1. The vial carrier is spring loaded and opens to accommodate the DEFINITY® or DEFINITY® RT 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® or DEFINITY® RT 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® or DEFINITY® RT.

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

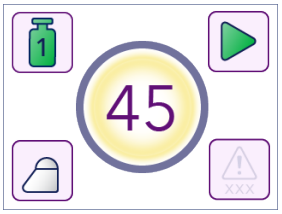


3. Release the lever and the spring action of the carrier will hold the vial securely. Make sure that the vial is evenly supported by both cups of the carrier.
4. Close the VIALMIX®*RFID* cover.

Activating the DEFINITY® or DEFINITY® RT Vial

With VIALMIX®*RFID* powered on, the vial in place, and the cover is closed, the following will be displayed when the user is ready to activate DEFINITY® or DEFINITY® RT. DEFINITY® is identified as 1 in the green vial icon in the upper left corner of the display. DEFINITY® RT is identified as 2 in the green vial icon in the upper left corner of the display.

DEFINITY®



DEFINITY® RT

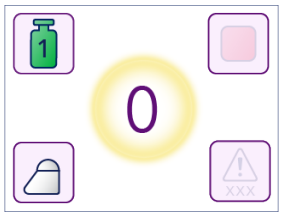
The activation time of "45", representing 45 seconds, will appear on the VIALMIX®*RFID* display. If it does not display, refer to the "Troubleshooting" section located on page 12.

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® or DEFINITY® RT 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:

DEFINITY®



DEFINITY® RT

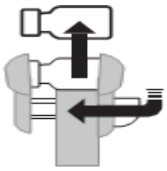
If the DEFINITY® or DEFINITY® RT vial does not shake for the full 45 second duration or at the acceptable rate, activation is not considered successful and the vial must not be used. An error message will be displayed and an audible alarm will sound to alert the user. Refer to page 9 for a list of error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

If an interruption in power (power failure) occurs during an activation cycle, the activation is not considered successful and the DEFINITY® or DEFINITY® RT vial must not be used. Once the power is restored, power cycle the unit using the power switch located on the back of the unit. A new DEFINITY® or DEFINITY® RT vial is required for activation.

Removing the DEFINITY® or DEFINITY® RT Vial

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



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

Powering Off VIALMIX®*RFID*

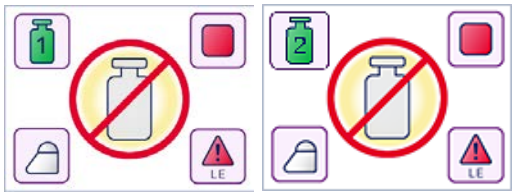
VIALMIX®*RFID* should be powered off at the end of the day. This is done by moving the switch on the back of the unit to the "O" position.

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® or DEFINITY® RT, 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. DEFINITY® is identified as vial 1 in the green vial icon in the upper left corner of the display and DEFINITY® RT is identified as vial 2 in the green vial icon in the upper left corner of the display.

Error	Associated VIALMIX® *RFID* Response	Likely Cause of Message	Action Required by User
HE High Oscillation Rate Error	High Oscillation Rate error message on main screen (HE) Audible alert **DEFINITY®** **DEFINITY® RT** 	DEFINITY® **or** DEFINITY® RT vial has shaken at higher than acceptable shake rate.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Press the STOP button to clear the error.
LE Low Oscillation Rate Error	Low Oscillation Rate error message on main screen (LE) Audible alert **DEFINITY®** **DEFINITY® RT** 	DEFINITY® **or** DEFINITY® RT vial has shaken at lower than acceptable shake rate.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Press the STOP button to clear the error.

Error	Associated VIALMIX® *RFID* Response	Likely Cause of Message	Action Required by User
MC Motor Overcurrent	Motor Overcurrent error message on main screen (MC) Audible alert **DEFINITY®** **DEFINITY® RT** 	Excess mechanical loading or motor failure.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Power cycle the unit using the power switch on the back of the unit to clear the error.
OH Thermal Fault	Thermal Fault error message on main screen (OH) Audible alert **DEFINITY®** **DEFINITY® RT** 	Unit is overheating.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Power the unit off and allow to cool. Once cooled, power the unit on using the power switch on the back of the unit.
MO Motor Overvoltage	Motor Overvoltage error message on main screen (MO) Audible alert **DEFINITY®** **DEFINITY® RT** 	Motor is operating higher than standard voltage condition indicating potential future failure.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Power cycle the unit using the power switch on the back of the unit to clear the error.
MU Motor Under voltage	Motor Under voltage error message on main screen (MU) Audible alert **DEFINITY®** **DEFINITY® RT** 	Motor is operating lower than standard voltage condition indicating potential future failure.	**Do not use the DEFINITY® or DEFINITY® RT vial.** Vial was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18). Power cycle the unit using the power switch on the back of the unit to clear the error.

Error	Associated VIALMIX® *RFID* Response	Likely Cause of Message	Action Required by User
RE RFID Read Error	RFID Read error message on main screen (RE) Audible alert 	1. RFID Tag does not have correct string of data. 2. RFID Tag is unreadable. 3. No DEFINITY® or DEFINITY® RT vial in the Carrier.	Re-position the DEFINITY® **or** DEFINITY® RT vial in the carrier. If the error re-occurs, remove the vial and place a new DEFINITY® vial in the carrier**.** **Do not use the DEFINITY® or DEFINITY® RT vial.** Retain the vial and call Lantheus Medical Imaging (see page 18).
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
IC 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® or DEFINITY® RT vial.** Vial was not properly activated. The error will clear once the cover is opened, a new DEFINITY® or DEFINITY® RT vial is placed in the carrier, and the cover is closed.
IC 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® or DEFINITY® RT vial.** Vial was not properly activated. Press the STOP ■ button to clear the error Place a new DEFINITY® or DEFINITY® RT vial in the carrier and initiate activation cycle by pressing the START ▶ button.

Error	Associated VIALMIX® *RFID* Response	Likely Cause of Message	Action Required by User
>95% Usage Count Alert	Usage Count Alert message on main screen (>95%) **DEFINITY®** **DEFINITY® RT** 	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 18). VIALMIX®*RFID* will cease to operate once 100% of programmed limit of activation cycles has been reached.**
100% 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 18). 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 18).
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® or DEFINITY® RT vial since it was not properly 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® or DEFINITY® RT vial since it was not properly activated. Please refer to page 9 for a list of errors. Retain the vial and call Lantheus Medical Imaging (see page 18).
	Fuse is blown	Do not use the DEFINITY® or DEFINITY® RT vial since it was not properly activated. Retain the vial and call Lantheus Medical Imaging (see page 18).

MAINTENANCE

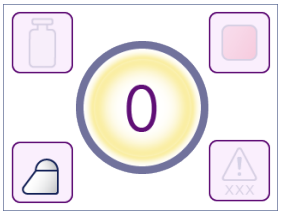
All internal components in VIALMIX®*RFID* are maintenance-free. Therefore, maintenance of any internal components of the unit is not required. If the unit is not operating as expected, please contact Lantheus Medical Imaging (See page 18). **Do not open unit housing or attempt to perform any maintenance 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 18) 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

The following is a summary of EMC testing:

Emissions Executive Test Summary		
Test Type	**Test Level**	**Compliance Level**
Conducted Emissions EN55011:2009 + A1:2010, IEC/CISPR 11:2009 +A1:2010, and EN55032:2012	Group 1, Class A 150 kHz to 30 MHz	Group 1, Class A 150 kHz to 30 MHz
Radiated Emissions EN55011:2009 + A1:2010, IEC/CISPR 11:2009 +A1:2010,and EN55032:2012	Group 1, Class A 30 MHz to 1 GHz	Group 1, Class A 30 MHz to 1 GHz
Harmonics IEC/EN 61000-3-2:2006/A2:2014	Class A Device	Per Clause 5 of the Standard
Flicker IEC/EN 61000-3-3:2013	Per Clause 5 of the Standard	Per Clause 5 of the Standard

Immunity Executive Test Summary		
Test Type	**Test Level**	**Compliance Level**
Electrostatic Discharge IEC/EN 61000-4-2	± 2, 4, 6 & 8kV contact discharge ± 2, 4, 8 & 15kV air discharge	± 2, 4, 6 & 8kV contact discharge ± 2, 4, 8 & 15kV air discharge
Radiated Immunity IEC/EN 61000-4-3 .	80 MHz - 6 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation	80 MHz - 6 GHz 3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation
Proximity field from RF wireless communications equipment IEC 61000-4-3	See Section 6.17.3.1 Or Table 9 of standard	See Section 6.17.3.1 Or Table 9 of standard
Conducted Immunity (AC Power) (I/O Lines) IEC/EN 61000-4-6	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains	0.15 - 80 MHz 3 Vrms & 6Vrms in ISM Band 1 kHz AC Mains
Electrical Fast Transients (AC Power) IEC/EN 61000-4-4	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz &100 kHz	±2 kV AC Mains ±1 kV I/O Lines 5/50 5kHz &100 kHz
Surge Line to Line (AC Power) IEC/EN 61000-4-5	±1 kV Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground
Magnetic Immunity IEC/EN-61000-4-8	30 A/m	30 A/m
Voltage Dips & Interruptions IEC/EN 61000-4-11	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T 5 Sec	0% U_T .5 cycle 0% U_T 1 cycle 70% U_T 25 cycles 0% U_T 5 Sec

General Requirements Summary				
Standards	**Description**	**Severity Level or Limit**	**Criteria**	**Results**
IEC 60601-1-2:2014 Clause 4.1	Risk Management Process for ME equipment and ME System	Per Section One, Clause 4	Verification of Electromagnetic Disturbance Risk Management	Complies
IEC 60601-1-2:2014 Clause 5	ME Equipment and ME System Identification, marking and documents	See requirements called out in standard.	Review	Complies

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 their own expense.

Changes or modifications not expressly approved by Lantheus Medical Imaging could void the user's authority to operate the equipment.

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 +/- 2% oscillations per minute for DEFINITY® 4950 +/- 2% oscillations per minute for DEFINITY® RT
Shaking Duration:	45-seconds
Recommended Operating Temperature/Humidity:	15 to 30° C / 20 to 95% 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:	330 VA
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:	2ASDC-VMIX2

CONTACT LANTHEUS MEDICAL IMAGING

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

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

Distributed in USA by:

Lantheus Medical Imaging, Inc.
331 Treble Cove Rd.
North Billerica, Massachusetts 01862 USA

Distributed in USA by:
Lantheus Medical Imaging
331 Treble Cove Road
North Billerica, Massachusetts 01862 USA
Telephone toll free: 1-800-362-2668
For Massachusetts and International: 1-978-667-9531

516041-0723 September 2023