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URGENT FIELD SAFETY NOTICE

Undetectable battery depletion in the event of recurrent shock capacitor charging

FSCA identifier:	**CRM201701**
Affected Devices:	Ovatio, Paradym, Paradym RF, Paradym 2 and Intensia Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)
Date:	April 11, 2017
Attention:	Physicians, Medical centers, Healthcare professionals
Reason:	LivaNova is notifying physicians of the possibility of undetectable battery depletion in the event of recurrent shock capacitor charging and what actions to take

Dear Doctor:

You are receiving this notification because according to our records, you may have some patients implanted with an Ovatio, Paradym, Paradym RF, Paradym 2 or Intensia ICD or CRT-D.

What is the issue?
In the event of a right ventricular lead issue (e.g. broken or disconnected lead), recurrent shock capacitor charging due to ventricular oversensing may result in depletion of the ICD or CRT-D battery. Because the battery status is not updated for a 24-hour period following a charge, battery depletion may remain undetectable during the 24 hours following the last charge. Recurrent charging will stop either after deactivation of the shock therapies, or when the oversensing stops, such as in the case of a lead revision.
Attachment 1 provides a list of warnings and observations that can potentially be displayed in case of a lead issue or battery depletion.

How does this affect patients?
If an updated battery status is not obtained prior to the lead revision, the need for an ICD or CRT-D replacement cannot be assessed. If the battery is found to be depleted after the lead revision, adequate therapy may not be available and the patient may have to undergo another surgical procedure to replace the ICD or CRT-D.

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What actions should physicians take?
If you have decided to revise the right ventricular lead due to oversensing issues, the following steps should be taken:

1. Prior to lead revision:
    a) Deactivate the shock therapies to avoid further charging[1],
    b) Wait 24 hours[1], and
    c) Re-interrogate the ICD or CRT-D to check the updated battery status. If RRT is reached, initiate a device replacement.

Or

2. If it is not possible to wait 24 hours prior to replacing the lead, the lead revision may be performed as scheduled and the device may be replaced prophylactically during the same procedure since the battery status is unknown.

LivaNova has communicated this information to the Competent Authority of your country.

Please make sure that all personnel involved in the management of patients implanted with Ovatio, Paradym, Paradym RF, Paradym 2 or Intensia ICDs or CRT-Ds in your organization are aware of the information outlined in this letter.

Please complete and return the Customer Reply Form as soon as possible to acknowledge that you have read and understand this Field Safety Notice. Returning the Customer Reply Form will also prevent repeat notifications of this notice.

If you need further information, please contact your local LivaNova representative or contact LivaNova at 01452 638500. We appreciate your assistance in this matter.

Sincerely,

Carmel Breen
LivaNova UK CRM Local QA Representative

Enclosed:
- Attachment 1: List of potential warnings
- Attachment 2: Customer Reply Form

[1] These operations should be performed by medical personnel in an appropriate care unit, with resuscitation equipment present, and after having weighted the benefit/risks for the patient.

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Attachment 1

List of potential warnings

Ovatio[2]	Paradym family[3]	Paradym RF family[4]	RMS[5]	Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System
X	X			[2] Charge time > 40 s: x. Defibrillation system potentially ineffective.
X	X	X		[3] Low shock impedance. Defibrillation system potentially ineffective.
X				Load resistance of last shock < 0 ohm
X	X	X	X	[4] Last shock impedance > 150 ohms. Defibrillation system potentially ineffective.
X	X			[6] Ventricular lead impedance < 200 ohms: x Defibrillation system potentially ineffective.
		X	X	[6] Ventricular lead impedance < x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[7] Right ventricular lead impedance < 200 ohms: x Defibrillation system potentially ineffective.
		X	X	[7] RV lead impedance < x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[8] Left ventricular lead impedance < 200 ohms: x
		X	X	[8] LV lead impedance < x ohms: x, x/x/x.
X	X			[10] Ventricular lead impedance > 3000 ohms: Defibrillation system potentially ineffective.
		X	X	[10] Ventricular lead impedance > x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[11] Right ventricular lead impedance > 3000 ohms: Defibrillation system potentially ineffective.
		X	X	[11] RV lead impedance > x ohms: x, x/x/x. Defibrillation system potentially ineffective.
X	X			[12] Left ventricular lead impedance > 3000 ohms
		X	X	[12] LV lead impedance > x ohms: x, x/x/x.
		X	X	[14] RV shock electrode continuity > 3000 Ohms x/x/x. Defibrillation system potentially ineffective.
	X			[15] Ventricular shock electrode continuity > 3000 Ohms: defibrillation system ineffective.
X				[16] Ventricular shock electrode continuity ABNORMAL : defibrillation system potentially ineffective.
X	X	X	X	[17] Battery depletion detected (end of life indicator): replace the device. Magnet rate (min-1) : x
X				[18] ERI (Elective Replacement Indicator) detected: plan to replace device. Magnet rate (min-¹) : x
	X	X	X	[18] R.R.T. (Recommended Replacement Time) detected: plan to replace device.
X	X	X		[19] Abnormal battery voltage values from x/x/x to x/x/x. Defibrillation system potentially ineffective.
X	X	X		[20] Abnormal battery voltage measured since x/x/x. Defibrillation system potentially ineffective.
X				[28] Last battery voltage measurement abnormal.

[2] Ovatio VR 6250, Ovatio DR 6550, Ovatio CRT 6750
[3] PARADYM VR 8250, PARADYM DR 8550, PARADYM CRT-D 8750, PARADYM SonR 8770
[4] PARADYM SonR TriV 8970, PARADYM 2 VR 8252, PARADYM 2 DR 8552, PARADYM 2 CRT-D 8752, PARADYM 2 SonR CRT-D 8772, PARADYM RF VR 9250, PARADYM RF DR 9550, PARADYM RF CRT-D 9750, PARADYM RF SonR 9770, INTENSIA VR 124, INTENSIA DR 154, INTENSIA CRT-D 174, INTENSIA SonR CRT-D 184
[5] Remote Monitoring System

Ovatio[2]	Paradym family[3]	Paradym RF family[4]	RMS[5]	Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System
	X	X		[29] Last battery voltage measurement abnormal.
X	X			[34] Last charge time (s): x. Defibrillation system ineffective.
X	X			[35] Max energy charge time > 40 s: x Defibrillation system potentially ineffective.
X	X			[37] Last saved ventricular lead impedance < 200 ohms: x (x x x), defibrillation system potentially ineffective.
X	X			[38] Last saved right ventricular lead impedance < 200 ohms: x (x x x), defibrillation system potentially ineffective.
X	X			[39] Last saved left ventricular lead impedance < 200 ohms: x (x x x)
X	X			[41] Last saved ventricular lead impedance > 3000 ohms (x x x), defibrillation system potentially ineffective.
X	X			[42] Last saved right ventricular lead impedance > 3000 ohms (x x x), defibrillation system potentially ineffective.
X	X			[43] Last saved left ventricular lead impedance > 3000 ohms (x x x)
	X			[45] Low shock impedance detected on x x x: defibrillation system ineffective.
	X			[46] High shock impedance detected on x x x: defibrillation system ineffective.
	X			[47] Excessive electrical consumption detected on x x x. Risk that system is ineffective.
	X			[48] Max shock energy ineffective on x x x
	X			[50] Suspected abnormal ventricular lead impedance on x x x (x): defibrillation system potentially ineffective.
	X			[51] Suspected abnormal right ventricular lead impedance on x x x (x): defibrillation system potentially ineffective.
	X			[52] Suspected abnormal left ventricular lead impedance on x x x (x).
	X			[53] Abnormal RV coil impedance on x x x: defibrillation system ineffective.
	X			[54] Abnormal SVC coil impedance on x x x: defibrillation system ineffective.
	X			[55] Insufficient electrical performance detected on x x x: defibrillation system ineffective.
	X			[56] Charge time > 25 s on x x x: defibrillation system potentially ineffective.
	X			[57] R.R.T. (Recommended Replacement Time) detected on x x x: plan to replace device.
		X		[58] Last shock energy delivered (J) : x. Defibrillation system potentially ineffective.
X	X			Delivered energy of last shock (J) : x
		X	X	[62] Excessive charge time detected. Defibrillation system potentially ineffective.
		X		[63] xV lead impedance < x ohms: x, x/x/x. (Applicable to TriV only)
		X		[64] xV lead impedance > x ohms: x, x/x/x. (Applicable to TriV only)
	X			[73] The last battery voltage measurement was performed more than 3 days ago. An updated measurement will be displayed 24hrs after the latest capacitor charge.
		X	X	[A1] Low shock impedance on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A2] High shock impedance on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A4] Max shock energy ineffective on x/x/x.
		X	X	[A9] Ventricular lead impedance < x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A11] Ventricular lead impedance > x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A13] RV lead impedance < x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A15] RV lead impedance > x ohms: x, x/x/x, x. Defibrillation system potentially ineffective.
		X	X	[A17] LV lead impedance < x ohms: x, x/x/x, x.
		X	X	[A19] LV lead impedance > x ohms: x, x/x/x, x.

Ovatio[2]	Paradym family[3]	Paradym RF family[4]	RMS[5]	Warnings/Observations potentially displayed by the programmer or received through the Remote Monitoring System
		X	X	[A21] RV shock electrode continuity > 3000 Ohms on x/x/x. Defibrillation system potentially ineffective.
		X	X	[A24] Excessive Charge Time, x/x/x. Defibrillation system potentially ineffective.
		X	X	[A25] R.R.T. (Recommended Replacement Time) detected x/x/x: plan device replacement.
		X	X	[A27] Percentage of V pacing in CRT less than [programmed threshold]%: [dd/mon/yyyy].
		X	X	[A28] AT/AF Daily Burden higher than [programmed threshold]: [value measured], [dd/mon/yyyy].
		X	X	[A31] Shocks delivered, x/x/x.
		X	X	[A32] Ineffective shocks delivered, x/x/x.
		X	X	[A33] V oversensing suspected.
		X		[A35] xV lead impedance < x ohms: x, x/x/x, x. (Applicable to TriV only)
		X		[A37] xV lead impedance > x ohms: x, x/x/x, x. (Applicable to TriV only)

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Attachment 2

Customer Reply Form

1. FSN information	
FSN Reference	CRM201701
FSN Date	April 11, 2017
Device(s)	Ovatio, Paradym, Paradym RF, Paradym 2, Intensia

2. Customer Details	
Organization Name	
Organization Address	
Department/Unit	
Shipping address if different from above	
Contact Name	
Telephone number	
Email	

3. Customer action undertaken		
☐	I confirm receipt of the Field Safety Notice. The information and required actions have been brought to the attention of all relevant users.	*Customer to fill in or enter N/A*
☐	I have identified and/or quarantined affected devices - enter number of devices and date complete	*Customer to fill in or enter N/A* *N/A*
☐	I have returned affected devices - enter number of devices returned and date complete	*Customer to fill in or enter N/A* *N/A*
☐	I have destroyed affected devices – enter number destroyed and date complete	*Customer to fill in or enter N/A* *N/A*
☐	I do not have any affected devices	*Customer to fill in or enter N/A*
☐	I have a query please contact me	*Customer to enter contact details if different from above and brief description of query*

Print Name	Signature	Date
Customer print name here	*Customer sign here*	*Date here*

4. Return acknowledgement to Manufacturer/Supplier/Distributor	
Email	***Carmel.breen@Livanova.com***
Fax	***01452 638530***
Customer Helpline	***01452 638500***
Postal Address	***LivaNova UK Ltd, CRM Division, 1370 Montpellier Court, Gloucester Business park, Glocs GL3 4AH***

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5. Distributors/Suppliers Only		
☐	I have checked my stock and quarantined inventory	*Distributor/Supplier to enter quantity and date, or enter N/A* *N/A*
☐	I have identified customers that received or may have received this device and attached a list of customers	
☐	I have attached a list of customers that have confirmed receipt of the FSN	
☐	Neither I nor any of my customers has any affected devices in inventory	

Print Name	Signature	Date
Distributor print name here	*Distributor sign here*	*Date here*

It is important that your organization takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organization's reply is the evidence that we need to monitor the progress of the corrective actions.