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Health innovation that matters

Vigtig sikkerhedsmeddelse

Uopdaget fuldstændig batteriafladning efter gentagen shock kapacitor opladning

FSCA identitet:	**CRM201701**
Berørte enheder:	Ovatio, Paradym, Paradym RF, Paradym 2 og Intensia Implantable Cardioverter Defibrillators (ICDs) og Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)
Dato:	11. april, 2017
Attention:	Læger, Hospitaler, Sundhedspersonale
Årsag:	LivaNova underretter læger om risikoen for uopdaget fuldstændig batteriafladning efter gentagen shock kapacitor opladning og om hvilke forholdsregler der skal tages.

Kære Doktor:

Du modtager denne information da du ifølge vores fortegnelser kan have nogle patienter som har implanteret en af disse enheder: Ovatio, Paradym, Paradym RF, Paradym 2 eller Intensia ICD eller CRT-D.

Hvad er problemet?
I tilfælde at et problem med RV ledningen (f eks brud eller dårlig forbindelse), kan gentagen kapacitoropladning, som følge af ventrikulær oversensing, føre til fuldstændig afladning af batteriet i ICD'en eller CRT-D'en. Da batteristatus ikke bliver opdateret i 24 timer efter en opladning kan en fuldstændig batteriafladning være uopdaget i 24 timer efter sidste opladning. Den gentagne opladning vil standse ved deaktivering af shockterapi, eller når oversensing ophører, f eks i forbindelse med en ledningsrevision.
Bilag 1 viser en liste over advarsler og observationer som kan vises af programmeren i tilfælde af et ledningsproblem eller batteriafladning.

Hvordan påvirker dette patienterne?
Hvis batteristatus ikke er opdateret forud for en ledningsrevision er det ikke muligt at afgøre behovet for et samtidigt generatorskifte. Hvis batteriet viser sig at være afladet efter ledningsrevisionen er det ikke sikkert at nødvendig terapi er mulig og patienten risikerer at måtte gennemgå endnu en kirurgisk procedure for at udskifte generatoren.

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Hvad skal lægen gøre?
Hvis du har besluttet at revidere RV ledningen pga oversensing bør du gøre følgende:

1. Forud for ledningsrevision:
   a) Deaktiver shockterapier for at undgå yderligere opladning[1],
   b) Vent I 24 timer[1], og
   c) Interroger ICD'en eller CRT-D'en igen for at kontrollere den opdaterede batteristatus. Hvis RRT er nået, udskift da enheden.

   Eller

2. Hvis det ikke er muligt at vente 24 timer før udskiftning af ledningen kan ledningsrevisionen udføres som planlagt og enheden udskiftes forebyggende i samme procedure da batteristatus er ukendt.

LivaNova har sendt denne information til den ansvarlige myndighed i Danmark.

Vær venlig at sikre dig at alt personale i din organisation, som er involveret i håndtering af patienter som har implanteret en Ovatio, Paradym, Paradym RF, Paradym 2 eller Intensia ICD eller CRT-D, er opmærksomme på den information som er givet i dette brev.

Udfyld og retuner venligst vedhæftede Svarformular (Bilag 2) så hurtigt som muligt for at tilkendegive at du har læst og forstået denne "Vigtige Sikkerhedsmeddelelse" (FSN). Returnering af svarformularen vil også forhindre yderliger henvendelser om dette.

Kontakt venligst din lokale LivaNova repræsentant eller LivaNova hvis du ønsker mere information, [*Sten Andersen +45 2999 0480*]. På forhånd tak for hjælpen.

Med venlig hilsen,

Sten Andersen
Nordic Product Manager, CRM

Vedhæftet:
- Bilag 1: Liste over mulige advarsler
- Bilag 2: Svarformular

[1] Disse tiltag skal udføres af medicinsk personale på en passende afdeling, hvor der er genoplivningsudstyr til stede og efter at have overvejet fordele og ulemper for patienten.

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Bilag 1

Liste over mulige advarsler

Ovatio[2]	Paradym family[3]	Paradym RF family[4]	RMS[5]	Advarsler/observationer som kan vises på programmeren eller via fjernmonitoreringssystemet (RMS)
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.

[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]	Advarsler/observationer som kan vises på programmeren eller via fjernmonitoreringssystemet (RMS)
X				[28] Last battery voltage measurement abnormal.
	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

Ovatio[2]	Paradym family[3]	Paradym RF family[4]	RMS[5]	Advarsler/observationer som kan vises på programmeren eller via fjernmonitoreringssystemet (RMS)
				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.
		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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Bilag 2

Svarformular

1. FSN information	
FSN Reference	CRM201701
FSN Dato	April 11, 2017
Enheder	Ovatio, Paradym, Paradym RF, Paradym 2, Intensia

2. Kundeoplysninger	
Organisationsnavn	
Organisations Adresse	
Afdeling	
Postadresse	
Kontaktnavn	
Telefon	
E-mail	

3. Kundens handlinger		
☐	Jeg bekræfter at have modtaget denne FSN. Denne information og de nødvendige handlinger er blevet meddelt alle relevante brugere.	*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*
☐	Jeg har ingen enheder der er omfattet af dette	*Customer to fill in or enter N/A*
☐	Jeg har en forspørgsel, kontakt mig venligst	*Evt kontaktoplysninger*

Navn	Underskrift	Dato
Kundens navn	*Kundens underskrift*	*Dato*

4. Returnering af svar	
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Det er vigtigt at din organisation handler som beskrevet i denne ”Vigtig information” (FSN) og bekræfter at du har modtaget den.

Din organisations svar på denne er det bevis vi behøver for at følge fremskridtet i de korrektive handlinger.