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[Physician / medical center contact information to be inserted]

September 29th, 2016

Urgent Field Safety Notice

Applicable to REPLY, ESPRIT, KORA and FACIL[1] pacemakers

manufactured by Sorin Group Italia S.r.l.

Improved residual longevity displayed by the programmer

Dear Doctor,

This letter provides information about a new software version[2] that improves the accuracy of **the estimated residual longevity** calculated and displayed by the programmer during a follow-up exam of patients implanted with LivaNova[3] pacemakers.

The overall longevity of these devices is not affected.

When an implanted device approaches the Recommended Replacement Time (RRT[4]), the previous, less accurate, residual longevity estimate provided by the programmer at follow-up could result in reaching RRT between two follow-up visits. No permanent injury or death has occurred as a result of this inaccuracy.

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[1] FACIL pacemakers are only commercialized in Japan

[2] The following versions are concerned:
- SmartView 2.54 version (or higher) in European Community
- SmartView 2.54J (or higher) in Japan
- SmartView 2.52UG1 and 2.52UC1 (or higher) in US
- SmartView 2.54UG2 (or higher) in Canada
- RMS3.7 (or higher) for SmartView Hotspot in European Community, Japan and US

[3] LivaNova PLC is a U.K. holding company with a number of wholly-owned subsidiaries. In this document, we refer to all entities using the brand name LivaNova.

[4] Formerly described as ERI or Elective Replacement Indicator

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Overestimation of the displayed residual longevity has been reported among the following pacemaker models:

- REPLY Models D, DR, VDR, SR
- ESPRIT Models D, DR, S, SR
- FACIL Model DR

We began commercial distribution of these devices in 2008. As a result, under typical use conditions[5], the number of devices expected to reach RRT is limited today.

To assist you in adjusting the follow-up interval, especially when nearing the RRT, LivaNova has taken corrective actions by developing a new programmer software version[2] that displays more accurate residual longevity values. In addition, the residual longevity will be re-calculated upon changes in programmed settings during a follow-up session.

Background information

When the pacemaker is interrogated by the programmer, the programmer software displays four different indicators of the battery status:

- Time to RRT: estimated residual longevity of the device. This estimation is based on the programmed pacemaker settings, the percentage of pacing events, the lead impedance values and the measured battery impedance at the time of the interrogation.
- Last battery impedance measurement (measurement performed every day).
- Magnet rate: the magnet rate is equal to 96min^{-1} at Beginning of Service (BOS) and 80min^{-1} at RRT; its value depends on the battery impedance.
- Color-coded gauge representing the battery status according to the battery impedance.

[5] Refer to the user manual for battery longevity in different conditions

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Description

As of August 31, 2016, LivaNova received thirty-one (31) reports (i.e. 0.006 %) of overestimation of the displayed residual longevity during use of the current programmer software version[6].

Pacing functions were maintained between follow-ups in all thirty-one (31) reported cases; the RRT was reached between follow-up exams in 14 of these 31 cases (0.003 %). No permanent injury or death has occurred as a result of the reported events.

In-depth investigation of these reported events revealed that the overall device longevity and battery capacity is unaffected, meeting device specifications. Analysis of these cases and real-time battery depletion tests determined that the root cause was due to greater than expected variability in battery discharge profiles.

LivaNova actions to address the issue

LivaNova has taken corrective actions to address this issue. We will release a new programmer software version[2] to improve the Time to RRT. Your Sorin representative will contact you to upgrade the software in your facility's programmer.

The new programmer software version displays a more accurate estimated residual longevity, corresponding to a **typical** battery discharge profile. In addition, when approaching the RRT, it provides a **minimal** residual longevity estimation to cover the variability in battery characteristics (please refer to Annex 1).

Also, the residual longevity is re-calculated upon changes in programmed settings during a follow-up session.

LivaNova is **preventively** extending these actions to the following new pacemaker models that were fully commercialized starting from 2013:

- REPLY 200 Models DR, SR
- REPLY 250 Model DR[7]
- KORA 100 Models DR, SR
- KORA 250 Models DR, SR
- REPLY CRT-P

The overall longevity of REPLY, ESPRIT, FACIL, REPLY 200, REPLY 250, KORA 100, KORA 250 and REPLY CRT-P pacemakers is NOT impacted by this change *and corresponds to what is stated in the instructions for use.*

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[6] The following versions are concerned:
- SmartView 2.40 to 2.50 in European Community
- SmartView 2.40J to 2.50J in Japan
- SmartView 2.40UG1 (and 2.40UC1) to 2.50UG1 (and 2.50UC1) in US
- SmartView 2.42UG2 in Canada

[7] Reply 250 is limited to the AUTOMAAT clinical study

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Patient Management Recommendations

After consulting with LivaNova CRM's independent Product Performance Monitoring Board, LivaNova recommends:

<table>
<tr><th>#</th><th>Recommendation</th><th>Applicable to the following patients</th><th>Applicable to the following models</th></tr>
<tr><td>1</td><td><u>Pending the first pacemaker interrogation with the new programmer software</u>:
For pacemaker-dependent patients implanted with single or dual chamber pacemaker models[8], you should consider checking the battery impedance and the residual longevity displayed during the last follow-up exam[9]. Based on these two values, the Annex 2 provides the new recommended follow-up interval.</td><td>Pacemaker-dependent patients</td><td>All, except Reply CRT-P</td></tr>
<tr><td rowspan="2">2</td><td rowspan="2"><u>Once the programmer software is upgraded</u>:
When the minimal estimated residual longevity <u>displayed by the new programmer software version</u> is less than or equal to 12 months:
a. We recommend conducting patient follow-up visit at an interval that is between the minimal and the typical residual longevities displayed by the programmer, without exceeding 12 months (i.e. the annual standard follow-up).
b. For pacemaker-dependent patients, we recommend conducting patient follow-up visit at an interval equal to the minimal residual longevity displayed by the programmer.
Refer to Annex 1.</td><td>2.a:
Non pacemaker-dependent patients</td><td rowspan="2">All</td></tr>
<tr><td>2.b:
Pacemaker-dependent patients</td></tr>
</table>

[8] List of single or dual chamber pacemaker models: REPLY Models D, DR, VDR, SR; ESPRIT Models D, DR, S, SR; FACIL Model DR; REPLY 200 Models DR, SR; REPLY 250 Model DR; KORA 100 Models DR, SR; KORA 250 Models DR, SR.

[9] If the last follow-up exam was performed with a SmartView version before 2.40 (in Europe); 2.40J (in Japan); 2.40UG1 (in US); 2.42UG2 (in Canada), the Annex 2 cannot be used to schedule the follow-up interval. Contact your LivaNova representative.

#	Recommendation	Applicable to the following patients	Applicable to the following models
3	When the residual longevity indicators are not available through the programmer, a maximum of 6 month follow-up interval should be applied when the battery impedance becomes greater than or equal to 3.5 kΩ. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
4	When pacemaker operation is checked by the simple application of a magnet: a magnet rate less than 95 min^{-1} should trigger a follow-up exam in the pacemaker centre, and in any case the follow up interval should not be greater than 6 months. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
5	Annual standard follow-up. *This recommendation applies now, and remains applicable after the upgrade.*	All	All
6	The device should be replaced as soon as the RRT point is reached. The RRT is defined as follows: • 10kΩ (magnet rate of 80min^{-1}) for single and dual chamber pacemaker models • 8.5kΩ (magnet rate of 80min^{-1}) for Reply CRT-P *This recommendation applies now, and remains applicable after the upgrade.*	All	10kΩ for non CRT-P models 8.5kΩ for Reply CRT-P

LivaNova has communicated this information to [*Name of the Local Competent Authority to be added*].

Please make sure that all personnel involved in the management of patients implanted with REPLY, ESPRIT, FACIL, REPLY 200, REPLY 250, KORA 100, KORA 250 and REPLY CRT-P pacemakers in your organization are aware of the information outlined in this letter.

We hope that this software upgrade helps improve the level of care for your patients. If you have any questions, please contact your local LivaNova representative or contact LivaNova at [*local phone number to be inserted*].

Sincerely,

Enclosed:

- Annex 1
- Annex 2
- Customer Reply Form

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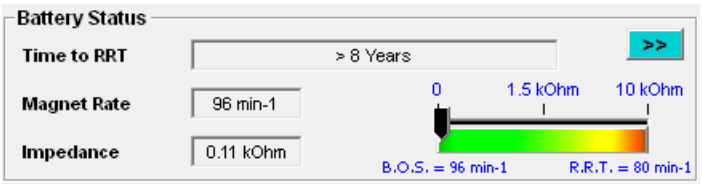
Annex 1

The new programmer software version displays a more accurate estimated residual longevity, corresponding to a **typical** battery discharge profile. In addition, when approaching the RRT, it provides a **minimal** residual longevity estimation to cover the variability in battery characteristics.
Also, the residual longevity is re-calculated upon changes in programmed settings during a follow-up session.

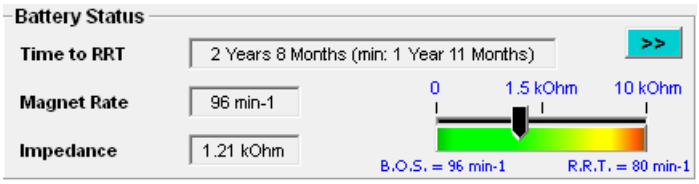
With the new programmer software version, the Time to RRT is displayed as follows:

- If the **typical estimated time to RRT** is **>3 years**, the "*typical time to RRT"* is displayed and the corresponding text field background is grey.

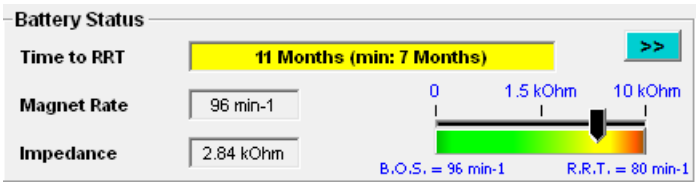


- If the **typical and minimal estimated time to RRT** are **between 3 months and 3 years**, the "*typical time to RRT in years and months (Minimal time to RRT)"* are displayed and:

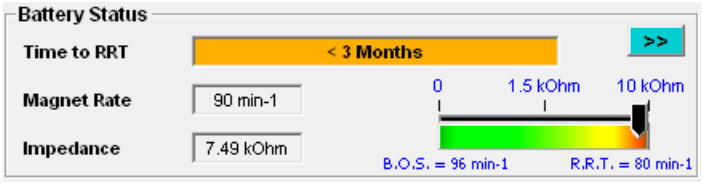
  - the corresponding text field background is grey, if the **minimal estimated time to RRT is >12 months;**



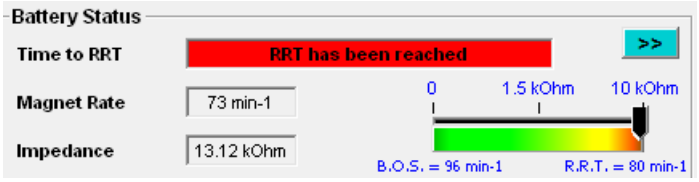
  - The corresponding text field background is yellow, if **the minimal estimated time to RRT is ≤12 months.** A Warning will be displayed *"In the current conditions of use, the minimum residual longevity ≤ 12 months."*



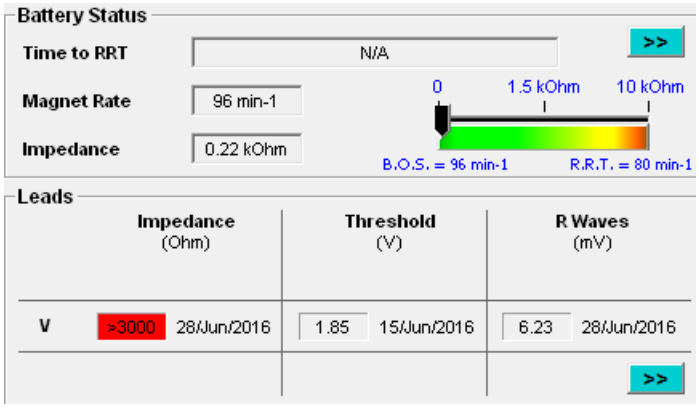
- If the **minimal estimated time to RRT** is **<3 months**, *"< 3 months*" is displayed and the corresponding text field background is orange. A Warning will be displayed: *"In the current conditions of use, the minimum residual longevity ≤ 3 months."*



- If the **RRT has been reached**, "*RRT has been reached*" is displayed and the corresponding text field background is red.



- "*NA*" is displayed in the text field, and the corresponding text field background is grey:
  - If less than 5 minutes statistics are available (i.e. first interrogation at implant, device reset),
  - If lead impedance is abnormal (< 200 and ≥ 3000 Ω) in any of the programmed cavity.



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Annex 2

The table overleaf provides the new recommended follow-up interval for pacemaker-dependent patients implanted with single or dual chamber pacemaker models [10]:

- **REPLY Models D, DR, VDR, SR**
- **ESPRIT Models D, DR, S, SR**
- **FACIL Model DR**
- **REPLY 200 Models DR, SR**
- **REPLY 250 Model DR**[7]
- **KORA 100 Models DR, SR**
- **KORA 250 Models DR, SR**

Pending the availability of the new programmer software version: for **pacemaker-dependant** patients implanted with **single** or **dual** chamber pacemaker models, you should consider checking the battery impedance and the residual longevity displayed during the last follow-up exam[9]. Based on these two values, and provided that the settings were not reprogrammed during the last follow-up, the table overleaf provides the new recommended follow-up interval (X months). A follow-up visit must be scheduled within a maximum of X months from the last follow-up visit. During the next follow-up:

- If the battery impedance is greater than or equal to 10 kOhms, the pacemaker should be replaced.
- If the battery impedance is inferior to 10 kOhms:
    - If your programmer software is not upgraded yet, use the table overleaf to schedule the follow-up interval.
    - If your programmer software is upgraded[11]: When the minimal estimated residual longevity displayed by the new programmer software version is less than or equal to 12 months, we recommend conducting patient follow-up visit at an interval that is between the minimal and the typical residual longevities displayed by the programmer, without exceeding 12 months (i.e. the annual standard follow-up). For pacemaker-dependent patients, we recommend conducting patient follow-up visit at an interval equal to the minimal residual longevity displayed by the programmer.

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[10] This recommendation does **not** apply to patients implanted with Reply CRT-P model.

[11] To one of the following versions:
- SmartView 2.54 version (or higher) in European Community
- SmartView 2.54J (or higher) in Japan
- SmartView 2.52UG1 and 2.52UC1 (or higher) in US
- SmartView 2.54UG2 (or higher) in Canada

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Recommended follow-up interval (X months)		Battery impedance displayed at last follow-up (kOhms)												
		1.0 kΩ	1.5 kΩ	2.0 kΩ	2.5 kΩ	3.0 kΩ	3.5 kΩ	4.0 kΩ	4.5 kΩ	5.0 kΩ	5.5 kΩ	6.0 kΩ	6.5 kΩ	7.0 kΩ
Time to RRT displayed at last follow-up[9] (months)	**34 M**	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	33 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	32 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	31 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	30 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	29 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	28 M	12 M	12 M	12 M	12 M	12 M	NA	NA	NA	NA	NA	NA	NA	NA
	27 M	12 M	12 M	12 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA	NA
	26 M	12 M	12 M	9 M	9 M	9 M	12 M	NA	NA	NA	NA	NA	NA	NA
	25 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	24 M	12 M	12 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	23 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	22 M	12 M	9 M	9 M	9 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	21 M	12 M	9 M	9 M	6 M	9 M	9 M	NA	NA	NA	NA	NA	NA	NA
	20 M	9 M	9 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA	NA
	19 M	9 M	9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA
	18 M	9 M	9 M	6 M	6 M	6 M	6 M	9 M	NA	NA	NA	NA	NA	NA
	17 M	9 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	16 M	9 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	15 M	6 M	6 M	6 M	6 M	6 M	6 M	6 M	NA	NA	NA	NA	NA	NA
	14 M	6 M	6 M	6 M	3 M	3 M	6 M	6 M	6 M	NA	NA	NA	NA	NA
	13 M	6 M	6 M	3 M	3 M	3 M	3 M	6 M	6 M	NA	NA	NA	NA	NA
	12 M	6 M	3 M	3 M	3 M	3 M	3 M	6 M	6 M	NA	NA	NA	NA	NA
	11 M	6 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	6 M	NA	NA	NA	NA
	10 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA	NA
	9 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA	NA
	8 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	3 M	NA	NA	NA
	7 M	3 M	3 M	ASAP	ASAP	ASAP	ASAP	3 M	3 M	3 M	3 M	NA	NA	NA
	6 M	3 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	3 M	3 M	3 M	ASAP	NA	NA
	5 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	NA
	4 M	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP	ASAP

- This table should be used for pacemaker-dependent patients implanted with single or dual chamber pacemaker models: REPLY Models D, DR, VDR, SR; ESPRIT Models D, DR, S, SR; FACIL Model DR; REPLY 200 Models DR, SR; REPLY 250 Model DR; KORA 100 Models DR, SR; KORA 250 Models DR, SR.
- This table does not apply to patients implanted with Reply CRT-P model.
- If the last follow-up exam was performed with a SmartView version before 2.40 (in Europe); 2.40J (in Japan); 2.40UG1 (in US); 2.42UG2 (in Canada), this table cannot be used to schedule the follow-up interval. Contact your LivaNova representative.
- If some of the following settings were reprogrammed during the last follow-up, this table may not be applicable: pacing mode, pacing amplitude(s), pulse width(s), rate response, sensors, auto-threshold, basic rate.
  If the reprogramming tends to increase the current consumption (e.g. higher pacing amplitude, longer pulse width etc.), contact your LivaNova representative.
  If the reprogramming tends to decrease the current consumption, it is safe to use the above table.
- NA: Not Applicable. NA indicates that it is not possible that this combination (battery impedance; Time to RRT) was displayed during the last follow-up.
- ASAP: a follow-up should be scheduled without delay. We recommend that this anticipated follow-up take place within 1 month from the previous follow-up visit.

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Customer Reply Form

1. FSN information	
FSN Reference	Improved residual longevity displayed by the programmer
FSN Date	September 29th, 2016
Device(s)	Reply, Esprit, Kora, Facil

2. Customer Details	
Account Number	
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*

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4. Return acknowledgement to Manufacturer/Supplier/Distributor	
Email	*Pre-filled by manufacturer*
Fax	*Pre-filled by manufacturer*
Customer Helpline	*Pre-filled by manufacturer*
Postal Address	*Pre-filled by manufacturer*

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	*Distributor/Supplier to fill in or enter N/A*
☐	I have attached a list of customers that have confirmed receipt of the FSN	*Distributor/Supplier to fill in or enter N/A*
☐	Neither I nor any of my customers has any affected devices in inventory	*Distributor/Supplier to fill in or enter N/A*

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.