Premarket Approval [PMA] Review
180-Day Supplement
P950037/S088

Date: April 20, 2011
To: The Record
From:

Office: ODE
Division: DCD

Device Name: Reliaty External Pacemaker Pulse Generator
Model 3145 External Pacemaker Pulse Generator

PMA Holder: Biotronik, Inc.
Lead Reviewer: Biomedical Engineer
Consultants: , EMC/EMI Review
, Software

Recommendation: Approve

Date

Date

I. Purpose and Submission Summary

Amendment 1 (A001) is in response to February 11, 2011 letter which identified four major deficiencies:

1. EMC Testing
2. EMC Test set-up
3. RF Immunity
4. PC Board (W1) Jumper

The 180-day PMA-S is requesting approval for 7 design modifications to the Reliaty / Model 3145 Pacing System Analyzers. The PSA was originally approved in P950037/S079.

Table 1: Product Information

	Trade or Proprietary Name	Model Number
1	Reliaty Pacing System Analyzer	365 383
2	Model 3145 Pacing System Analyzer	369 041
3	Model 3150 Cable	365 782
4	Model 6653 Cable	375 397
5	Model 6646 Cable	123 861
6	Model 6652 Adapter	123 862

II. Device Description

Indications for Use: The Reliaty/Model 3145 is indicated for use in pacing lead system analysis during the implantation of pacemakers and defibrillators.

The Reliaty/Model 3145 Pacing System Analyzer (PSA) is a stand-alone triple chamber pacing system analyzer for use during pacemaker and ICD implantation.

The device is available in 2 versions: the Reliaty is marketed by Biotronik and the Model 3145 is marketed by Boston Scientific. Unless otherwise noted in this memo, both versions will be referred to as Reliaty.

Figure 1: Reliaty Stand Alone PSA

The user interface is a touch screen in combination with a turning knob containing a mechanic-optical encoder with wheel, six LED indicators and seven buttons on the front panel. The user controls the operations of the device through its LCD touch-screen, control-knob and control buttons. The user monitors device measurements, heart activity and device status through its LCD display and LED indicators.

The Reliaty provides 3-chamber pacing and sensing. It can display up to 3 channels of real-time IEGMs (intracardiac electrograms) and markers. With the exception of bi-ventricular pacing, the device provides standard PSA functionality identical to previous PSA devices with measurements such as lead impedance measurements, intrinsic amplitude, timing measurements and pacing thresholds. It has a report feature that provides a summary of device measurements along with optional IEGM traces. It has a freeze/timing feature that allows the user to snap shot IEGM traces for contrast and to analyze IEGM morphologies. The Reliaty/Model 3145 can also deliver an emergency VVI pacing feature that provides immediate single chamber pacing.

Two connector ports (one for the RA and RV and one for the LV) on the back of the pacing system analyzer allow connection of cables linking the Reliaty/Model 3145 to the lead system for pacing and lead system tests or to the implantable pulse generator for parameter measurements. The technical interface has USB and VGA connections. The device has a VGA output port that can be connected to an external CRT/LCD display. The device also has a standard USB 2.0 (12 MBit/s) connector that can be used to export measurement reports to a USB flash memory stick or print those reports to a Bluetooth printer.

Accessories

Table 2 shows the various accessories that are included with this system and are included in this supplement.

Table 2: Accessories

Accessory	Description	PMA or 510(k)
Model 3150	Patient cable with alligator clips, sterile, Resterilizable.	Approved with the original PSA in P950037/S079.
Model 6653	Patient cable, sterile, resterilizable (identical to PK-67-S)	Approved with the original PSA in P950037/S079.
Model 6646	Patient cable, sterile, resterilizable (identical to PK-67-L)	Approved with the original PSA in P950037/S079.
Model 6652	Adapter with alligator clips, sterile, resterilizable (identical to PA-4)	Approved with the original PSA in P950037/S079.

Response to Deficiencies

has reviewed responses 1, 2, and 3. His full review is in his 4/12/11 memo and is included as Attachment 1.

<u>Deficiency 1:</u> You have provided EMC information in the EMC Test Report – Appendix 29 of your submission. It is not clear that all functions/configurations of your device were tested. Some functions/configurations may require the presence of an implantable pulse generator (IPG). For, example the clinician may elect to test only one lead at a time leaving the other two leads attached to the functioning IPG to continue pacing. If such functions exist, the IPG should be present during EMC immunity tests. Please describe all functions/configurations that were tested and how the presence of an IPG or

patient were addressed. This information is needed to determine basic safety and essential performance with regard to EMC.

Response: The Reliaty / Model 3145 devices can be connected only to the pacing leads and there is no connection cable or adapter that allows the pacemaker or ICD device to be connected directly to the Reliaty / Model 3145 devices.

Review: The response is adequate and the IPG can be excluded from the IEC 60601-1-2 testing.

Deficiency 2: You provided test setup photos from your EMC Test Report (page 187 of submission). It does not appear that leads were attached to your PSA in these photos. The connection of leads to your PSA can effect both emissions and immunity with your device. Please submit additional EMC testing with leads (longest approved length) present or provide scientific justification to why the leads were excluded.

Response: Based on FDA's question, BIOTRONIK went back and reviewed the test data. BIOTRONIK understands FDA's concern and has performed additional EMC testing with (b) (4). This testing was performed by the external testing laboratory, (b) (4), with the Reliaty / Model 3145 pacing system analyzers connected to the (b) (4) leads, (b) (4) and (b) (4)).

Review: has reviewed the test data and believes that it is adequate. I agree with his recommendation and have no further questions or concerns.

Deficiency 3: You tested the RF immunity of your device from 80-2500 MHz with (b) (4) (b) (4) (b) (4) *% depth). Since your device controls, monitors, or measures a physiological parameter IEC 60601-1-2 requires RF immunity testing with 2 Hz AM modulation (80% depth). Please provide test data for RF immunity testing to the appropriate modulation frequency. This information is needed to demonstrate compliance to IEC 60601-1-2.*

Response: Biotronik has responded that the (b) (4) was a typographical error and has updated it accordingly.

Review: has reviewed the response and believes it is adequate. I agree with his recommendation.

Deficiency 4: In Section 4.7 (page 11 of 25) of your submission you state that a fixed jumper was (b) (4) *to fix a* (b) (4) *. The nature and scope of this modification is vague and does not provide any details. It is unclear what impact – if any – the* (b) (4) *has on the current design, how the new component fixes the* (b) (4) *was found. In addition, you have provided a test report in Appendix 26 for the communication between* (b) (4) *and* (b) (4) *but have not*

stated if this is in anyway related to the (b) (4) *. Please provide additional information to clarify these issues as well as an explanation of any validation testing performed.*

Response: Biotronik states that the description of this change as a "(b) (4) " was something of a misnomer. During the initial design phase, Biotronik received a technical notice from the supplier of the CPU indicating that the performance of CPU during boot-up could be (b) (4) if specific (b) (4) were made. They recommended one of the following two fixes/work-around solutions should be used in order to avoid problems during the boot up process:

1. Connect (b) (4) to (b) (4) to ensure that a (b) (4) takes place in all cases.
2. Connect (b) (4) to (b) (4) if no (b) (4) capabilities are required.

The notice was received after design of the PCB was completed. Therefore, in the original Reliaty device design (P950037/S079), Biotronik chose to use Option #1 with a (b) (4) because it did not require any layout changes to the PCB. Figures 1 to 4 (beginning on page 17) show the PCB layout of each option.

With the modification introduced in this Reliaty PMA Supplement, the sponsor will implement Option #2 by introducing a (b) (4) between (b) (4) and (b) (4). The modification introduces a (b) (4) that can be mounted automatically rather than the manual modification discussed above, which also blocked the service connector.

Review: I agree with the sponsor's claim that the term "(b) (4) " is a misnomer for the previous PCB design. This modification is an optional redesign and is not being implemented as a corrective fix. The firm provided validation testing in Section 8.2 of the original submission and also performed additional testing which was submitted in Appendix 3 of the amendment. The response is adequate and I have no further questions.

III. Description of Changes

This supplement is for the following seven design modifications

1. Display Screen

The currently used display screen model (b) (4) has been discontinued by the manufacturer. Biotronik proposes use of the successor model, (b) (4) , to replace the obsolete screen in the Reliaty/Model 3145 devices. The replacement display screen has the same display parameters such as angle viewing, size, resolution and brightness. The only change recognizable to the user will be the movement of the 'Save' button from above the Sensing, Threshold, Impedance buttons to below them.

Since hardware components of the new display screen (e.g. internal controller) were changed, additional EMC measures were necessary in order to meet EMC requirements from the EN 60601-1-2 Standard. These measures include the addition of:

- A (b) (4) to the back of the display screen
- (b) (4) shielding additions to the connector cables
- (b) (4) additional resistors were added to the PCB W1
- Change of a resistor value for an EMI filter

(CDRH/OSEL) provided a consulting review and believes that Biotronik has addressed all EMC/EMI issues. I agree with his recommendation.

2. Alternate Battery

Biotronik has identified a new battery, Energizer E 91, as a second source to be used with the Reliaty/Model 3145. Currently, the device is shipped with Duracell MN1500 AA LR6 batteries. The Technical Manuals have been updated to include the new Engergizer battery as an alternate battery source. They state that this battery is widely available worldwide and it will be easier for the users to replace than the originally provided Duracell batteries. There were no changes to the device specifications and the Energizer battery meets the same battery specifications. I have reviewed the dimensions and performance of the new battery and it is adequate to power the PSA. It's performance characteristics are nearly identical to the currently used battery and I have no questions or concerns.

3. Battery Cartridge

The battery cartridges were modified to include two cut-outs on each side. The modification was implemented for easy removal of depleted batteries. Figure 5 on page 9 of the submission shows the current design and the proposed design. This is adequate and I have no questions or concerns.

4. Battery Contacts

Along with the battery cartridge change, the battery contacts and the connector mounting were also modified. The modified contacts have a different shape and are composed of Nickel-plated steel. The current contacts are made of stainless steel only. This change is being introduced because the new contacts are cheaper to manufacture and allow for easier assembly of the cartridges. The change does not impact the user, device specifications, or device operation. This is adequate.

5. Firmware

Biotronik has made modifications to the device firmware which will result in a new firmware version 2.8.6. This firmware is stored on the (b) (4) in the

processor of (b) (4) and the (b) (4) in the processor of (b) (4). The following changes were implemented in the new firmware version:

- An adjustment of ERA battery voltage levels for the battery indicators by (b) (4) due to the modified (b) (4) battery contacts.
- The screen measurement calipers can now be saved with the freeze function.

In addition to the changes above, the following bug fixes were also implemented with the new version of the firmware:

1. Multiple text corrections and text optimizations.
    - The legend of marker channels that are not fully displayed in languages ESP, FRA, ITA
    - The RA wording was corrected in the French language only
    - The labeling for non-English or non-German languages was corrected for consistency.
    - The description input field for "New Report" was corrected, since it wasn't working properly. This bug caused an internal error message during viewing of detailed reports under certain conditions. A rapid selection of detailed reports followed by the abortion of this selection would cause an internal handling problem which led to an error message. This bug was fixed so that the error message wouldn't appear inappropriately under this situation.
    - Critical Error text of Reliaty was not fully visible and was made to be visible
    - Displayed bpm differed from selected/programmed bpm due to minor calculation rounding differences in the device since it is measured and calculated in ms but displayed as bpm. This display inconsistency was corrected
    - Activating key preference settings results in information not comprehensible to the user. The new activation key rules are consistent and easier for the user to understand.
    - In cases where the Max Stim is activated several times in quick succession, a critical error message is shown. This was fixed so that the critical error message wouldn't appear inappropriately under this situation.
2. Optimization of several memory and CPU interactions were made to improve device reaction time.
    - Reports could not be exported under certain circumstances. A modification now allows reports to be exported consistently
    - The export message was corrected so that it displays an appropriate number and does not show "0%" in cases with a stored value.
    - The empty system error logs were removed from memory.
    - The internal error message while viewing detailed reports under certain conditions, such as a rapid selection of detailed reports and abortion of this selection, causes an internal handling problem which led to an error. The internal handling problem was corrected.
    - Memory handling was corrected to avoid memory blocking after rapid printing and subsequent cancelling printing jobs.

- Rapid activation of the burst pacing could cause an internal handling error of the burst requests, which may have resulted in a program abortion. This issue was resolved.
- Optimized attenuation of CPU PLL to reduce cross talk.
- The VGA button ON auto detect was corrected to turn off when no monitor is connected.
- A correction was implemented so that an exemption wouldn't be shown when the brightness of the display is changed more than 250 times.

3. Improved accuracy of displayed information.
   - Accuracy of Export status message was improved.
   - Accuracy of displayed interval measurement was improved to function consistently for all pacing modes.
   - The version of the operating system will now be displayed when a release code is used
4. Correction of device reactions to battery status changes.
   - The battery indicator changes do not always match associated device conditions. The battery indicator was corrected to accurately reflect the device condition.
   - Under certain conditions, the device would be shut down in cases where the same battery pack is removed twice in a short period of time. A bug fix was implemented so that, as defined, the device will not shut down.

provided a consulting review of these modifications and his memo is included as Attachment 2 to my original review memo. He does not raise any questions or concerns and I agree with his Approval recommendation.

6. Control Knob

The fixation mechanism inside of the control knob (see Figure 1 above) has been modified for a tighter connection. The result is that the knob can be mounted more securely and remain centered while turning. It does not affect the user, device specifications, or device use. I have no questions or concerns.

7. Circuit Board

During the initial design phase, Biotronik received a technical notice from the supplier of the CPU indicating that the performance of CPU during boot-up could be enhanced if specific electrical connections were made. They recommended one of the following two fixes/work-around solutions should be used in order to avoid problems during the boot up process:

1. Connect to to ensure that a correct power up sequence takes place in all cases.
2. Connect to if no debug capabilities are required.

The notice was received after design of the PCB was completed. Therefore, in the original Reliaty device design (P950037/S079), Biotronik chose to use Option #1 with a

fixed jumper because it did not require any layout changes to the PCB. Figures 1 to 4 (beginning on page 17) show the PCB layout of each option.

With the modification introduced in this Reliaty PMA Supplement, the sponsor will implement Option #2 by introducing a between and . The modification introduces a that can be mounted automatically rather than the manual modification discussed above, which also blocked the service connector.

This modification is an optional redesign and is not being implemented as a corrective fix. The firm provided validation testing in Section 8.2 of the original submission and also performed additional testing which was submitted in Appendix 3 of the amendment. The information provided is adequate and I have no questions or concerns.

A001 Changes
In addition, Biotronik submitted three modifications in their March 21, 2011 amendment:

1. Software Update
2. Addition of Kit Catalog Numbers
3. Technical Manual and Device Labeling

Software Update – the modification submitted in A001 would result in software version C1.16.0. The changes are bug fixes and to not add, remove, or modify functionality of the software reviewed in the original submission. The bug fixes are:

- Bug fix to adjust the pointer: During one of the last production steps for the Reliaty / Model 3145 devices the date is set via a (b) (4) . It was discovered that due to a software error in the pointer that the correct date can't be set (b) (4) . As a result of this error, the function isn't able to determine the correct number of days in the month. Due to this bug the users have had to manually set the dates in the preference setting of the Reliaty / Model 3145 devices. With this bug fix, the function was corrected to allow the date to be set appropriately.

- Bug fix to suppress the interrupt conflict: During (b) (4) for the Reliaty / Model 3145 devices the manufacturer name is programmed into the device. During this procedure the information (b) (4) (b) (4) has to (b) (4) for the programming. Due to some interrupt conflicts within the software program, this (b) (4) wouldn't (b) (4) for programming. This bug fix suppressed this interruption conflict to allow the (b) (4) to (b) (4)p for programming.

- Bug fix to adjust a variable for IEGM data storage: It was discovered that there is a possibility (b) (4) . This (b) (4) failure isn't apparent to

the user. This bug fix adjusts a variable for IEGM data storage so that the data can be stored in separate folders.

The version C1.16.0 software modifications have no impact on the device functionality and performance specifications remain unchanged. Therefore, no changes to the risk analyses were required as a result of the software update. Additionally, there is no change to the product labeling or catalog numbers as a result of this minor modification. I reviewed the three software updates in the amendment file and they are adequate.

Addition of Kit Catalog Numbers – This amendment includes the addition of two new catalog numbers: 365530 for the Reliaty kit (Reliaty device plus accessories) and 369041 for the Model 3145 kit (Model 3145 device plus accessories). Additionally, a new catalog number 371106 was also introduced for refurbished Model 3145 devices that have been returned to BIOTRONIK for repairs, tested and then redistributed to customers. The new numbers are for identification purposes only and there is no change to any aspect of the device.

Technical Manual and Device Labeling – The amendment made the following minor changes to the technical manual and device labeling

- three wording changes to the technical manual to increase clarity
- addition of UL certification to the technical manual
- addition of the UL certification to the device label
- addition of symbols to indicate which items have been refurbished

I have reviewed all three changes submitted in the amendment and they are adequate.

IV. Validation Testing

The following table describes all validation testing submitted in the supplement:

Table 3: Validation Testing

Test	Description	Test Report
1. (b) (4)	(b) (4) vice	Appendix 1
2. (b) (4)	(b) (4)	Appendix 2
3. (b) (4)	(b) (4)	Appendix 3
4. (b) (4)	(b) (4)	Appendix 4
5. (b) (4)	(b) (4)	Appendix 5
6. (b) (4)	(b) (4)	Appendix 6

Test	Description	Test Report
7. (b) (4)	(b) (4) .	Appendix 7
8. (b) (4)	(b) (4)	Appendix 8
9. (b) (4)	(b) (4)	Appendix 9
10. (b) (4)	(b) (4)	Appendix 10
11. (b) (4)	(b) (4)	Appendix 11
12. (b) (4)	(b) (4)	Appendix 12
13. (b) (4)	(b) (4)	Appendix 13
14. (b) (4)	(b) (4)	Appendix 14
15. (b) (4)	(b) (4)	Appendix 15
16. (b) (4)	(b) (4)	Appendix 16
17. (b) (4)	(b) (4)	Appendix 17
18. (b) (4)	(b) (4)	Appendix 18

Additional information about change #7 was submitted in this amendment. The firm provided validation testing in Section 8.2 of the original submission and also performed additional testing which was submitted in Appendix 3 of the amendment.

The March 21, 2011 amendment included three software modifications that were not submitted in the original supplement. Table 4 shows the additional validation testing performed for these changes.

Table 4: Amendment 1 Software Verification Testing

Test	Description	References
(b) (4)	(b) (4) .	Appendix 4

Test	Description	References
(b) (4)	(b) (4)	Appendix 5
(b) (4)	(b) (4)	Appendix 6

I have reviewed the submitted validation test reports and all testing passed. The information provided is adequate and I have no further questions or concerns.

V. Biocompatibility

This section is not applicable because neither the device nor any of the accessories make patient contact.

VI. Software

has provided a consulting review of the firmware changes in this supplement [Note: He did not review Amendment 1 information]. He states:

> RISK ANALYSIS
> During the development process of the modifications to the Reliaty/Model 3145 pacing system analyzers, there were no changes to the Risk Management Plan and Risk Analysis as there were no new risks associated with the device hardware modifications or firmware updates.
>
> VERIFICATION AND VALIDATION TESTING
> The updated firmware for the Reliaty/Model 3145 has been subjected to verification and validation testing as summarized in Table 3. The Reliaty/Model 3145 updated firmware has passed all verification/validation tests, and all test reports are found in the referenced appendices.
>
> Each test report details the testing performed, equipment used, specification(s) followed and the actual test results.

KNOWN ANOMALIES
An examination of the provided firmware test reports shows that there are no mentions of known anomalies in any of the test reports except for appendix 23 which mentions minor anomalies that are deemed acceptable by Biotronik.

CONCLUSION
The firmware changes effected by the sponsor are minor changes that appear to have been appropriately and adequately verified and validated through functional testing and code inspections. It is recommended that the Reliaty/Model 3145 firmware version 2.8.6 be approved for use.

I agree with his recommendation and have no questions or concerns. His review is provided as Attachment 2 to my original review memo.

In Section 3.1 of the March 21, 2011 Amendment, Biotronik has submitted the minor software updates described in Section III of this review memo. I reviewed the additional verification testing described in Table 4 (above). The changes are minor and the information submitted is adequate. I have no questions or concerns.

VII. Sterilization/Shelf life/Packaging

Only the cable and adapter accessories are provided sterile – the device itself is not.

With the exception of the new batteries, none of the changes impact sterilization, shelf life, or packaging. The new battery manufacturer has provided shelf life information which is nearly identical to the currently used batteries. This is adequate and I have no questions or concerns.

VIII. Labeling

There were no changes to the device labels – only the Technical Manual and its related documents.

The Technical Manuals were updated to include the changes from the hardware modifications and the firmware updates. Changes to the technical manuals include the addition of the alternate Energizer E 91 battery and the addition of the contraindication "Use as a pacemaker outside of the implantation procedure" per the Amendment to PMA Supplement P950037/S79, approved on September 2, 2010.

Other minor changes to the technical manuals include spelling and grammar corrections, minor wording changes and updated symbols/figures/images/caption references and index updates. The same information was updated on the Reliaty / Model 3145 outer packaging labels, the quick reference guide, and the sections for explanation of symbols.

I have reviewed this information and it is adequate.

IX. Deficiencies:

None