



MEMORANDUM

SUMMARY OF:

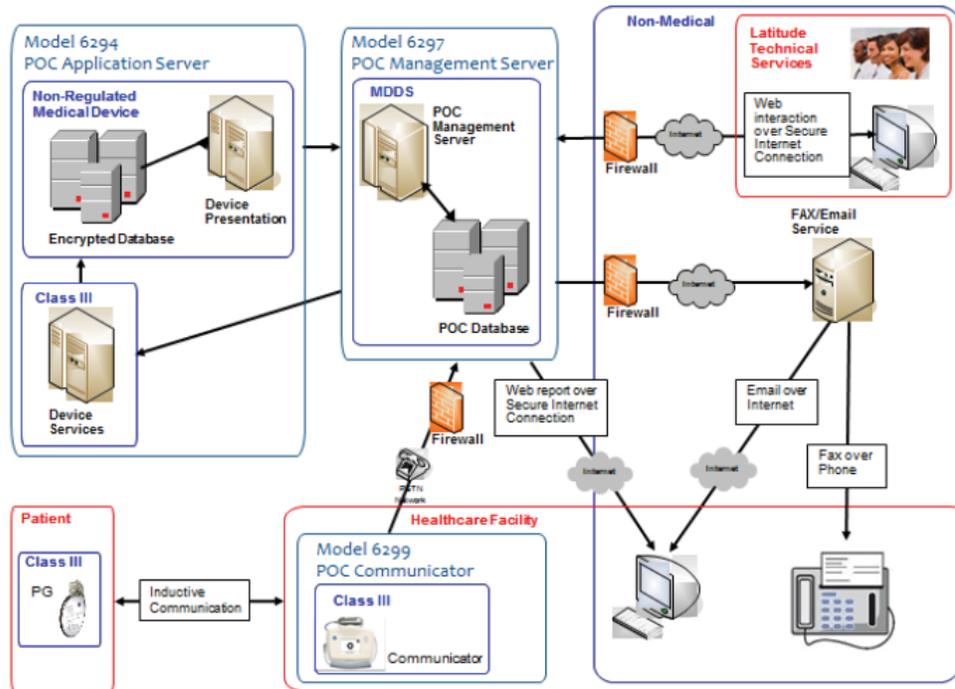
P910077/S138  
LATITUDE Consult Communicator Model 6299 and Application Server Model 6294  
Boston Scientific

BACKGROUND

Boston Scientific Corporation (BSC) is requesting approval for the LATITUDE Consult™ System which includes application server software model 6294, Communicator model 6299, and related literature and labeling. This system reads data from a patient's implanted BSC pulse generator (PG) and generates reports from this data.

The LATITUDE Consult™ Communicator is used to read data from a patient's implanted device via a telemetry wand placed over the patient's device. Once the data is read, the clinician uses the Communicator to send the data to the secure LATITUDE Consult™ server. The clinician then contacts Boston Scientific to request a review of the data and optionally obtain reports.

Figure 1-1: LATITUDE Consult™ System Components



Boston Scientific is requesting approval for the LATITUDE Consult™ System Communicator Model 6299 including the communicator specific software and Model 6294 LATITUDE Consult™ Application Server Software, and both are included in this submission. The Model 6297 LATITUDE Consult™ Management Server is classified as a Medical Device Data System

(MDDS) and is included for reference only. The MDDS subsystems described above are not considered part of this medical device submission. The PGs supported within this new LATITUDE Consult™ System are market-released system components.

*Reviewer Comment: The proposed system classification was previously discussed with FDA and agreed to back in November 2012.*

This submission seeks approval of the following system components:

**Table 1-1: Summary of Components Submitted for Approval in This Submission**

Component	Description	Submitted for Approval
Communicator	The Communicator (model 6299) is used in a health care facility and interfaces with a patient's PG via a proprietary inductive link. The Communicator collects PG data for subsequent upload to the LATITUDE Consult™ Management Server (model 6297). The Communicator does not reprogram or change any functions of the patient's implanted PG device. Only the patient's clinician can reprogram the patient's device during an in-office visit using the appropriate device programmer.	Yes. Based on the model 6481 G1 Wanded Communicator approved in the US, and wanded communicator models 6420/6443 approved for use in Japan.
Management Server	The model 6297 LATITUDE Consult™ Management Server is a new system. It is implemented as secure server software accessing a separate centralized computer database. The Management Server passes unmodified data to the Application server to produce device reports. Also, the Management Server is responsible for allowing LATITUDE Consult™ Technical Services personnel to view patient device reports and allow them to provide technical support to the health care facility.	No. In the LATITUDE Consult™ system, this new functionality is implemented within the MDDS (Medical Device Data System) as part of an ISO 62304 class B process.
POC Application Server - (b)(4) Trade Secret/CCI	(b)(4) Trade Secret/CCI is part of the model 6294 LATITUDE Consult™ Application Server. It is implemented as secure server software accessing a centralized computer database. (b)(4) Trade Secret/CCI is responsible for receiving, storing, and managing PG device data gathered via the Communicator. (b)(4) Trade Secret provides the stored data for the (b)(4) Trade Secret/CCI component to use within the generation of patient reports.	Yes. In the existing LATITUDE NXT system, this functionality is similar to and also called (b)(4) Trade Secret/CCI, which is approved as regulated software in the previous LATITUDE NXT approval.

Component	Description	Submitted for Approval
POC Application Server - (b)(4) Trade Secret/CCI	(b)(4) Trade Secret/CCI is also part of the model 6294 LATITUDE Consult™ Application Server. It is implemented as system software used to read data from the database and generate patient reports to be made available for viewing from the LATITUDE Consult™ Management Server website.	No. In the existing LATITUDE NXT system, this functionality is also called (b)(4) Trade Secret/CCI, which is approved as non-regulated software in the previous LATITUDE NXT approval.
Operations and LATITUDE Consult™ Technical Services	The Operations role is performed by authorized personnel with system access. In the existing LATITUDE, LATITUDE NXT, and LATITUDE Consult™ systems, the Operations function provides the interface for system administrators to perform system maintenance functions.  The Technical Services role is performed by authorized personnel who provide customer support functions to clinicians.	No. Operations and Consult™ Technical Services processes are not medical devices or medical device software.  Information on Operations and Technical Services is provided in this submission, as in previous LATITUDE submissions, in order to present a complete overview of the system.

In **Amendment A001**, the sponsor provided a response to the four deficiencies from the original review of the submission. **Amendment A002** was sent as an additional response to a question from review of the response of deficiency #1.

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## INDICATIONS FOR USE

The LATITUDE Consult™ system is intended to read data from a compatible Boston Scientific implanted device and transfer it to a central server. The LATITUDE Consult™ system can provide implanted device data that may be used as part of the clinical evaluation of the patient. This literature is intended for use by health care providers of the LATITUDE Consult™ Communicator System.

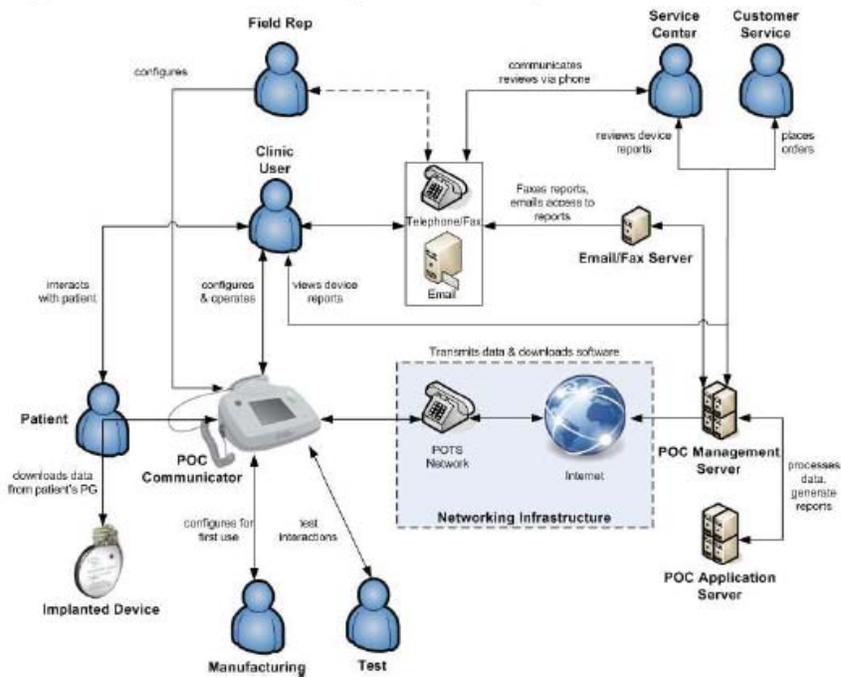
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## DEVICE DESCRIPTION AND CHANGE DESCRIPTION

The LATITUDE Consult™ Communicator is used to read data from a patient's implanted device via a telemetry wand placed over the patient's device. Once the data is read, the clinician uses the Communicator to send the data to the secure LATITUDE Consult™ server. The clinician then contacts Boston Scientific to request a review of the data and optionally obtain reports.

An overview of Consult system functionality is provided below in Figure 1-2.

**Figure 1-2: LATITUDE Consult™ System Functionality**



A summary comparison of the existing LATITUDE systems and the LATITUDE Consult™ system is provided in Table 2-1.

The Intended Use and Contraindications for the Consult™ system are unchanged from the current LATITUDE and LATITUDE NXT remote patient monitoring system.

**Table 2-1: Comparison of Existing LATITUDE and LATITUDE NXT System with LATITUDE Consult™ System**

Feature	Existing LATITUDE System	LATITUDE Consult™ System
Intended Use	The LATITUDE Patient Management system is intended to remotely communicate with a compatible Boston Scientific or Guidant PG device and transfer data to a central database.	The LATITUDE Consult system is intended to read data from a compatible Boston Scientific implanted device and transfer it to a central server. The LATITUDE Consult system can provide implanted device data that may be used as part of the clinical evaluation of the patient.
Indications for Use	Supports Boston Scientific families of implantable devices.	No change
Contraindications	The LATITUDE Patient Management system is contraindicated for use with any PG other than a compatible Boston Scientific or	The LATITUDE Consult™ Communicator is contraindicated for use with any implanted device other than a compatible Boston

Feature	Existing LATITUDE System	LATITUDE Consult™ System
	Guidant device. For contraindications related to the use of Boston Scientific or Guidant PG, refer to the System Guide for the Boston Scientific or Guidant PG being interrogated.	Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE Consult™ system. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being interrogated.
Communicator	Model 6481 LATITUDE Communicator	Model 6299 LATITUDE Consult™ Communicator has smaller physical size and simplified user interface. This Communicator does not perform any diagnostics or monitoring of PGs, and does not have any alerts or alarms.
PGs Supported	Supports COGNIS, TELIGEN, PUNCTUA, ENERGEN, INCEPTA, VITALIO, FORMIO, INGENIO, ADVANTIO, INTUI, INLIVEN, and INVIVE families of Boston Scientific implantable devices.	Supports COGNIS, TELIGEN, PUNCTUA, ENERGEN, INCEPTA, VITALIO, FORMIO, INGENIO, ADVANTIO, INTUI, INLIVEN, INVIVE, INSIGNIA, and ALTRUA families of Boston Scientific implantable devices.
External Health Sensors	Blood pressure monitor and weight scale.	No external sensors are supported.
Server	(b)(4) Trade Secret/CCI performs the device decoding as part of the Regulated Medical Device software.	No functional changes.
	(b)(4) Trade Secret/CCI and (b)(4) Trade Secret/CCI performed the display of Web pages and device reports for the clinical user.	(b)(4) Trade Secret/CCI continues to perform the generation of device reports while there is no (b)(4) Trade Secret/CCI component in the new LATITUDE Consult™ system.
Operations	The Operations role is performed by Boston Scientific personnel. The Operations function provides the interface for system administrators to perform system maintenance functions.	No functional changes.
LATITUDE Customer Support Center (LCSC)	In the LATITUDE NXT system, LCSC utilizes (b)(4) Trade Secret/CCI and (b)(4) Trade Secret/CCI software to implement the customer support role.	In the LATITUDE Consult™ system, Technical Services utilizes a new web interface to review device reports and provide technical support. This web interface is part of an Medical Device Data System (MDDS) system that is external to

Feature	Existing LATITUDE System	LATITUDE Consult™ System
Electronic Medical Record (EMR) Support	(b)(4) Trade Secret/CCI data from LATITUDE into EMR systems. (b)(4) Trade Secret/CCI widely in the healthcare industry to convert and securely transmit electronic medical record information.	this submission. No direct EMR export support is included.
(b)(4) Trade Secret/CCI	(b)(4) Trade Secret/CCI	There are no (b)(4) Trade Secret/CCI used by the system.

### **LATITUDE CONSULT™ COMMUNICATOR**

The Model 6299 LATITUDE Consult™ Communicator is similar in design to the Model 6481 LATITUDE Communicator; a small portable device that is operated using a touchscreen interface, uses an inductive telemetry wand to collect data from a patient's implanted PG, and interfaces via analog telephone line to communicate with an authenticated server. The LATITUDE Consult™ Communicator is different from previous products in that it is intended for use in a clinical environment where clinician users may want to collect data from a patient's implanted device as part of a clinical evaluation. To support this new intended use, the Communicator is not uniquely assigned to a specific PG. The Communicator contains a new simplified user interface which provides clinician users with a single-patient workflow; allowing the Communicator to be used with various patients one-at-a-time to collect data from their implanted PG and to upload the collected data to an authenticated server. The Communicator does not perform any monitoring, diagnostics, or programming of the patient's implanted PG and does not perform any automatic clinical analysis of the collected data. The LATITUDE Consult™ Communicator is provided with an AC power supply, a standard telephone cable, and a user manual.

### **LATITUDE CONSULT™ APPLICATION SERVER**

The Model 6294 LATITUDE Consult™ Application Server supports the features needed to provide the device status information to the LATITUDE Consult™ Technical Services and the inquiring health care professional. This Server is responsible for receiving device data, decoding device data, and generating device reports for subsequent analysis of the clinical device data gathered from compatible implanted PGs through the Model 6299 LATITUDE Consult™ Communicator. The Application Server makes the device reports available to the Model 6297 LATITUDE Consult™ Management Server.

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## **RISK ANALYSIS**

To ensure that Boston Scientific CRM provides acceptably safe products to the marketplace, a formal safety risk management process is in place that facilitates risk analysis, evaluation, and control. Safety risk management is performed throughout the product life cycle. The formal process is documented in procedure (b)(4) Trade Secret/CCI

Safety risk analysis, evaluation, and control activities are specified in the Safety Risk Management Plan. The formal processes are documented in the following procedures: (b)(4) Trade Secret/CCI

The Safety Risk Management Report contains a confirmation that the safety risk management process has been performed according to Boston Scientific CRM policies and procedures, that the hazards associated with the designed system have been identified, and that the risks have been mitigated to an acceptable level. The report also confirms that Boston Scientific CRM believes that the residual safety risk associated with the use of the system is acceptable, and that the system is acceptable for use in humans. The formal process is documented in the following procedure: (b)(4) Trade Secret/CCI Safety Risk Management Process, and form: (b)(4) Trade Secret/CCI Safety Risk Management Report.

The risk management activities that were completed for this submission are listed below and detailed in the submission.

- Hazard Analysis
  - Exhibit 7-15: (b)(4) Trade Secret/CCI
- Security Risk Assessment Report
  - Exhibit 7-16: (b)(4) Trade Secret/CCI
- Reliability Prediction Analysis
  - Exhibit 7-17: (b)(4) Trade Secret/CCI
  - Exhibit 7-18: (b)(4) Trade Secret/CCI
- Safety Risk Management Report
  - Exhibit 7-19: (b)(4) Trade Secret/CCI

*Reviewer Comment: I reviewed the Hazard Analysis and reports identified above. It appears that the sponsor has completed the appropriate analysis by identifying the hazards and evaluating the residual risk of the hazards. Due to past concerns about communicators causing premature battery depletion in the PG, the hazard analysis was reviewed to determine if the sponsor has identified this hazard. The sponsor did identify (b)(4) Trade Secret/CCI and appears to have completed the appropriate analysis. There are no further concerns.*

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## CLINICAL

The Clinical reviewer provided a clinical review of the labeling. He found the manual acceptable from a clinical perspective, offering basic startup instructions for the device that are clear and noncontroversial.

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## NON-CLINICAL LABORATORY STUDIES

### ***System Evaluation Plan/Report***

The System Evaluation Plan identifies the appropriate evaluation activities for a given product. The evaluation process then continues with the development of test protocols, testing and recording results, and documenting the analysis of the test results for each activity. Traceability is performed from requirements to verification tests.

The System Evaluation Plan (b)(4) Trade Secret/CCI is provided as Exhibit 7-01.

The System Evaluation Report provides a comprehensive view of the evaluations performed for LATITUDE Consult™, in the context of Boston Scientific CRM's product development and evaluation processes. The System Evaluation Report focuses on the acceptable system performance of the product being submitted and provides traceability to documented rationale

for decisions made regarding testing. Also, it covers testing performed as part of the formal evaluation of the product.

The System Evaluation Report (b)(4) Trade Secret/CC) is provided as Exhibit 7-02.

*Reviewer Comment: The System Evaluation Report and Plan were reviewed and found acceptable. The sponsor appears to have successfully completed the testing.*

### **Design Validation Testing**

#### **System Features Testing**

System Features Testing is one part of a comprehensive system evaluation plan and consists of design validation test cases that demonstrate that the system meets user needs and intended uses. System Features Testing focuses on the overall integration of the system elements using a simulated environment, rather than the detailed function of the individual devices. Individual tests demonstrate the functionality of a given feature or system behavior, rather than provide exhaustive testing of possible scenarios.

The system features test used the following test articles:

- Consult™ communicator
- Consult™ application Server
- Consult™ management server
- Market approved Boston Scientific pulse generators

All tests passed and confirmed intended use and conformance to user needs. The System Features Test Report (b)(4) Trade Secret/CC) is provided as Exhibit 7-03.

*Reviewer Comment: The System Features Test Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware.*

#### **Simulated Use Testing**

The purpose of simulated use testing is to provide an opportunity for users to accurately replicate the use of device/system to validate the behavior of the LATITUDE Consult™ System under simulated clinical use conditions.

The primary focus of this test is the interface between the system and user. It validates that simulated clinicians are able to operate the communicator in the environments similar to hospital or clinic environment . This testing also includes simulated follow-up scenarios.

The system under evaluation consists of the following test articles:

- Consult™ communicator
- Consult™ application Server
- Consult™ management server
- Consult™ Clinician Manual
- Market approved Boston Scientific pulse generators

All tests passed and confirmed intended use and conformance to user needs. The Simulated Use Test Report (b)(4) Trade Secret/CC) provided as Exhibit 7-04.

*Reviewer Comment: The Simulated Use Test Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware. There were no uncorrected failures.*

### **Usability Engineering Study**

This study validated the usability of the communicator user interface and associated labeling (the Clinician Manual).

The usability of the Consult™ Communicator user interface and associated labeling tested in this study were validated to demonstrate that no use errors are present that lead to hazardous consequences that exceed the acceptable residual risk levels defined in the hazard analysis. Any residual risk that remains would not be further reduced by any modifications to the design of the user interfaces and is outweighed by the benefits that may be derived from the use of the system.

The Usability Engineering Summary Report (b)(4) Trade Secret/CCI is provided as Exhibit 7-05.

*Reviewer Comment: The Usability Engineering Summary Report was reviewed and found acceptable.*

### **Design Verification Testing**

Design verification testing (DVT) confirms that the design output meets the design input requirements. DVT protocol development addressed the requirements associated with the device and its software. The protocols were peer reviewed to determine that each requirement traced to one or more test cases, the coverage of each requirement was adequate, and the acceptance criteria were correct and verified the requirements.

The traceability from system requirements to verification tests is described by the traceability report Exhibit 7-06 System DVT Traceability Report (b)(4) Trade Secret/CCI

The DVT tests assure that the product meets its requirements, and are sufficient to verify the product under evaluation.

### **System DVT**

System design verification tests demonstrate that systems consisting of two or more devices or elements meet design input requirements that define the interoperability and interaction of each device or element.

All testing was completed with no uncorrected failures. The System DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 7-07.

*Reviewer Comment: The System DVT Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware. There were no uncorrected failures.*

### **Model 6299 Communicator SW DVT**

Testing was conducted to ensure that the communicator model 6299 software application met all applicable requirements.. Testing used wanded telemetry to exercise all functionality of the communicator application, including interrogating the PG.

All testing was completed with no uncorrected failures. The Software DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 7-08.

*Reviewer Comment: The Software DVT Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware. There were no uncorrected failures.*

### **Model 6294 Application SW DVT**

A DVT was conducted to ensure that the model 6294 Application Server Software met all requirements. This DVT effort executed test cases to verify that the software correctly and completely implements all requirements.

All testing was completed with no uncorrected failures. The Application Software DVT Report (b)(4) Trade Secret/CCI is provided as Exhibit 7-09.

*Reviewer Comment: The Application Software DVT Report was reviewed and found acceptable. The sponsor appears to have successfully completed the testing with the latest version of software/firmware. There were no uncorrected failures.*

### **Mechanical DVT**

Mechanical Design Verification Testing (MDVT) was conducted to ensure that the communicator model 6299 met mechanical requirements, as defined in system requirements specifications. The mechanical DVT ensures that the mechanical requirements were met including, but not limited to, operational environment, vibration, mechanical shock, and thermal shock. Since the communicator model 6299 is mechanically equivalent to the model 6443 Bobcat Japan Communicator, various tests in the MDVT report refer to testing performed during the model 6443 project. Report (b)(4) Trade Secret/CCI provided as Exhibit 7-10 summarizes the MDVT assessment performed to analyze the mechanical differences between the model 6299 and 6443 and determine the required mechanical testing for the model 6299.

All testing was completed with no uncorrected failures. The Mechanical DVT report (b)(4) Trade Secret/CCI provided as Exhibit 7-11.

*Reviewer Comment: The Mechanical DVT was reviewed by the mechanical reviewer. He had no concerns with the testing or the test results.*

### **Electrical DVT (includes EMI)**

Electrical Design Verification Testing (EDVT) was performed to ensure that the Consult™ Communicator met electrical requirements, as defined in system requirements specifications. Areas tested included electromagnetic compatibility (EMC) testing, electrical safety testing, RF exposure analysis, radio compliance testing and general functional testing.

All testing was completed with no uncorrected failures. The Electrical DVT Report 1114037 is provided as Exhibit 7-12. The following reports are provided, which are referenced within (b)(4) Trade Secret/CCI

- Exhibit 7-12 Appendix 1: Communicator Electrical Equivalency (b)(4) Trade Secret/CCI
- Exhibit 7-12 Appendix 2: EDVT Communicator Model 6420 (b)(4) Trade Secret/CCI
- Exhibit 7-12 Appendix 3: EDVT Communicator Model 6443 (b)(4) Trade Secret/CCI
- Exhibit 7-12 Appendix 4: EDVT Modem Test Model 6299 (b)(4) Trade Secret/CCI

- Exhibit 7-12 Appendix 5: EDVT Electrical Safety Model 6299 (b)(4) Trade Secret/CCI
- Exhibit 7-12 Appendix 6: EDVT EMC Model 6299 (b)(4) Trade Secret/CCI

*Reviewer Comment: In summary the sponsor has appeared to have successfully completed their electrical bench testing. There were no protocol deviations affecting the test methods or acceptance criteria. The sponsor does claim electrical equivalency between the Model 6299/6443 and Model 6443/6420 devices. The different models do require custom firmware to properly configure the device prior to testing. There are no further concerns. Note that the electrical EMI tests in section 3 of the report were reviewed separately by the EMC/Wireless Reviewer as part of his EMC and Wireless consult review.*

### **Off the Shelf SW Test**

The Off-the-Shelf Software products represent the commercial software components, used in the LATITUDE Consult™ Server environment. The Off-the-Shelf Software are non-medical device products and are listed here to document testing for the components used in the model 6294 software application.

All testing was completed with no uncorrected failures. Off-the-Shelf Software Validation Report (b)(4) Trade Secret/CCI is provided as Exhibit 7-13.

*Reviewer Comment: The OTS SW Validation Report was reviewed and found acceptable. There were no uncorrected failures.*

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## **EMC/EMI AND WIRELESS**

The EMC/Wireless reviewer reviewed the EMC and Wireless technology areas of the original submission. He identified two deficiencies which need addressing, one for EMC and one for wireless.

In **Amendment A001**, the sponsor provided a response to the two deficiencies. He reviewed the response and found that the sponsor did not fully address deficiency #1. Deficiency #2 was adequately addressed. An additional question was asked interactively to the sponsor for deficiency #1. The sponsor response was reviewed and found acceptable. Since the response contained a large number of pages, the sponsor was asked to submit this response as a formal amendment. The response is included in **Amendment A002**.

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## **SOFTWARE**

The LATITUDE Consult™ system consists of a model 6299 Communicator, a model 6294 Application Server, and a model 6297 Management Server. The Communicator is used to read device data from a patient's ICD and transmit it to the LATITUDE servers. The Application Server processes the transmitted device data and generates device data reports. The Management Server can then be used to locate and view the device data reports. The LATITUDE system software description (Exhibit 2-1: Software Information per FDA Guidance) outlines the software system per the FDA 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'.

The 6294 Application Server is a deployment of the LATITUDE NXT application that is configured for use in a LATITUDE Consult™ workflow. It is responsible for processing of medical device data and for configuration information downloaded to the Communicator. The following paragraphs describe the features controlled by this server.

The 6294 Application Server receives device data from the Communicator. The data is decoded from the specific binary representation into values that can be interpreted by a clinician. The data is stored in the database and used to generate device data reports that can be retrieved and stored in another software application. For the LATITUDE Consult™ system the store and view application is the model 6297 Management Server.

The Application Server downloads configuration data to the Communicator. The configuration information consists of ISP connection information, time synchronization and available Communicator firmware versions.

The interface to the 6294 Application Server is built for secure exchange of data over the public internet. Only Boston Scientific Communicators are allowed to connect. Confidentiality of the data in transit and protection against replay attacks is provided through (b)(4) Trade Secret/CCI by the Communicator and verified by the Application Server.

The documentation provided by the sponsor was reviewed in accordance to the guidance document, Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005. The following areas were reviewed:

- Level of Concern – Server and Communicator
- Software Description – Server and Communicator
- Device Hazard Analysis – Server and Communicator
- Software Requirements Specification (SRS) – Server and Communicator
- Architecture Design Chart – Server and Communicator
- Software Design Specification (SDS) – Server and Communicator
- Traceability Analysis – Server and Communicator
- Software Development Environment Description – Server and Communicator
- Verification and Validation Documentation – Server and Communicator
- Revision Level History – Server and Communicator
- Unresolved Anomalies – Server and Communicator

Review Comment: The initial review of this documentation identified deficiencies in the areas of the SRS, SDS, and Verification and Validation. In **Amendment A001**, the sponsor responded to these deficiencies. The response was reviewed and found to be acceptable. There are no further concerns.

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## **MANUFACTURING AND QUALITY SYSTEM**

The manufacturing and quality system in section 6 of the submission was reviewed by the Mechanical reviewer. During his review there was a request for additional information and clarification from the sponsor. A teleconference was held and the sponsor response is included as part of his review. He found that all manufacturing processes have been adequately validated. However he did note that the BSC facility identified in the submission has not been inspected since November 2006. The Office of Compliance (OC) has been made aware of this and will proceed accordingly.

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## **LABELING**

The Clinician User Manual is provided as Exhibit 5-01.

The following device and package labels were also provided in the submission:

- Exhibit 5-02: Communicator Bottom Label

- Exhibit 5-03: Communicator Wand Artwork
- Exhibit 5-04: Communicator Box Label
- Exhibit 5-05: Communicator Shipping Box
- Exhibit 5-06: Model 6693 Power Adapter Box Label
- Exhibit 5-07: Model 6471 Phone Cord Box Label

*Reviewer Comment: The labeling changes were reviewed and found acceptable. The Clinical reviewer reviewed the Clinician User Manual as part of his clinical review and found it acceptable. There are no further concerns.*

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## **OTHER REVIEW ELEMENTS**

The following areas are not relevant for the subject review:

- Animal Testing
- Biocompatibility
- Packaging, sterilization, shelf-life
- Marketing
- Post Market

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## **CONCLUSION/RECOMMENDATION**

The sponsor responses to the deficiencies have been found to be acceptable. The sponsor has shown the LATITUDE Consult System is safe and effective at this time. I recommend that the sponsor receive an **APPROVAL** letter.