

October 10, 2015

Subject: DSI Quality Management System and PhysioTel Digital (PTD) Implant Testing

Data Sciences International (DSI) was founded on the Values of Inspiration, Innovation and Integrity. Customer First is our guiding philosophy and Quality Products and unsurpassed Customer Service / Technical Support are integrally linked to our success. Our global management systems are compliant to ISO9001 and we consistently pass customer audits without significant issues.

DSI's products are built by highly skilled operators utilizing proven process controls and all performance parameters of every transmitter produced are thoroughly tested. Our corporate headquarters (including all business functions and manufacturing) is located at 119 14th St NW, St. Paul, MN 55112.

DSI's PhysioTel Digital (PTD) Implants are thoroughly tested and pertinent results are recorded (see Appendix for tested performance parameters).

DSI no longer provides calibration values because they are automatically stored into the implant's memory during testing. When an implant is configured to a CLC, it transmits its' calibration values. The calibration data stored in the implant is Cyclic Redundancy Checked (CRCed) to ensure it is correct and not corrupted. This is repeated when data is transmitted to the CLC. If either of these checks fail, it will not be possible for the implant to either join onto a system or be placed into active mode to start to collect data (since valid calibration data would not be available for that implant).

If you have any questions or comments, please do not hesitate to contact me directly.

Best regards,



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APPENDIX (PTD tested performance parameters)

Typical Test Information

Model Number: XX-XXXXX
Date: XX/XX/XXXX
Tester Name: XXX
Test Name: XXXXXXXXXXXXX
Serial Number: XXXXXX

DSI Electrical Test

Current and voltage measurements

I OFF: XXX
I ON: XXX
RF Output Power: XXX
RF Receiver Sensitivity: XXX

Leak Test:

Vacuum test to ensure no housing leaks

Serial Number: XXXXXX
Date: XX/XX/XXXX
Results: Pass / Fail test

Temperature Compensation

Eliminate pressure changes over standard operating temperature

Pressure at 20C: XX.X
Pressure at 40C: XX.X
Difference in Pressure between 20C and 40C: XX.X

Pressure Calibration

Pressure is tested at ambient, 850 and 950mmHg to determine calibration values

Values are stored in non-volatile memory of the implant

Pressure calibration value at 750mmHG: XXX.XX
Pressure calibration value at 850mmHG: XXX.XX
Pressure calibration value at 950mmHG: XXX.XX

Temperature Calibration

Temperature is tested at 35°C, 37°C and 39°C to determine calibration values

Values are stored in non-volatile memory in the implant

Temperature calibration value at 35°C: XXX.X
Temperature calibration value at 37°C: XXX.X
Temperature calibration value at 39°C: XXX.X

Final Configuration

Check transmitter pressure versus actual, pressure drift, turn on “Chirp” and verify correct frequency

Initial ambient compensated Pressure: XXX.XX
Final ambient compensated Pressure: XXX.XX
Ambient compensated Difference: X.XX