https://cosmiic.org

Example - Early Feasibility Investigational Device Exemption

IDE Section:

Appendix E – Control Tower System Testing

E. Appendix E – Control Tower System Testing

This section contains:

E.1. Overview and Conclusions

Previous discussions with the FDA resulted in a common understanding that basic electrical safety testing of the external components of the NNP System would be necessary prior to the Early Feasibility IDE study. We have focused on characterizing dielectric strength and leakage currents for the Control Tower System, which includes the Control Tower, the recharge coil, external AC adapter, remote display, and USB isolator. While not claiming conformance with any standard at this time, we have designed the Control Tower System testing with considerable reference to existing standards. Results indicate adequate dielectric strength of insulation and safe leakage current levels. We believe these results should sufficiently characterize safety of the external components, and permit the start of our Early Feasibility study.

E.2. Control Tower System Specifications

The Control Tower system consists of the Control Tower (CT), the recharge coil, external AC adapter, remote display and USB isolator. Specifications for the Control Tower System are presented in Table L-1.

TABLE E-1. CONTROL TOWER SYSTEM SPECIFICATIONS.

Device Size	Dimensions Weight	12” x 10” x 3” 1.5 lbs
Product Use, Transport, and Storage	Temperature Humidity Atmospheric Pressure	+10 °C to +40°C 30% to 70% (non-condensing) 70 kPa to 106 kPa
Standards Compliance	AC Power Supply ONLY	TUV Certified to UL 60601-1:2003, ES 60601-1:2005
Mode of Operation		Intermittent
Power Requirements	AC DC	100-120 VAC, 50-60 Hz, 1.0 A max 12 VDC, 5.0 A max
Type of Protection Against Electrical Shock		Class II Equipment
Degree of Protection Against Electrical Shock		Type BF Applied Part
Degree of Protection Against Ingress of Water	Coil	IPX0 (not protected)
Magnetic Field Output	Coil	0.341 mT (coil surface) max, 3.5 KHz sine wave

An insulation diagram for the Control Tower system is shown in Figure E-1 with the Classification of Insulation for the Control Tower System Insulation Diagram presented in Table L-2.

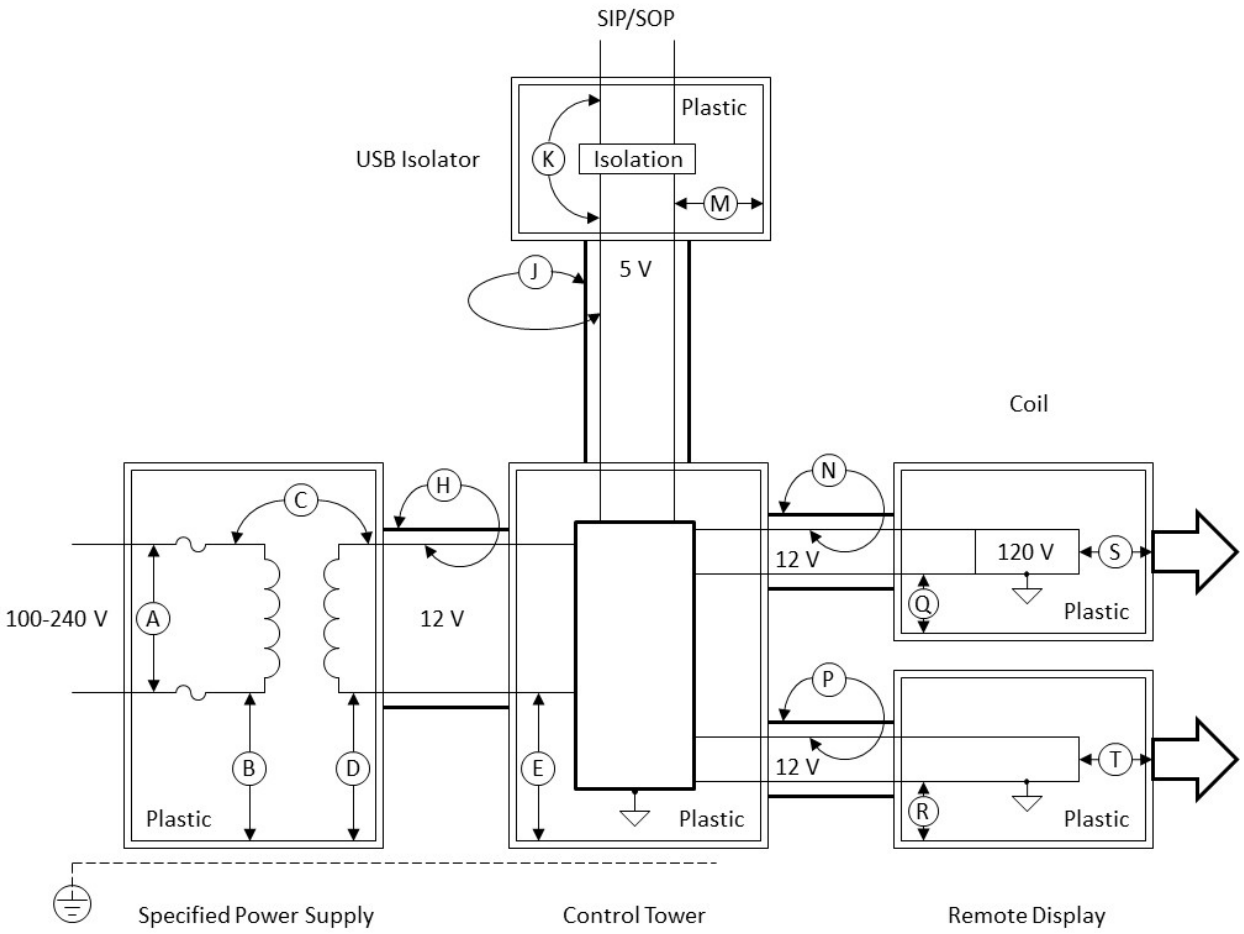

FIGURE E-1. CONTROL TOWER SYSTEM INSULATION DIAGRAM.

TABLE E-2. CLASSIFICATION OF INSULATION FOR THE CONTROL TOWER SYSTEM INSULATION DIAGRAM

Insulation ID (on Insulation Diagram)	Purpose	Classification	DI / clearance / creepage	Test Voltage
A	Opposite Polarity of Mains parts: {20.1 A-f}	BASIC @ 240VAC	Provided by 60601-1 certified Line Power Adapter	1500
B	Live Parts and outside of Enclosure: {20.1 A-a2}	DOUBLE @ 240VAC	Provided by 60601-1 certified Line Power Adapter	4000
C	Live Parts and accessible parts of Tower: {20.1 A-a2}	DOUBLE @ 240VAC	Provided by 60601-1 certified Line Power Adapter	4000
D	Circuitry at 12VDC (given Normal Condition of Tower Earthed through patient or other accessible metal parts) {20.1 A-a2}	DOUBLE @ 12VDC	Provided by 60601-1 certified Line Power Adapter	500
E, H, J, M, N, P, Q, R	Circuitry at 12VDC (given Normal Condition of Tower Earthed through patient or other accessible metal parts) {20.1 A-a2}	DOUBLE @ 12VDC		500
K	Protection of accessible metal of Tower from voltage injected by failed computer (SIP / SOP) {20.1 A-k}	DOUBLE @ 240VAC	Provided by USB Isolator	4000
S	Live Parts and Applied Part: {20.2 B-a} Enclosure and Type F Applied Part {20.2 B-d} Enclosure and Type F Applied Part {20.2 B-e}	DOUBLE @ 120VAC BASIC @ 240VAC DOUBLE @ 12VAC		3000 1500 500
T	Live Parts and Applied Part: {20.2 B-a} Enclosure and Type F Applied Part {20.2 B-d} Enclosure and Type F Applied Part {20.2 B-e}	DOUBLE @ 12VDC BASIC @ 240VAC DOUBLE @ 12VDC		500 1500 500

ASSERTIONS

- The Control Tower is not protected from Patient Contact, but it is not an Applied Part (i.e., patient contact is not required for operation; only donning and doffing)
- The Remote Display is an Applied Part
- The Charging Coil is an Applied Part
- The circuit common of the Control Tower is connected to accessible metal of the enclosure.
- ICCNexergy model MWB100012A 60601-1 certified Line Power Adapter.
- B&B Electronics UH401 single port USB isolator – 4kV isolation.

We are not claiming full conformity to any recognized consensus standards. We did follow key elements of UL 60601-1:2003, IEC 60601-1-1:2000, IEC 60601-1-2:2001 and BS EN 60601-1-11:2010 to guide the design and testing of the Control Tower. The key elements are summarized in Table L-3.

TABLE E-3. LIST OF KEY ELEMENTS FROM VARIOUS STANDARDS USED IN THE DESIGN AND TESTING OF THE CONTROL TOWER SYSTEM.

STANDARD	SECTION	COVERAGE
UL 60601-1:2003	19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	- Enclosure Leakage Testing - Patient Leakage Testing - Patient Auxiliary Testing
UL 60601-1:2003	20 Dielectric strength	- Hipot Testing
UL 60601-1:2003	42.3 APPLIED PARTS of EQUIPMENT not intended to supply heat to a PATIENT shall not have surface temperatures exceeding 41°C.	- Surface Temperature Testing
IEC 60601-1-1:2000	Subclause 19.201 LEAKAGE CURRENTS	- Configuration
IEC 60601-1-2:2001	36.202.2 Electrostatic discharge (ESD)	- ESD Testing
BS EN 60601-1-11:2010	6 * Classification of ME EQUIPMENT and ME SYSTEMS	- Configuration

An example of one of the physical configurations of the Control Tower and its intended connections to the Host Computer Notebook, mains power, remote display, and the user are depicted in Figure E-2, below.

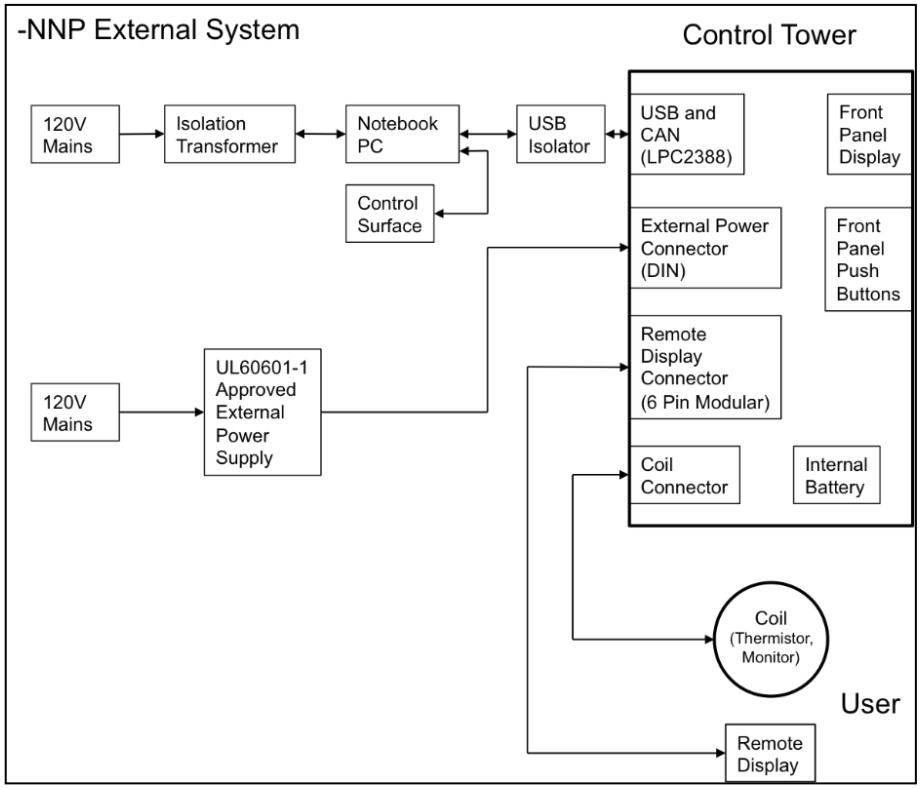

FIGURE E-2. ELECTRICAL CONNECTIONS FROM CONTROL TOWER

For the purposes of establishing the appropriate assumptions for testing in accordance with UL60601-1, IEC 60601-1-1, and -11, all possible configurations between the host computer and Control Tower were considered, as well as the fact that both the host computer and the Control Tower can be powered by either mains or battery. In the subject's home use environment, the Control Tower functions as a stand-alone system and does not require connection to the host computer. Table E-4 provides a summary of Control Tower and Host Computer Notebook configurations.

TABLE E-4. EXTERNAL SYSTEM CONFIGURATION SUMMARY

CONFIG. #	HOST COMPUTER POWER	CONTROL TOWER POWER	ENVIRONMENT	TYPE
1	N/A	Battery	Home	Equipment
2	N/A	Mains	Home	Equipment
3	Mains	Mains	Clinic / Surgical Suite	System
4	Battery	Mains	Clinic / Surgical Suite	System
5	Mains	Battery	Clinic / Surgical Suite	System
6	Battery	Battery	Clinic / Surgical Suite	System

The following assumptions are made:

- When configured as a system, the entire system is considered to be inside of the patient environment.
- It is assumed that the programming host computer does not meet enclosure leakage current specifications.
- When the Control Tower is mains powered, a specified Class II power supply is used with Class II ME equipment with type BF applied parts with surfaces made of insulating material and with a signal input and signal output port.
- When the Control Tower is battery powered, it is considered internally powered equipment with type BF applied parts with surfaces made of insulating material and with a signal input and signal output port.

Allowable continuous leakage current and patient auxiliary current are indicated in Table E-5. Allowable dielectric strength test voltages are presented in Table E-6. ESD immunity test levels are shown in Figure E-7. Maximum applied part surface temperature is presented in Table E-8.

TABLE E-5. ALLOWABLE LEAKAGE CURRENTS.

CURRENT (UA)	NORMAL CONDITION	SINGLE FAULT CONDITION
ENCLOSURE LEAKAGE CURRENT	100	500
PATIENT LEAKAGE CURRENT (AC)	100	500
PATIENT LEAKAGE CURRENT (mains voltage on the SIGNAL INPUT or SIGNAL OUTPUT)	-	-
PATIENT LEAKAGE CURRENT (mains voltage on the APPLIED PART)	-	5000
PATIENT AUXILIARY CURRENT (AC)	100	500

Results are presented in Section E.4, below.

TABLE E-6. DIELECTRIC STRENGTH TEST VOLTAGE.

INSULATION TO BE TESTED	TEST VOLTAGE
Basic insulation	1500
Supplementary insulation	2500
Reinforced and double insulation	4000

Results are presented in Section E.3, below.

TABLE E-7. ESD IMMUNITY TEST LEVELS.

TEST	LEVEL
Air Discharge	±2 kV, ±4 kV, ±8kV
Contact Discharge	±2 kV, ±4 kV, ±6kV

Please see *Appendix F – Electromagnetic Compatibility (EMC) Testing* for applicable test results for the external components of the Control Tower System.

TABLE E-8. ALLOWABLE APPLIED PART SURFACE TEMPERATURE.

TEST	LEVEL
Surface Temperature	41° C

Please see *Appendix I – Battery Testing and Heating Characterization* for applicable test results for the external coil.

E.3. Control Tower System Dielectric Strength Test

METHODS

Dielectric Strength testing (hipot) was performed on the Control Tower system as described in UL 60601-1:2003 - 20 Dielectric Strength (up to 4000V). We do not claim compliance with this standard in the Early Feasibility stage.

The equipment under test (EUT) consisted of the Control Tower, Recharge Coil, Remote Display, USB Isolator, and AC Power Adapter. Please refer to the insulation diagram shown in Figure E-1, above, and the key for the insulation diagram and test voltages given in Table E-2, above.

The test was conducted on a non-conducting table with metal legs. A Quadtech Sentry 10 Hipot Tester (SN 2353023) was used to deliver 60 Hz AC test voltages. The test voltage was ramped up from 0V to the prescribed voltage over a period of 20 seconds and then held at the prescribed voltage for 60 seconds. The Recharge Coil and Remote Display were wrapped with aluminum foil for electrical connection. In addition a 10cm x20cm conductive surface was used for insulated surface testing (enclosures).

RESULTS

A summary of the hipot tests performed is presented in Table E-9, below.

TABLE E-9. CONTROL TOWER SYSTEM DIELECTRIC INSULATION TEST SUMMARY

ITEM	TEST CONFIGURATION	INSULATION DIAGRAM	TEST VOLTAGE	RESULT
1	20.1 A-f	A	1500	**PASS**
2	20.1 A-2	B	4000	**PASS**
3	20.1 A-2	C	4000	**PASS**
4	20.1 A-k	K	4000	**PASS**
5	20.2 B-a	S	3000	**PASS**
6	20.2 B-d	T	1500	**PASS**
7	20.2 B-a	T	500	**PASS**

CONCLUSIONS

Insulation of the Control Tower System provides sufficient protection to users.

E.3.1. Recharge Coil Dielectric Strength Test

While not a requirement of the standard, a separate test of the Recharge Coil was also performed. All 6 contacts of the Recharge Coil connector were tied together and connected to the hipot tester ground. The AC connection of the hipot tester was connected to aluminum foil for three different configurations of the coil: 1) placed face down on aluminum foil; 2) placed face down and wrapped on its sides; and 3) completely wrapped with foil. A plot of the leakage current as a function of the test is presented in Figure E-3, below. The test voltage is plotted to the highest value achieved without arcing.

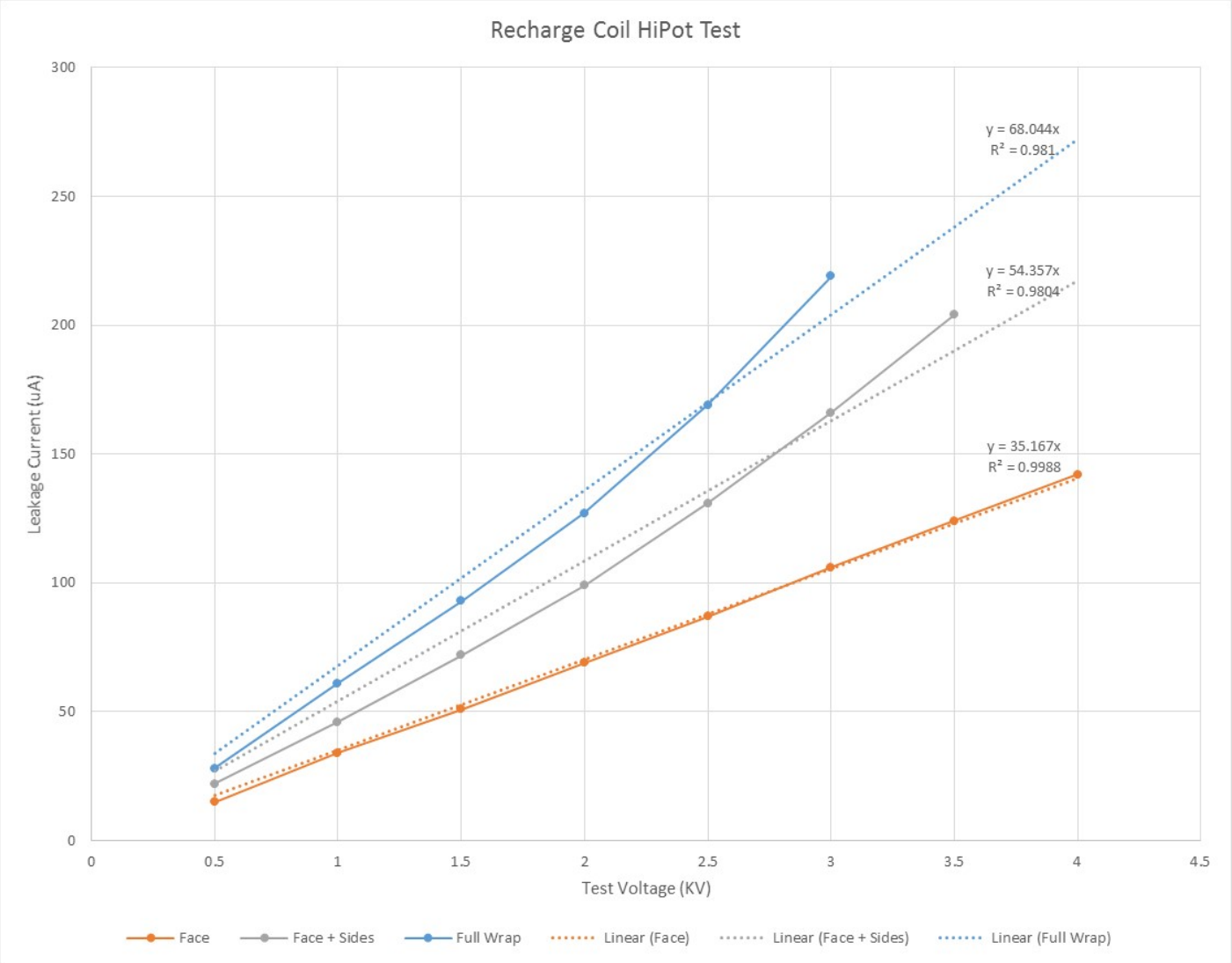

FIGURE E-3. INDEPENDENT HIPOT TEST OF THE RECHARGE COIL.

E.4. Control Tower System Leakage Current Testing

METHODS
Testing was conducted following the methods described in IEC60601-1, Section 19.4g, although conformance to this standard is not being claimed for the Early Feasibility IDE study. The unit under test consisted of a Control Tower, recharge coil, AC power adapter, and USB isolator.

Because the Control Tower System makes no intentional electrical connection to the user (such as EMG electrodes), DC leakage current testing was not characterized. Earth leakage was not characterized in accordance with footnotes 2), 3), and 4) of Table IV, UL 60601-1.

ACCEPTANCE CRITERIA
The test was considered PASSED if the unit under test met the criteria specified in Table E-5, above.

RESULTS
Results are presented in Table E-10, below.

TABLE E-10. CONTROL TOWER SYSTEM LEAKAGE CURRENTS.

CURRENT (UA)	NORMAL CONDITION LIMIT	SINGLE FAULT CONDITION LIMIT	MAXIMUM RECORDED	RESULTS
ENCLOSURE LEAKAGE CURRENT	100	500	82.5, 104.3	**PASS, PASS**
PATIENT LEAKAGE CURRENT (AC)	100	500	13.5, 16.3	**PASS, PASS**
PATIENT LEAKAGE CURRENT (mains voltage on the SIGNAL INPUT or SIGNAL OUTPUT)	-	-	32.9	
PATIENT LEAKAGE CURRENT (mains voltage on the APPLIED PART)	-	5000	13.8	**PASS**
PATIENT AUXILIARY CURRENT (AC)	100	500	3.8, 3.8	**PASS, PASS**

CONCLUSIONS
The Control Tower System demonstrates safe levels of leakage currents.