

WHALETEQ

HFCN Test Fixture

Model: HFCN

User Manual



Version 2020-07-15
Hardware Version 1.3

1. Introduction

HFCN (High Frequency Coupling Network) is a test fixture specifically designed for testing electrosurgical interference with ECG devices/Patient monitor. The HFCN is built to satisfy the interference testing requirements as stated in IEC60601-2-25/-2-27/-2-49, AAMI EC13 & China YY1079.

While the manufacturer claims that the ECG/Patient monitor is intended to be used in an electrosurgery environment, a means shall be provided for protection against malfunction caused by electrosurgery.

The electrosurgery interference test requirements and the test circuits as described in IEC60601-2-25/-2-27/-2-49 and AAMI EC13/ China YY1079 are different. For the convenient of the manufacturer, WhaleTeq HFCN test fixture is designed to support all the above described standards. There are two modules/test circuits embedded in WhaleTeq HFCN test fixture and each module supports different standards. According to the purpose of testing or standards to follow, the HFCN user may select the different modules with a simply switch toggle.

ESU generates a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and a working frequency of 400 kHz \pm 10 %. To withstand the high-voltage waveforms of ESU, specific components and cooling methods are designed into the WhaleTeq HFCN.

2. Safety Summary

Please review the following safety warnings to avoid injuries and prevent damage to this product or any related products. To avoid potential hazards, only use the product in accordance with this instruction. Only WhaleTeq qualified professionals should repair/adjust the operation program.

The equipment shall be operated by a qualified electrical engineer or a professional with equivalent qualification and knowledge in the principle of high-voltage operation. **Please read this user manual carefully for the working principles and possible risks before first operating the HFCN.**

WARNING: Be aware that the shield around this fixture, the fixture's ECG outputs, and the entire ECG system and cable of the monitor under test all have dangerous voltages present on them whenever the electrocautery unit is enabled. Proper precaution and safety measures must be exercised. To prevent a short circuit, keep metal plate and NE has a certain distance.

3. Features

- Compliance with IEC 60601-2-25/-2-27/-2-49:2011, China YY1079:2008, & AAMI EC13:2002 electrosurgery interference test requirements
- High power rating (>300 W) and low inductance circuits. Good heat dissipation capacity and fulfill the requirements of the standard stated less than 5 μ H inductance
- Uses the same breakout box as WhaleTeq ECG test equipment. Both male & female terminals are available for plugging to the HFCN directly.

4. Specification

- Standard coverage: Built-in test circuits as defined in IEC 60601-2-25/-2-27/-2-49:2011 Clause 202.6.2.101 (Electrosurgery interference); China YY1079:2008 Clause 5.2.8.13/AAMI EC13:2002 Clause 5.2.9.14 ESIO/ESIS tests
- Test Fixture Power Rating: >300 W
- Resistor Inductance: <5 μ H
- Frequency range: DC to 100 MHz
- Use Non-Inductive Power Resistors: Resistance Tolerances to $\pm 5\%$, TCR of ± 100 ppm/C, Power Rating 200 W/pcs
- Skin impedance simulated circuit: Resister : 51 k Ω $< \pm 5\%$, Capacitor: 47 nF $< \pm 5\%$ COG
- ECG simulator in Module B : (defined in EC13, acting on LL, V1~V6)
 - A. Amplitude: 1 mV $\pm 10\%$
 - B. Pulse width: 75 ms $\pm 10\%$
 - C. Rate: 73 bpm $\pm 5\%$

5. Functions

- **Module A (Electrosurgery Interference Overload Test module)**
 - Comply with the test requirements of IEC 60601-2-25/27 “Electrosurgery interference” & China YY1079/ AAMI EC13 electrosurgical interference overload (ESIO)
 - Built-in simulated skin impedance circuits (51 kΩ/47nF) per standard requirements. The DB15 directly connect to WhaleTeq Breakout Box: BB-A1(Male terminals) 、 BB-C1(Female terminals).

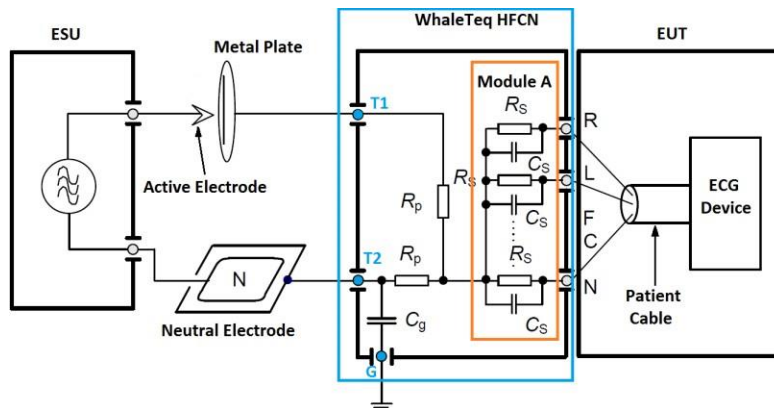


Figure 1. Test circuit for HF surgery protection measurement (module A)

- **Module B (Electrosurgery Interference Suppression Test module)**
 - Comply with the test requirements of China YY1079/ AAMI EC13 electrosurgical interference suppression (ESIS)
 - Built-in test circuit, ECG signal generator, simulated skin impedance circuit (51 kΩ/47 nF),. The DB15 directly connect to WhaleTeq Breakout Box: BB-A1(Male terminals) 、 BB-C1(Female terminals).
 - The LED indicator will flash to indicate that a valid signal. While there is no sign of a flashing LED, it is an indication to replace the battery.

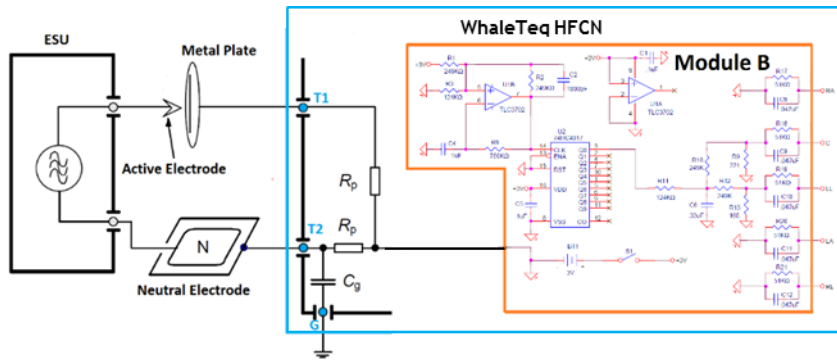


Figure 2. Test circuit for HF surgery protection measurement (module B)

- Toggle Switch: Select Module A & Module B
- External Terminals :

T1: terminal for connecting to “Metal plate”

T2: terminal for connecting to “Neutral electrode”

G: Grounding terminal

6. Test setup

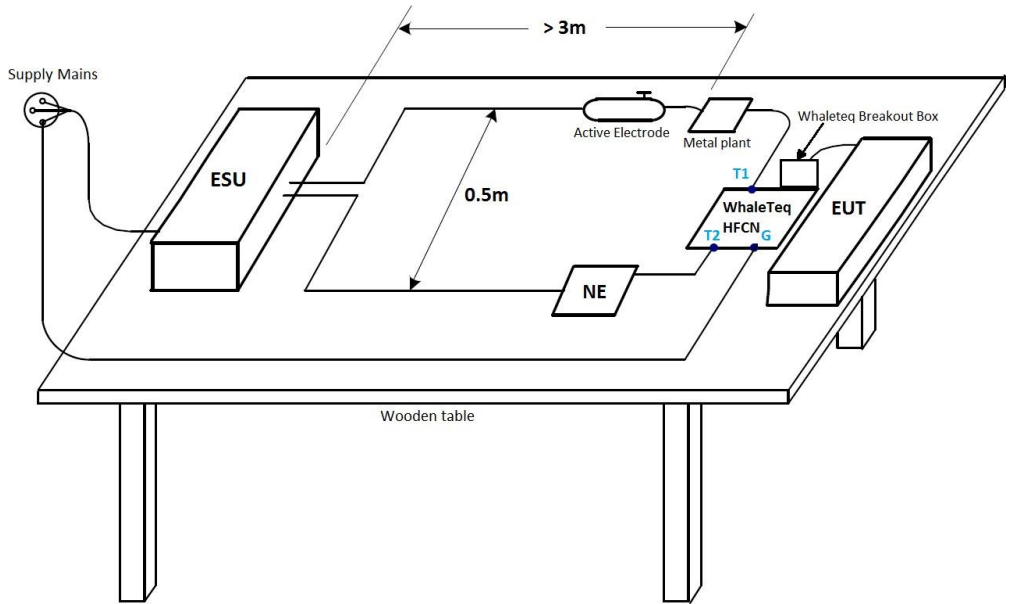


Figure 3. Test setup for HF surgery protection measurement

7. Test Cases

A. Electrosurgery Interference / Overload Test

- Standard Coverage
 - IEC 60601-2-25/27:2011 Clause 202.6.2.101 Electrosurgery interference
 - China YY1079:2008 Figure 12a Electrosurgical interference overload test
 - AAMI EC13:2002 Figure 13a Electrosurgical interference overload test
- Test Setup
 - Set up the test environment as illustrated in Figure 3
 - Use “WhaleTeq HFCN Module A” and connect to “WhaleTeq ECG Breakout box” with EUT lead wires connected
- Test Circuit

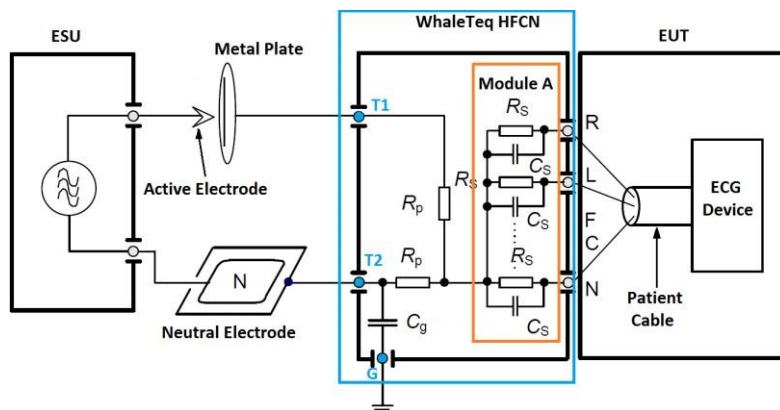


Figure 4. Test circuit for HF surgery protection measurement (module A)

WARNING: Be aware that the shield around this fixture, the fixture's ECG outputs, and the entire ECG system and cable of the monitor under test all have dangerous voltages present on them whenever the electrocautery unit is enabled. Proper precaution and safety measures must be exercised. To prevent a short circuit, keep metal plate and NE has a certain distance.

- *Test in Cut mode*
 - *Set the output power of the ESU cut mode to the 300 W position.*
 - *Hold down the button “Cut” of active electrode*
 - *Touch the metal plate in the test set-up (see Figures 3) with the active electrode and remove the electrode slowly to get an arc.*
 - *Verify whether the recorded/displayed ECG baseline returns to its normal position within 10 s and the ME EQUIPMENT returns to the previous operating mode without loss of any stored data*
 - *Repeat the procedure five times*

- *Test in Coagulation mode*
 - *Set the output power of the ESU Coag mode to the 100 W position.*
 - *Hold down the button “Coag” of active electrode*
 - *Touch the metal plate in the test set-up (see Figures 3) with the active electrode and remove the electrode slowly to get an arc.*
 - *Verify whether the recorded/displayed ECG baseline returns its normal position within 10 s to and the ME EQUIPMENT returns to the previous operating mode without loss of any stored data*
 - *Repeat the procedure five times*

B. Electrosurgery Interference Suppression Test

- Standard Coverage
 - China YY1079:2008 Clause 5.2.8.14 Electrosurgical interference suppression test
 - AAMI EC13:2002 Clause 5.2.9.14 Electrosurgical interference suppression test
- Test Setup
 - Set up the test environment as illustrated in Figure 3
 - Use “WhaleTeq HFCN Module B” and connect to “WhaleTeq ECG Breakout box” with EUT lead wires connected
- Test Circuit

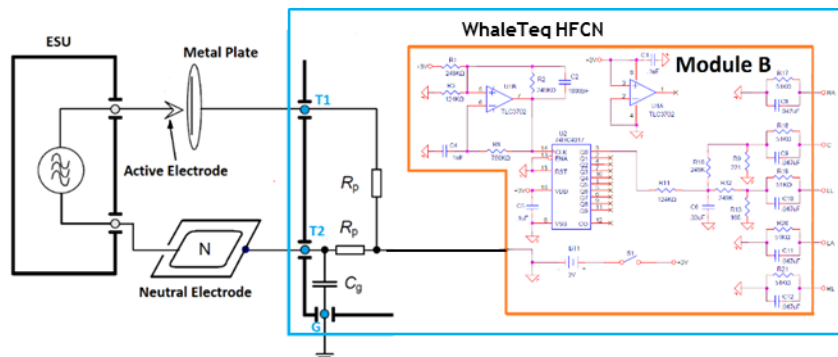


Figure 5. Test circuit for HF surgery protection measurement (module B)

WARNING: Be aware that the shield around this fixture, the fixture’s ECG outputs, and the entire ECG system and cable of the monitor under test all have dangerous voltages present on them whenever the electrocautery unit is enabled. Proper precaution and safety measures must be exercised. To prevent a short circuit, keep metal plate and NE has a certain distance.

- *Test in Cut mode*
 - *Power-ON the HFCN module B “Simulated ECG Output”, a flashing LED will indicate the power-ON status. Once powered up, the EUT will receive and display a 1 mV simulated ECG signal as illustrated in figure 6.*
 - *Set the output power of the ESU cut mode to the 300 W position.*
 - *Hold down the button “Cut” of active electrode*
 - *Touch the metal plate in the test set-up (see Figure 3) with the active electrode and remove the electrode slowly to get an arc.*
 - *Verify whether the recorded/displayed ECG baseline returns to its normal position within 10 s and the ME EQUIPMENT returns to the previous operating mode without loss of any stored*
 - *Verify lead II \ lead III \ V1 ~ V6 appears 1mV simulated ECG signal as figure 6.*

- *Test in Coagulation mode*
 - *Power-ON the HFCN module B “Simulated ECG Output”, a flashing LED will indicate the power-ON status. Once powered up, the EUT will receive and display a 1 mV simulated ECG signal as illustrated in figure 6.*
 - *Set the output power of the ESU coag mode to the 100 W position.*
 - *Hold down the button “Cut” of active electrode*
 - *Touch the metal plate in the test set-up (see Figure 3) with the active electrode and remove the electrode slowly to get an arc.*
 - *Verify whether the recorded/displayed ECG baseline returns to its normal position within 10 s and the ME EQUIPMENT returns to the previous operating mode without loss of any*

stored data

- Verify lead II 、 lead III 、 V1 ~ V6 appears 1mV simulated ECG signal as figure 6.

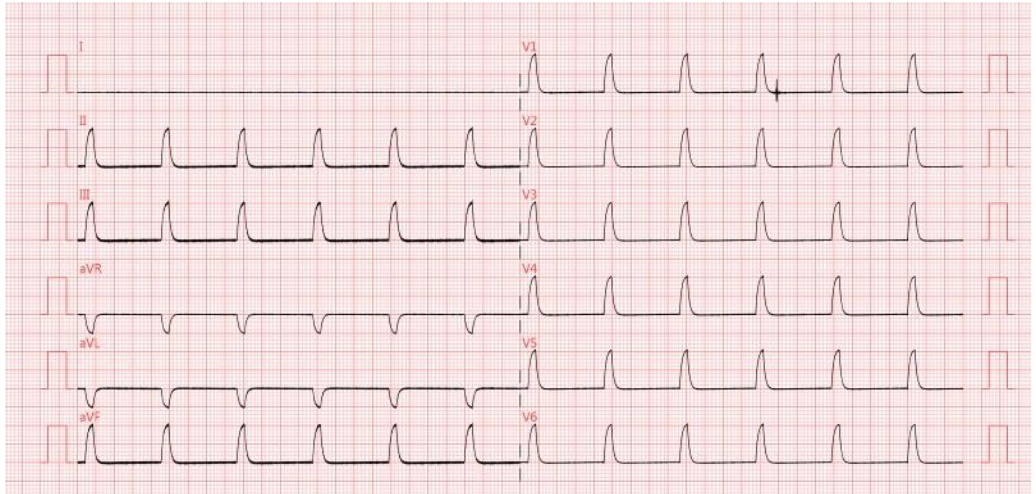


Figure 6. EUT displays the waveform that is generated by HFCN

8. Contact WhaleTeq

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