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MEDICAL EQUIPMENTS
FOR
ARMOURED AMBULANCE TRACKED VEHICLE

ACCEPTANCE TEST PROCEDURE

COMBAT VEHICLES
RESEARCH & DEVELOPMENT ESTABLISHMENT
AVADI,CHENNAI- 600 054.

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ACCEPTANCE TEST PROCEDURE FOR MEDICAL EQUIPMENTS

1. TECHNICAL REQUIREMENTS

1.1. GENERAL:

1.1.1. Units and parts to be removed from its packaging to be inspected visually for damage.

1.1.2. Don’t use non approved products or in a non -approved manner.

1.1.3. The devices must be used only by qualified medical staff who have been suitably trained and know about the safety measures to be taken in case of emergency.

1.1.4. The devices must be operated in compliance with the instructions contained in User’s manual.

1.1.5. Check all the operating knobs for any damage.

1.2. CHARACTERISTICS OF EQUIPMENTS:

1.2.1. Suction Apparatus:

1.2.1.1. Check the battery inserted properly

1.2.1.2. Check the battery status by the indicator.

1.2.1.3. Check the green LED is continuously lit while external AC or DC power is connected.

1.2.1.4. Check connectors, tubes and canister lid for leakage or damage

1.2.1.5. Check the device with device test procedure on external DC power and from the internal battery.

1.2.2. Ventilator:

1.2.2.1. Make sure that the environment housing the device is free from anesthetic, toxic or inflammable gases since the device sucks in the air from the environment.

1.2.2.2. Make sure that the supply of medical gas is connected to the ventilator.

1.2.2.3. Make sure that the line cord is properly connected and socket well fixed by means of its own screw lock if the device is connected to an external source of power supply.

1.2.2.4. Check the commands (cursors & buttons) are in good operating order. The admitted tolerances as per EN / 794-3 technical rule are

a) ± 10% for the pressures
b) ± 15% for the Flows
c) ± 5% for the Frequencies

1.2.3. Defibrillator:

1.2.3.1. Avoid moisture or contact with water, extreme atmospheric pressure, excessive humidity and temperatures and dust, saline or sulphuric air.

1.2.3.2. Switch on the inverter before power on the defibrillator.

1.2.3.3. Check that battery level is acceptable and battery condition is good.

1.2.3.4. Check the device as per instructions given in the user manual.

2. CHECKING PROCEDURE

2.1. SUCTION APPARATUS

1. Before starts the device tests (ie. before press the TEST button) make sure the patient suction tubing is not occluded or bend and the Suction Catheter Adopter is removed from its holder (if applicable).

2. The device test program is to identify whether the device operates satisfactorily, is assembled correctly or if it needs service. There are 4 steps.

   i). Step 1: Checking for occlusions in the Suction system (including canister and tubing)

   ii). Step 2: Checking vacuum build up efficiency of pump system (how much vacuum is built up with in 3 seconds).

   iii). Step 3: Checking the maximum achievable vacuum level of device (reaches this level with in 10 seconds).

   iv). Step 4: Checking for air leakage in the pump system (including canister and tubing)

3. The green LED bargraph will indicates which step of the test is currently in progress or which corresponding test result is being displayed.
   Eg. LED 1 (lower LED) lit = Step 1 & LED 2 lit = Step 2 etc

Connect the equipment to an external power source provide in the vehicle

i). Press and hold the TEST–Button while setting the Operating knob to 500+mmHg.

Note: *Do not release the TEST- Button until minimum 2 seconds after the operating knob has been set to 500+mmHg. The test will start immediately*

ii). As soon as LED 2 of the Battery Status indicator comes on (takes approx. one second), fully occlude the patient Suction Tubing.*

iii). Keep the tubing occluded until LED 1 comes on. Read the test results.

Note: *If you need to interrupt the test and revert to normal operation, turn the operating knob to another position and then select the required setting.*

- *If the tubing is not occluded within 2 minutes, the test will be interrupted and the power **ON** indicator will start t flash slowly (approx. once per second). To restart the test, set the Operating knob to **"0"** and then start over again.*

After the test is completed, the Vacuum indicator will automatically display the result from STEP 1. To display the results from STEP 2,3 and 4, simply press the TEST- Button once for each STEP. If you continue pressing the button after the STEP 4 result has been displayed, the earlier results will be repeated (STEP 1,2,3,4,1,etc.). To exit the test program, set the Operating Knob to another position.

TEST STEP DISPLAYED ON THE BATTERY STATUS INDICATOR	TEST RESULT DISPLAYED ON THE VACUUM INDICATOR	ACTION IF TEST FAILED
STEP – 1: Occlusions	Test Passed: ≤ 100 mmHg.	Check possible occlusions (e.g. twisted tubing) and run the device Test again.
STEP – 2: Vacuum Build-Up Efficacy- within 3 Seconds	Test Passed: ≥ 300 mmHg.	Check Connectors, Tubes and Canister Lid for leakage or damage. Check exhaust outlet for occlusion and run the device Test again.
STEP -3: Max. Achievable Vacuum-within 10 seconds	Test Passed: ≥ 500 mmHg.	Check Connectors, Tubes and Canister Lid for Leakage or damage. Check exhaust outlet for occlusion and run the Device Test again.
STEP – 4: Air Leakage	Test Passed: ≥ 450 mmHg.	Check connectors, Tubes and Canister Lid for leakage or damage and run the Device Test again.

2.2. VENTILATOR :

1. Before starts the tests install the device as follows:

    a) Connect the ventilator to a charged bottle (oxygen cylinder in filled condition)
    b) Supply the ventilator with the compressed gas through pressure regulator.
    c) Connect the device to an external power source and verify that the green led placed between the electrical 12 V DC socket and the fuse F1 lights.

2. Turn the ventilator **ON**.

3. Verify that the ventilator don't run the **O_2 Alarm ON** (in case this alarm will be turned **ON**, it means that the pressure of the external gas source is lower that **3 bar**)

4. Adjust the ventilation frequency to **10 BPM** (check the value displayed on the screen)

5. By adjusting on the FLOW knob, adjust the displayed value of **TVC= 1000 ml.**

6. Adjust the Trigger on (-) minus**10mbar.**

7. Adjust the pressure limit to **60mbar** (end of scale).

8. Verify that the **AUTO** ventilation mode has been selected.

9. Verify that the ventilation start (the gas will start to flow through the patient circuit).

10. Verify the displayed **I/E ratio (IE = 0.5)**

11. Because the patient circuit is not connected to a patient, the **PMIN (Pressure Minimum)** alarm turns **ON** and the acoustic alarm starts.

12. Activating the **RESET button**, the acoustic alarm stops (for about 50 Seconds) and O_2 alarm excluded, all the visual alarm (red leds near to the RESET button) will flash.

13. Close the **Pop-Off valve** by thumb or lock it.

14. Close the exhalation valve output port to block the blow of the gas supplied by the ventilator and maintain it closed.

15. Verify that the **AIRWAY PRESSURE** displayed by the light bar will be greater than **50mbar** or above

16. Open the output port of the exhalation valve.

    Note: with the out put port of the exhalation valve open, the **PMIN** pressure alarm will turn on during the ventilation acts.

17. Adjust the **TRIGGER** to **0 mbar**.

18. Verify the displayed I/E ratio (**IE = 1**).

19. Verify that the value of the **FREQUENCY** displayed on the screen is now **FR = 15bpm** instead of the previous **FR = 10bpm**.

20. Select the **AMV** ventilation mode.

21. Verify that every time you will push the AMV button, the ventilator will supply the medical gas to the patient (manual ventilation).

    The device under test (DUT) can be accepted if it complies the above mentioned test procedure.

2.3. DEFIBRILLATOR

1. Before turning on the power check the following items

   a) Power cord, cables and pins of the paddle connector are not frayed or damaged.

   b) Operation panel is not torn or broken

   c) All keys, buttons and control are undamaged and function properly.

   d) Recording paper is loaded properly

   e) Paddles, pads and cables prepared

   f) Battery fully charged (battery charge complete lamp is (lit)

   g) Specified 3 prong power cord is properly connected.

2. After turning the power on check the following

   a) The AC lamp lights when the power cord is connected to the defibrillator.

   b) There is no fire, no smoke or smell.

   c) There is no electrical shock when touching the instrument.

   d) Instrument is not abnormally hot.

   e) Lamp indication is correct.

   f) All settings are correct.

   g) The battery is fully charged.

3. During the basic checks, the following six functions are checked.

   i) Discharge check

   ii) Battery check

   iii) Recorder check

   iv) Alarm check

   v) Voice check

   vi) Defibrillation wave form check.

   To perform the basic check, proceed as follows:

   a) Turn the **Energy / Mode** Select control to the **SETUP** position. The Setup screen appears.

   b) Select Basic Checks by pressing the Key for **"Item ↓"** or **"Item ↓"**

   c) Press **SET key**. The basic checks screen appears.

   When start the basic checks, all the items are checked automatically. Follow the guidance on the screen and press the corresponding key.

   Results are displayed on the screen. When all the checks are completed and found alright, **"OK"** appears on the screen.

   d) Press the key for **"OK"** to start the basic checks. Discharge check starts.

      i) DISCHARGE CHECK:

      Energy charging starts. The CHARGE lamp blinks, there is a beeping sound and a **"CHARGING**J"** message displayed on the screen.

      When charging completes, the CHARGE lamp lights and there is a continuous buzzing sound. Confirm that **"270J"** and **"CHARGED"** messages appear on the screen. Then, the **"Press discharge buttons until discharge"** message appears. With the paddles in the paddle holder,

simultaneously press both **DISCHARGE** buttons on the external paddles. Hold the buttons pressed until energy is discharged to the paddle holders. The energy is discharged in synchronization with the **TEST** wave form.

Check the displayed energy value becomes **"0J"** and **"√"** is displayed on the screen.

II) BATTERY CHECK:

Confirm that **"√ "** is displayed on the screen.

III) RECORDER CHECK:

A **"Did the recorder print?"** message is displayed on the screen. Press the **Yes** key when paper was output, and the **No** key when the paper was not output.

IV) ALARM CHECK:

A **"Did the alarm sound?"** message displayed. Press **Yes** key when the alarm sounded, and **No** key when the alarm did not sound.

V) VOICE CHECK:

This check is performed when the voice prompt unit (option) is installed. A **"Was the voice heard?"** message is displayed and there is a voice **"Use disposable paddle".** Press the **Yes** key when the voice was heard and the **No** key when the voice was not heard.

VI) DEFIBRILLATION WAVE FORM CHECK:

The defibrillation wave form that is output in the Discharge check can be displayed by pressing the Wave shape key. To return to the Basic check menu press the return key.

e) When all checks finish, a **"Basic checks complete"** message appears on the screen and the check result is recorded on the recording paper.

f) Press the Menu key to return to the **SETUP** screen.

4. **SpO_2 Monitoring:**

SpO_2 is monitored by attaching a probe to the patient and connecting the SpO_2 adapter cable to the SpO_2 / CO_2 connector on the defibrillator.

SpO_2 normal measurement should be between 95 to 100.

5. **NIBP** (**N**on – **I**nvasive **B**lood **P**ressure) **Monitoring:**

It is measured by wrapping the cuff on the patient upper arm and connecting the cuff to the NIBP socket on the monitor.

Put the cuff on the upper arm so that the arrow mark of the ARTERY aligns with the artery of the patient.

Place the cuff upper arm (brachium) at the same height as the patients heart.

The best measuring condition is when the patient is lying on his / her back with arms and legs relaxed.