



C CONTINUOUS P POSITIVE A AIRWAY P PRESSURE

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EN ISO 13485:2012

V1-V3 SERIES USER AND SERVICE MANUAL

Смття

IMPORTANT INFORMATION

This manual will help you install and perform preventive maintenance on your MTTS CPAP device.

Refer to MTTS Youtube channel for more instructions:

https://www.youtube.com/user/MTTSasia

Note that preventive maintenance should be performed every 6 months and all the information required to do this is enclosed in this manual.

If you have any technical problem please contact nearest MTTS distirbutor. List of distributors can be found at:

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INTRODUCTION

CPAP - Continuous Positive Airways Pressure - is one method used to support neonates with respiratory distress and assists them in maintaining continuous positive airway pressure while breathing on their own.

What does CPAP do?

- Keeps alveoli open during exhalation,
- Increases continuous O2/CO2 exchange in the lungs,
- Increases exchanges between the alveoli and the blood vessels,
- Removes and redistributes the water in the blood vessels of the lungs,
- Inflates the small bronchi and drains sputum,
- Increases the volume of air circulation,
- Reduces respiratory tract resistance and respiratory frequency,
- Stabilizes the thorax,
- Improves function of the diaphragm,
- Maintains Functional Residual Capacity (FRC),
- Helps reduce the amount of work required by the infant to breathe,
- Can reduce the need for intubations and mechanical ventilation,

Note:

Before beginning any technical tasks, DO NOT FORGET to put the brake on the wheels in order to prevent the CPAP from moving. Turn OFF the CPAP and unplug it from the 220V.

Сттт

CPAP SYSTEM

The MTTS CPAP system is composed of:

I.Air Compressor,

- 2. FiO2 Blender with flow meters (Air and O2),
- 3. Pressure Thermos,
- 4. Humidifier and Heater,
- 5. Front panel of CPAP,
- 6. Back panel of CPAP,
- 7.Tube-set.



DRAW.I

AIR COMPRESSOR

I. OPERATING PRINCIPLE:

The main function of the air compressor is to provide a low pressure (408 cmH2O) air flow at a maximum rate of 10 l/minute. Compression pressure is at 285,5 cmH2O.

The air compressor operates using a diaphragm mechanism similar to the cardiopulmonary system. The diaphragm rests between the motor and machinery cover to ensure clean air is used during compression. Two rubber layers push continuously so the compressor does not need a lubricant which in turn ensures it passes clean air.

2. PREVENTIVE MAINTENANCE

Preventive maintenance must be performed every 6 months by a hospital technician.

2.1. Look at the general aspect of the air compressor

- 2.1.1. Sticker: can the text on the sticker be read? If not call MTTS for a replacement.
- 2.1.2. Inspect the <u>tube connector</u>. If broken or leaking call MTTS for a replacement.









Open the compressor 2.2.

- 2.2.1. Remove the compressor from its base and turn it upside down on the floor. **BEVERY CAREFUL.**
- 2.2.2. Remove the 4 screws on the base of the compressor.

4 screws: if one is missing replace it.



- 2.2.3. Turn the compressor right-side-up.
- 2.2.4. Remove the screw on the side and remove the cover.
- 2.2.4.1. Remove the screw:

M4 button-head, self-tapping 30mm (VI Series only)

2.2.4.2. Remove the cover.

NOTE: CPAPV3 Series comes with wing nut which can be removed without any tools.



2.2.6. Remove 2 screws.



2.2.7. You can open the air compressor by removing the grey cover

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Unscrew the 4 screws and remove the black cover.



Pic.6



Pic.7

2.2.5. Remove filter(s)

Стття

2.2.8. Use a vacuum-cleaner or compressed air to remove dust inside the air compressor

Clean with a vacuumcleaner or compressed air to remove ALL the dust in the air compressor and around the diaphragm.



Pic.8

- 2.3. Close the compressor and replace parts
- 2.3.1. Replace the black cover and screw it in with the 4 screws and washers. (M4, buttonhead, machine screw, 10mm).

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Replace the black cover and screw in the 4 small screws and washers.

M4, buttonhead, 10mm

Pic.10

Pic.9

2.3.2. Replace the grey cover on the air compressor.



2.3.3. Turn the unit upside down and screw in the 4 screws.



Pic.12

4 screws: if one is missing replace it.

screw M5



Pic.13





2.3.6. Substitute the old seal for a new one and replace the blue cover.

2.3.5. Screw in the two smaller screws and put in new filters.



Pic.14

2.3.5.1. Screw in the 2 screws (VI Series only) M4 flat countersunk, self tapping 30mm



2.3.5.2. Change the two filters. Put the white filter in first and then the green. NOTE: CPAP Series V3 comes only with white filter

Pic.17



2.3.6.2. Close the cover.2.3.6.3. Screw in the screw and use a bit of 502 or similar (superglue)

Pic.18

2.3.6.1. Change the seal.

M4 buttonhead, self-tapping 30mm



Pic.20

2.3.7. Finally, use a tissue to clean the outside surface of the compressor with an antimicrobial hand sanitizer used in your hospital or MTTS Optima. NEVER use water as it could penetrate the air compressor and damage it.

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FiO2 BLENDER

I. OPERATING PRINCIPLE:

Oxygen and air enter the blender through 2 tubes. The oxygen and air is mixed to become FiO2 and transmitted into the patient in a ratio set by the user.

The FiO2 blender is composed of 2 identical parts.

2. PREVENTIVE MAINTENANCE

Preventive maintenance should be performed every 6 months. It can be done on both flow meters at the same time or separately.

2.1. Inspect the blender

On the front panel:

- 2.1.1. Stickers: can the text on the sticker still be read? If not call MTTS for a replacement.
- 2.1.2. Check that the knobs for air and O2 work perfectly and you can still read the text on the knobs. Turn the knobs right and left to check if they turn smoothly.

On the back panel:

- 2.1.3. Inspect the three connectors :
- 2.1.3.1. Connect and disconnect each tube to ensure the connectors work well and don't need to be forced.

Pic.22

2.1.3.2. If any of them are broken call MTTS for a replacement part.





2.2. Clean the two flow meters (O2 and Air)

The following steps show the cleaning process for ONLY one flowmeter BUT you have to do this EVERY 6 months for BOTH flow meters.

2.2.1. Remove the outer tube from the flow meter by turning the cylinder in an anticlockwise direction. Put the cylinder to one side







Pic.25

- 2.2.2. Clean the outer tube with a tissue moistened with an antimicrobial hand sanitizer used in your hospital or MTTS Optima.
- 2.2.3. Remove the inner tube with the metal ball from the flow meter.

BE VERY CAREFUL NOT TO LOSE THE METAL BALL.



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2.2.4. Open the inner tube, put all the parts aside and clean the tube.



Take a large cotton bud, put some antimicrobial hand sanitizer used in your hospital or MTTS Optima on it and clean the inside of the tube (be very careful not to lose the small parts).

BE VERY CAREFUL NOT TO LOSE THE METAL BALL.

If you are missing some parts, you will find replacements in the tool box.

2.3. Replace the two flow meters (O2 and Air)

- 2.3.1. Take the tube and replace the ball, inner-tube cap and the inner-tube plug.
- 2.3.1.1. Replace the ball in the tube. Be careful not to lose it.
- 2.3.1.2. Replace the cap and plug.



Pic.31

2.3.2. Replace the inner tube on the blender.



Pic.32

2.3.3. Then take a tissue moistened with an antimicrobial hand sanitizer used in your hospital such as MTTS Optima and then clean the outer tube. When this is done, place this outer tube over the inner tube (Pic.33) and fix it to the machine by turning it clockwise (Pic.34).





2.3.4. Finally, clean the blender with a tissue moistened with an antimicrobial hand sanitizer used in your hospital such as MTTS Optima. NEVER use water - it could penetrate the machine and damage it.

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PRESSURE THERMOS

I. OPERATING PRINCIPLE:

Breaths from the patient are transmitted into the CPAP thermos to maintain continuous positive airway pressure through the output airway system. The CPAP water thermos is made of a transparent bottle and a blue lid which can be opened. On the lid you will notice:

- a white adapter with a metal tube running through it. One end of the metal tube goes into the bottle and the other end is used to connect the canula which goes to the nose of the patient.

- a hole which helps in removing the redundant air when the patient is breathing.

When the patient exhales, their breath travels through the tube and into the water. The depth of the tube in the water controls the resistance against both the patient's exhaling breath and the FiO2 supply. The deeper the tube is in the water the stronger the resistance is, and vice-versa.



Canula going to the patient White adapter with hole Blue lid Metal tube immersed

in distilled water

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Pic.36

2. PREVENTIVE MAINTENANCE

Preventive maintenance should be performed every 6 months.

2.1. Disconnect the canula from the metal tube

The canula should slide off easily by lifting the blue ring as you pull gently.

Black connector to canula

Blue ring

Lid assembly



Pic.37

2.2. Clean the bottle

Open the bottle by turning the blue lid anticlockwise.

Take the bottle and wash it with a bottle brush using soap and water. Rinse it twice and then dry it upside down.



Pic.38



- Clean the blue lid, white adapters and tube 2.3.
- 2.3.1. Now you have to remove the lid assembly from the metal tube. Slide the tube out of the lid assembly to obtain 2 separate parts.



2.3.2. Separate the blue lid from the white adapter to obtain 2 separate parts.



Pic.41

2.3.3. On the white adapter, detach the upper part from the lower part by turning the upper part anticlockwise.



Pic.42

2.3.4. Moisten a large cotton bud with an antimicrobial hand sanitizer used in your hospital such as MTTS Optima and then clean inside both parts.

2.3.5. Use a tissue moistened with an antimicrobial hand sanitizer used in your hospital or MTTS Optima to clean the metal tube.



2.4. Clean the canula.

If you can access compressed air in your hospital, use it to clean the inside of the canula. If not, rinse the inside several times with water.

2.5. Reassemble everything and change parts if required.

2.5.1. Put the white adapter back together by screwing the upper part into the lower part in a clockwise direction. Do not tighten the upper part as the metal tube is still to be inserted. Place the blue lid over the white adapter.







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2.5.2. Slide the metal tube halfway through this assembly. Make sure the bevelled end of the metal tube is at the bottom. Tighten the upper part of the white adapter.



Pic.47

2.5.3. Lift the blue ring of the canula connector and gently push it onto the metal tube.



Pic.48

2.5.4. Screw the blue lid into the pressure thermos bottle by turning the blue lid clockwise.



Pic.49

HUMIDIFIER AND HEATER

I. OPERATING PRINCIPLE:

FiO2 from the air blender is sent through the humidifier bottle and then to the patient. The humidifier is composed of:

- Humidifier bottle,
- A water heater element which creates humid FiO2,
- A tube-set which heats the FiO2 to a set temperature.



DRAW.2



- Tube-set going to the back panel of the CPAP Ι.
- FiO2 tube (from blender to humidifier bottle) 2.
- 3. Warming tube
- Canula and tube-set (see following page for tube-set information) 4.
- 5. Humidifier
- Thermos plate 6.
- 7. Heat resistance

2. **PREVENTIVE MAINTENANCE**

Preventive maintenance must be performed every 6 months by a hospital technician.

Clean bottle 2.1.

- 2.1.1. Completely disconnect the FiO2 tube.
- 2.1.2. Open the bottle by turning the blue lid anticlockwise.
- 2.1.3. Take the bottle and wash it with a bottle brush using soap and water. Rinse it twice and then dry it upside down.



Pic.50

2.1.4. Rinse the inside of the FiO2 tube and dry it with compressed air.

2.2. Clean the tube-set (found in the canula)

The tube set is composed of different parts:



Now that you know the components of the tube-set, you can clean it. For this you need to take the tube-set out of the canula.

2.2.1. Firstly, pull the canula off the Y-adaptor.



2.2.2. Remove the tube-set from the back panel of the CPAP by turning the ring on the connector anticlockwise and then unplugging.



2.2.3. Remove the element adaptor from the T-connector by pulling it. If it is difficult to remove wriggle it loose.



2.2.4. Continue to extract the tube-set from the canula. When it is completely removed, put it to one side and clean with a tissue moistened with antimicrobial hand sanitizer used in your hospital such as MTTS Optima.

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Clean the metal tube 2.3.

> Take a tissue moistened with antimicrobial hand sanitizer used in your hospital such as MTTS Optima and clean the metal tube.



Pic.55

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- Put everything back together 2.4.
- 2.4.1. Replace the bottle in its holder
- 2.4.2. Screw the blue lid clockwise onto the bottle
- 2.4.3. Re-connect all the parts to the humidifier bottle:



- Pic.56
- 2.4.3.1. Make sure the electrical connector is in good condition. If not, please call MTTS to get a replacement. Do not use the CPAP if this connector is faulty.



2.4.3.2. Take the tube-set and slide it into the canula, until the element adaptor reaches the T-connector on the bottle. You may need to lay the canula out flat to do this. Push these two connectors together until they mate firmly (Pic.59 to Pic.61).



Pic.58



Pic.59







2.4.4. Plug the tube-set into the back panel of the CPAP.

Plug in the electrical connector and turn the ring on the connector clockwise.



2.4.5. Now connect the canula to the Y-adaptor,



Pic.64

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2.4.6. Reconnect the FiO2 tube to both the blender and the humidifier bottle. If the humidifier-end of the FiO2 tube is in poor condition, cut 1 cm off with scissors. In case the tube becomes too short please call MTTS for a replacement. Do NOT cut the blender-end of the FiO2 tube.





Pic.65





Tube connected to the humidifier.

FRONT PANEL OF CPAP Control Unit

I. OPERATING PRINCIPLE:

The CPAP is controlled by the user interface on the front panel of the Control Unit. The Control Unit runs on 220V, 50-60Hz and has a maximum power consumption of 45W.

I.I. SET TEMP and alarm

The FiO2 temperature in the tube-set canula can be set from 35° C to 39° C by the SET TEMP knob.

If the FiO2 temperature in the canula exceeds set point +/- $1^{\circ}C$ an alarm will sound and a light will flash.

The orange button can be used to enable the alarm audio.





If anything on the Control Unit front panel is not working please call MTTS for service.

I.2. Alphanumeric displays

The top alphanumeric display (red 7 segments) shows the set temperature (not the current temperature). This value is changed by the SETTEMP knob. The numbers will appear in red. If the numbers do not appear correctly then call MTTS for service.

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On the bottom alphanumeric display (LCD display) there are 2 lines:

- The first line shows "Sensor: XX °C", where XX corresponds to the air temperature at the sensor in the tube-set (see tube-set Pic.51).

- The second line shows "Heater: YY%", where YY% corresponds to the power of the air heater element in the tube-set. 100% indicates that the air heater is running at maximum power. 0% indicates that the heater is off. The power of the heater automatically changes in order to match the SETTEMP.



I.3. Humidifier control:

This knob controls the level of humidity from minimum to maximum. If water is condensing in the canula then turn the humidity down. The humidity setting may need to be changed depending on atmospheric humidity.

If the knob appears broken or isn't functionning call MTTS for service.



BACK PANEL OF THE CPAP CONTROL UNIT

On the back panel you will find:

- power supply cord (1),
- I-2 x 220V outlets (connect

compressor to one of these) (2, 3),

- tube-set connector (4),
- 2-4 diagnostic buttons (their function will be explained in the next section) (5).



Pic.73

2 (V3 Series) and 4 (V1-2 Series) buttons on the back panel are used only for technicians to aid service personnel in testing the CPAP. When you press one of these buttons the bottom display will respond as follows:



If you press button I:

You will read: - first line:

- second line:

current date and time (dd-mm-yy hh:mn), number of hours CPAP in use(------ hour on),

If you press button 2:

You will read:

- first and second line show temperature values of all internal temperature channels:
I:Tube-set temperature
3:Ambient temperature
4: Not connected (NC)

Сття

If you press button 3:

You will read:

- first line: product name (Infant CPAP)
- second line: Firmware software version (CPSW LH081017 DS)

Button 4 currently has no function.

Now you are almost finished with preventive maintenance. Clean the outside of the machine, the wheels, the support of the CPAP and the front panel using a tissue with antimicrobial hand sanitizer used in your hospital or MTTS Optima.

Plug the CPAP power cable into 220V and turn ON the CPAP with the ON/OFF switch on the front panel. Perform the tests found in section 3 of this book and send a copy of the results to MTTS. Keep one copy for yourself.

If, during testing, you discover some problems with the CPAP write the problem down in the relevant part of the test report. Use the troubleshooting file in section 2 of this book to try and solve the problem. If you cannot solve the problem call MTTS for service.



TROUBLESHOOTING

I. When I turn ON the CPAP the alarm doesn't sound.

Verify the audio alarm enable button is ON (depressed). If not, press it in. Try turning the CPAP ON again. If there is still no sound please call MTTS for servicing.

2. When I turn ON the CPAP the alarm indicator doesn't light.

Please call MTTS for servicing.

- 3. When I turn the air knob to maximum the metal ball doesn't rise.
- 3.1 Verify the power cable of the compressor is connected to the back panel of the control unit. If not, turn OFF the CPAP and plug the compressor in. Turn the CPAP ON and check.
- 3.2 If the ball is still not responding, verify the airway tube from the compressor to the AIR connector (on the back panel of the blender) is firmly in place. If not, tighten the connections and see if the ball responds.
- 3.3 If the ball still doesn't respond, turn OFF the CPAP and clean the flow meter with a large cotton bud and MTTS OPTIMA (see section 2.2 page 15 of this manual).
- 4. When I turn the O2 knob to maximum the metal ball doesn't rise.
- 4.1 Verify the oxygen hose is connected to an oxygen supply and the blender. If you cannot connect the oxygen hose to your oxygen supply because the connector doesn't fit please call MTTS and ask for an adaptor.
- 4.2 If everything seems well connected, and the ball still doesn't respond, turn OFF the CPAP and clean the flow meter with a large cotton bud and MTTS OTIMA (see section 2.2 page 15 of this manual).



- 5. There are no bubbles in the humidifier bottle.
- 5.1 Verify that FiO2 is getting into the humidifier by viewing the air and O2 flow meters. If the flowmeters indicate no flow (the ball is resting at the bottom) increase the air or O2 flow rate.
- 5.2 If there are still no bubbles, verify the bottle is completely closed. Turn the blue lid on the humidifier bottle clockwise.
- 5.3 If there are still no bubbles verify the FiO2 tube is firmly in place. If not, tighten the connections. If it is in bad condition follow the instructions in section 2.4 page 26 of this manual.
- 5.4 If bubbles are still not present please call MTTS for assistance.
- 6. There is an alarm and the display says "Sensor OFF and NO TUBESET!!"
- 6.1 Make sure the tube-set is connected properly to the back panel of the CPAP control unit (see section 2.4 page 26 of this manual).
- 6.2 If you still see the error message, change the tube-set (you should have a replacement tube-set in your tool box. If not please call MTTS for a new one).
- 7. There is an alarm and the display says "TEMP TOO HIGH"
- 7.1 Ask a nurse to remove the tube from the patient's nose and turn OFF the CPAP. Wait at least 30 minutes then check if the tube-set canula has cooled down before the nurse replaces it on the patient. If the canula is still hot then wait longer.
- 7.2 If this does not stop the alarm, stop using the CPAP and please call MTTS for assistance.



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