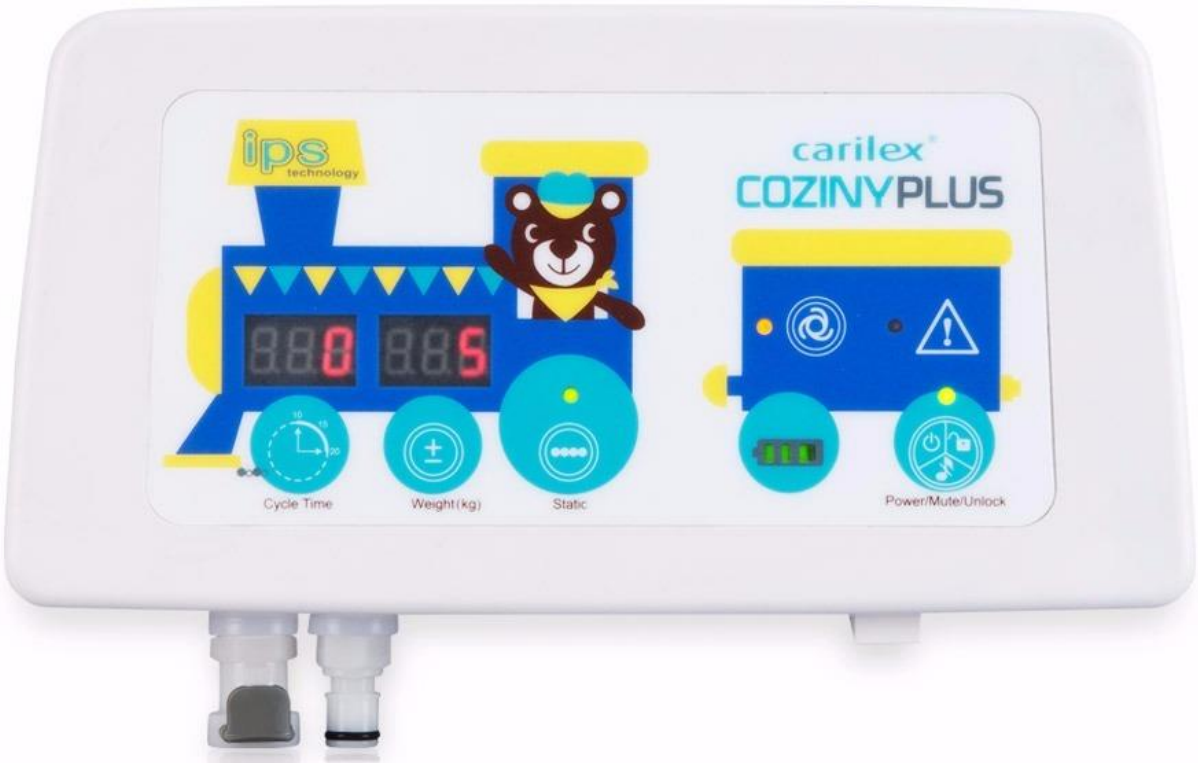
carilex®



COZINYPLUS POWER UNIT

SERVICE MANUAL

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General Information

A. Introduction

The CozinyPlus Power Unit can be matched with the Coziny 100 M-Set, with the Coziny 200 M-Set and with the Coziny 300 M-Set

This Carilex Service Manual provides repair and maintenance instructions for the CozinyPlus Power Unit.

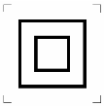
Any trained maintenance staff member can perform the procedures described in the sections of this manual that are designated Level 1.

Only manufacture-authorized service personnel can perform the procedures described in the sections of the manual that are designated Level 2.

If the system cannot be repaired using the procedures described in the Level 1 sections of this manual and there are no manufacture-authorized service personnel available, please contact Carilex or your local distributor to receive a return authorization number and a return address where the system can be sent for repair and servicing.

B. Symbols Reference

 Operating instructions (ISO 7000-1641)

 Class II Equipment (AC Adaptor) IEC 60417-5172

 Type BF Applied Part (IEC 60417-5333)

 WEEE Logo subject to WEEE Directive 2012/19/EU

 CE Marking: European Conformity to product Directive

 Catalogue number

 Caution (ISO 7000-0434A)

 NRTL_SGS Product Certification Mark

IP22 Protected against ingress of solid foreign objects ≧12.5mmdiameter (finger) and Protected against falling water drops when enclosure tilted up to 15°

 Date of manufacture

 Manufacturer Name and Address

Indications:

The air alternating mattress system is designed for patients who endure pressure ulcer and potential patients who wish to reduce the likelihood of pressure ulcer. The device is intended to treat and prevent pressure ulcers by facilitating blood circulation and decreasing pressure of each tissue's contact area. Anti-decubitus Air Alternating Mattress CozinyPlus System intended to treat and/or prevent decubitus ulcers otherwise known as bed sores, pressure sores, and pressure ulcers. Always consults a physician or health professional before using this device.

Contraindications:

Certain patient conditions are not suitable for using this type of device such as fracture of instable vertebrae and illness of instable vertebrae. Always consult a physician or health professional before using this device. The use of this system does not replace the regular repositioning, monitoring, and nursing of the patient. Certain patient conditions (e.g. unstable cervical fracture, fracture of unstable vertebrae and illness of unstable vertebrae) are contraindicated for use with this device. Always consult a physician or health professional before using this device.

C. Safety Precautions

Installation:
Verify mattress anchor straps are attached to bed frame securely to ensure proper operation, Inspect and verify air cells are upright and in place. Test all bed frame functions to verify no interference. Do not place anything on the power unit. Route power cord underneath bed frame and verify freedom from hazard.

Bed Linens:
This device incorporates a waterproof cover that is moisture vapor permeable; therefore, it is recommended to limit bed linens to one sheet in order to maximize the system's performance.

NOTE: Only "breathable" incontinent pads are recommended for use with this device.

 **Open Flames:**
Do not expose this device to open flames, lighters, or cigarettes. This device draws room air continuously, therefore cigarette smoking is not recommended near this device. Cigarette smoke may damage internal components. Cigarettes may ignite bed linens.

CAUTION: DO NOT SMOKE CIGARETTES, PIPES, CIGARS, OR ANY OTHER RELATED PRODUCTS ON OR AROUND THIS SYSTEM. FLAMMABILITY HAZARD EXISTS.

D. Warnings

 **Cross Contamination:**
This device should be decontaminated between patient installations. Refer to Power Unit and Mattress Maintenance Sections of this Manual for proper instructions. Failure to disinfect may result in cross contamination.

 **Weight Limitation**
Verify that the patient weight, therapeutic support surface, bed rails, etc. do not exceed weight capacity of the bed frame. Verify patient weight does not exceed this device's weight capacity.

 **Entrapment:**
When using side rails and/or assist devices, use a mattress thick enough and wide enough so that the gap between the top of the mattress and the bottom of the side rails and the gap between the side of the mattress and the side rails is small enough to prevent a patient from getting his or her head or neck between the ma tress and the side rail. Failure to do so could result in serious patient injury or death.

 **Patient Falls:**
Failure to use bed rails in raised position could lead to accidental patient falls. Air mattresses have soft edges that may collapse when patients roll to that edge.

 **Risk of Electric Shock:**
DO NOT open back cover. This device is NOT user serviceable. This device should only be opened by qualified personnel approved by Carilex. Refer all service to your local Carilex authorized dealer.

 **Oxygen Equipment:**
Explosion risk if used in the presence of flammable anesthetics.

Fuse:
Danger! Risk of fire. Replace fuses as marked: T1A/250VAC (Power Fuse).

Electrical:
Do not insert items into any opening of the power unit. This could short internal components, which could cause fire or electrical shock. This product is NOT AP/APG protected. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

IP22:
Protected against ingress of solid foreign objects ≧12.5mmdiameter (finger) and Protected against falling water drops when enclosure tilted up to 15°

Class II product:
This product is a Class II product. Do NOT cut or remove the grounding prong for shock prevention from the plug on this product if it is present. In the event that a non-compatible wall receptacle is found, it is the customer's personal responsibility and obligation to contact a qualified electrician to replace it with a compatible wall receptacle in accordance with the National Electrical Code.

Extension Cord:
If for any reason, you find it necessary to use an extension cord, ONLY use an appropriate extension cord that has the same or higher electrical rating as the device it is being connected to.

Proper Mattress Set:
The power unit and mattress are design to work together for patient's safety reason. Power unit should only be used with the correct mattresses recommended by the manufacture. Mismatching the power unit and mattress is strictly prohibited. Misusage may lead to patient risk.

Hospital Grade receptacle:
Note: Grounding reliability can only be achieved when the plug is connected to an equivalent receptacle marked "Hospital Grade" or "Hospital Only".

Maintenance - Level 1

A. Introduction

Any trained maintenance staff member can perform the procedures described in the sections of this manual that are designated Level 1.

B. Tools Required

Wire Cutters ---------- 

Needle Nose Pliers ---------- 

Sharp Knife ---------- 

Power Unit

A. Part Identification Overview

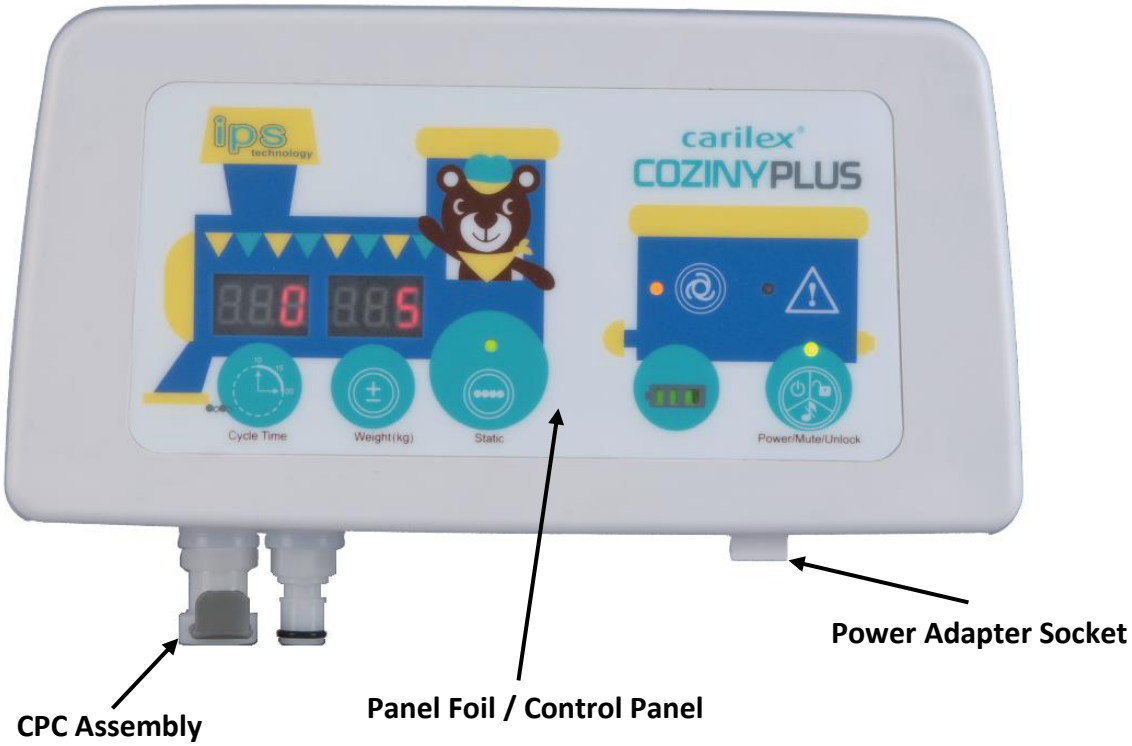


Fig: 1

B. Control Panel Reference

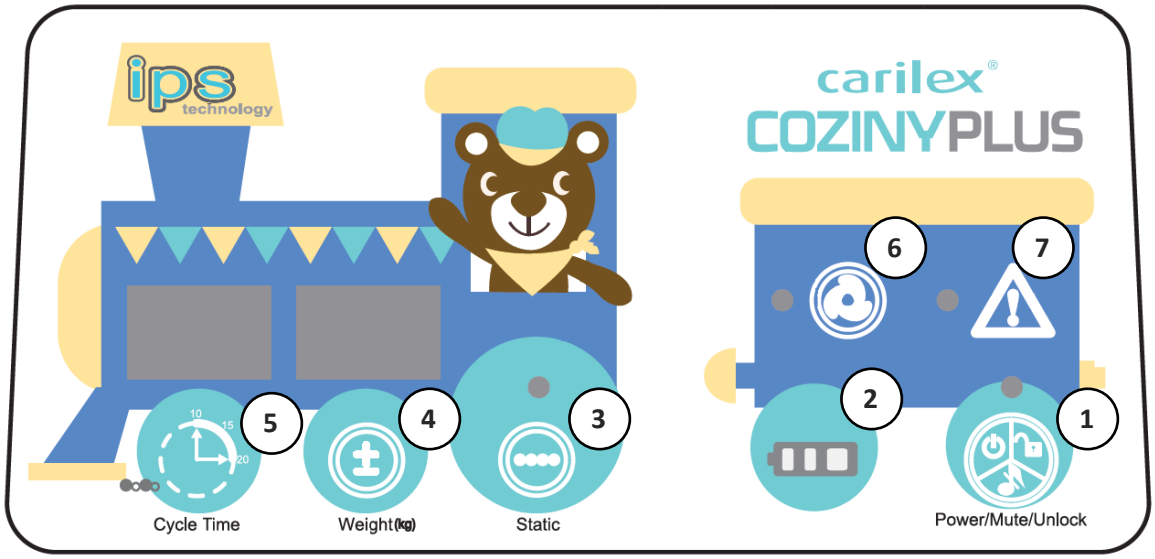


Fig: 2

1. Power/Mute/Unlock
2. Battery Indicator
3. Static Mode
4. Weight Setting
5. Dynamic Mode Cycle Time
6. Pressure Monitoring LED
7. Low Pressure Alarm LED

C. Setting Up and Switching on the Power Unit

1. Switch on the power switch on the back of the power unit. (Fig: 1).
2. Press the power button (1) on the control panel (Fig: 2).

D. General Pump Maintenance

Body and CPC Assembly

1. Thoroughly inspect the body casing and panel foil for any damage, such as cracks, where moisture might get inside.
2. Check the CPC assembly for damage that may have occurred through impact or misuse.
3. Check that the O-ring on the male CPC connector (Fig: 3) is in place and not damaged or cracked.

Power Adapter

1. Thoroughly check the full length of the power cord for any damage such as brittleness or splits.
2. Check the power adapter casing for any damage such as cracking or splitting.

⚠ **IF THE POWER ADAPTER IS DAMAGED IN ANY WAY, DISCARD IT IMMEDIATELY**

Rubber Seal (O-Ring)

Fig: 3

E. General Cleaning Instructions

ALWAYS UNPLUG THE POWER UNIT BEFORE CLEANING

NEVER SPRAY LIQUIDS DIRECTLY ONTO A POWER UNIT

NEVER IMMERSE A POWER UNIT IN ANY LIQUID

Routine Cleaning During Use

1. Dampen a clean cloth with soap and water or a mild, neutral detergent and then wipe the power unit.

Routine Decontamination Between Patients

1. Dampen a clean cloth with soap and water or a mild, neutral detergent and then wipe the power unit.
2. Disinfect the power unit with hospital grade registered disinfectant. Let the power unit stand for the appropriate contact time, according to the manufacturer's instructions.
3. Dry the power unit using a clean, dry cloth or disposable paper towels.
4. Wrap the power unit in plastic and store in a cool, dry place.

F. Air Inlet Maintenance

It is recommended that the air inlet is serviced annually.

1. Turn the air filter clockwise a short way and lift it to remove it from the power unit. (Fig: 4)
2. Remove the cotton filter from the air inlet cover. (Fig: 5)
3. Wipe any dust from the air inlet cover and power unit casing using a dry cloth.
4. Place a new cotton filter into the air inlet cover and return it to the casing, fitting the lugs on the air inlet cover into the larger side of the slot in the casing and then turning the air inlet cover anti-clockwise until it is secure. (Fig: 5)

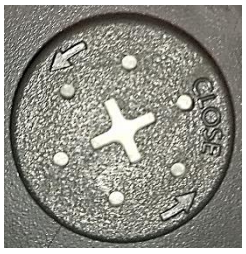


Fig: 4

Fig:5

G. Replacing the Panel Foil

NEVER SPRAY LIQUIDS DIRECTLY ONTO A POWER UNIT

IF LIQUID IS ALLOWED INTO THE CASING OF THE POWER UNIT, EXTENSIVE DAMAGE MAY RESULT

1. The panel foil is held in place by a self-adhesive backing. Use a small, thin, flat bladed knife to pry up an edge and gently pull the panel foil to remove it. (Fig: 6)
2. Clean the surface thoroughly to remove any excess adhesive that may remain on the body case.
3. Remove the backing material from the new panel foil and position it on the pump casing. Slowly roll down the new panel foil pressing firmly on the entire surface to ensure full adhesion and taking care when fitting the panel foil over the potentiometer shaft.

Fig: 6

Maintenance and Repair - Level 2

A. Introduction

The procedures described in Maintenance and Repair – Level 2 must only be carried out by manufacture-authorised service personnel. If your system cannot be repaired using the instructions in the Level 1 sections of this manual and you are not a manufacture-authorised service person, please contact Carilex Medical Inc. regarding repairs.

Be sure to seal the power unit with a new warranty void if broken sticker after carrying out any of the procedures designated Level 2 and fill out a Product Service Record and email to Carilex Medical Inc. or to your distributor.

B. Tools Required

Philips PH2 Screwdriver 

Wire Cutters 

Sharp Knife 

Superglue 

Power Unit

A. Part Identification Overview

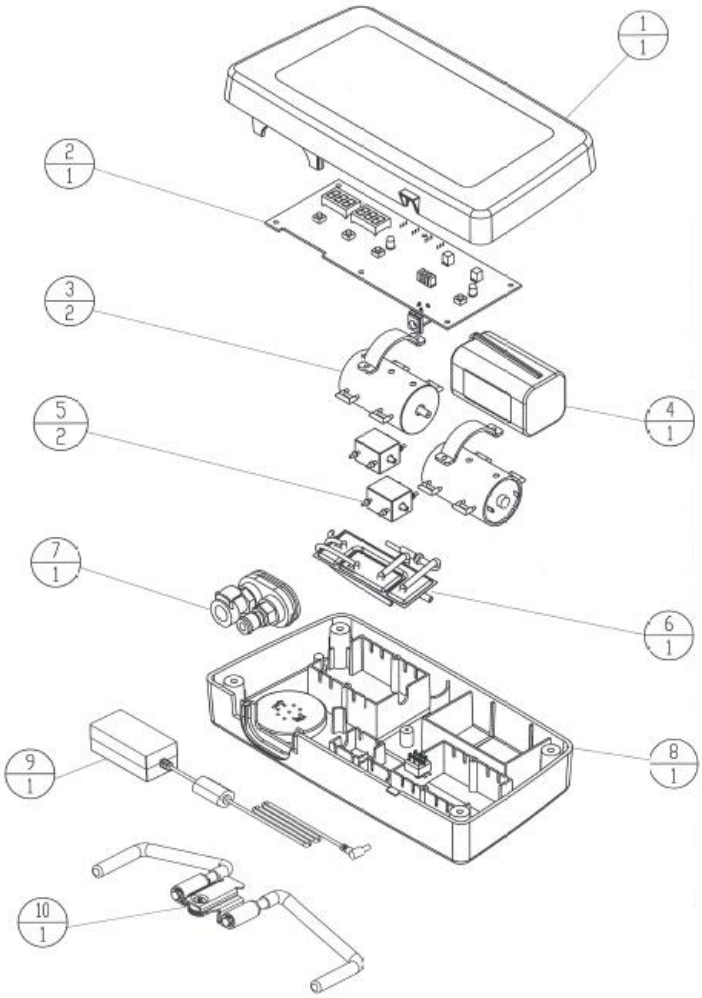


Fig: 7

1. Top Case
2. Control PCBA
3. Compressor
4. Battery Assembly
5. Solenoid Valve Set
6. Silicone Tube Set
7. CPC Assembly
8. Bottom Case
9. Power Adapter
10. Hanging Hook Set

B. Replacing the Top Case

ALWAYS DISCONNECT THE POWER ADAPATER FROM THE POWER UNIT AND SWITCH THE POWER SWITCH OFF BEFORE CARRYING OUT REPAIRS ON THE POWER UNIT

1. Remove the four screws from the rear of the power unit. (Fig: 8)
2. Remove and layover the top case taking care not to pull on the silicone tubes and wires. (Fig: 9)
3. Remove the connectors and silicone tubes from the control PCBA. (Fig:9)
4. Disconnect the battery. (Fig: 10)
5. Remove the six screws from the control PCBA and lift the control PCBA from the top case. (Fig: 8)
6. Reverse the procedure to install the new unit, taking care that the plastic isolation panel is secured onto the Control PCBA (Fig: 11) and ensuring that the wire and silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

TAKE CARE NOT TO TRAP ANY WIRES OR SILICONE TUBES BETWEEN THE TOP AND BOTTOM CASES AS THIS MAY RESULT IN MALFUNCTION OF THE POWER UNIT

To avoid electrostatic discharge, ground yourself by using a wrist grounding strap or by periodically touching an unpainted metal surface, such as the back panel of your computer.

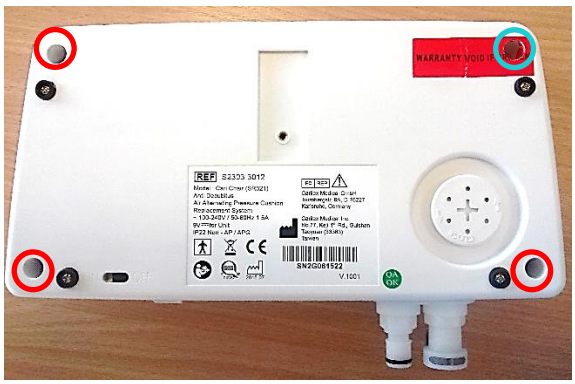


Fig: 8

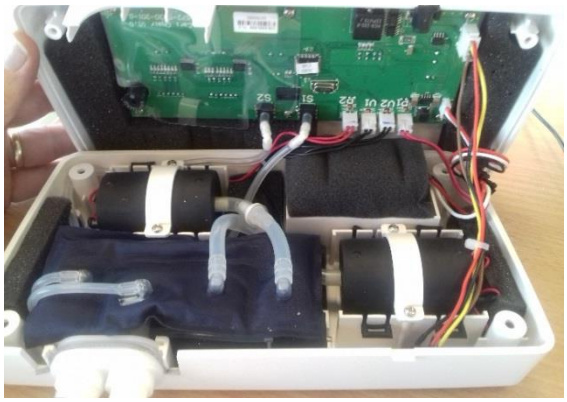


Fig: 9

Fig: 10

Fig: 11

C. Replacing the Control PCBA

1. Follow the steps in “Replacing the Top Case” to remove the Control PCBA.
2. Reverse the procedure to install the new Control PCBA, ensuring that wire and silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

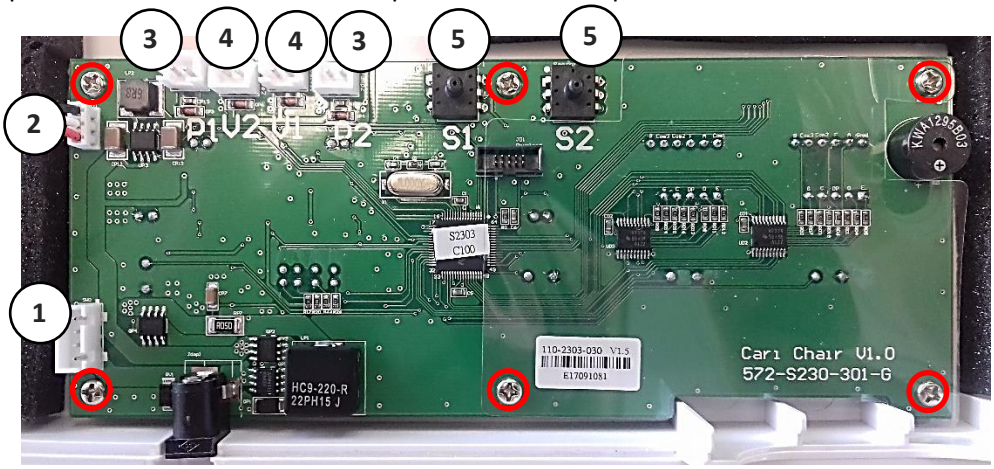


Fig: 12

1	Power Switch
2	Battery Wire
3	2 Compressor Connectors
4	2 Solenoid Valve Connectors
5	2 Pressure Sensors

D. Replacing the Compressor

1. Follow the steps in “Replacing the Top Case” to remove the top case.
2. Disconnect 2-pin compressor connector from Control PCBA. (Fig: 12)
3. Disconnect silicone tube from the compressor. (Fig: 13)
4. Remove the four black suspension rubbers on the sides of the compressor from the power unit casing. (Fig: 13)
5. Gently lift the compressor from the power unit casing.
6. Reverse procedure to install the new compressor, ensuring that wire and silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

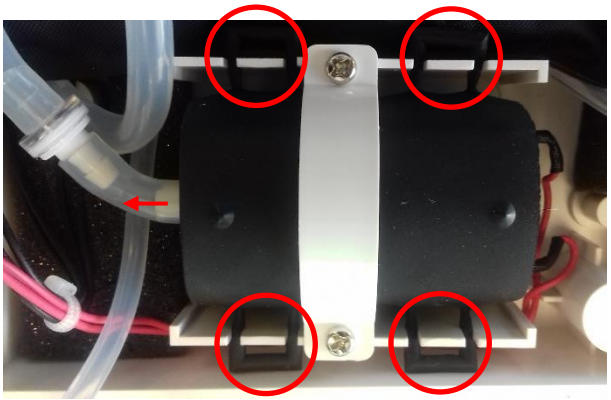


Fig: 13

E. Replacing the Battery Assembly

1. Follow the steps in “Replacing the Top Case” to remove the top case.
2. Disconnect the battery assembly wire from the Control PCBA battery wire. (Fig: 10)
3. Lift the battery assembly from the power unit.
4. Unwrap the foam from around the battery assembly. (Fig: 14)
5. Reverse the procedure to install a new battery assembly, ensuring that wire and silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

Fig: 14

F. Replacing the Solenoid Valve Assembly

1. Follow the steps in “Replacing the Top Case” to remove the top case.
2. Disconnect 2-pin solenoid valve connector from Control PCBA. (Fig: 12)
3. Disconnect silicone tube from the solenoid valve. (Fig: 15)
4. Remove the four black suspension rubbers on the sides of the solenoid valve from the power unit casing. (Fig: 15)
5. Gently lift the solenoid valve from the power unit casing.
6. Reverse procedure to install the new solenoid valve, ensuring that wire and silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

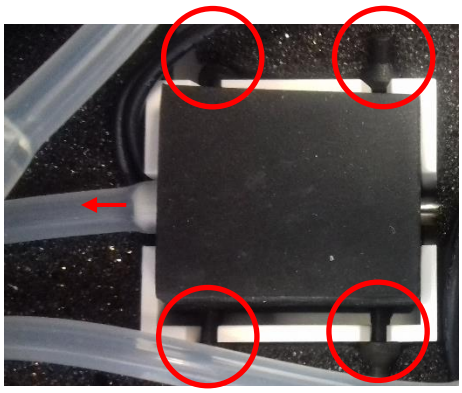


Fig: 15

G. Replacing the Silicone Tube Set

1. Follow the steps in “Replacing the Top Case” to remove the top case.
2. Remove the two wide silicone tubes from the compressors (Fig: 16)
3. Remove the two wide silicone tubes from the CPC assembly (Fig: 16)
4. Remove the two narrow silicone tube from the pressure sensors. (Fig: 16)
5. Remove the two narrow silicone tubes from the solenoid valves. (Fig: 16)
6. Lift the silicone tube set from the power unit.
7. Reverse the procedure to install the new silicone tube set, ensuring that the silicone tube routing is exactly as found and complete a function test once the top case has been replaced and secured.

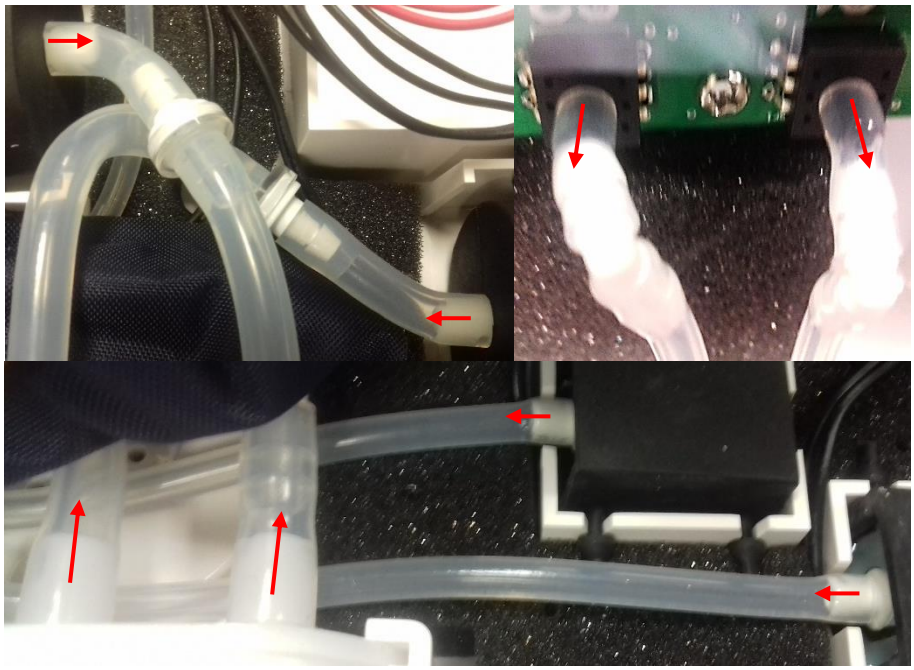


Fig: 16

H. Replacing the CPC assembly

1. Follow the steps in “Replacing the Top Case” to remove the top case.
2. Carefully remove the grey sealing foam from the top of CPC assembly. (Fig: 17)
3. Remove the silicone tubes from the CPC assembly. (Fig: 16)
4. Lift the CPC assembly from its slot in the bottom case. (Fig: 9)
5. Remove the grey sealing foam from the bottom of the CPC assembly. (Fig: 17)
6. Reverse the procedure to install the new CPC assembly, gluing the grey sealing foam back onto the CPC assembly, ensuring that each silicone tube is returned to the correct side of the CPC assembly and that the silicone tube routing is otherwise exactly as found and complete a function test once the top case has been replaced and secured.

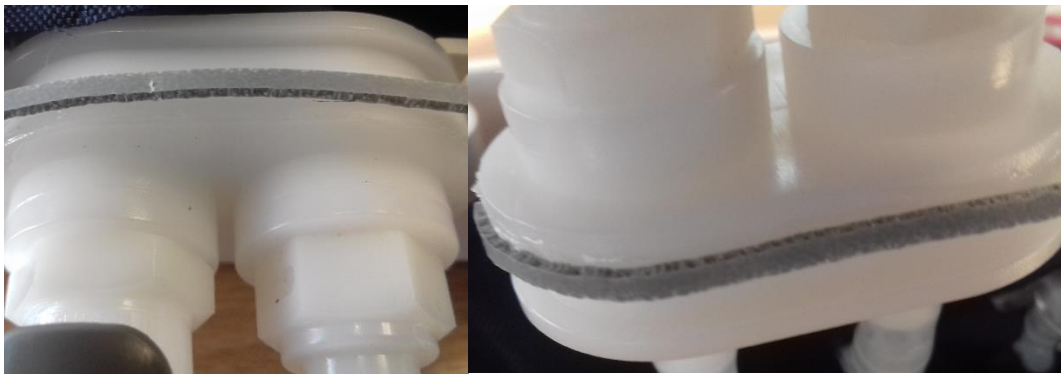


Fig: 17

I. Replacing the Bottom Case

1. Follow the steps in “Replacing the Top Case” to remove the top case, including disconnecting the power switch.
2. Follow the steps in “Replacing the Compressor” without disconnecting the silicon tubes to remove both of the compressors from the bottom case.
3. Follow the steps in “Replacing the Solenoid Valve Assembly” without disconnecting the silicone tubes to remove both of the solenoid valve assemblies from the bottom case.

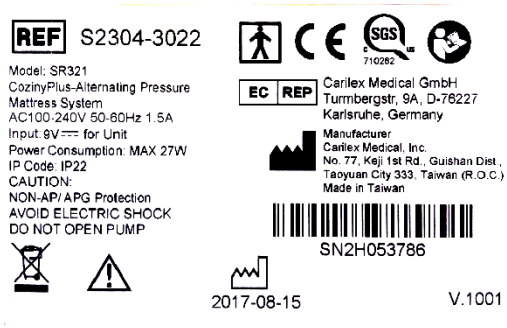


Fig: 18

4. Follow the steps in “Replacing the CPC Assembly” without disconnecting the silicone tubes to remove the CPC assembly from the bottom case.
5. Follow the steps in “Replacing the Battery Assembly” to remove the battery assembly from the bottom case.
6. Using a small, thin, flat-bladed knife, lift the corner of the information sticker (Fig: 18) on the bottom case and pull it away gently.
7. Reverse the procedure to install the new bottom case, ensuring that the information sticker (Fig: 18) is replaced securely using super glue if required, ensuring that the wire and silicone tube routing is exactly as found, that any cable ties that were removed are replaced with new cable ties and complete a function test once the top case has been replaced and secured.

Testing

A. Introduction

The procedures described in this section of the manual can be carried out by any trained member of staff.

B. Tools Required

Service Kit

CPC assembly ----------

Power Unit

A. Function Test

Stage	Steps
Power On	• Switch on the power switch on the back of the unit • Press the power button on the control panel to power on the power unit • The power unit will power on with the setting that was previously used, the control panel should display the relevant lights
Start Up	• Attach a CPC assembly to the CPC assembly on the underside of the pump • Press on both pipes to block the air until you hear a click • Remove your fingers from the pipes
Cycle Time	• Press the cycle time button to cycle through the cycle time settings • The cycle time LED display should change with each press
Weight Setting	• Press the weight setting button to cycle through the weight settings • The weight setting LED display should change with each press
Static	• Press the static mode button • The static mode LED should light and the cycle time should change to ‘0’.
Solenoid Valves	• Attach a manometer with a vent to one of the tubes and block the other with your finger • You should hear two clicks after the compressors have stopped pumping • Vent the air from the manometer • The compressor should pump briefly then the solenoid valve should click open and closed, releasing the excess pressure in the tube • Check that the reading on the manometer shows this • Attach the manometer to the other tube and repeat the process
Power off	• Press the power button to switch the power unit off • If the power unit does not switch off but displays the lock symbol on the LED display, press and hold the power button to unlock the control panel then press it again to switch the power unit off • Switch off the power switch on the back of the unit

B. Flow Test

1. Power up the unit and attach a CPC assembly as described in “Function Test”.
2. Power up and connect the flow meter to one of the tubes and put your finger over the other. (Fig: 19)
3. Take note of the reading on the flow meter. (Fig: 20) If the flow is less than 1.8 L/min then the power unit may require servicing.

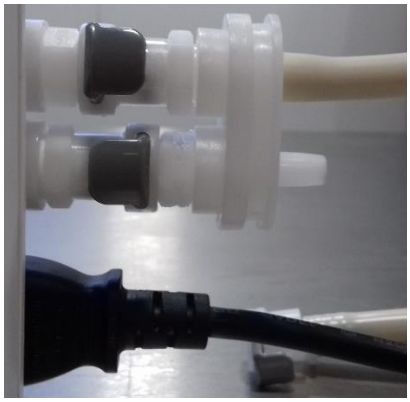


Fig: 19

Fig: 20

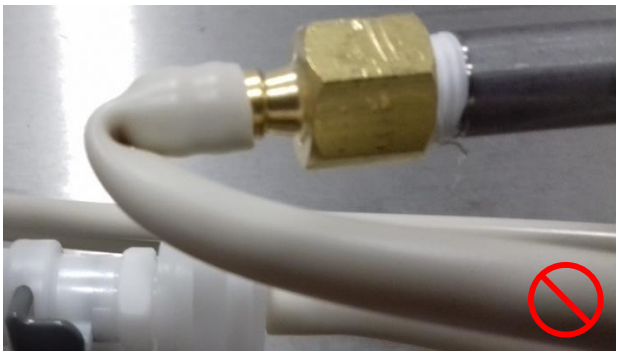


Fig: 21

⚠ The minimum flow in this test is based on the TIC TF601-D flow meter as found in the Carilex Service Kit. Flow readings may vary between different flow meters and configurations.

⚠ When taking a reading from the flow meter, ensure that its silicone tube is not kinked. (Fig: 21)

⚠ Ensure that all meters used in testing are properly calibrated.

Troubleshooting

A. Introduction

The procedures described in Troubleshooting that are marked Level 2 must only be carried out by manufacture-authorised service personnel. All other procedures in described in Troubleshooting can be carried out by any trained maintenance personnel.

If your system cannot be repaired using the instructions in the Level 1 sections of this manual and you are not a manufacture-authorised service person, please contact Carilex Medical Inc regarding repairs.

B. Power Unit

No Lights on Power Unit	No Airflow from Power Unit	Battery Error (Orange battery LED flashing and buzzer sounding)	Excessive Noise / Vibration from Power Unit	Troubleshooting Guidelines
★	★			• Check that the power switch is on • Level 2: Check that all internal wires are connected and not broken
★				• Level 2: Change the control PCBA for a new one and check its function using "Function Test"
	★			• Check the battery indicator for low battery • Check the CPC assembly for blockages • Level 2: Check the compressors using "Flow Test" • Level 2: Check that all internal wires are connected and not broken • Level 2: Check that all internal tubes are connected and not punctured
		★		• Level 2: Change the battery for a new one • Level 2: Change the control PCBA for a new one and check its function using "Function Test"
			★	• Level 2: Check that the compressors are correctly mounted in the bottom case

 **ENSURE THAT THE POWER ADAPTER IS NOT CONNECTED TO THE POWER UNIT AND THAT THE POWER SWITCH IS OFF BEFORE OPENING THE POWER UNIT CASE**

 **ENSURE THAT THE POWER UNIT CASE IS CLOSED AND SCREWED TOGETHER BEFORE CONNECTING THE POWER ADAPTER**

carilex®

Product Service Record

F101.03

General Information	
Date:	
Service Technician:	
Company:	
Location:	
Product Serviced:	
Serial Number:	
Device Article Number:	
Invoice Number:	
In Warranty	Yes / No
General Problems Description:	

Parts Replaced or Repaired	Problems Identified	Serial Number (Record if applicable)
		Old: New:
		Old: New:
		Old: New:
		Old: New:
		Old: New:

For Carilex QA Division use only: 類別： A: 硬體設計類 B:軟體設計類 C:機構設計類 D:製造品質
E:檢驗品質 F: 供應商品質 G:其他

是否建議開立 ECR ☐No. ☐ Yes, ECR/ECN#_____

For Carilex Sales Div. use only: (已經超過保固期之維修費用請打 D/N 收款, 請在此記錄 D/N#)
Device sent back to customer on _____ via _____
(表格與 D.C.C 發行之最新版本相符)