Service Manual

COMFORTCOUGH® II

Mechanical In-Exsufflator(CC20)



2021.06

Doc No: CC20SM-R1

CONTENTS

HOW TO USE THIS MANUAL	4
1. GENERAL SAFETY INSTRUCTIONS	5
2. DESCRIPTION & OPERATION	7
2.1. External Description	7
2.2. Internal Description	9
2.3. Description of PCB	10
2.3.1. Main PCB	10
2.3.2. Charger PCB	11
2.4. Operation	12
2.4.1. Block Diagram	12
3. MAINTENANCE	14
3.1. Tools	14
3.1.1. Standard Maintenance Tools	14
3.1.2. Specific Tools	14
3.2. Routine Care	15
3.2.1. External Housing	15
3.2.2. Patient Circuit	15
3.2.3. Institutional (Hospital) Use	15
3.2.4. Home (Individual) Use	15
3.3. Preventative Maintenance	15
3.4. Corrective Maintenance	16
3.5. Disassemble and Reassemble	18
3.5.1. Disassembling FRONT CASE MODULE	
3.5.2. Disassembling PCB MODULE	23
3.5.2.1. Replacing MANUAL CONTROL LEVER	
3.5.2.1. Replacing LCD MODULE	
3.5.3. Disassembling REAR CASE MODULE	27
3.5.3.1. Replacing BATTERY CHARGER PCB	27
3.5.3.2. Replacing COOLING FAN	29
3.5.3.3. Replacing SMPS	30
3.5.3.4. Replacing AIR FILTER	32
3.5.4. Disassembling MANIFOLD-BLOWER MODULE	33
3.5.4.1. Replacing BLOWER MODULE	33
3.5.4.2. Replacing VALVE MODULE	35
3.5.4.3. Replacing MANIFOLD MODULE	36
4. REFERENCE AND PART LIST	37
5. APPENDIX 1	
5.1. COMFORTCOUGH® II Assembly Diagrams	39
5.2. FRONT CASE MODULE Assembly Diagrams	40
5.3. MAIN PCB MODULE Assembly Diagrams	41

5.4. MANIFOLD-BLOWER MODULE Assembly Diagrams	42
5.5. REAR CASE MODULE Assembly Diagrams	
6. APPENDIX 2	
6.1. Symbols	4!
7. APPENDIX 3	
7.1. COMFORTCOUGH® II Performance Test	4
7.1.1. Performance Test Standard	4
7.1.2. Performance Test Measurement	49

HOW TO USE THIS MANUAL

Each of the section in this manual has been described with a specific purpose in mind. Use this guide to find the materials which are relevant to your current task.

General Safety Instructions - Reminder of the basic safety requirements related to the applicable standards.

Description & Operation - Give the technical information to understand how the device works.

Maintenance - This is divided into a number of sub-chapters:

- 1. *Routine Care*: gives the information necessary for cleaning, disinfecting and sterilizing the detachable parts of the device.
- 2. *Prevention*: gives a preventative maintenance schedule with the associated kits and testing procedures, designed to keep corrective maintenance to a minimum.
- 3. Troubleshooting Guide: sets out the steps to take when technical alarms are triggered.
- 4. *Disassemble and Reassemble*: lists all of the disassemble and reassemble procedures needed for maintenance purposes.
- 5. *Tests performance*: sets out the procedures to be followed after carrying out preventative or corrective maintenance.

REFERENCE AND PART LIST - Includes all references for parts sold by SEOIL PACIFIC and also the references for the kits and special tools.

- Appendix 1 Diagrams for reassembling the assemblies and sub-assemblies and locating particular parts.
- Appendix 2 List of the abbreviations used in this manual and the symbols of COMFORTCOUGH® II.

Appendix 3 - Testing COMFORTCOUGH® II performance.

This manual contains special terms and icons that appear in the margins to draw your attention to specific and important information.



"Warning" alerts you to possible injury.



"Caution" explains special measures for the safe and effective servicing of the device.



"Note" is a helpful comment or piece of information.

1. GENERAL SAFETY INSTRUCTIONS

COMFORTCOUGH® II is applicable for adult and pediatric patients.

During transport, ensure that COMFORTCOUGH® II is properly fixed to its support.

Do not operate COMFORTCOUGH® II near ignitable or flammable/explosive substances, fumes, or gases of any kind. In such an environment, it may result in fire or explosion.

The user should take the necessary precautions to ensure the specified electromagnetic compatibility (EMC) limits are not exceeded. In particular, where the device is used in the presence of short waves or high frequency generators, such as defibrillators, diathermy, electro surgery or radiology devices, cell phones, etc., interference may occur if the energy emitted is higher than the levels stipulated in Directive 93/42 EC.

This device may be affected by interference from electromagnetic fields exceeding 10 V/m.

The degree of protection against ingress of water of COMFORTCOUGH® II is IP21 though, we recommend the device does not come into contact with water.

Keep the device away from direct sunlight.

Do not expose the device to violent impacts.

Do not operate COMFORTCOUGH® II immediately after storage or transport, or in conditions other than the recommended operating conditions.

Place COMFORTCOUGH® II where its cooling system is not obstructed or covered.

In case of blower failure, the device cannot be used.

The electrical installation must comply with the local regulation standard.

To avoid personal injury and the risk of electric shock, as well as damage to the device, do not operate the device removing its covers. For any servicing, refer to technicians who have been trained to the COMFORTCOUGH® II maintenance.

Under no circumstances shall the manufacturer be liable for the damages caused on the device by:

- ✓ Servicing or modifications that do not comply with the manufacturer's procedures or performed without prior authorization from the manufacturer
- ✓ Servicing or modifications not performed by authorized service agents or Servicing or modifications performed by unauthorized person.

Before connecting the device to a patient, check all accessories to avoid leakage risks and faulty elements.

All electrical accessories must comply with electrical safety standard and electromagnetic compatibility standard (EN60601-1, EN60601-1-2).

All faulty fuses from power supply or PCB board must be replaced by fuses with the same specifications. Decontamination and disinfection of the device and its accessories must be carried out according to the

manufacturer's directions and according to the hospital protocol.

The device should be operated by the trained personnel with understanding on the device.

COMFORTCOUGH® II is a restricted medical device intended for use by qualified and trained personnel.

In accordance with directive 2002/96/EC concerning waste of electrical and electronic equipment (WEEE), this device must be disposed of separately from other household rubbish. It must not be disposed of with ordinary waste. To dispose of this device, use the appropriate waste collection, reuse and recycling system available in your country.

Manufacturer: SEOIL PACIFIC CORP.

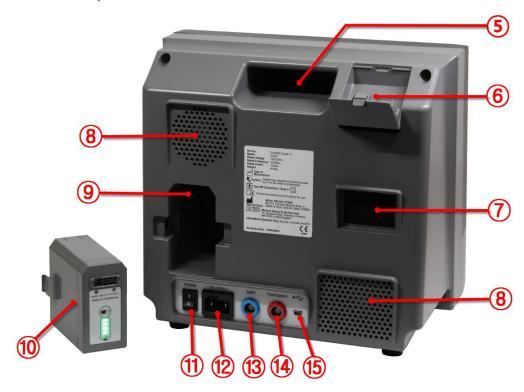
Rm. 515, 516, Ac-High End Tower, 5, Digital-ro 26-gil, Guro-gu, Seoul 08389 Korea

2. DESCRIPTION & OPERATION

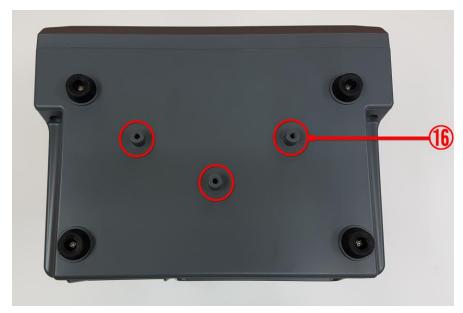
2.1. External Description



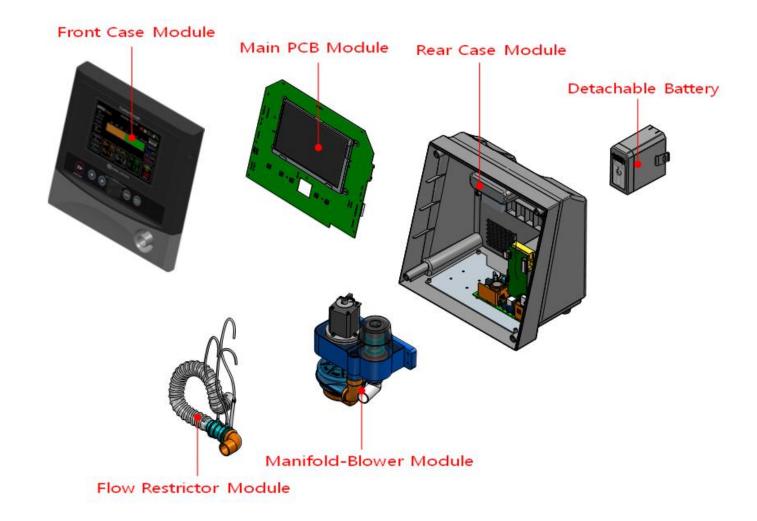
- ① Screen Panel: shows all the set value and operating status.
- ② SD Card Slot: is to save the data in use of the device to SD card
- ③ Control Panel: sets in-exhale pressure, time duration. It includes Manual Control Lever.



- 4 Patient Port: delivers in-exhale pressure to a patient.
- ⑤ Handle: is to hold the device when operator moves the device.
- 6 Breathing Hose Holder: holds the breathing hose when it is not used.
- 7 Patient Air Inlet: takes and delivers the air to the patient after filtering inside the device.
- (8) Air vent: takes the air to cool the inside of the device.
- Battery Slot: is to attach the detachable battery.
- [®] Battery Pack: supplies power when AC power is not applied.
- (1) Power Switch: is to turn on or off the device.
- ② AC Inlet: connects with the power supply cord.
- ③ SpO2: connects with the SpO2 cable.
- (4) Foot Switch: connects with the Foot Switch remote control cable.
- (5) USB Port: connects with the USB cable
- 16 Locking Part: is to attach the device to the stand.

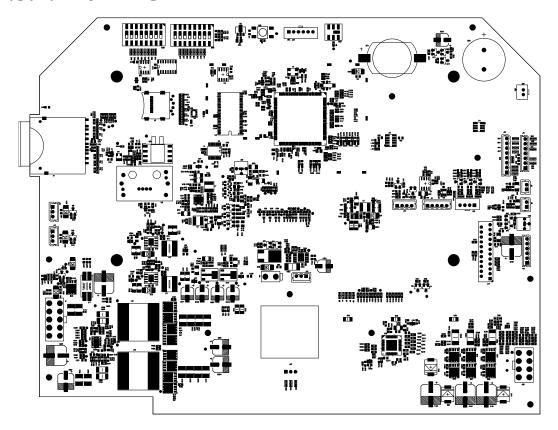


2.2. Internal Description

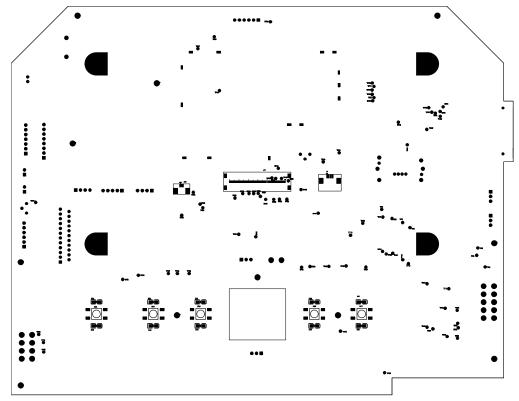


2.3. Description of PCB

2.3.1. Main PCB

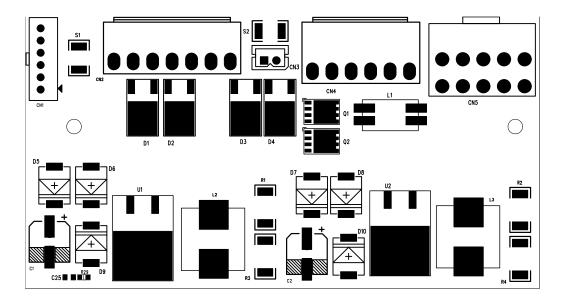


<Front Side>

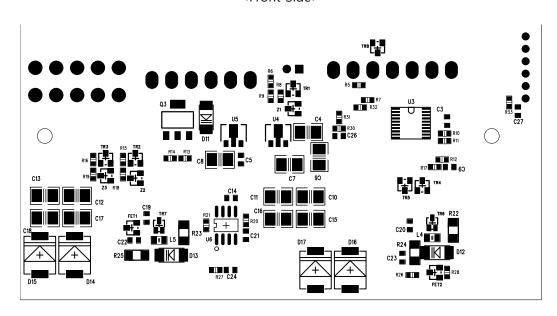


<Back Side>

2.3.2. Charger PCB



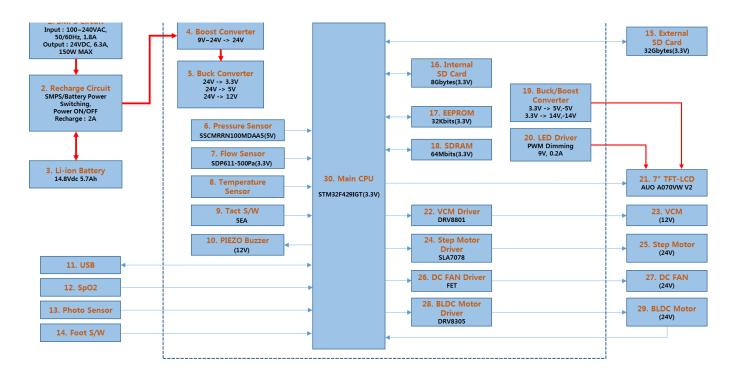
<Front Side>



<Back Side>

2.4. Operation

2.4.1. Block Diagram



- 1. To output 24VDC, 6.3A, 150W MAX, after being input 100~240VAC, 50/60Hz, 1.8A.
- 2. To charge(2A) Li-ion Battery by being input 24V from SMPS and supply 24Vdc Power to Main Board. When AC Power is blocked, 24Vdc Power is supplied to Main Board from Battery Pack. It receives the information of the remained charge amount and battery's ID from Battery Pack, and transmit it to Main Board.
- 3. 14.8Vdc, 5.7Ah Rechargeable Lithium-ion Battery Pack. It indicates the remained charge amount as LED lights. 4. It is DC/DC Converter to step up 9~24Vdc to 24Vdc, 10A.
- 5. It is DC/DC Converter to step down 24Vdc to 3.3V(500mA), 5V(500mA), 12V(1A). It supplies the power to each block.
- 6. It is a pressure sensor to converts the pressure value (-100mbar ~ 100mbar) to 0~5V.
- 7. To transmit the value of Mass Flow to Main CPU through I2C Communication.
- 8. To measure the temperature of Blower. It shuts down the device when the device is overheating.
- 9. START/STOP, UP, DOWN, MENU, ENTER Keys.
- 10. To sound a buzzer when the error is occurred.
- 11. It is for Program Writing or development of an engineer.
- 12. To measure SpO2 and Heart Rate and transmit the information to Main CPU through UART Communication.
- 13. It is a sensor to receive the information of sections of Inhale, Exhale and Pause.
- 14. When Foot S/W is installed, it substitutes Manual S/W in Manual Mode.
- 15. It is a memory to save the information of Therapy.

- 16. It is a memory to save the information of Therapy temporarily and save the image which is displayed on the LCD Screen.
- 17. It is a memory to save the information of the setting values, device and so on.
- 18. It is a memory to display TFT-LCD screen as Frame buffer.
- 19. It is a DC/DC converter to step up or down to generate the voltage which is to operate TFT-LCD.
- 20. It controls PWM Dimming to operate Backlights of TFT-LCD.
- 21. 800x480, 7 inches TFT-LCD.
- 22. It is a driver to control PWM of Voice Coil Motor.
- 23. To control the location according to the section of Inhale, Exhale or Pause. When Oscillation function is used, it does a reciprocating action up to 20Hz.
- 24. It is a driver to control PWM of Step Motor.
- 25. To control the location according to the section of Inhale, Exhale or Pause. It does a reciprocating action up to 13Hz in Percussor Mode.
- 26. It is a driver to operate DC FAN Motor.
- 27. It is a DC FAN to cool the device.
- 28. It is a driver to control PWM of 3 Phases BLDC Motor
- 29. A motor of Blower which is used to produce the air to supply it to the patient.

3. MAINTENANCE

3.1. Tools

3.1.1. Standard Maintenance Tools

- √ "+" head screwdriver 1PC
- ✓ Long Nose Plier
- ✓ "-" head screwdriver 1PC

3.1.2. Specific Tools

- ✓ Breathing Hose, 22mm * 1.2M
- ✓ Test Lung (Adult, Child)
- ✓ Digital Pressure Gauge (0~100 cmH2O)
- ✓ Flowmeter : TSI4040 or Digital Flowmeter Range: 0~300 L/min, Accuracy 2%
- ✓ Digital Multi-meter

3.2. Routine Care

Before using the device for the first time, and also between patients, it should be cleaned and disinfected.

3.2.1. External Housing

The exterior of the device may be washed with a mild detergent and water or with a bactericidal cleaning solution such as 70% isopropyl alcohol.



CAUTION! Do not sterilize the device with ethylene oxide gas or steam.

3.2.2. Patient Circuit



WARNING! The patient circuit should not be sterilized.

Always use a new circuit for a new patient.

X Notice! If you need additional accessories, please contact the distributor in your area.

3.2.3. Institutional (Hospital) Use

- a. Breathing Hose, Patient Interface and Adapter :

 If the device is to be used by more than one patient, the circuit must be replaced.
- b. Bacterial/Viral Filter:

If the device is to be used by more than one patient, the filter must be replaced to prevent cross contamination. Do not try to wash the filter.

3.2.4. Home (Individual) Use

- a. Breathing Hose, Patient Interface and Adapter:
 - After use, the breathing hose and patient interface should be washed thoroughly in soap and water. These parts must be completely dried before reuse.
- b. Bacterial/Viral Filter:

The filter, which protects the patient from entraining foreign material from the patient, can be left in place as long as it is not blocked by sputum or trapped moisture. Do not try to wash the filter.

3.3. Preventative Maintenance

- a. Keep the device's exterior clean.
- b. Check if the air inlet is not blocked.
- c. Keep the device away from curtains, blankets or any heat generating device.

3.4. Corrective Maintenance

List of maintenance troubleshooting

Status	Possible Causes	Solution
Device does not power on	 No Power available Defective Power Supply Cord Defective AC Inlet Defective SMPS Defective Main PCB Defective Charger PCB 	•Check AC Power and Detachable Battery •Replace Power Supply Cord •Replace AC Inlet •Replace SMPS •Replace Main PCB •Replace Charger PCB
Device turned on but LCD Screen is abnormal	Defective LCD CableDefective LCD PanelDefective Main PCB	•Replace LCD Cable •Replace LCD Panel •Replace Main PCB
Device turned on but it cannot be initialized. Screen displays 'E1'	Defective Step Motor SensorDefective Step MotorDefective Main PCB	•Replace Step Motor Sensor •Replace Step Motor •Replace Main PCB
Device turned on but Blower does not work.	Defective BlowerDefective Main PCBBreathing Hose is detached or	Replace BlowerReplace Main PCBCheck the connection of breathing
Device delivers incorrect pressures	damaged •Defective Blower •Defective V/V	hose or replace the hose •Replace Blower •Replace Main PCB
Screen displays 'TEMP'	•Damaged Manifold •The inside of the device is overheated •Defective Temperature Sensor	•Replace Manifold •If the temperature of the inside of the device falls, it will disappear. •Replace Temperature Sensor Cable
Screen displays 'E2'	•The pressure is higher than its maximum pressure •Incorrect operation •Defective Blower	•Turn off and then turn on again •Use the device in accordance with the user manual •Replace Blower
Fail to recognize Key buttons.	•Fail to press Key Button •Defective Main PCB	•Defective Key Button •Replace Main PCB
Device does not achieve max. pressure or flow	Breathing Hose is detached Defective Blower Defective Valve Internal Leakage Defective Main PCB	•Check the connection of breathing hose or replace the hose •Replace Blower •Replace Valve •Repair the leakage part •Replace Main PCB

Status	Possible Causes	Solution
	•Defective V/V Module	•Replace V/V Module
No inhalation or exhalation	•Defective VCM Motor	•Replace Manifold Module
	•Defective Main PCB	•Replace Main PCB
Device does not recognize detachable battery	•Defective Detachable Battery	•Replace Detachable Battery
	•Defective Charger PCB	•Replace Charger PCB
	•Defective Main PCB	•Replace Main PCB
Detachable Battery cannot be	•Defective Detachable Battery	•Replace Detachable Battery
charged/discharged	•Defective Charger PCB	•Replace Charger PCB
Device does not recognize Pulse Oximeter or Foot Switch	•Defective Accessory	•Replace Accessory
	•Defective Connector of device	•Replace the connector
	•Defective Main PCB	•Replace Main PCB
Device does not recognize SD Card	•Defective SD Card	•Replace SD Card
	•Defective Main PCB	•Replace Main PCB
Cooling Fan does not work	•Defective Fan	•Replace Fan
	•Defective Main PCB	•Replace Main PCB
Noisy cooling Fan	Obstruction at cooling fan	•Clear the obstruction
	•Defective Fan	•Replace Fan

3.5. Disassemble and Reassemble

For each stage of the disassemble and reassemble process, it is compulsory to wear an antistatic wrist strap and use an antistatic mat. Only authorized technicians can carry out this operation. All screws must be tightened with proper torque adequately, especially those used in the pressurized air assembly.

3.5.1. Disassembling FRONT CASE MODULE

- 1) Place the device at flat area.
- 2) Unscrew the four screws marked in red.

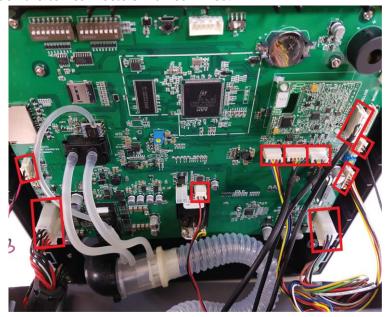


3) Open the front case softly in the direction of the red arrow.



4) It is when the case is safely opened.

Detach the ten connectors marked in red.



Incorrect disassembly method: Cable can be broken from Connector.



CAUTION: DO NOT grab the cable only when assembling and disassembling.







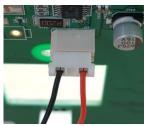




Correct disassembly method: Please grab the Connector firmly when assembling and disassembling.



CAUTION: It is compulsory to wear an antistatic wrist strap and use an antistatic



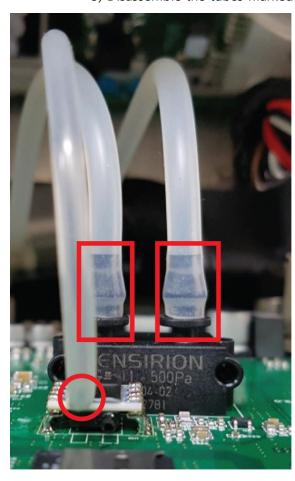








5) Disassemble the tubes marked in red.





The tube position must not be changed during assembly.



Correct disassembly method: As shown in the picture below, be sure to hold the tube marked in red and remove it.



6) Disassemble the ELBOW marked in red





Correct disassembly method: As shown in the picture below, with your thumb down, remove it in the direction of the arrow.







<Front side of FRONT CASE MODULE>



<Back side of FRONT CASE MODULE>

3.5.2. Disassembling PCB MODULE

- 1) PCB MODULE can be detached from FRONT CASE MODULE disassembled.
- 2) Unscrew the nine screws marked in red circle.





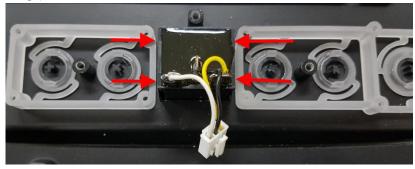
<PCB disassembled>



<FRONT CASE disassembled>

3.5.2.1. Replacing MANUAL CONTROL LEVER

1) Disassemble Key Buttons first, and disassemble Manual Control Lever by pushing the four locking parts.

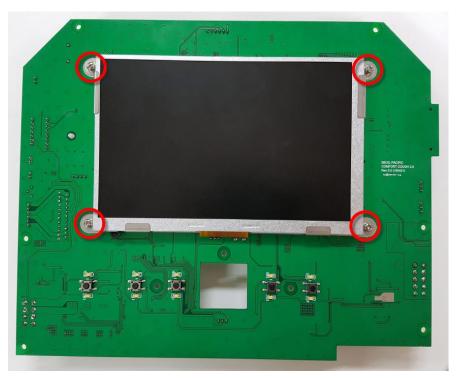


2) Assemble new Manual Control Lever in reverse order.

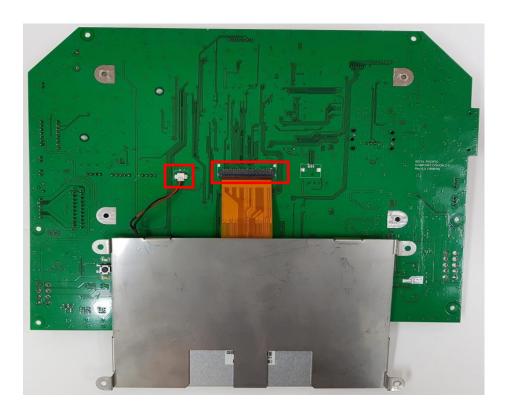


3.5.2.1. Replacing LCD MODULE

1) Unscrew the four screws marked in red.



2) Disassemble LCD Module and then detach the two cables marked in red.



3) Assemble LCD Module with New Main PCB or New LCD Module in reverse order.



3.5.3. Disassembling REAR CASE MODULE



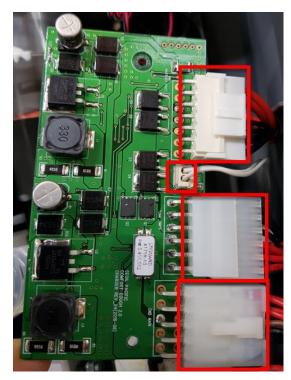
<REAR CASE MODULE disassembled.>

3.5.3.1. Replacing BATTERY CHARGER PCB

1) Unscrew the two screws marked in red.



2) Detach the four connecters marked in red.

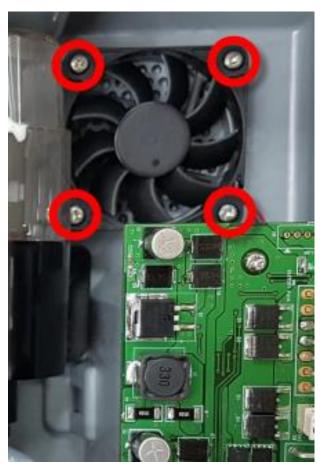


3) Replace BATTERY CHARGER PCB to new one and then assemble it in reverse order.



3.5.3.2. Replacing COOLING FAN

1) Unscrew the four screws marked in red.



2) Replace COOLING FAN to new one and assemble it in reverse order.



3.5.3.3. Replacing SMPS

1) Unscrew the four screws marked in red.



2) Detach the connector marked in red.



3) Unscrew the four screws marked in red.



4) Replace SMPS to new one and assemble it in reverse order.



3.5.3.4. Replacing AIR FILTER

1) Pull AIR FILTER COVER marked in red.



2) Take out the AIR FILTER and assemble new AIR FILTER in reverse order.





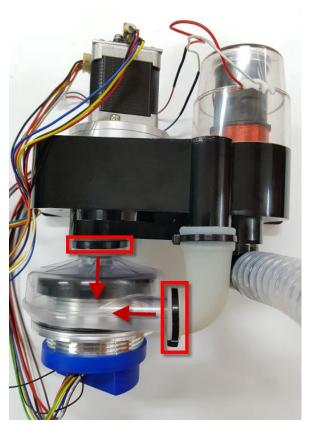
3.5.4. Disassembling MANIFOLD-BLOWER MODULE



<Unscrew the four screws marked in red.>

3.5.4.1. Replacing BLOWER MODULE

1) Remove the cable ties marked in red and detach the blower in the direction of the red arrows.

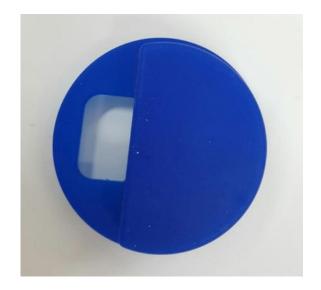


2) Take out BLOWER MOTOR CAP.



3) Unscrew a screw marked in red.



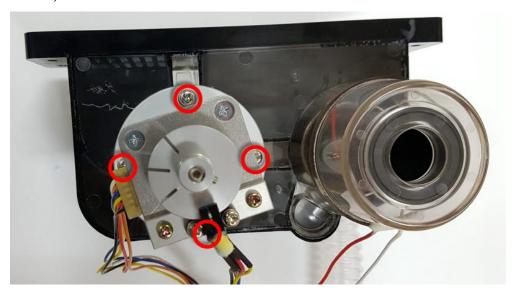


4) Replace BLOWER to new one and assemble it in reverse order.



3.5.4.2. Replacing VALVE MODULE

1) Unscrew the four screws marked in red.



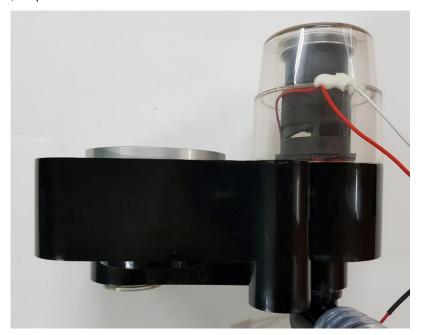
2) Replace VALVE to new one and assemble it in reverse order.





3.5.4.3. Replacing MANIFOLD MODULE

1) Replace MANIFOLD MODULE to new one and assemble it in reverse order.



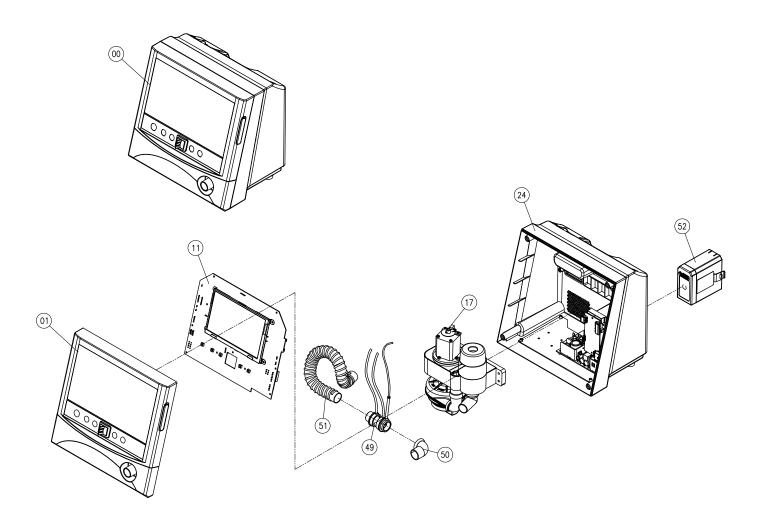
4. REFERENCE AND PART LIST

No.	Part No.	Part Name	Q'ty
1	A61000	FRONT CASE MODULE	1
2	1A6002	FRONT CASE	1
3	1A6004	PATIENT PORT	1
4	1A6026	KEY BUTTON	1
5	1A6008	SD CARD COVER	1
6	1A6028	LCD PANEL STICKER	1
7	1A6029	KEY MEMBRAIN	1
8	A61101	MANUAL SWITCH CABLE ASSY	1
9	1A6055	SD CARD	1
10	400022	PTS-2 (3*10L)	22
11	A62000	MAIN PCB MODULE	1
12	2A6002	MAIN PCB	1
13	1A6033	LCD BRACKET	1
14	2A6003	TFT LCD	1
15	400018	HEX NUT (M3)	4
16	400002	SEMS M3*8L	4
17	A63000	MANIFOLD-BLOWER MODULE	1
18	2A6001	BLDC BLOWER	1
19	A63100	MANIFOLD MODULE	1
20	A63200	VALVE MODULE	1
21	1A6015	BLOWER MOTOR CAP	1
22	1A6045	TEMPERATURE SENSOR CABLE	1
23	400004	SEMS M4*12L	12
24	A64000	REAR CASE MODULE	1
25	1A6003	REAR CASE	1
26	1A6007	CIRCUIT BRACKET	1
27	1A6035	AIR FILTER	1
28	1A6062	FAN	1
29	1A6017	BATTERY CHARGER PCB BRACKET	1
30	2A6005	CHARGER PCB	1
31	1A1023	BOTTOM CASE RUBBER	4
32	2A6009	USB PCB	1
33	1A6048	FOOT SWITCH SOCKET CABLE	1
34	1A6046	SPO2-MAIN CABLE	1
35	1A6063	FOOT SWITCH CABLE	1
36	1A6044	SPO2-DSUB CABLE	1
37	1A6047	USB-MAIN CABLE	1
38	1A6064	AC INLET CABLE ASSY	1

No.	Part No.	Part Name	Q'ty
39	1A6065	SWITCH-CHARGER CABLE ASSY	1
40	2A6008	SMPS	1
41	1A6022	SMPS PLATE	1
42	2A6007	BATTERY TERMINAL PCB	1
43	1A6042	CHARGER-MAIN CABLE	1
44	1A6040	SMPS-CHARGER CABLE	1
45	1A6041	CHARGER-BATTERY CABLE	1
46	400012	TMS (M4*12L)	4
47	400042	SEMS (M3*10L)	4
48	400043	PTS-2 (4*30L)	4
49	A64100	FLOW RESTRICTOR MODULE	1
50	1A6021	ELBOW FOR PATIENT PORT	1
51	1A6027	INTERNAL TUBE	1
52	A64200	DECHABLE BATTERY	1
53	1A6071	SpO2 MODULE ASSY	1
54	1A6068	FILTER COVER	1
55	1A1024	ONEWAY PAD	1

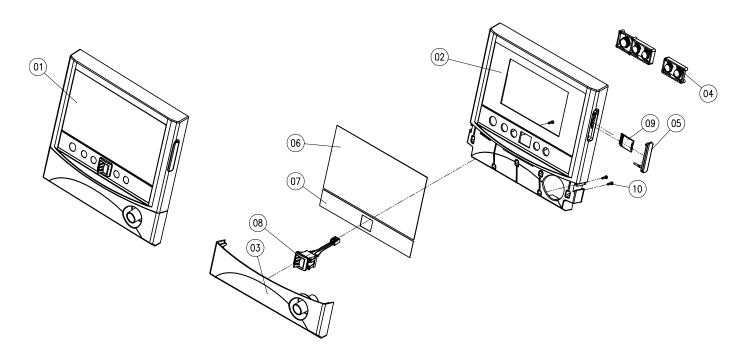
5. APPENDIX 1

5.1. COMFORTCOUGH® II Assembly Diagrams



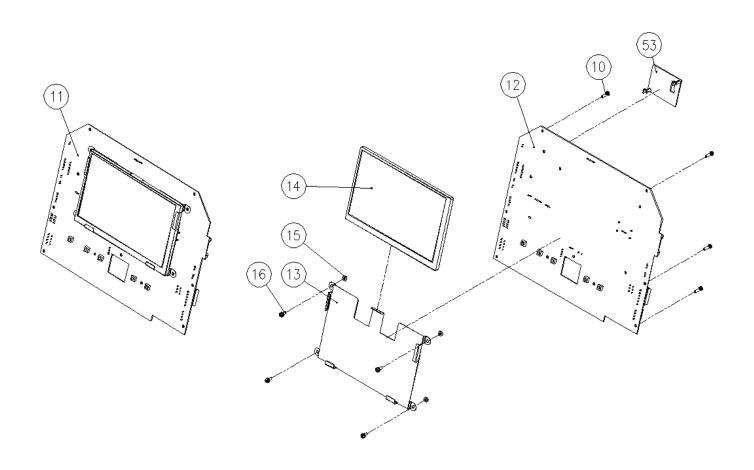
No.	Part No.	Part Name	Q'ty
1	A61000	FRONT CASE MODULE	1
11	A62000	MAIN PCB MODULE	1
17	A63000	MANIFOLD-BLOWER MODULE	1
24	A64000	REAR CASE MODULE	1
49	A64100	FLOW RESTRICTOR MODULE	1
50	1A6021	ELBOW FOR PATIENT PORT	1
51	1A6027	INTERNAL TUBE	1
52	A64200	DECHABLE BATTERY	1

5.2. FRONT CASE MODULE Assembly Diagrams



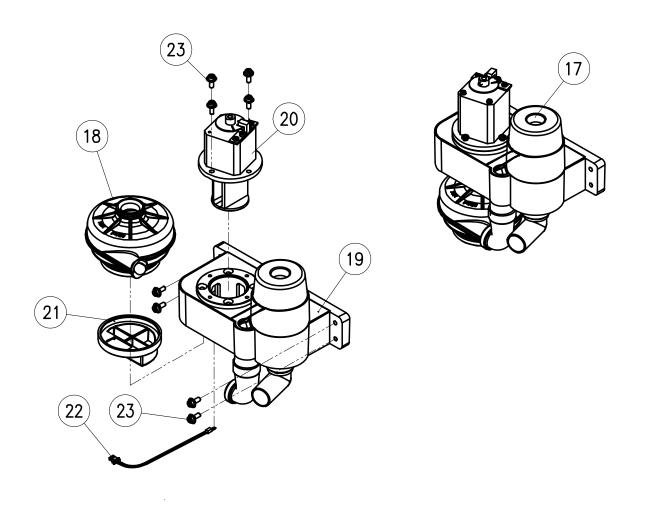
No.	Part No.	Part Name	Q'ty
1	A61000	FRONT CASE MODULE	1
2	1A6002	FRONT CASE	1
3	1A6004	PATIENT PORT	1
4	1A6026	KEY BUTTON	1
5	1A6008	SD CARD COVER	1
6	1A6028	LCD PANEL STICKER	1
7	1A6029	KEY MEMBRAIN	1
8	A61101	MANUAL SWITCH CABLE ASSY	1
9	1A6055	SD CARD	1
10	400022	PTS-2 (3*10L)	6

5.3. MAIN PCB MODULE Assembly Diagrams



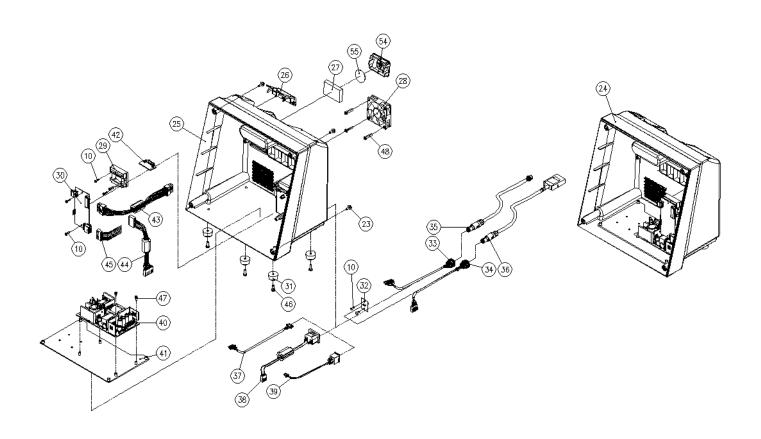
No.	Part No.	Part Name	Q'ty
11	A62000	MAIN PCB MODULE	1
12	2A6002	MAIN PCB	1
13	1A6033	LCD BRACKET	1
14	2A6003	TFT LCD	1
15	400018	HEX NUT (M3)	4
16	400002	SEMS (M3*8L)	4
10	400022	PTS-2 (3*10L)	9
53	1A6071	SpO2 MODULE ASSY	1

5.4. MANIFOLD-BLOWER MODULE Assembly Diagrams



No.	Part No. Part Name		Q'ty
17	A63000	MANIFOLD-BLOWER MODULE	1
18	2A6001	BLDC BLOWER	1
19	A63100	MANIFOLD MODULE	1
20	A63200	VALVE MODULE	1
21	1A6015	BLOWER MOTOR CAP	1
22	1A6045	TEMPERATURE SENSOR CABLE	1
23	400004	SEMS (M4*12L)	8

5.5. REAR CASE MODULE Assembly Diagrams



No.	Part No.	Part Name	Q'ty
24	A64000	REAR CASE MODULE	1
25	1A6003	REAR CASE	1
26	1A6007	CIRCUIT BRACKET	1
27	1A6035	AIR FILTER	1
28	1A6062	FAN	1
29	1A6017	BATTERY CHARGER PCB BRACKET	1
30	2A6005	CHARGER PCB	1
31	1A1023	BOTTOM CASE RUBBER	4
32	2A6009	USB PCB	1
33	1A6048	FOOT SWITCH SOCKET CABLE	1
34	1A6046	SPO2-MAIN CABLE	1
35	1A6063	FOOT SWITCH CABLE	1
36	1A6044	SPO2-DSUB CABLE	1
37	1A6047	USB-MAIN CABLE	1
38	1A6064	AC INLET CABLE ASSY	1
39	1A6065	SWITCH-CHARGER CABLE ASSY	1
40	2A6008	SMPS	1

No.	Part No.	Part Name	Q'ty
41	1A6022	SMPS PLATE	1
42	2A6007	BATTERY TERMINAL PCB	1
43	1A6042	CHARGER-MAIN CABLE	1
44	1A6040	SMPS-CHARGER CABLE	1
45	1A6041	CHARGER-BATTERY CABLE	1
46	400012	TMS (M4*12L)	4
47	400042	SEMS (M3*10L)	4
48	400043	PTS-2 (4*30L)	4
10	400022	PTS-2 (3*10L)	7
23	400004	SEMS (M4*12L)	4
54	1A6068	FILTER COVER	1
55	1A1024	ONEWAY PAD	1

6. APPENDIX 2

6.1. Symbols

The labels or labeling for this device may have the following symbols which have the meaning presented below.

Symbol Symbol	Description	
	Read the accompanying manuals	
\odot	"ON" for part of equipment	
Ċ	"OFF" for part of equipment	
<u> </u>	Attention, consult instruction manual	
፟	Type BF Equipment	
***	Manufacturer	
	Manufacturing Date	
EC REP	European Authorized Representative	
€ 0120	CE Mark (Certification Body SGS)	
	Class II (Double Insulated)	

Symbol	Description	
IP21	Degree of Protection against Ingress of Water	
Foot Switch	Foot Switch remote control	
•	USB connector	
SpO2	SpO2 connector	
AC Power		
===	DC	
Li-lon Li-ion Battery		
REF Catalogue No.		
	Compliant with the waste electrical and electronic equipment and restriction of the use of certain hazardous substances in electrical and electronic equipment (WEEE/RoHS) recycling directives.	

7. APPENDIX 3

7.1. COMFORTCOUGH® II Performance Test

When you replace the parts, or find any malfunction or error of the device, please check the device according to the instruction below.

7.1.1. Performance Test Standard

No.	Test	Standard	Method
		The pressure standard and range are as below.	The test is conducted under the various Inhalation and Exhalation pressures as 5, 10, 20, 40 and 70cmH ₂ O in Manual mode. Operate the
1	Inhalation Pressure Test (IP)	Set PressureTolerance $5\sim20\text{cmH}_2\text{O}$ $\pm3\text{cmH}_2\text{O}$ $21\sim40\text{cmH}_2\text{O}$ $\pm4\text{cmH}_2\text{O}$ $41\sim70\text{cmH}_2\text{O}$ $\pm5\text{cmH}_2\text{O}$	device by pushing the manual control lever to Inhale side for 10 seconds. Then measure the pressure with Mass Flow Meter. ** Pressure can be measured by Pressure gauge
	Exhalation		and Flow Analyzer. The test is conducted under the various Inhalation and Exhalation pressures as -5, -10, -20, -40 and -70cmH ₂ O in Manual mode. Operate
2 Pressure Test (EP)	Pressure	Set Pressure Tolerance $-5\sim-20\text{cmH}_2\text{O} \pm 3\text{cmH}_2\text{O}$ $-21\sim-40\text{cmH}_2\text{O} \pm 4\text{cmH}_2\text{O}$ $-41\sim-70\text{cmH}_2\text{O} \pm 5\text{cmH}_2\text{O}$	the device by pushing the manual control lever to Exhale side for 10 seconds. Then measure the pressure with Mass Flow Meter. X Pressure can be measured by Pressure gauge and Flow Analyzer.
3	Maximum Inhalation Air Flow	≥ 200 l/min	Set the Inhalation and Exhalation pressures as 70cmH ₂ O in Manual mode. Operate the device by pushing the manual control lever to Inhale side for 10 seconds. Then measure the pressure with Mass Flow Meter or Flow Analyzer.
4	Maximum Exhalation Air Flow	≥ -200 l /min	Set the Inhalation and Exhalation pressures as - 70cmH ₂ O in Manual mode. Operate the device by pushing the manual control lever to Exhale side for 10 seconds. Then measure the pressure with Mass Flow Meter or Flow Analyzer.
5	Zero Air Flow	Within -1cmH ₂ O to + 4cmH ₂ O	Turn on the Cough Sync function and set level 1 in Auto Mode. Then measure the pressure with Pressure Gauge in pause.

No.	Test	Standard	Method
No.	Test Safety	1) Locking Test When the device is locked, any button does not work except "Start/Stop". 2) Standby Mode Test -When power is supplied, the device has to be in standby initiallyWhen power is blocked and then resupplied during operation, the device has to be in standby. 3) VALVE Alarm Test The device rings an alarm when there is sensor error during operation. The setting values are initialized. 4) Temperature Alarm Test If the temperature sensor senses that the temperature is 80°C±5°C, LCD Screen displays "Temp" and the device rings an	Check if the device is locked/unlocked when an operator presses Up and Down buttons simultaneously for three seconds in pause. -Check if the device is in standby mode when power is suppliedTurn off the device during operation and then turn on it. Check if the device does not operate and is in standby. Check the valve alarm by removing the sensor connector(Photo) during operation. (It stops when the device turns off.) -Apply 80°C of heat to the normal temperature
		not work.	displays "Temp".

7.1.2. Performance Test Measurement

No	Test	Standard			Results			
		The pressure stand	ard and range	are as	Set	Measured	PASS	FAIL
		below.			5cmH ₂ O			
					(2~8cmH ₂ O)			
		Set Pressure	Tolerance		10cmH ₂ O			
	Inhalation	5~20cmH₂O	±3cmH₂O		(7~13cmH ₂ O)			
1	Pressure Test	21∼40cmH ₂ O	±4cmH₂O		20cmH ₂ O			
	(IP)	41~70cmH ₂ O	±5cmH₂O		(17~23cmH ₂ O)			
					40cmH ₂ O			
					(36~44cmH ₂ O)			
					70cmH ₂ O			
					(65~75cmH ₂ O)			
		The pressure stand	ard and range	are as	Set	Measured	PASS	FAIL
		below.			5cmH ₂ O			
					(2~8cmH ₂ O)			
		Set Pressure	Tolerance		10cmH ₂ O			
	Exhalation	-5~-20cmH ₂ O	±3cmH ₂ O		(7~13cmH ₂ O)			
2	Pressure Test		1		20cmH ₂ O			
	(EP)	Set Pressure	Tolerance		(17~23cmH ₂ O)			
		-21~-40cmH ₂ O	±4cmH ₂ O		40cmH ₂ O			
		-41~-70cmH ₂ O	±5cmH ₂ O		(36~44cmH ₂ O)			
					70cmH ₂ O			
					(65~75cmH ₂ O)			
	Maximum				Set	Measured	PASS	FAIL
3	Inhalation	≥ 200 l /min			≥ 200 {/min			
	Air Flow				2 200 (/111111			
	Maximum	≥ -200 { /min			Set	Measured	PASS	FAIL
4	Exhalation				> 200 l/min			
	Air Flow		≥ -200 l /min					
5	Zero	Within 1 cm O to						
5	Air Flow	Within -1cmH ₂ O to + 4cmH ₂ O						
		1) Locking Test		☐ Pass				
6		When the device is locked, any button does					Fail	
		not work except "Start/Stop".						
	Safety	2) Standby Mode Test -When power is supplied, the device has to			☐ Pass		☐ Fail	
		be in standby initially.			_			
		-When power is b	olocked and th	en re-				

supplied be in sta	during operation, the device has to andby.		
The devisensor	E Alarm Test vice rings an alarm when there is error during operation. The setting re initialized.	□ Pass	□ Fail
If the to tempera displays	erature Alarm Test emperature sensor senses that the ture is 80°C±5°C, LCD Screen "Temp" and the device rings an hen, the device and buttons do not	□ Pass	□ Fail