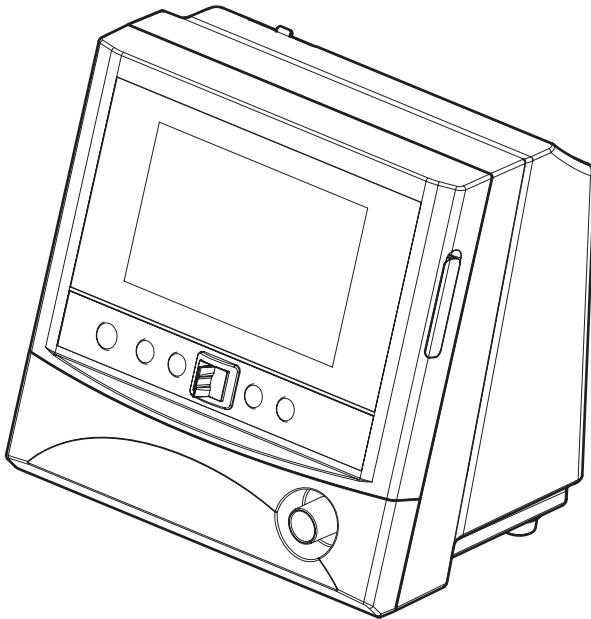




COMFORTCOUGH® II

Mechanical In-Exsufflator [CC20]

USER MANUAL



Contents

1. Device Introduction	2
1.1 Device Name	2
1.2 Intended Purpose	2
1.3 Overview	2
1.4 Applicable Disease	2
1.5 Patient Interface	2
1.6 Use Environment	2
2. Important Safeguards	3
2.1 Warning	3
2.2 Caution	4
3. General Description	5
3.1 Front View	5
3.2 Rear View	6
4. Package Contents	7
4.1 Package	7
4.2 Accessories (Optional)	8
5. Operating Instruction	9
5.1 LCD Screen (with Pressure Bar)	9
5.2 LCD Screen (with Pressure Graph)	10
5.3 LCD Screen (Automatic Mode/with Pressure Bar)	11
5.4 LCD Screen (Manual Mode/with Pressure Graph)	12
5.5 LCD Screen (Percussor Mode)	13
5.6 LCD Screen (No Setting Mode)	14
5.7 Control Panel	15
5.8 Screen Changes	15
6. How to use the device	16
6.1 Preparation before using	16
6.2 Initial Setting	19
6.3 Change a Menu Setting	20
6.4 Setting & Using the Automatic Mode	28
6.5 Setting & Using the Manual Mode	29
6.6 Setting & Using the Percussor Mode	30
6.7 Operation Verification	31
6.8 Setting the Control Lock	31
7. Cleaning & Disinfection	32
7.1 External Housing	32
7.2 Patient Circuit	32
7.3 Cleaning Air Filter	32
7.4 Preventive Maintenance	32
8. Storing	33
8.1 How to store	33
8.2 How to clean	33
8.3 How to move	33
9. Specifications	34
9.1 Information	34
9.2 Specification	34
10. EMC Information	35
10.1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions	35
10.2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity	35
11. Symbols	38
12. Trouble Shooting	40
13. Limited Warranty	40
14. Quality Warranty Certifications	41

1. Device Introduction

1.1 Device Name

- Device Name : COMFORTCOUGH® II (Mechanical In-Exsufflator)
- Model Name : CC20
- Medical Grade : Class II

1.2 Intended Purpose

 **Caution** : Federal law restricts this device is to sale by or on the order of a licensed healthcare practitioner.

For use on any patient unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, resulting from high spinal cord injuries, neuromuscular deficits or severe fatigue associated with intrinsic lung disease.

It may be used either with a face mask or with an connector to a patient's endotracheal or tracheostomy tube.

- Clinical Settings: For use in a hospital / institutional environment, or in the home, given adequate training and a physician's prescription.

- Patient Population: For use on children and adults. It should not be used on neonates and infants.

NOTE: The FDA defines pediatric in subgroups as follows: newborn—from birth to 1 month of age; infant-greater than 1 month to 2 years of age; child—greater than 2 to 12 years of age; adolescent—greater than 12 to 21 years of age

- Contraindications: Any patient with a history of bullous emphysema, known susceptibility to pneumothorax or pneumomediastinum or known to have had any recent barotrauma, should be carefully considered before use.

1.3 Overview

The ComfortCough® II mechanical In-Exsufflator(MI-E) noninvasively helps to clear bronchial secretions when patients can't cough for themselves. The patients with pulmonary disorders associated with impaired secretion clearance function might benefit from the use of the ComfortCough® II. The ComfortCough® II helps patients to clear bronchial secretions by gradually applying the positive pressure to the airway followed by a rapid shift to negative pressure. These rapid changes in pressure during different phases help to make the cough stronger and more effective. This user manual includes information on how the device operates, as well as information on how to set up the device to optimize treatment. This user manual is supplied with the device. Please ensure the patient has this user manual.

1.4 Applicable Disease


- Muscular Dystrophy • Spinal Muscular Atrophy • Amyotrophic Lateral Sclerosis

or any other neurological disorder with some paralysis of the respiratory muscles. This device can be used versatily as non-invasively with face mask or mouthpiece or invasively with endotracheal tube or tracheostomy tube.

 **Caution** : Please carefully read this User Manual before using to achieve the required result safely.

1.5 Patient Interface

- Face Mask

 For safe and correct use, please read this manual before use.

1.6 Use Environment

- The device must be used in accordance with the physician's prescription. And this device can be used in a hospital or at home.

1.7 Intended User

- Doctor or Nurse (Rehabilitation Medicine, Respiratory Medicine, Neurosurgery, Thoracic Surgery, Pediatrics, etc.)

2. Important Safeguards

2.1 Undesirable side effects of product use

- Soreness and/or pain in the chest from a pulled muscle may occur in patients using the device for the first time, if the positive pressure exceeds pressures which the patient normally receives during Positive Pressure Therapy. Such patients should start at a lower positive pressure, and gradually increase the positive pressure (over several days, or as tolerated)
- Any patient with a history of pneumothorax or mediastinal emphysema or barotrauma, should be carefully considered before applying this device.
- The accessories including the patient hose, must be used for single patient to prevent cross-contamination.

2.2 Warning

WARNING : A condition that would cause injury to a user or operator if instructions are not followed properly.

- Before using the device, please read the entire manual.
- Always check time and pressure setting before each use.
- Always use a new circuit for a new patient.
- For the patients known to have cardiac instability, pulse and oxygen saturation must be monitored very closely.
- Use the device only for its intended purpose as described in this manual.
- Do not use in the presence of flammable anesthetics.
- Connect the device to a grounded outlet only.
- Do not place or store the device where it can fall or be pulled into a tub or sink.
- If water comes into the device, unplug the device immediately.
- Never operate the device if it has a damaged cord or plug, not working properly, or dropped, damaged or immersed in water.
- The device is recommended to use the AC power cord provided with the device. Inappropriate power cable can cause overheat and damage.
- If any parts are replaced with inappropriate parts which are not provided by Seoil Pacific, it can lead Electromagnetic Interference or malfunction of the device.
- Cell phone and Portable RF communication equipment can affect the device.
- Refer to the Ch 10. EMC regarding the distance to avoid interference between the device and RF generator.
- The device has to be installed carefully considering EMC information that described in the manual. Medical devices need special precautions about EMC.
- Before connecting the device to the patient, check the circuit carefully not to have any risk of leaks or defective parts.
- Do not use when there are any damages on the outside of the device or when the sign of mal function is showing on the monitor.
- Before cleaning the exterior of the device, turn off and unplug the device.

- Do not disassemble, open, drop, bend, transform or thirl a detachable battery pack.
- If you dropped or misused a detachable battery, stop using it and contact to Seoil Pacific or local sales manager.
- Do not remodel or re-manufacture the battery. Do not insert foreign material into the battery. Do not expose the battery to water, fire or heat. Do not put the battery in the microwave.
- The battery is for CC20, CC20P only. Do not use for other purpose or other devices.
- Do not short out the battery or attach a metallic or conductive object to the bottom of the battery.
- When a battery needs to be replaced, please use the battery only that provided by manufacturer. Inappropriate battery can cause fire, explosion, leak and so on.
- Discard the used battery according to manufacturer's instruction.
- Be sure to keep away the battery from children.
- Repairing or checking-up should be carried only by authorized person or dealer who were educated by Seoil Pacific Corp.

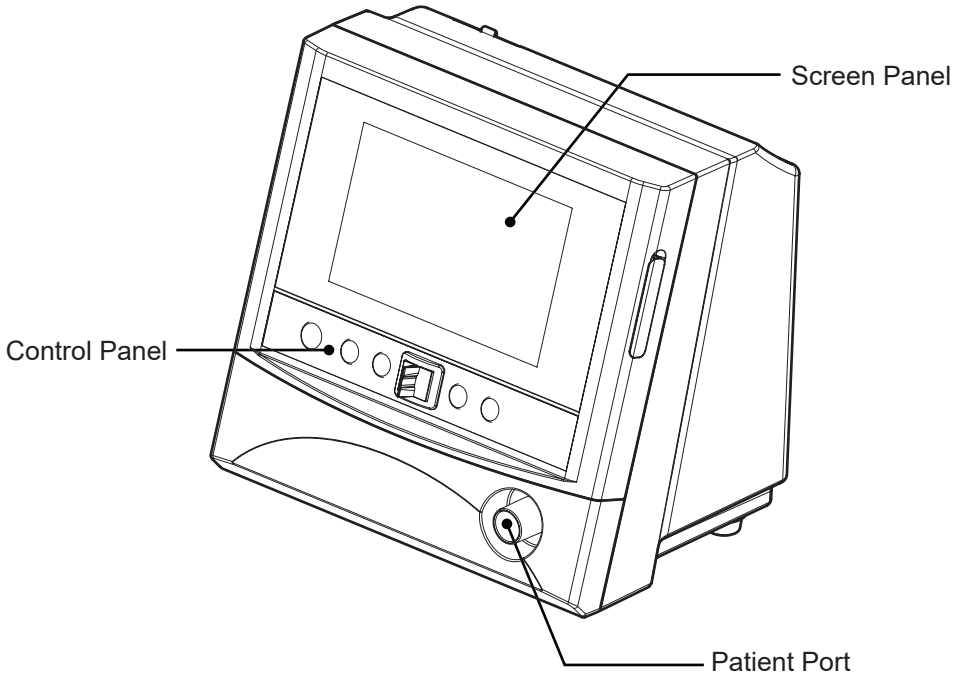
2.3 Caution

- Make sure that the Cooling Fan, Cooling Air Inlet, Patient Air Inlet are not blocked.
- Check if the device is properly equipped with the bacterial filter before using.
- Do not use in the area with strong electromagnetic waves.
- Do not operate the device with wet hand.
- Turn the device off when not in use.
- Keep the power cable away from heated surfaces.
- The device may be affected by electromagnetic fields greater than 10V/M.
- The device is not protected against water penetration (IP22). During transportation, we recommend to take the device in water proof condition, to provide maximum protection against accidental splashes.
- The device must not be exposed to direct sunlight.
- The device must be used by only a trained personnel.
- Do not use the device when it is equipped in the transport package.
- If you use a detachable battery for a long time or frequently, the battery life can be reduced.
- The lifetime of detachable battery depends on charge-discharge cycle and battery's age. The battery's capacity and lifetime can be reduced if stored or operated at high temperature area.
- The battery may discharge itself during storing. If you want to keep the battery in full-charged level, for spare, connect AC power to the device for 6 hours every 20 days. You can also apply AC power to the device continuously.
- It is not recommended to leave the battery uncharged. It may result in longer charging time.
- Do not use the battery in the area over 40°C. Do not store the battery where the temperature is over 60°C.

3. General Description

3.1 Front View

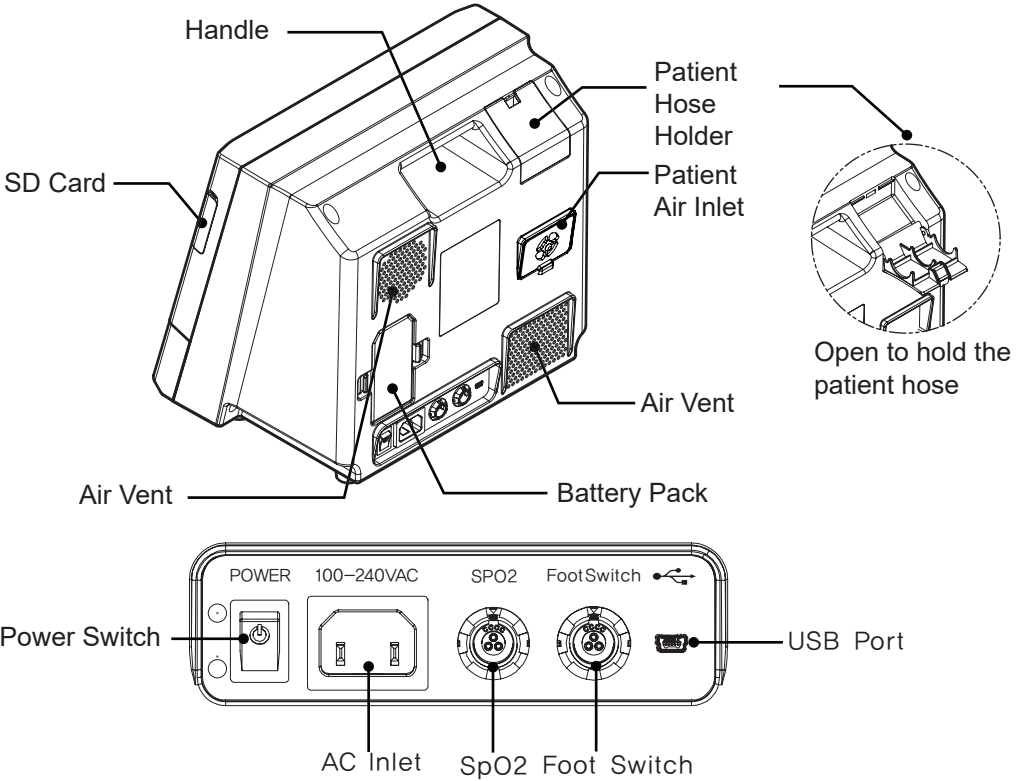
On the front side of the device, there are Screen Panel, Control Panel and Patient Port.



Part	Function
Screen Panel	Shows all the set value/parameters and operating status.
Control Panel	Sets in-exhale pressure and time duration. Includes the manual control lever.
Patient Port	Delivers in-exhale pressure to the patients.

3.2 Rear View

On the backside of the device, there are Patient Air Inlet, Air Vent, Power Switch, etc.



Parts	Function
SD Card	Saves the data for data management.
Handle	Is to hold the device when operator moves the device.
Patient Hose Holder	Holds the patient hose when not in use.
Patient Air Inlet	Takes and delivers the air to the patient after filtering inside the device.
Air Vent	Takes the air to cool the inside of the device.
Battery Pack	Supplies power when AC power is not available.
Power Switch	Is to turn on or off the device.
AC Inlet	Connects with the power cable.
SpO2(Optional)	Shows oxygen saturation level of the patients when connected. (Available only for CC20P)
Foot Switch	In manual mode, controls the in-exhalation by foot when connected.
USB Port	Connects with the USB cable for Software upgrade.




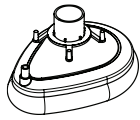



4. Package Contents

COMFORTCOUGH® II provides the replaceable accessories as below.

All components are for single-patient use and must not be re-used for other patients to avoid the risk of cross-contamination. In case of repeated use for single patient, these parts must be completely washed and dried before re-use.

Do not wash the bacterial filter. If it is damaged or blocked, discard and replace with the new filter.

4.1 Package

Part name	Part No.	Description	Reference
Patient Circuit		Patient Hose 1ea, Bacterial Filter 1ea, Face Mask (Adult) 1ea, Conector 1ea	
Patient Hose	38017	Flexible, Smoothbore tube with inside diameter 22mm and the total length of 1.2 meters.	
Bacterial Filter	70015	Block the foreign materials to avoid the risk of cross-contamination	
Face Mask	5353	Child(*Option)	
	5354	Adult(*Option)	
	5355	Adult Large(Basic)	
Connector	74505	O.D: 22mm / I.D: 15mm	
Air Filter	1A6035	50*34*10(60PPI)	
Detachable Battery	A64200	14.8V, 5.7Ah	
SD Card	1A6055	8GB	

Pouch	1A6054		
Power Cable	1A6053	European type	
	1A6100	UL/CSA Type	

4.2 Accessories (optional)

4.2.1 Foot Switch

Foot Switch is optionally available for manual therapy.

Foot Switch can be connected with the Foot Switch Connector on the back side of the device.

If the Foot Switch is activated, the Manual Control Lever on front panel is deactivated.

4.2.2 Stand

CC20 can be mounted to the stand.

4.2.3 Exhalation Valve

Use Exhalation Valve connecting to a face mask while operating Percussor mode.

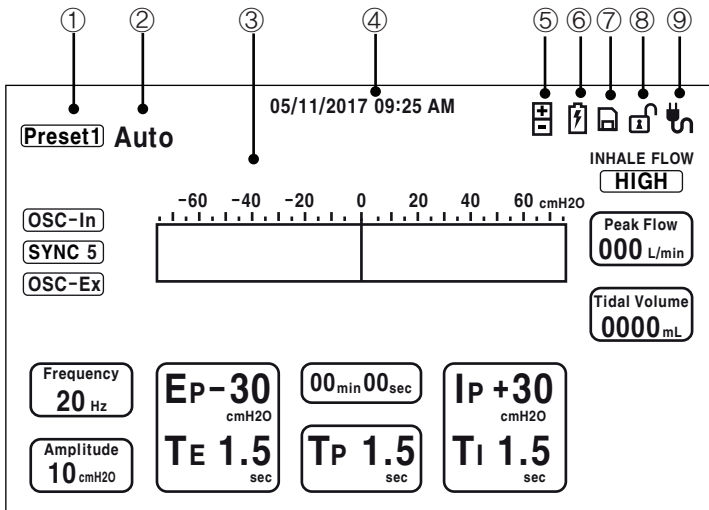
5. Operating Instruction

5.1 LCD Screen (with Pressure Bar)

The LCD screen displays the various parameters and operation status.

To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.



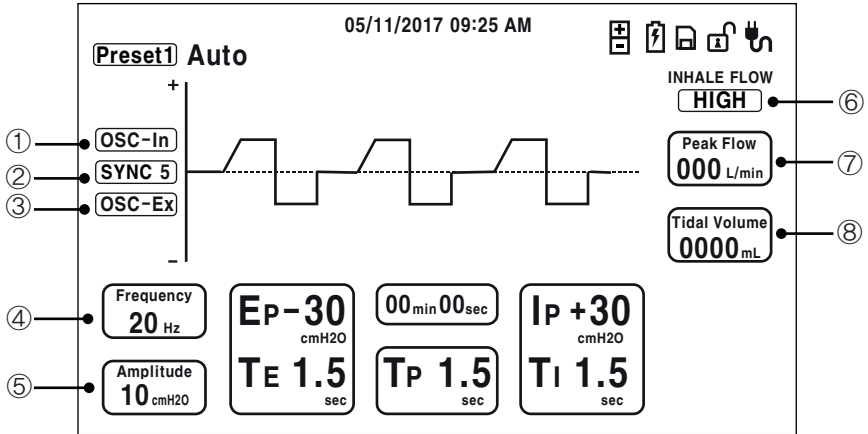
No.	Symbol or Text	Function	Description
1	Preset	Preset	Displays the number of the currently available preset (1 to 9)
2	Auto	Current Mode	Indicates the current cycling mechanism.
3	PRESSURE BAR	Pressure Bar	Displays the level of generated inhale and exhale pressures as bar.
4	05/11/2017 09:25AM	Current Time	Displays current time
5		Foot Switch connection	Indicates the connection between the device and the foot switch (Option)
6		Battery Indicator	Indicates the remained charge amount or charging status.
7		SD Card connection	Indicates the connection between the device and the SD Card
8		Control Lock	Indicates the setting keys are unlocked.
9		Power cable connection	Indicates the connection between the device and the power cable.

5.2 LCD Screen (with Pressure Graph)

The LCD screen displays the various parameters and operation status.

To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.



No.	Symbol or Text	Function	Description
1	OSC-In	Inhale Oscillation	Displays the current oscillation status at inhalation phase.
2	SYNC	Sync	Displays the current sync status.
3	OSC-Ex	Exhale Oscillation	Displays the current oscillation status at exhalation phase.
4	Frequency	Frequency	Displays the current frequency.
5	Amplitude	Amplitude	Displays the current amplitude.
6	HIGH/MID/LOW	Inhale Flow	Displays the Inhale Flow status (High/Mid/Low)
7	Peak Flow	Peak Flow	Displays the Peak Flow.
8	Tidal Volume	Tidal Volume	Displays the Tidal Volume.

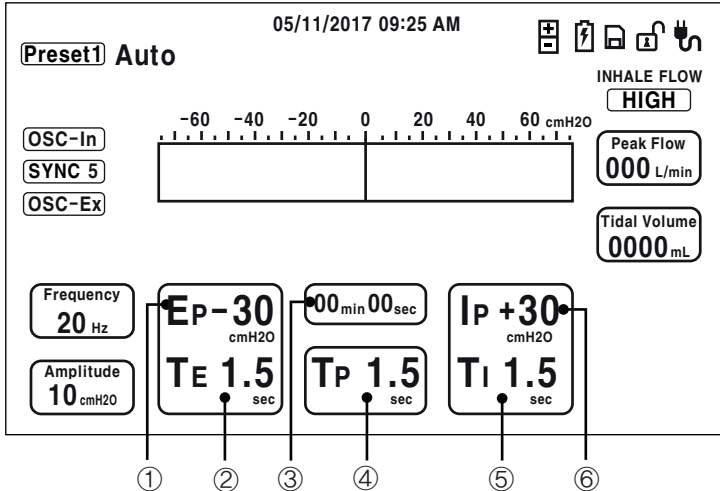
5.3 LCD SCREEN (Automatic Mode/with Pressure Bar)

The LCD screen displays the various parameters and operation status.

To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.

(*Pressure can be displayed as either bar or graph)



No.	Symbol or Text	Function	Description
1	EP	Exhale Pressure	Indicates the setting value of Exhale Pressure
2	TE	Exhale Time	Indicates the setting value of Exhale Time.
3	00min 00sec	Operating/standby Time	Displays the operating/standby time.
4	TP	Pause Time	Indicates the setting value of Pause Time.
5	TI	Inhale Time	Indicates the setting value of Inhale Time.
6	IP	Inhale Pressure	Indicates the setting value of Inhale pressure.

* If you want to set the pressure as bar or graph, please refer to the page 20.

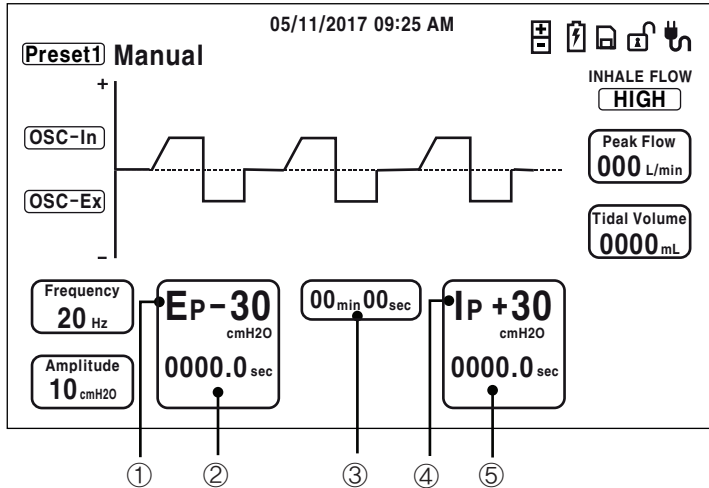
5.4 LCD Screen (Manual Mode/with Pressure Graph)

The LCD screen displays the various parameters and operation status.

To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.

(*Pressure can be displayed as either bar or graph.)



No.	Symbol or Text	Function	Description
1	EP	Exhale Pressure	Indicates the setting value of exhale pressure.
2	0000.0 sec	Exhale Time	Indicates the operating exhale time.
3	00min 00sec	Operating/standby Time	Displays the operating/standby time.
4	IP	Inhale Pressure	Indicates the setting value of inhale pressure.
5	0000.0 sec	Inhale Time	Indicates the operating inhale time.

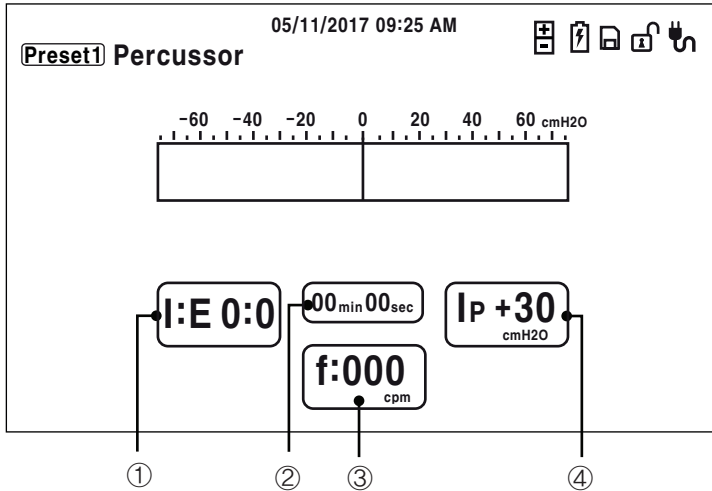
* If you want to set the pressure as bar or graph, please refer to the page 20.

5.5 LCD Screen (Percussor Mode)

The LCD screen displays the various parameters and operation status.

To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.



No.	Symbol or Text	Function	Description
1	I:E 0:0	Inhale/ Exhale Ratio	Indicates the time ratio of Inhale/Exhale.
2	00min 00sec	Operating/ standby Time	Displays the operating/standby time.
3	f:000cpm	Frequency	Indicates the setting value of frequency by CPM
4	IP	Inhale Pressure	Indicates the setting value of Inhale pressure.

* The maximum frequency (CPM) is limited in accordance with the I:E ratio.

Refer to the table of Maximum frequency(CPM) below in accordance with the I:E ratio

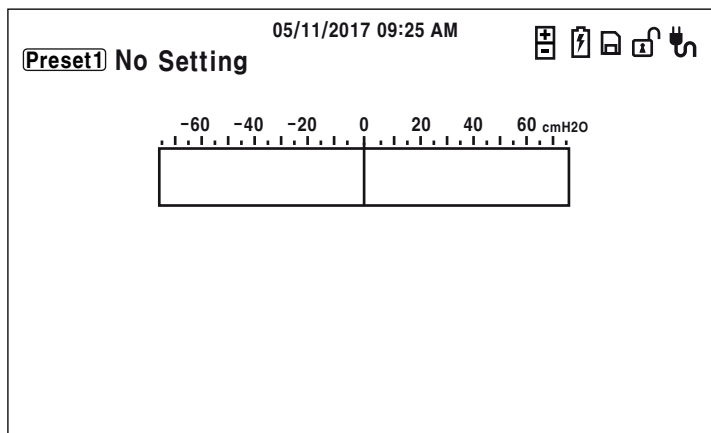
	I:E Ratio set				
	1:1	1:2 or 2:1	1:3 or 3:1	1:4 or 4:1	1:5 or 5:1
Maximum frequency (CPM)	780	400	300	240	200

5.6 LCD Screen(No Setting Mode)

The LCD screen displays the various parameters and operation status.

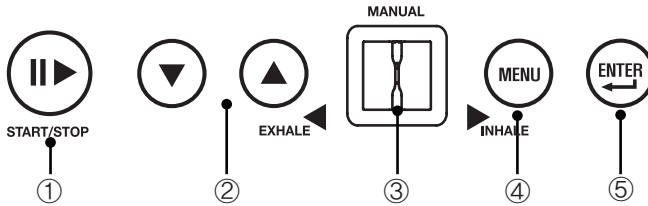
To assist you in adjusting the device, the LCD is equipped with a backlight.

The LCD backlight lights up when the device is turned on and goes out when the device is not in use more than 5 minutes.



※ Notice! At No Setting mode, the device is not working

5.7 Control Panel



No.	Button	Funtion	Description
1		START/ STOP	To start and stop the device.
2		Increase/ Decrease Value	To increase and decrease the parameter. Control Lock is activated/deactivated by pushing 'Up' and 'Down' keys simultaneously in stop mode.
3		Manual Control Lever	To manually change inhale to exhale phase or vice versa (It is disabled in Automatic Mode)
4		Menu	To set Setting, Options, Data, Clear Patient Data, Remove SD Card and Writing In Progress
5		Enter	To select the item in the menu settings.

5.8 Screen Changes

- Monitor Screen : If you do not operate the device in manual mode or Cough-Sync more than 5minutes, the device returns to the standby screen.
- Standby Screen : If you do not operate the device in standby mode more than 5 minutes, the screen is off. The screen is on again when you touch any buttons or the manual control lever.
- Menu Settings Screen : If you do not select none of menu settings, the device displays the standby mode.
- Each Menu Item : In the each menu item, the device displays relevant setting screen for 30 seconds. If you do not set within 30 sec., it will return to the previous screen.
- Confirmation Message : Confirmation message is displayed for 30 seconds, then it disappears and the device displays the previous screen.

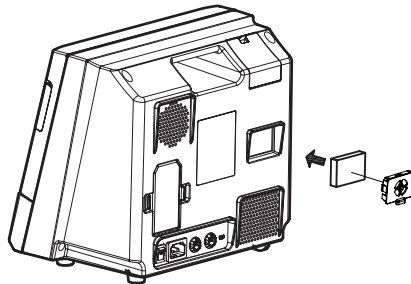
6. How to use the device

6.1 Preparation before using

1. Please read this User Manual carefully before operating.
2. Use the provided power cable only.
3. Combined use with other devices without prior approval of Seoil Pacific Corp. can cause malfunction or unexpected results. Please pay attention when you use the device.
4. Do not operate this device if unskilled.
5. If more than 2 patients use this device, please change patient's circuit(Patient Hose, Bacterial filter, Face mask, Connector) to avoid unexpected cross-contamination.
6. Operating erature : 5°C ~ 35°C , Operating pressure : 700~1060hPa
Operating humidity : 15%~90%, non-condensation

6.1.1 Install Air Filter

If there is no Air Filter, insert the Air Filter into the patient air inlet on the backside of the device.
Use provided Air Filter only.

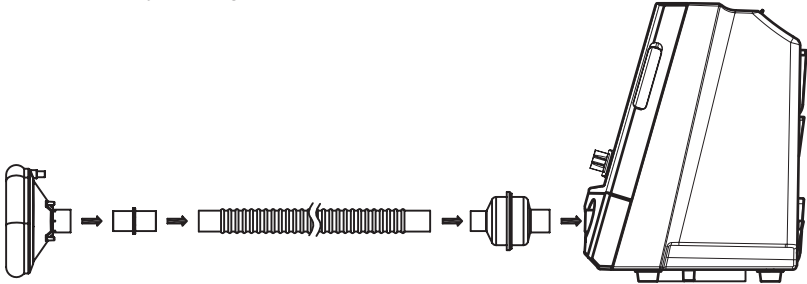


6.1.2 Patient Circuit Assembly

Place the device on a stable and flat area within operator's easy reach.
Make sure not to block the patient air inlet and air vent.

1. Attach the patient interface to the patient hose.
2. The patient interface are such as an connector and face mask, mouthpiece, endotracheal tube or tracheostomy tube.
3. Connect the patient circuit to the bacterial filter on the side of the device.

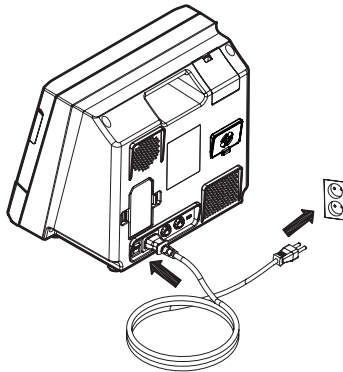
* Refer to the assembly drawing as follows.



6.1.3 Supply Power to the Device

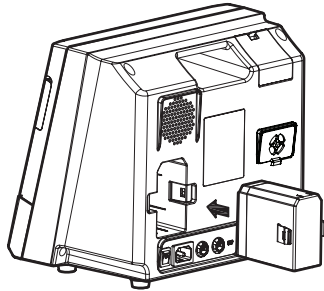
The device can operate by AC power and AC Power cable is included in the package

1. Insert the socket of the power cable into the AC inlet on the backside of the device and plug the other side of the power cable into an electrical outlet as follows.
2. Secure all the connections





6.1.4 Install and Use a Detachable Battery

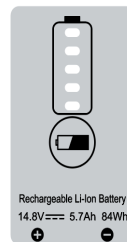
1. Put a detachable battery on the backside of the device. Insert the battery softly until “click” sounds in order to lock it.
2. The battery provides power in case AC Power isn't available.
3. The operation time with the battery depends on the battery's charge amount, condition, age or the device setting.
4. When AC Power is connected, the battery is charged automatically. When the device is in use, the battery is not charged.
5. In case it is completely discharged and then charged at around 23°C, the battery can be charged 80% within 4 hours. Consider the charge amount depends on the battery's characteristics.
6. LED light indicates remaining charge amount of the battery by pressing the button below LED light. LED light will be on for three seconds.



6.1.5 Marks for a Detachable Battery

1. Battery Mark(): It indicates the battery is inserted and ready to use. Level of white block indicates an amount of the battery. The level goes down as the battery is discharged.
2. Battery recharge Mark(): When AC power is connected, recharging mark comes up. Battery is recharged depending on the conditions

- 5 LED lights : Battery amount 80~100%
- 4 LED lights : Battery amount 60~79%
- 3 LED lights : Battery amount 40~59%
- 2 LED lights : Battery amount 20~39%
- 1 LED light : Battery amount 11~19%
- 1 LED light flashes : Battery amount 1~10%
- 0 LED light : Battery amount 0%



6.1.6 Disuse of a Battery

A battery has to be discarded in accordance with local regulations.

6.1.7 Battery Specification

1. Voltage : 14.8VDC
2. Capacity : 84Wh(Standard)
3. Battery type : Lithium-ion
4. Operating temperature : 5°C~40°C
5. Storage temperature : -20°C~60°C
6. Relative humidity (Operating and storage) : 15~95%, non-condensation
7. Operating pressure : 700~1060hPa
8. Operating time : Fully charged battery can operated at least 4 cycles to the typical patients.
Typical cycle leads 36 times of cough at $\pm 40\text{cmH}_2\text{O}$.

6.2 Initial Setting

1. Place the device on a stable and flat area within operator's easy reach.
 - ⚠ Caution : Be sure not to block the patient air inlet and air vent.
2. Insert the socket of the power cable into the AC inlet on the backside of the device.
3. Secure all the connections and plug the other side of the power cable into an electrical outlet.
4. Assemble the patient's circuit.
 - a. Connect the bacterial filter to the patient's port in the front side of the device in order to avoid the cross-contamination.
 - b. Connect a patient hose(1.2m x 22mm ID) to the bacterial filter.
 - ⚠ Warning : Please use the hose provided by Seoil Pacific. A different type of hose may affect efficiency such as pressure or leaking.
 - ⚠ Warning : Do not use conductive or anti-static hoses or tubes.
 - c. Connect a proper patient interface to the patient hose. The patient interface are such as a facemask and connector, mouthpiece, lip seal or tracheostomy tube connector.
5. Turn on the device. Power can be turned on/off by pressing the power switch on the back side of the device.
 - ⚠ Warning : Be careful not to place the device where it can be dropped.
 - ⚠ Warning : Make sure to use the device in the dry and clean area as it is medical device.
 - ⚠ Warning : Make sure the power cord and plug are in good condition before using.
 - ⚠ Warning : The filter protects the device from the event of accidental liquid spillage.
6. When the device is on, it conducts self test automatically.
7. Set the pressure and time, and press the 'START/STOP' button.
8. Block the end of patient port for 4~5 cycles of therapy and check if the pressure bar or graphic shows an intended value.

6.3 Change a Menu Setting

Menu
Settings
Options
Data
Clear Patient Data
Remove SD Card
Patient data to SD Card
Format SD Card

※ The above screen shows various menu settings. It will be displayed when you stop the device and press MENU button. If you choose a menu item and press ENTER button, the device will show relevant setting values.

① Settings

Settings	page 1/2
Preset	1
Mode	Auto
Pressure Display	Graph
Cough-Sync	Off
Inhale Pressure	50 cmH2O
Inhale Flow	Low
▼ Inhale Time	2.0 sec

1. Preset : Select Preset menu and press ENTER button. Set the preset from 1 to 9 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
2. Mode : Select Mode menu and press ENTER button. Set the mode among Auto, Manual, Percussor and No Setting by pressing '▲(UP)/▼(DOWN)' button and then ENTER button. If you select Manual mode, Cough-Sync, Inhale time, Exhale time and Pause Time setting will be disappeared. If you select Percussor mode, there will be an other screen for setting. If you select No Setting mode, other contents will be disappeared except Preset and Mode.
3. Pressure Display : Select Pressure Display menu and press ENTER button. Set the display pressure as graph or bar by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.

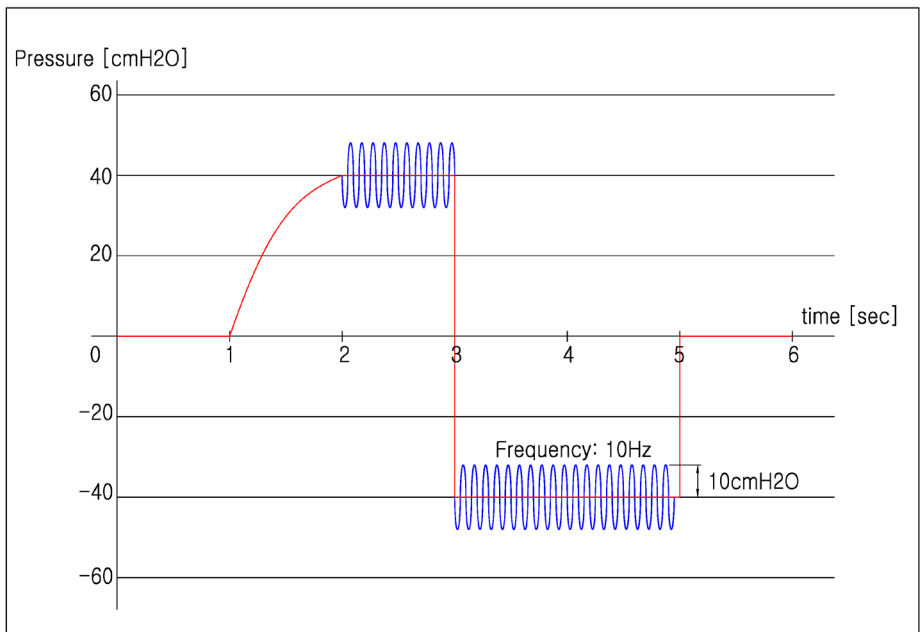
4. Cough-Sync: Select Cough-Sync menu and press ENTER button. Set the Cough-Sync by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
5. Inhale Pressure : Select Inhale Pressure menu and press ENTER button. Set the inhale pressure from 0 to 70cmH2O by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
6. Inhale Flow : Select Inhale Flow menu and press ENTER button. Set the low, medium or high inhale flow by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
7. Inhale Time : Select Inhale Time menu and press ENTER button. Set the inhale time from 0 to 5 seconds by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.

Settings		page 2/2
▲ Exhale Pressure		2.0 sec
Exhale Time		2.0 sec
Pause Time		1.5 sec
Oscillation		Both
Frequency		10 Hz
Amplitude		10 cmH2O

8. Exhale Pressure : Select Exhale Pressure menu and press ENTER button.
Set the exhale pressure from 0 to 70 cmH2O by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
9. Exhale Time : Select Exhale Time menu and press ENTER button. Set the exhale time from 0 to 5 seconds by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
10. Pause Time : Select Pause Time menu and press ENTER button. Set the pause time from 0 to 5 seconds by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
11. Oscillation : Select Oscillation menu and press ENTER button.
Set the oscillation among Both, Inhale, Exhale and Off by pressing '▲(UP)/▼(DOWN)' button and then ENTER button. If you select OFF, Frequency and Amplitude will be disappeared.
12. Frequency : Select Frequency menu and press ENTER button. Set the frequency from 0 to 20Hz by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
13. Amplitude : Select Amplitude menu and press ENTER button. Set the amplitude from 0 to 10cmH2O by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.

※ Note:

- The graph below is an example of Oscillation setting.
- Oscillation : Inhale pressure : 40cmH₂O, Exhale pressure : 40cmH₂O, Amplitude : 10cmH₂O, Frequency : 10Hz.
- Red line shows a pressure curve when the oscillation is not applied.
- Blue line shows a vibration and pressure waveform when the oscillation is applied.
- As per the Amplitude setting, the pressure oscillates between 10cmH₂O above/below the set pressure in both phases of the breath.
- As the frequency value is 10Hz and in-exhalation values are 2 seconds each, the pressure oscillates 20 times each in both phases of the breath.
- If you set Pressure Display as graph, it will be helpful to understand the operation.



Oscillation / Amplitude

Settings	
Preset	2
Mode	Percussor
Inhale Pressure	70 cmH2O
Percussor Frequency	780 CPM
Percussor Time Minute	5 min
Percussor Time Sec	30 sec
I/E Ratio	1:1

14. Inhale Pressure : Select Inhale Pressure menu and press ENTER button.
Set the inhale pressure from 0 to 70cmH2O by pressing '▲(UP)/▼(DOWN)'button and then ENTER button. (1cmH2O increment)
15. Percussor Frequency : Select Percussor Frequency menu and press ENTER button.
Set the percussor Frequency from 10 to 780CPM by pressing '▲(UP)/▼(DOWN)'button and then ENTER button. (10CPM increment)
16. Percussor Time Minute : Select Percussor Time Minute menu and press ENTER button.
Set the minute from 0~5min by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
17. Percussor Time Sec : Select Percussor Time Sec menu and press ENTER button.
Set the seconds from 0 to 59 seconds by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
18. I / E Ratio: Select this menu and press the ENTER button. Change the setting from 5: 1 to 1: 5 to the ▲ (Up) / ▼ (Down) button and press the ENTER button.

② Options

Options		page 1/2
Language	English	
LCD Brightness	10	
Date Format	mm/dd/yyyy	
Time Format	hh:mm AM	
Month	5	
Day	11	
▼ Year	2017	

Options		page 2/2
▼ Hour		9
Minute		25
Therapy Hours		0 hour 59 min

1. Language : Select Language menu and press ENTER button. Set the language among English, Chinese, Japanese, German, Spanish and Portuguese, Slovenian, and others by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
2. LCD Brightness : Select LCD Brightness menu and press ENTER button.
Set the brightness from 1 to 10 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
3. Date Format : Select Date Format menu and press ENTER button.
Set the date format as mm/dd/yyyy or dd/mm/yyyy by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
4. Time Format : Select Time Format menu and press ENTER button.
Set the time format as hh:mm AM or hh:mm by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
5. Month : Select Month menu and press ENTER button.
Set the month from 1 to 12 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
6. Day : Select Day menu and press ENTER button.
Set the date from 1 to 31 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
7. Year : Select Year menu and press ENTER button.
Set the year from 2000 to 2100 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
8. Hour : Select Hour menu and press ENTER button.
Set the hour from 0 to 23 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
9. Minute : Select Minute menu and press ENTER button.
Set the minute from 0 to 59 by pressing '▲(UP)/▼(DOWN)' button and then ENTER button.
10. Therapy Hours : Select Therapy Hours menu and press ENTER button.
The therapy hours can be set by pressing '▲(UP)/▼(DOWN)' button.

③ Data

Data		page 1/2
SD Card Capacity	7.26GB free of 7.27GB	
Serial Number	1705A6122	
Software Version	1.05	
Model Number	CC20	
Therapy Hours	0 hour 20 min	
Calibration Date	2017-05-11	
▼ Detachable Battery SN	1705E1100	

Data		page 2/2
▲ Detachable Battery Cycles	0	

1. SD Card Capacity : Displays a capacity of the SD Card if the SD Card is inserted.
2. Serial Number : Displays the serial number.
3. Software Version : Displays a software version of the device.
4. Model Number : Displays a model number.
5. Therapy Hours : Displays the total therapy hours.
6. Calibration Date : Displays a date when the device is calibrated.
7. Detachable Battery SN : Displays the serial number of a detachable battery.
8. Detachable Battery Cycles : Displays the number of recharging cycle.

④ Clear Patient Data

Clear Patient Data?
No
Yes

- Clear Patient Data : Clear the data of the patient recorded in the device.

⑤ Remove SD Card

Remove SD Card?
No
Yes

- Remove SD Card : Remove SD Card from the device safely.

⑥ Patient data to SD Card

Patient data to SD Card?
No
Yes

- Patient data to SD Card : Patient data copy to the SD card

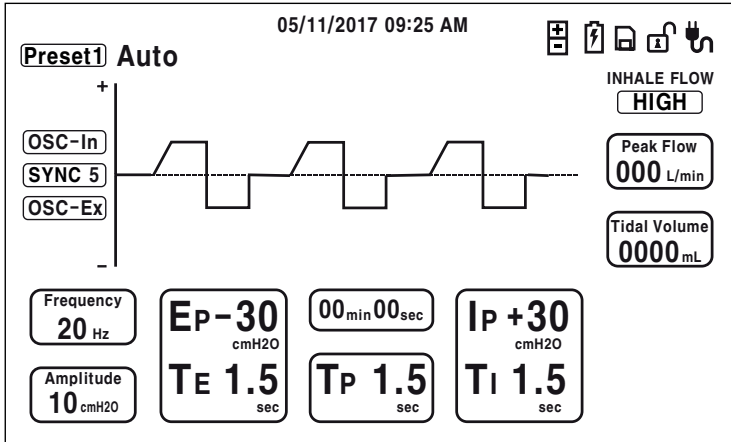
⑦ Format SD Card

Format SD Card?
No
Yes

- Format SD Card : Format the SD Card.

 Do not remove the SD card during formatting.

6.4 Setting & Using the Automatic Mode



* The above screen displays pressure as graph. The pressure can be displayed as bar. Please refer to the 6.3 Change a Menu Setting for changing the setting.

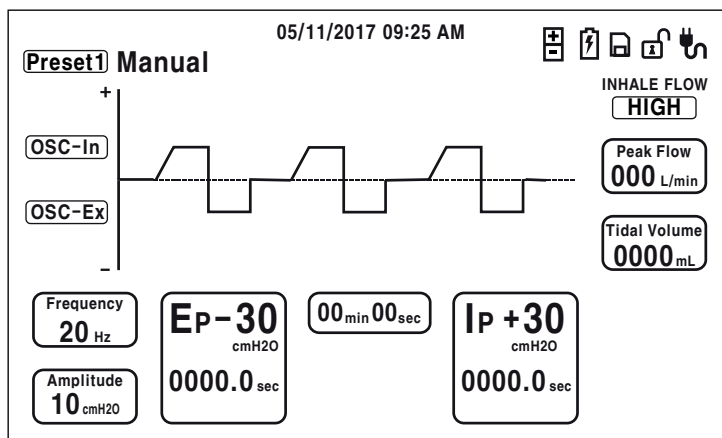
1. Connect the patient circuit to the device.
2. Turn on the device.
3. Before therapy, check the settings.
4. Attach the appropriate patient interface to the patient.
5. Start the device by pressing 'START/STOP' button.
6. Automatic mode consists of an inhalation phase, an exhalation phase and a pause phase in sequence.
7. After the therapy, remove the patient interface from the patient. Remove secretions that may have become visible in the mouth or tracheostomy tube.
8. The therapy can be repeated based on the prescription of the physician.



Warning : Make sure to check the settings before each therapy.

Normally a therapy consists of 4~5 times of breathing. After 4~5 times of breathing, the patient is then recommended to take rest for 20~30 seconds, which helps to avoid hyperventilation. The cycles can be repeated 4~6 times for a full treatment.

6.5 Setting & Using the Manual Mode



*The above screen displays pressure as graph. The pressure can be displayed as bar. Please refer to the 6.3 Change a Menu Setting for changing the setting.

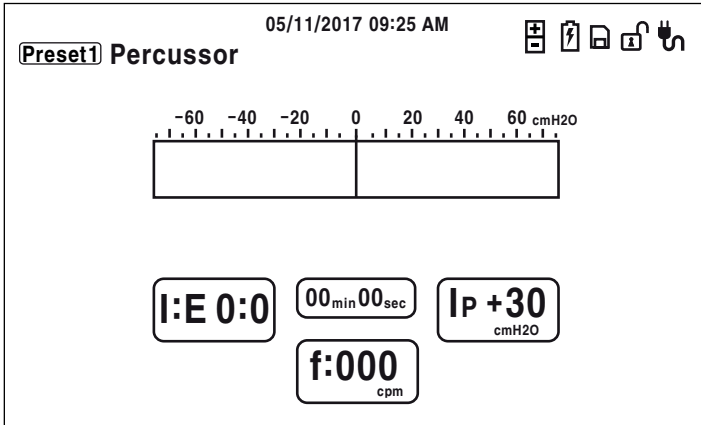
1. Connect the patient circuit to the device.
2. Turn on the device.
3. Before therapy, check the settings.
4. Attach the appropriate patient interface to the patient.
5. Start the device by pressing 'START/STOP' button.
6. Push the manual control lever to inhale position and hold for a moment.
7. Rapidly shift the manual control lever to exhale position and hold for a moment.
8. Release the manual control lever to pause position and hold for a moment. Then repeat the cycle checking the patient's condition.
9. After the therapy, remove the patient interface from the patient. Clean secretions that may have become visible in the mouth, throat or tracheostomy tube.
10. The therapy can be repeated based on the prescription of the physician.



Warning : Make sure to check the settings before each therapy.

Normally a therapy consists of 4~5 times of breathing. After 4~5 times of breathing, the patient is then recommended to take rest for 20~30 seconds, which helps to avoid hyperventilation. The cycles can then be repeated 4~6 times for a full treatment.

6.6 Setting & Using the Percussor Mode



*Only pressure bar can be displayed in Percussor Mode.



When using Percussor Mode, at the pressure range of 50~70cmH2O, we highly recommend to use the device within 5 minutes. If you use the device more than 5 minutes, it may lead to get "Temp." message. In this case, please refer to the 12. Trouble Shooting.

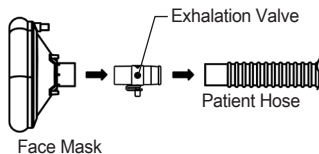
Apply Percussor Mode to a spontaneous respiration patient



Warning Strongly recommend to use the accessories which the manufacturer recommends. In case of using other accessories, please be noted that the actual pressure and the therapy effect can be changed and decreased.

1. Connect a bacteria filter and a patient hose to the device, and then connect them to face mask by using Exhalation Valve as a connector.
2. Turn on the device.
3. In Percussor Mode, set pressure, frequency, I:E ratio.
4. Before starting the therapy, recheck the setting value which will be applied to the patient.
5. Press 'START/STOP' Button

Note : To get the best results from treatment, the patient is recommended to try to exhale against the percussion as possible as the patient can do so. Do not use for more than 5 minutes continuously. Observe the patient carefully during the treatment. According to the patient's condition, stop the therapy for a few seconds.

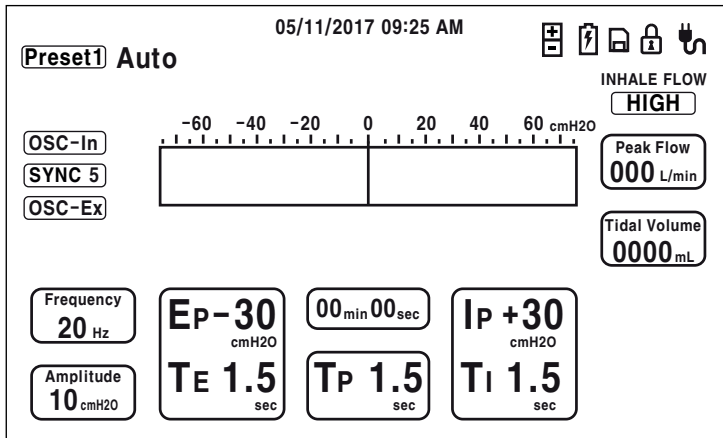


6.7 Operation Verification



It is recommended that the device is to be periodically tested to ensure that the cycling valve returns to the pause position after either the inhale or exhale phase. To determine this, follow these steps.

1. Turn on the device.
2. Attach the patient circuit to the device and block the end of the patient port.
3. Set the manual mode.
4. Set the maximum inhale pressure and exhale pressure.
5. Press the 'START/STOP' button.
6. Shift the manual control lever from inhale to exhale checking the pressure indicator to ensure that the positive and negative pressure is being applied to the patient circuit.
7. Release the manual control lever from the inhale position and observe that the pressure immediately drops to 0cmH₂O. Repeat this process from the exhale position also. In either case, if the pressure does not drop to 0 cmH₂O immediately, the device should be returned to the distributors or dealers for checking.

6.8 Setting the Control Lock



To prevent unintentional or accidental touch to the keys, the control keys can be locked.

1. Stop the device and press the '▲(UP)/▼(DOWN)' buttons simultaneously for three seconds.
 2. The padlock symbol  is displayed on the screen.
 3. To unlock the setting keys, stop the device and press the '▲(UP)/▼(DOWN)' buttons simultaneously for three seconds.
 4. The open padlock symbol  is displayed on the screen.
- ※ Notice! Power ON/OFF and 'START/STOP' buttons will not be locked at anytime.

7. Cleaning & Disinfection

7.1 External Housing

Once contaminated, in unplugged status, the exterior of the device and housing should be cleaned with a mild detergent and water, or with a bactericidal cleaning solution such as 70% isopropyl alcohol.



CAUTION : Completely dry the device before plugging.

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

7.2 Patient Circuit



WARNING : The patient circuit is prohibited to reuse after sterilized.

Always use a new circuit for a new patient.

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

7.2.1 Institutional (Hospital) Use

Patient circuit (Patient hose, Bacterial filter, Face mask, Connector) : If the device is to be used by more than one patient, the circuit must be replaced

7.2.2 Home(Individual) Use

- a. Patient Hose, Patient Interface and Connector : After use, the patient hose and patient interface should be washed thoroughly in soap and water. These parts must be completely dried before reuse.
- b. Bacterial Filter : The filter, which protects the device from foreign material to the patient, can be left in place as long as it is not blocked by sputum or trapped moisture. Do not reuse after washing the filter.

7.3 Cleaning Air Filter

The air filter has to be cleaned every 2 weeks and replaced every 6 month if it is under the normal usage condition. Or if air flow/pressure does not reach up to the target value during operation,

1. Turn off and unplug the device.
2. Detach the air filter from the air inlet.
3. Check if the filter is clean and not defective.
4. Wash the filter with a mild detergent and water and rinse it thoroughly.
5. Dry the filter completely and re-insert it to the device. If the filter is damaged, replace it. Only use the filter provided by Seoil Pacific.

7.4 Preventive Maintenance

The device doesn't need a preventive maintenance service.
Please refer to the detailed service information in the manual.

8. Storing

8.1 How to store

1. If not in use for more than a year, the device must be checked by trained personnel per year.
2. Be sure to store the device away from water source.
3. Be sure to store the device to prevent dust from outside.
4. Do not place put the device on a slope or an unstable place.
5. After use, turn off and unplug the device, and disassemble the accessories.
6. Refrain from having direct ray of sunlight on the device.
7. Be sure to clean the device for storage.
8. Store it away from children's reach.
9. When using the device after a long storage period, make sure that the device functions properly before using the device.
10. Be sure not to block the patient air inlet and air vent.
11. Do not store the device nearby heating places.
12. Do not store the device in extremely high or low temperatures.

Operating temperature : 5°C~ 35°C

Operating humidity : 15% ~ 90%, non-condensation

Operating pressure : 700~1060hPa

Transport & storage temperature : -25°C ~ 60°C

Transport & storage humidity : 15% ~ 90%, non-condensation

8.2 How to clean

1. Turn off and unplug, then clean the device.
2. Do not give any shock to the device.
3. Be sure to clean the device with dried towel.
4. Prevent water intrusion
5. Be sure to dry the device completely after cleaning.

8.3 How to move

1. Turn off and unplug, then move the device.
2. Pack the device in a pouch(1A6054) if moving the device long distance.
3. Protect the device from severe shock during transportation.

9. Specifications

9.1 Information

Device Name	COMFORTCOUGH® II
Model Name	CC20
Intended Purpose	Mechanical In-Exsufflator(MI-E) helps to clear bronchial secretions when patients can't cough by themselves.
How to Use	Refer to the manual
Rated Voltage	100-240V~
Rated Frequency	50/60Hz
Rated Power	120VA
Electrical Protection	BF, Class II
Dimensions	287 x 273 x 218mm(WxHxD)
Weight	1 set, 4.6Kg(without accessories)

9.2 Specification

Inhale Pressure(Ip)	0 ~ +70cmH2O (1cmH2O Increment)
Exhale Pressure(Ep)	0 ~ -70cmH2O (1cmH2O Increment)
Inhale Time(Ti)	0.0 ~ 5.0 seconds (0.1 second Increment)
Exhale Time(Te)	0.0 ~ 5.0 seconds (0.1 second Increment)
Pause Time(Tp)	0.0 ~ 5.0 seconds (0.1 second Increment)
Trigger (Synchronization)	1(Sensitive) ~ 9(less sensitive)
Inhale Flow	LOW, MID, HIGH
Modes	Automatic, Manual, Percussor
Frequency	1~20Hz
Amplitude	1-10 cmH2O
Percussor mode	
Inhale Pressure	0 ~ +70cmH2O (1cmH2O Increment)
Frequency	10 ~ 780CPM (10CPM Increment)
I:E Ratio	5:1 ~ 1:5
Degree of Protection Against Ingress of Water	IP22
Mode of Operation	Continuous

10. EMC Information

10.1 Guidance and manufacturer's declaration – electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

10.2 Guidance and manufacturer's declaration – electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity


The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic Discharge(ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-2	±15 kV air	±15 kV air	
Electrical fast Transient/burst	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical home or hospital environment.
IEC 61000-4-4	±1 kV for input/output lines	±1 kV for input/output lines	
Surge	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical home or hospital environment.
IEC 61000-4-5	±2 kV common mode	±2 kV common mode	
Voltage dips, short interruptions and voltage variations on power supply input lines	<5 % UT (>95% dip in UT) for 0.5 cycle	<5 % UT (>95% dip in UT) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or battery.
IEC61000-4-11	40 % UT (60 % dip in UT) for 5 cycle	40 % UT (60 % dip in UT) for 5 cycle	
	70 % UT (30 % dip in UT) for 25 cycles	70 % UT (30 % dip in UT) for 25 cycles	
	<5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 5s	
Power frequency (50/60 Hz)magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note : U_T is the A.C. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance: $d = 1.2 \sqrt{P}$</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5GHz</p>
Radiated RF IEC61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	<p>Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in meters(m).^b</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

Note 1 At 80MHz and 800MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum power output of transmitter (Watts)	Separation distance according to frequency of transmitter (meters)		
	150kHz to 80 MHz $d = 1.2 \sqrt{P}$	80MHz to 800 MHz $d = 1.2 \sqrt{P}$	800MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.3
100	12	12	23











For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.








NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

11. Symbols

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

Symbol	Description
	Read the accompanying manuals
	"ON" for part of equipment
	"OFF" for part of equipment
	Attention, consult instruction manual
	Type BF Equipment
	Manufacturer
	Date of Manufacture
	Authorized representative in the European community
	Notified body of CE/MDD(SZU)
	Class II (Double Insulated)

Symbol	Description
IP22	Protected against finger sized objects protection against vertically falling water drops.
Foot Switch	Foot Switch remote control
	USB connector
SpO2	Oximeter connector
	Alternating current
	Direct current
Li-Ion	Lithium Ion battery
	Catalogue number
	Serial Number
	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.
	Prescription only : Federal law restricts this device to sale by or on the order of a physician.

12. Trouble Shooting

Please check the following categories before asking for after service.

Status	Handling method
The power is not turned on even if I press the power switch.	- Please check the connection status of the power cable. - Check to see if the power switch is turned on. - Check to see if the fan is operating.
When the air is not coming out.	- Check the pressure setting.
When the air is weak.	- Check the pressure setting. - Check the filter and change if necessary.
When 'Temp.' appears on the screen.	- Blower temperature is too high. - Device will stop automatically, and if you keep the device in standby, the cooling down process is accelerated by fan. 'Temp.' will be disappeared when the temperature is in appropriate condition. If 'Temp.' is not shown, you can use again.
When 'E1' appears on the screen.	- The position of stepping motor which controls the valve is not correct. - Device will reset by itself and will start after checking automatically. - Call service center if still E1 shows on the monitor even you have restarted the device.
When 'E2' appears on the screen.	- The pressure exceeds the set value. - Call service center if still E2 shows on the monitor even you have restarted the device.
When "Internal Memory is Full! Please backup your patient data and clear the patient data!" appears on the screen	- Booting time ERR(over than 7 seconds) - The message will disappear automatically after 5 seconds.

- If there are any sign of malfunctions, please stop using the device, turn off the power switch and pull the power cable out. Then, contact Seoil Pacific Service Center for repairs or local sales manager.
- Please contact your local Seoil Pacific dealer or authorized representatives for any inquiries.
- If the device is used in normal usage, it is fully guaranteed for 1 year from the purchasing date from the authorized dealer of Seoil Pacific Corp.

13. Limited Warranty

Seoil Pacific Corp. warrants that the device shall be free from defects in parts and functions and will perform based on the product specifications for a period of one year from the purchasing date from the authorized dealer.

Seoil Pacific Corp. warrants that the accessories(Patient Circuit, excludes single-use appliances) shall be free from defects in parts and functions for a period of 90 days from the purchasing date from the authorized dealer.

If the device fails under conditions of normal use, Seoil Pacific Corp. will repair or replace, at its option, the defective device or any of its components.

This warranty is not subject to cover the damages by accident, incorrect use, over use, transform, or defects on the parts which are not affecting the function of the device.

A term of guarantee of a detachable battery is 6 months from the purchasing date from the authorized dealer, this warranty is not subject to cover the damages caused by incorrect use.

For further information on your warranty rights, contact your local Seoil Pacific dealers or authorized representatives.

14. Quality Warranty Certifications

Device number (S/N)		
Purchase date (dd/mm/yy)		
Free repair warranty period		1 year from purchase date from seoil pacific to the dealer
Warranty area		
Purchaser	Name	
	Address	□□□□
	Telephone	TEL : () - / Mobile : - -
Seller	Branch name	
	Address	□□□□
	Telephone	

This certificate promises free repairs based on its terms.

When any malfunctions occur during the warranty period, please submit this warranty certificate with the device.

- If the above blanks are left blank, this certificate loses its power. If they are not filled out, please contact the authorized dealer of purchasing place immediately.
- This certificate may not be reissued.
- Our device is manufactured under a strict inspection process.

< Summary of warranty >

- | | |
|---|--|
| <ol style="list-style-type: none"> 1. If any malfunction occurs during normal use condition mentioned in this manual and device label, customers are entitled to free repairs based on customer protection regulations. 2. When receiving repair service during the warranty period, please submit this certificate with the device. Repair costs will be charged when the repair occurs after the warranty period is over. 3. When moving from your house, please contact your sales manager or Seoil Pacific Service Center. 4. If the following incidents occur, customers will be charged with repair cost even during the warranty period. <ol style="list-style-type: none"> (1) When malfunction occurs due to user's misuse, unauthorized repairs and device adjustments. (2) When the device is damaged during transportation or by any means of shock. | <ol style="list-style-type: none"> (3) When the device is used in abnormal environment that is not covered within the manual. (4) When malfunction occurs due to foreign objects such as drinks, coffee and other objects. (5) When malfunction occurs due to combination use with other devices. (6) When the damaged parts are consumable parts. (7) When the device is damaged by force majeure such as fire accidents, earthquake, water accidents and lightning. (8) When this certificate is not presented. (9) When the date of purchase, customer name and sales branch have been tampered. (10) When it has been damaged due to improper use <p>5. Please keep this certificate for better A/S.</p> |
|---|--|

※ This certificate promises free repairs based on mentioned period and terms. Therefore, this certificate does not limit customer's legal rights. If you have any questions about service and repairs after the warranty period, please contact Seoil Pacific Service Center or your sales manager.

DOC NO. : CC20E-R6
PRINTED DATE : 2020.03

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