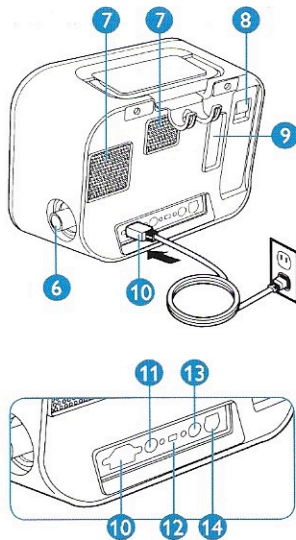
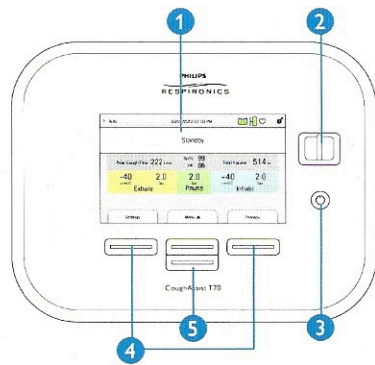


1 Device overview

- 1 Display screen
- 2 Manual switch to activate inhale (right) and exhale (left) phases
- 3 Power on/Power off
- 4 Perform action specified on screen
- 5 Navigate menus or change setup

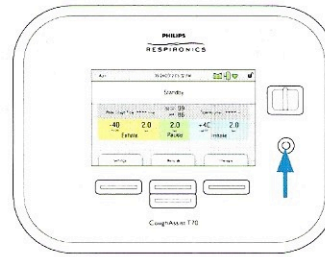


- 6 Breathing circuit connection
- 7 Fan exhaust – Air outlet must be kept uncovered
- 8 Detachable battery
- 9 Filter – Air inlet
- 10 AC power inlet
- 11 Remote control connector
- 12 USB connector (for service only)
- 13 SpO₂ connector
- 14 DC power inlet


Note: When the remote control foot pedal is connected, the manual switch is disabled.

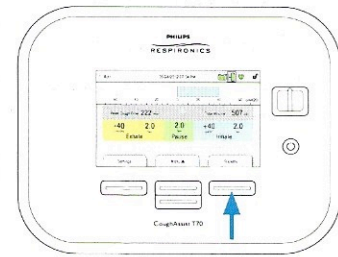
2 Starting therapy

How to start/stop therapy




To start therapy

- Connect the device to AC or DC power source or use the detachable battery
- Press  to power on the device
- Select **Therapy** to start the treatment

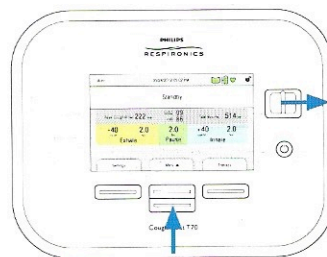


To stop therapy



- Select **Standby**
- To turn power off, press 


How to lock/unlock

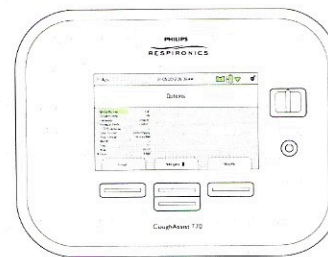
Limited access (lock) permits the user to select between Preset therapy settings, while Full access (unlock) will allow the user to change all settings.




To temporarily unlock the device

- While in Standby screen, press the down button  below **Menu** and hold manual switch  to the right for 5 seconds

Note: When  appears on the main screen, the device is unlocked. If the Access menu is not set to Full, the device will switch automatically to limited access after 5 minutes of inactivity.





To select access option

- Press the up button  below **Menu**
- While 'Option' is highlighted in green press **Select**
- While 'Menu Access' is highlighted, press **Modify** and then **Edit** to select 'Limited' or 'Full' access
- Press **OK** to validate
- Press **Finish** and **Exit** to return to the main screen

3 Modifying therapy settings

To modify settings

- The therapy settings are accessible through the left button  below **Settings**
- The scroll buttons  allow selection of desired parameter
- Pressing **Modify** will allow changing the parameter highlighted in green, **OK** validates the choice and **Finish** returns to main screen
- Three Presets are available to save a group of settings for different circumstances




The settings available are displayed in the table below:

Preset	1, 2, 3	
Mode	Auto, Manual	
Cough-Trak	OFF/ON	Only available in Auto mode
Inhale pressure	0 to 70 cmH ₂ O, in increments of 1 cmH ₂ O	
Inhale flow	Low, Medium, High	
Inhale time	0 to 5s, in increments of 0.1s	Only available in Auto mode
Exhale pressure	0 to -70 cmH ₂ O, in increments of 1 cmH ₂ O	
Exhale time	0 to 5s, in increments of 0.1s	Only available in Auto mode
Pause time	0 to 5s, in increments of 0.1s	Only available in Auto mode with Cough-Trak OFF

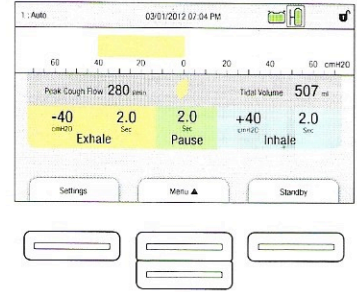
Note: Any change of settings made during therapy will automatically take effect at the beginning of that phase in the next cycle.

4 Monitoring view and icons

To change monitoring view

- Press the up button  below **Menu**
- While 'Option' is highlighted in green, press **Select** and navigate down to 'Detailed View'
- Press **Modify** and **Edit** to change 'OFF' or 'ON'
- Press **OK** to validate
- Press **Finish** and **Exit** to return to the main screen

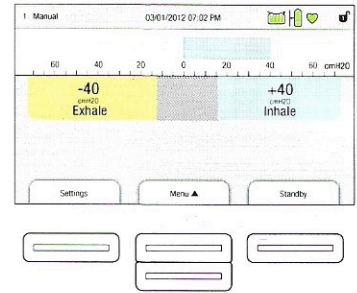
Detailed View 'ON'

















Note: When selecting detailed view 'OFF', the following parameters are not displayed:

- Peak Cough Flow
- SpO₂
- HR
- Tidal Volume
- Exhale and Inhale Time setting and counter
- Pause Time setting


Detailed View 'OFF'




Symbols and icons

- Color code:**
 - green = pause
 - yellow = exhale
 - blue = inhale
-  SD card inserted
-  SD card error
-  Memory card writing: copying data to SD card
-  Full access
-  Remote control: (foot pedal) connected
-  External battery indicator: red = few minutes left
-  Detachable battery indicator: red = few minutes left
-  Pulse oximeter: green means connected (flashing)
-  With ? means questionable data
-  Breath synchronization tool: displayed remaining time of each phase during Auto mode
-  No measurement is performed or questionable data
-  Informational message: information available in the Information Log
-  Power source in use indicator: box is placed around the battery being used
-  Charging indicator: detachable battery is being charged

6 Device menu

To access device menu, press the up button  below the menu.

The menu selection and their corresponding parameters are displayed in the table below:

Options	LCD brightness, date format, time format, month, day, year, hour and minutes. Only in Full access mode: menu access, detailed view, language, pressure units, therapy hours
Data	SpO ₂ , heart rate (HR), peak cough flow, tidal volume, serial number, model number, software version, calibration date, SD card capacity, detach battery serial number, detach battery cycles, therapy hours
Information Log	Informational messages about the device will be indicated by the  icon. The log menu displays the list of messages that occurred, i.e. 'battery not charging' or 'replace battery' and allows them to be cleared
Clear Patient Data	Allows clearing previous data from device memory and SD card to record new data (i.e. for a new patient)
Safely Remove SD Card	Allows removing SD card without risk of losing or damaging recorded information; follow messages displayed on screen
Write Event Log to SD Card	Copies event log data from the device to the SD Card; follow message displayed on screen

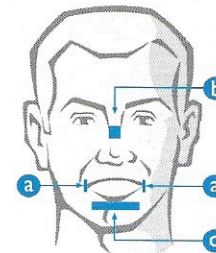
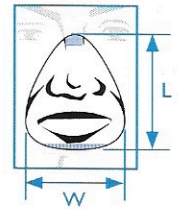
7 Mask fitting

To choose a well fitted mask, **ensure the entire mouth and nose are included** inside the mask.

Make sure the top of the cushion is not too high on the bridge of the nose area. No leak should remain.

Landmarks

- a Side of mouth
- b Bridge of nose zone
- c Below the lower lip



Mask size (inches)	Length	Width	Height
Infant	2.76	2.60	1.93
Toddler	3.46	3.15	2.32
Small adult	4.53	3.74	3.19
Medium adult	4.84	4.02	3.54
Large adult	4.92	4.33	3.54



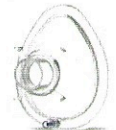
Mouthpiece



Trach adaptor



Toddler mask



Small, medium and large masks

5 Suggested guidelines for therapy

Standard treatment procedure

Adapting to the patient

For a patient using this device for the first time, it is advisable to begin with lower pressures, such as 10 – 15 cmH₂O positive and negative pressure, and low inhale flow. It will familiarize the patient with the feel of mechanical insufflation-exsufflation.




As the patient becomes more comfortable with the therapy, progressively increase the inspiratory and expiratory pressures by 5 to 10 cmH₂O each sequence of 4 to 6 breaths. Effective pressures may be around 35 – 45 cmH₂O.


Cough-Trak may also be enabled to help synchronize the therapy with the patient's inspiratory effort to make acclimation to the therapy easier.

General therapy description

- 1 cough cycle is composed of an inspiratory, expiratory and pause phase
- 4 to 6 cough cycles compose a sequence
- 20 to 30 seconds of resting time is suggested between sequences allowing for secretion removal
- A treatment is composed of 4 to 6 sequences and can be performed several times a day, whenever needed
- Preferably, therapy should be performed in the morning, before meals and bedtime

Tip: To help the patient understand and become comfortable with the therapy, the patient synchronization dial  is provided in the center of the screen during Auto mode.

Feature	Adults	Pediatrics	
Basics	Effective pressure (cmH ₂ O)	+/- 35 up to +/- 45 adjust to patient condition	
	Inhale time (in s)	2 to 3	1 to 2
	Exhale time (in s)	2 to 3	2 or less
	Pause time (in s) In Auto mode	2 to 3	As small as possible
Customize	Cough-Trak triggering feature In Auto mode	For patients who have some inspiratory drive this feature will trigger on the patient's inspiration to help synchronize the therapy with the patient's effort.	
	Mode and Preset	Therapy parameters can be titrated/modified in Manual mode to evaluate the best therapy for the patient before setting up automatic settings Up to 3 different Presets can be saved to provide different therapies (i.e. prophylactic use, mucus plugs, lung volume recruitment, etc.)	
Follow-up	Data management	Data such as peak cough flow, tidal volume, SpO₂ or time counters, available in detailed view ON, can be useful for both setting therapy parameters and assessing therapy efficiency	
	DirectView EncorePro	Therapy data recorded (internal memory and SD card): peak cough flow, tidal volume, pressure, SpO ₂ , heart rate, pattern of usage	

 The settings should always be checked before beginning therapy. Guidelines are intended to serve only as reference. They do not supersede established medical protocols or instructions from physician.