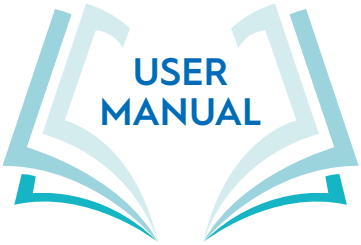
Cipla



Spirofy™

spirometer

Cipla Spirofy™ spirometer

PATIENT CENTRIC DESIGN

- Portable
- Lightweight (200gms)
- Ergonomic design for ease-of-patient use
- New airway for each patient

Spirofy™ spirometer

About this User Manual

This user manual is designed to guide you, step by step, through the various features and aspects of the **Spirofy™ device**. The aim of this manual is to enable you to operate, clean and troubleshoot the possible issues with **Spirofy™**. It is assumed that the user has a smartphone or a tablet (Android or iOS) or a Windows PC (desktop/laptop), as the spirometry test is directly dependant on the **Cipla Spirofy™ application** (app) for data display, access, storage, and printing.

This user manual has a mixture of text and pictures to make it easier for you to understand.

Please note that the screenshots of the app shown in the manual are intended only as examples and are liable to change with periodic app updates.

In case of any doubts or queries, please email at **support.spirofy@cipla.com** or call on **1800 2020 060** (toll-free number).

The Spirofy™ spirometer Kit

Kit contents

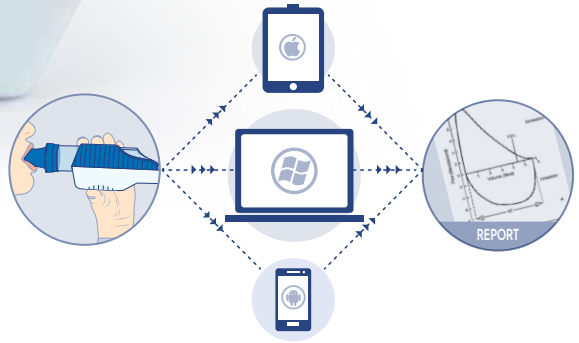
Spirofy™ spirometer

Content

Spirofy™ spirometer

Assembled Device

Link with Mobile or Windows app.



Introduction

Spirofy™ is a compact, rechargeable, battery-operated and portable spirometer that can be used for diagnostic and monitoring purposes. Its ergonomic and user-friendly design allows the device to be used in a wide range of clinical settings. **Spirofy™** is a pneumotach-based spirometer, where a pneumotachometer converts the flow of gases through it into a proportional signal of pressure difference on either side of a central mesh whose design ensures signal linearity over a range of flow rates with minimum dead space.

Its features include the following:

- Measurement of forced expiratory volume in 1 second (FEV1), forced vital capacity (FVC), FEV1/FVC, peak expiratory flow rate (PEFR), and forced expiratory flow at 25–75% (FEF25-75)
- Post-bronchodilator comparison
- Ability to share, save and print the test report with the help of the Cipla **Spirofy™** app

Intended Use

The **Spirofy™** device is intended to measure the maximal volume and flow of air that can move in and out of a patient's lungs. This device is intended for use in adult patients in hospitals, physician clinics, laboratories, or occupational testing environments.

How spirometry is useful

Spirometry helps with the following:

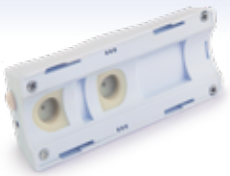
- Diagnosis of obstructive and restrictive lung diseases.
- Risk assessment of patients undergoing cardiothoracic surgeries.
- Diagnosis and risk assessment of patients undergoing non-cardiothoracic surgery and suspected to have chronic obstructive pulmonary disease (COPD) and other chronic lung diseases.
- Prognostication in several conditions such as COPD, asthma, bronchiectasis, interstitial lung disease (ILD), and neuromuscular diseases.
- Monitoring disease progression in ILD, COPD, asthma and bronchiectasis.

Device Installation

A retail unit (box pack) of the **Spirofy™** device contains relevant papers and a portable EVA kit containing the following items*:

Airway tubes (8)

Spirofy™ device (x1)



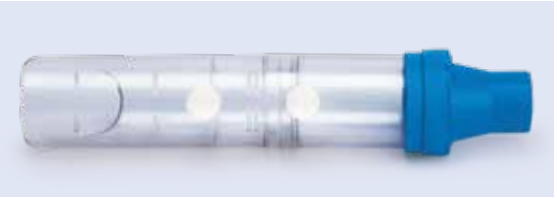
Charging dock (x1)

Charging cable & adapter (x1)

Top slide cover (x1)

* Depending on the **Spirofy™** device model, a USB dongle and/or a **Spirofy™** Bluetooth thermal printer (along with its charging cable and adapter) may or may not be included in the kit.

Airway Tube



Attachment points/filter ports

The airway tube will be the primary contact point for a patient while taking a test. The tube consists of a mouthpiece for the patient to exhale into.

The airway tube has a pair of attachment points/filter ports (see image) to help affix it onto the **Cipla Spirofy™** device. Please ensure proper fitting of the airway tube onto the device before performing a test.

*Please Note: If the fitting is incorrect, the test readings can be affected. Please contact customer care [email support. **spirofy@cipla.com** or call on **1800 2020 060** (toll-free number)] immediately in case of queries.*

Spirofy™ airways are to be used for every test to prevent contamination of the ambient air while performing a spirometry on a potentially infected patient. The airways are sterilized and intended for single-patient use. This is necessary to prevent any cross-contamination. However, an airway can be used for the same patient for several manoeuvres.

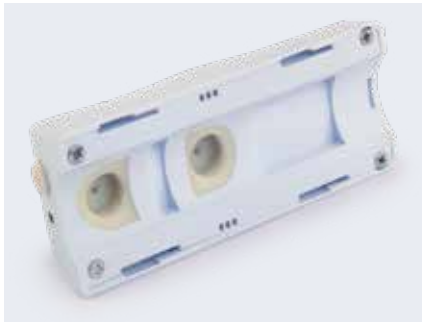
Store the airways in a cool and dry place. Avoid placing them in direct sunlight. Keep them away from water, high temperature, high humidity and acidic gases.

Airway tube: Usage and disposal instructions

1. The airway tube should be used immediately after opening the pouch packaging. Opened but unused airway tube should not be used for a test.
2. Do not use the airway tube if the inner packaging has been previously opened or damaged.
3. It is recommended that both the **Spirofy™** airway tube be used only once per patient and in a single test session. It should be replaced immediately in case moisture/condensation is observed inside or in case of excessive sputum/saliva discharge from the patient.
4. After a test, put back the used airway tube into the same pouch packs and dispose them off following local biomedical waste disposal procedures Never throw the airway tube in a regular dustbin/open environment or in any water body without prior authorization from a competent legal authority.
   Never incinerate the used airway tube without prior authorization from a competent legal authority.

Spirofy™ spirometer

Spirofy™ device



The **Spirofy™** device acts as a base for the airway tube while a test is being performed. It also houses critical electronics and sensors that make the **Spirofy™** as accurate as it is. Due to this reason, avoid dropping the device or subjecting it to any sort of external impact as it may damage the internal components and cause improper functioning. Also, do not damage/bend the charging points on the device.

Charging dock

The **Spirofy™** device acts as a base for the airway tube while a test is being performed. It also houses critical electronics and sensors that make the **Spirofy™** as accurate as it is. Due to this reason, avoid dropping the device or subjecting it to any sort of external impact as it may damage the internal components and cause improper functioning. Also, do not damage/bend the charging points on the device.

Top slide cover

The top slide cover is intended to be used while administering a test. It attaches over the airway tube and secures it properly and securely with the device, and ensures that the airway tube does not slide off or detach while the patient is taking a test.

The top slide cover is made from soft plastic. Do not subject the cover to excessive external impact or bending as it may damage the cover.

Charging cable and adapter

A standard USB-C (broad end) to mini-USB (narrow end) cable is provided with the device to allow you to charge the device. The mini-USB end is to be inserted in the port on the charging dock and the USB-C end is to be attached to the adapter provided. This cable can be used only for charging and is not meant for data transfer.

Charging the device

It is recommended to charge your **Spirofy™** device before the first use.

1. To charge your device, take out the USB cable, adapter and the charging dock provided in the kit.

2. Attach the larger end of the cable to the adapter and the smaller end to the port on the dock.

3. Now pick up the **Spirofy™** device.

4. Note that its base has two vertical edges, one thinner than the other.

5. You will notice the charging pins on the thinner edge of the device base. Align the thinner edge with the charging dock slope such that the charging pins slide in to attach with the corresponding contact grooves on the dock.

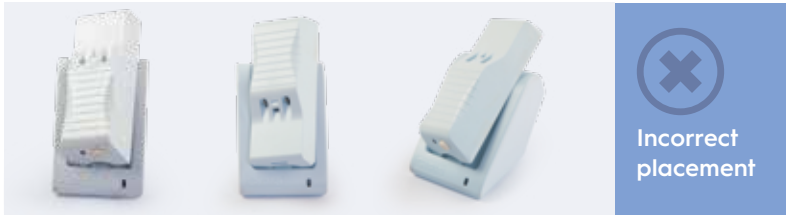
CAUTION: Please avoid using excessive force when attaching the device onto the dock. Ensure that only the contact grooves, and not the plastic edge, meet the charging pins to avoid damage to the pins (see images depicting correct and incorrect placement).

6. To ensure flush fitting, check for the latch on the dock and the corresponding cavity on the **Spirofy™** device. Slide the **Spirofy™** device completely onto the dock such that it fits flush with the dock.

7. Once the device is successfully attached to the dock, switch on the power supply and check whether the LED at the bottom right corner of the dock is glowing. This indicates that the device is being charged. It will glow RED when it is being charged, and GREEN when fully charged.

8. It takes approximately 3 hours for the device to get fully charged. Charge the device fully before first use. Ensure that the device is fully charged or charged at least up to 85% before every use. It is recommended that y ou re-charge the device when the battery level (can be checked on the app) goes down to 30%.

CAUTION: Do not touch the dock or the device while it is being charged. Avoid using unapproved cables for charging as they may damage the port.



Attaching the airway tube to the device

Please Note: Images shown vary and are intended as examples only.

1. To perform a test, you need to attach the airway tube to the **Spirofy™** device.
2. To do so, remove the **Spirofy™** device from the charging dock. Do not attach the airway tube to the device and/or attempt to perform a test while it is being charged.
3. Take a fresh, sterile airway tube – always use a new and sterile airway tube for a new test. Do not reuse tubes.
4. Carefully align the attachment points/filter ports on the base of the tube with the corresponding holes (as shown in the video) on the device. Apply gentle force to attach them together securely. Do not apply excessive force while attaching the tube as it may damage the **Spirofy™** device.
5. Once both the tube and the device are attached together, attach the top slide cover. This prevents the tube from accidentally detaching itself while a patient is taking a test.
6. Now all that is left to do is to connect the device to the Cipla **Spirofy™** app.

Spirofy™ spirometer

Downloading the Cipla Spirofy™ app.

- The **Spirofy™** device has been designed to work in tandem with the Cipla **Spirofy™** app.
- The app is available on the Google Play Store and the Apple App Store. It requires Android version 4.4.4 or above and iOS 8 or above. (Please refer to the "Windows app setup" section to download and connect to the Cipla **Spirofy™** Windows app).

Steps for downloading (for Android users)

1. Go to Google Play Store.
2. Search for Cipla **Spirofy™** (enter the term 'Cipla **Spirofy™**' in the search bar at the top).
3. Tap on the icon and then the install button to download the app.
4. The app may take some time to download and install, depending on the internet and processor speed.

Steps for downloading (for iOS users)

1. Go to the Apple App Store.
2. Search for Cipla **Spirofy™** (tap the magnifying glass on the bottom right of the app, and then type Cipla **Spirofy™**).
3. Tap on the icon and then tap 'GET' to download.
4. The app may take some time to download and install, depending on the internet and processor speed.

Registering on the app.

When using the device for the first time, follow the steps mentioned below for Android/iOS.
(Please refer to the "Windows app setup" section to download and connect to the Cipla **Spirofy™** Windows app).

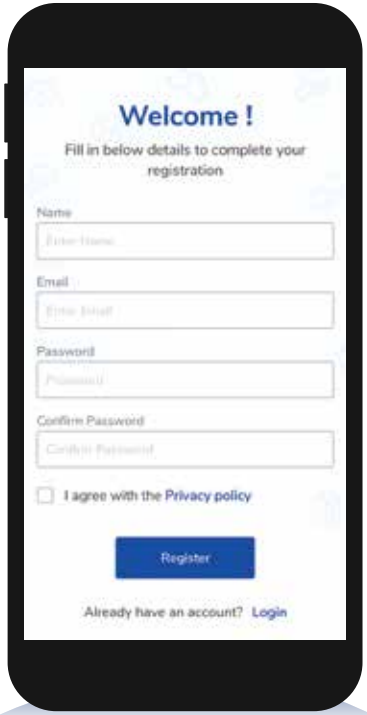
Creating an account/logging in

STEP 1:

To log in with an existing account, enter the registered email address and password.

STEP 2:

First-time users should choose **"Register Here".**



STEP 3:

Fill in the details, such as your name, email address, and set and confirm the password.

STEP 4:

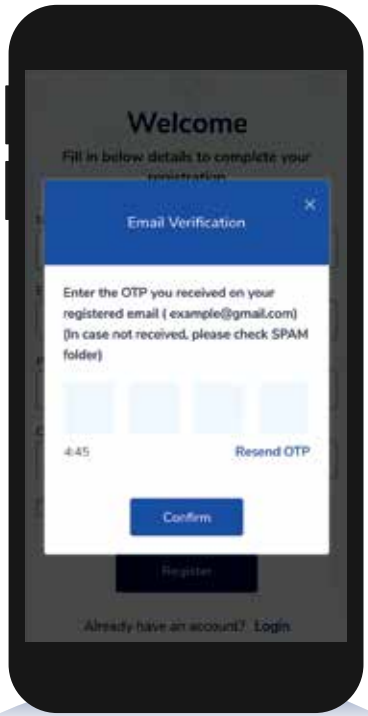
Read and tap the "I agree with the Privacy Policy" checkbox, and then tap on **"Register".**

STEP 5:

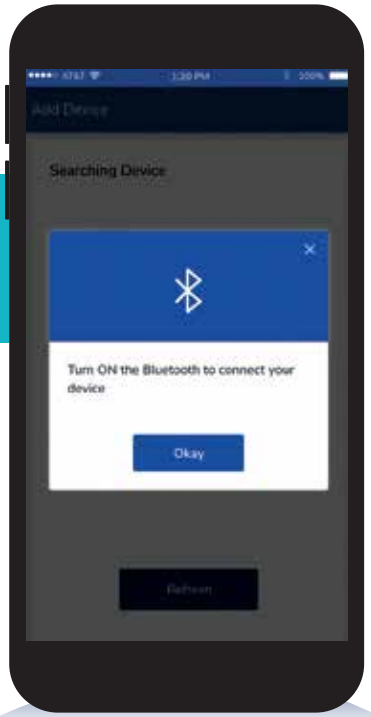
An email verification screen will appear. Check your email address inbox for the OTP email. If not in the inbox, then check in the spam/junk folder. If the OTP doesn't arrive, check your internet connection and tap on **"Resend OTP".**

STEP 6:

Next, enter the OTP and tap on **"Confirm".**



Connecting the Spirofy™ device to the app.

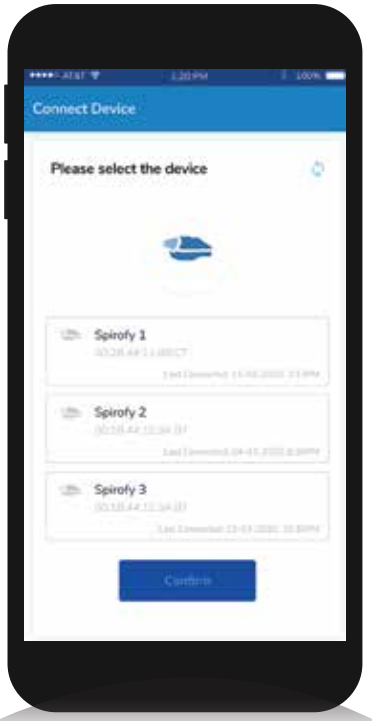


STEP 1:

Switch ON the **Spirofy™** device. Also turn on Bluetooth and location services on your phone/tablet.

STEP 2:

Once done, tap on **"Refresh".**



STEP 3:

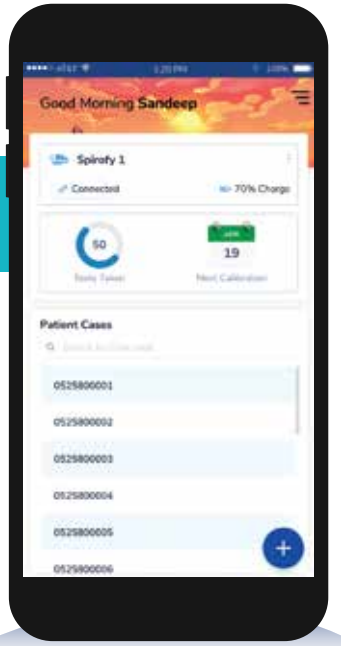
If multiple **Spirofy™** devices are switched ON, and not connected to another phone, all of them would be displayed on the screen. Hence, only switch ON the device that you want to connect.

STEP 4:

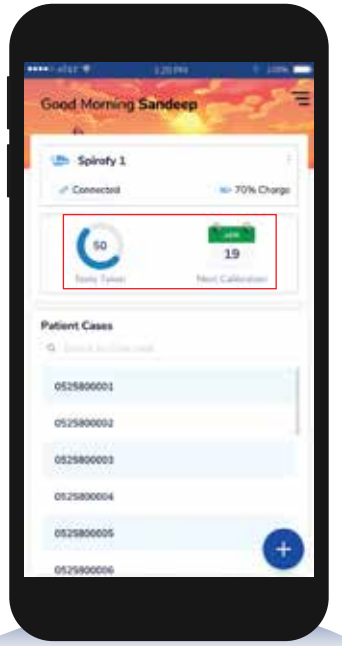
Tap on the device name (displayed as **Spirofy™** followed by a number, depending on the number of active devices nearby) and tap on "Confirm" to add the device.

App home screen

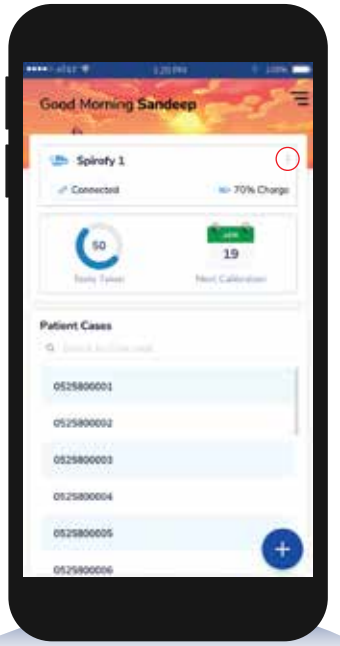
The app home screen will display the following:



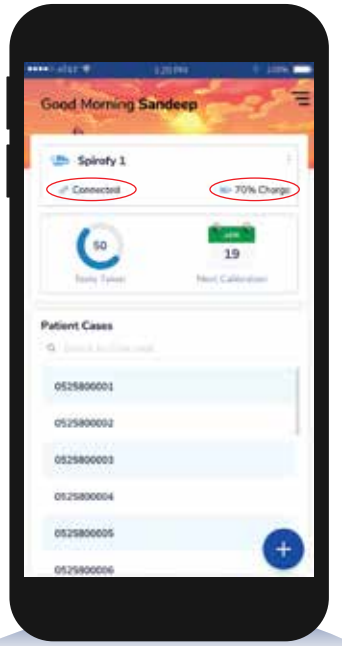
Device options menu



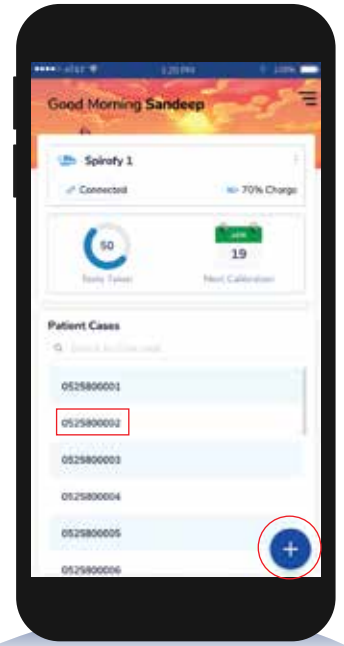
Calibration timeline



Text/symbol to rename the device



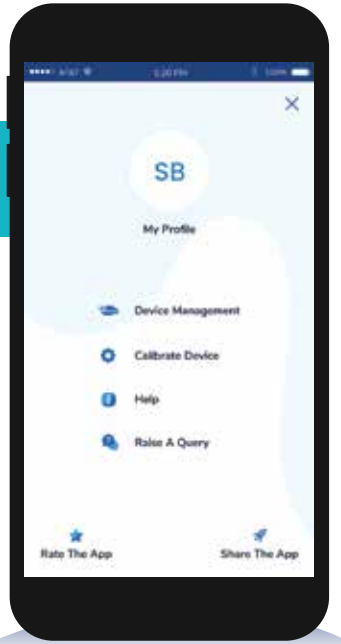
Connection status and device battery percentage



Connection status and device battery percentage

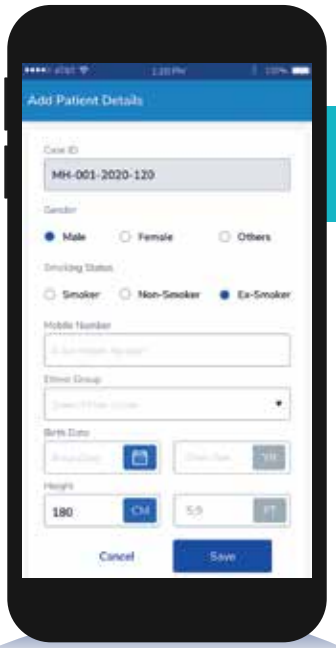
Device options menu

The device options menu can be accessed by tapping on the text/symbol in the top right corner of the app home screen. It contains the options shown alongside:



STEP 3

Enter the OTP received on the phone/tablet and tap on **"Confirm"** to create a patient case code.



4.7 Adding a case

STEP 1

To generate a new case code, tap the "+"button on the app homescreen. A patient ID is automatically generated.

STEP 2

Enter the patient's details and phone number* in the fields provided. Tap on "Save" to proceed.

**Any working phone number can be used patient's or doctor's.*

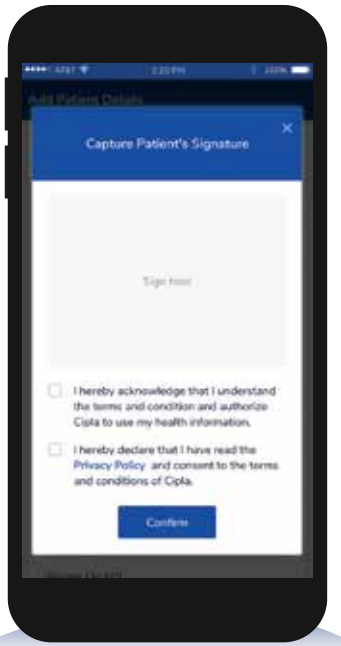
STEP 4

If the OTP is not received within 30 seconds, a digital signature option will be made available. Tap the "Sign here" window and have the patient sign on the screen.

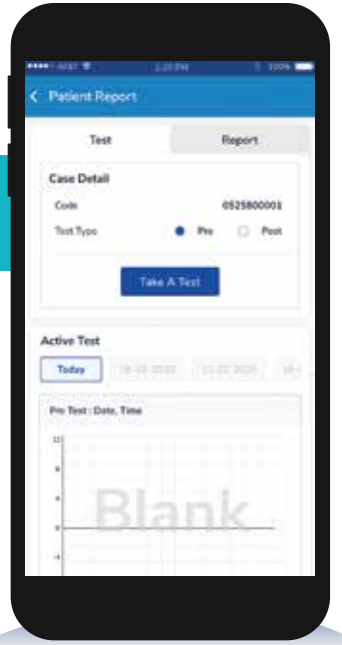
STEP 5

Tap the two check boxes provided and then on **"Confirm"** to create the case code.

You can read the full privacy policy by tapping the highlighted text "Privacy Policy".

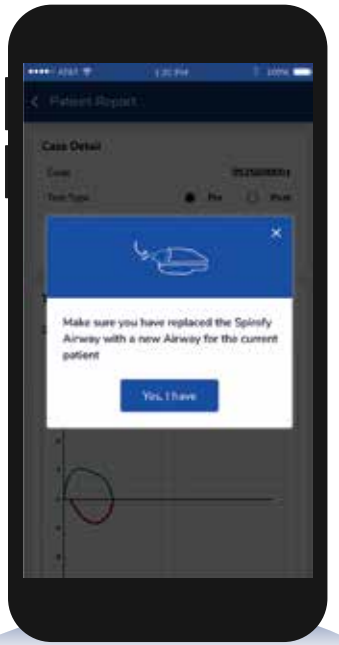


4.8 Taking a test



STEP 1

To take a test on the **Spirofy™** device, tap the casecode number. The Patient Report screen will be displayed; it shows the case code and options to select the type of test ("Pre" and "Post"). Choose"Pre" and then tap on "Take A Test".



STEP 2

A pop-up window will open up with a message. Ensure that you are using an unused airway tube for the patient. Tap on "Yes, I have".

STEP 3

The device will do a quick self-calibration. During this process, ensure zero flow through the device by instructing and ensuring that the patient does not breathe into it before beginning the test.

STEP 4

Spirometry can be performed once you see the Test screen. Ensure that the test is done in a closed, quiet environment with minimal to no airflow as far as possible.

STEP 5

Have the patient perform spirometry. Tap on "Retry" to take multiple tests. Tap on **"Cancel"** to cancel the attempts and not save any data.

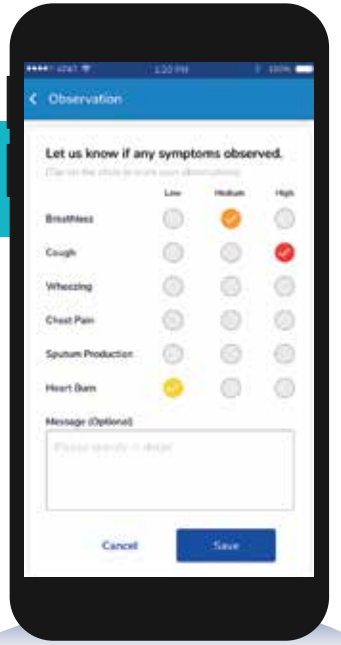
STEP 6

Select a minimum of three attempts by tapping the green check box on the top right corner of the screen.

STEP 7

You can toggle between the tests taken by tapping the test number tabs on the top. Tap on **"Proceed"** to save the successful test results.

4.8 Taking a test



STEP 8

Next, on the observation screen, select any symptoms and their intensity, if observed in the patient. Add additional observations, if any, in the text box provided.

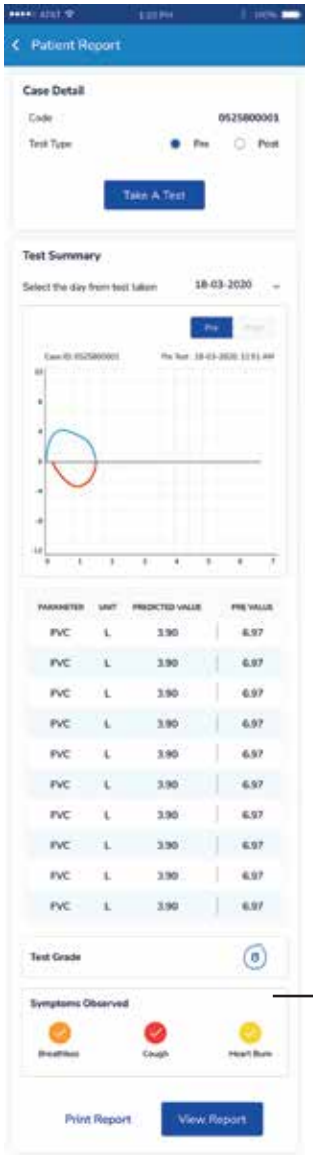
STEP 9

Finally, tap on "Save" and go to the result screen for report generation.

STEP 10

Tap on "Cancel" to cancel the effort.

Report generation, sharing and printing



STEP 1

The test summary will appear below the **"Take A Test"** box in the Patient Report page.

STEP 2

Date and time of the test along with type (Pre or Post) will be displayed in the summary.

STEP 3

The test graph and values will also be displayed, along with test grade and symptoms observed.

STEP 4

Choose **"View Report"** to see a full-size A4 format report. Choose "Print Report" to view a thermal printer-printable report.

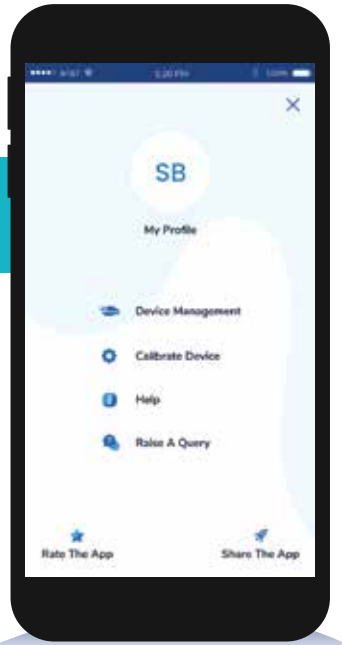
STEP 5

Both reports are in PDF format and can be viewed in any PDF reader. Drive PDF Viewer is recommended for Android devices. Reports can be shared as PDFs via compatible applications on your phone/tablet.

Disclaimer: All parameters may not come on thermal print. Hence for final opinion please refer to the pdf print.

Device options menu

The device options menu can be accessed by clicking on the text/symbol in the top right corner of the app home screen. It contains various options, as shown:



Device management

STEP 1

Choose this option to manage paired devices in case multiple devices are added to your account.

STEP 2

The screen shows a list of all the devices that you have connected to the app in the past, listed in reverse chronological order with respect to the time of connection.

STEP 3

The number below the device is the media access control (MAC) address of the device, which can be used for identification or while submitting a query. For example, long-pressing the **Spirofy™** 1 box will display the device's calibration history on the app.

STEP 4

Each device name box also contains the last-entered data and time of connection.

STEP 5

The selected device is set as the default device and the app will auto-connect the next time it is opened and the device is switched ON.

STEP 6

In case the device is switched OFF, the app will display a list of other devices that are switched ON and are in the vicinity. You can connect to any of them by tapping on the appropriate device name box and then tapping on the "Connect" button.

Calibrate the device

STEP 1

The **Spirofy™** device must be calibrated with a 3 litre (3L) calibrated syringe for every 10,000 tests.

STEP 2

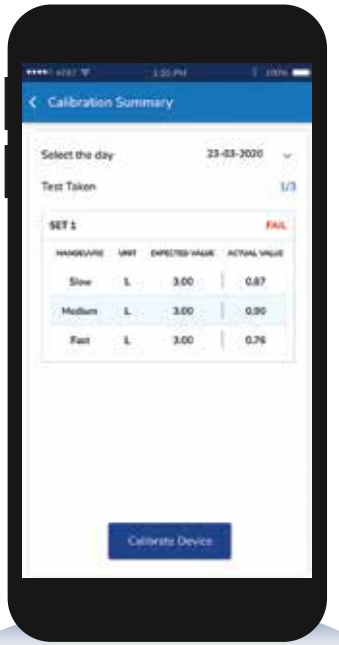
Tapping on "Calibrate Device" in the device options menu will open a Calibration Summary screen. This will display previous calibration history, if any. You can toggle between the previous data by selecting from the dates in the drop-down window at the top right.

STEP 3

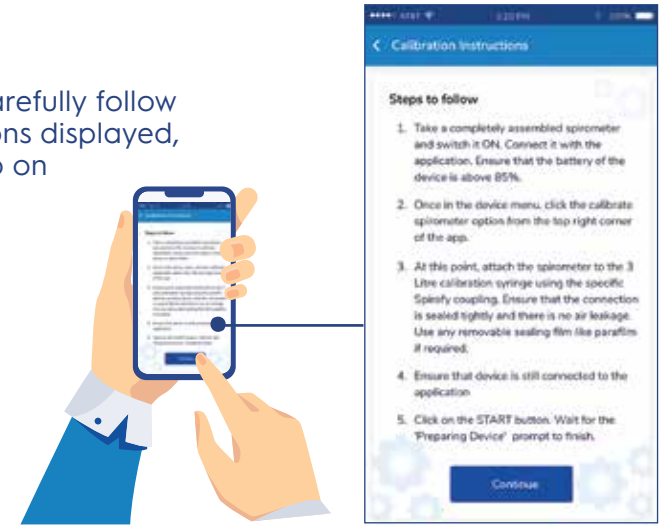
The summary details the test result along with actual values for a 3L calibration syringe at slow, medium and fast flow rates.

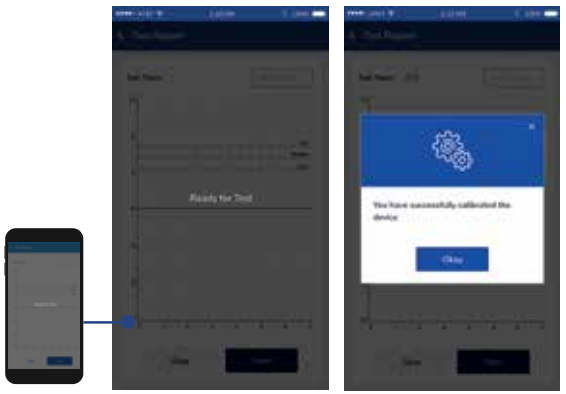
STEP 4

Tap on "Calibrate Device" to calibrate.



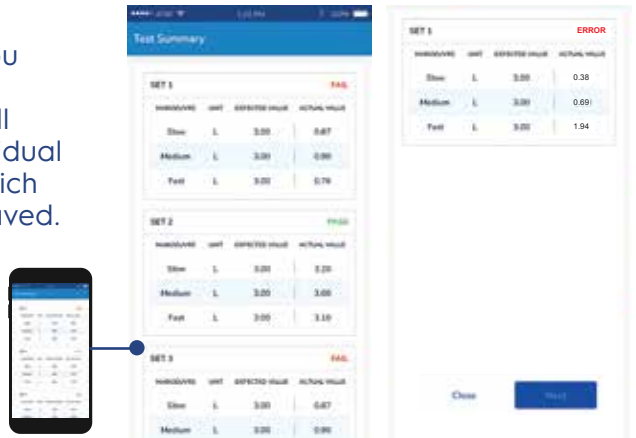
Read and carefully follow the instructions displayed, and then tap on “Continue”.





Once you get the “Ready for Test” screen, calibrate the device three times with a 3L calibration syringe at slow, medium and fast flow rates, in that order. Ensure that the graphs are plotted below the respective dotted line for each flow.

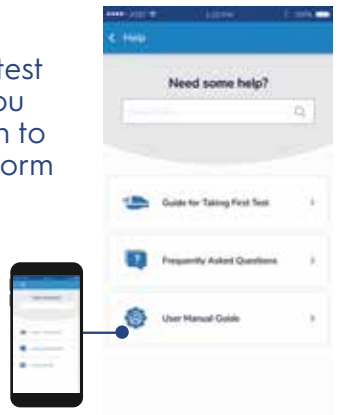
Tap on “Okay” once you have completed the calibration. The app will display results for individual sets with the values, which will be automatically saved. Tap on “Next” to go to the Calibrate menu or tap on “Close” to go to the device home screen.



Spirofy™ spirometer

Help

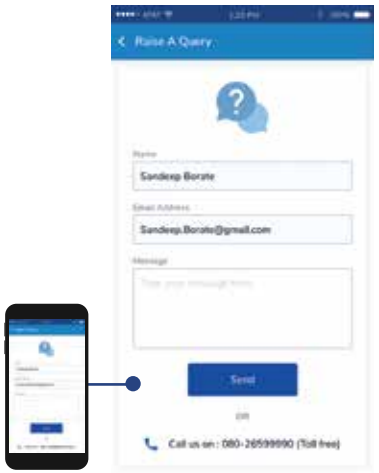
In the device options menu, tapping on “Help” opens up a few quick pointers and links to help you in case of any problem while using the device or the app. It has the following sections:



- **Guide for Taking Test:** Choose this option for stepwise instructions on how to take a test using the **Spirofy™** device and the app. You can also take a mock test under this option to demonstrate to the patient on how to perform spirometry correctly.
- **Frequently Asked Questions:** This section contains a list of frequently asked questions that a user may face while using the device along with possible solutions for each of them.
- **User Manual Guide:** Choose this option to read this user manual on the app.

Raise a query

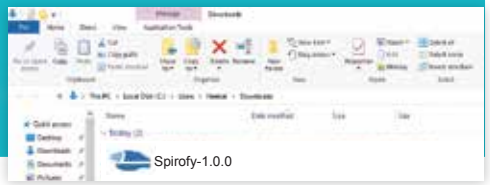
Use this feature in the device options menu in case of a query that cannot be resolved by referencing the “Help” section. Add your name, email address and message in the text fields and tap on “Send”. You can also call directly via the number given below the “Send” button.



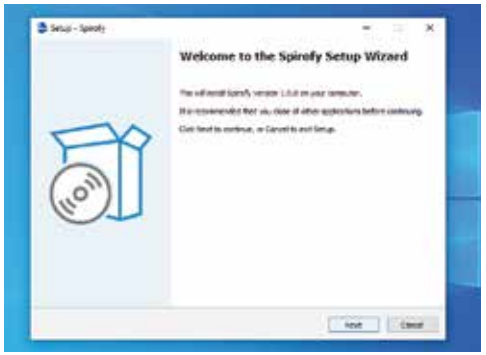
Using Spirofy™ with the Cipla Spirofy™ Windows app.

Downloading the Cipla Spirofy™ app.

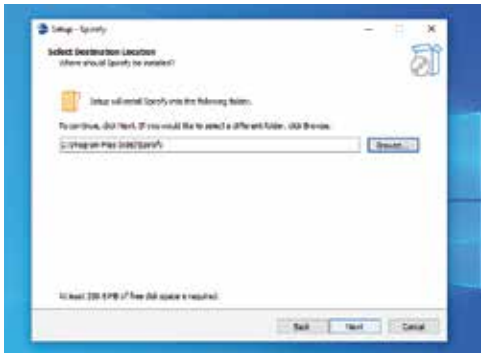
1. Download the **Spirofy™** exe file from the **Spirofy Windows app** site and install it on your Windows PC/laptop.



2. A dialogue box will appear prompting you to install the application. Click on “Run” to install the application. If the application requires admin permission, then click on “Yes”.

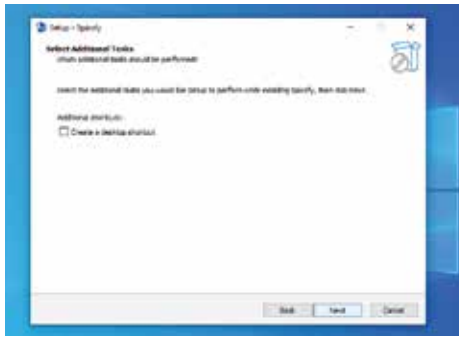


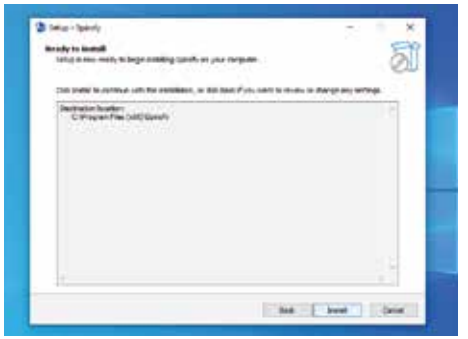
3. Select the default installation path and click on “Next”.



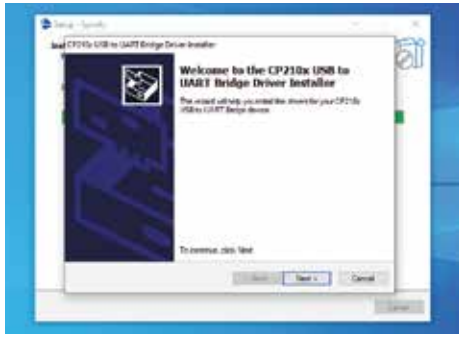
Spirofy™ spirometer

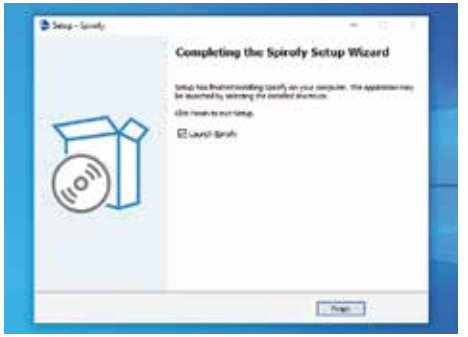
4. Click on “Install” and wait for the installation to finish.





5. Create a desktop shortcut if you want to and click on “Finish”.



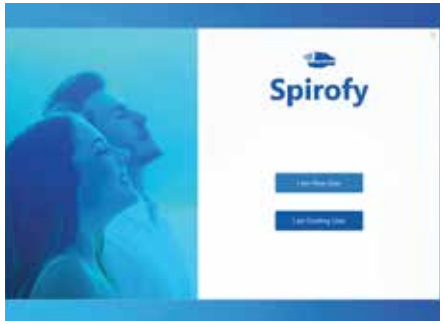


User registration

If you are a new user, follow the steps given below. If you are an existing user, please refer to the steps given in the next subsection "Existing user".

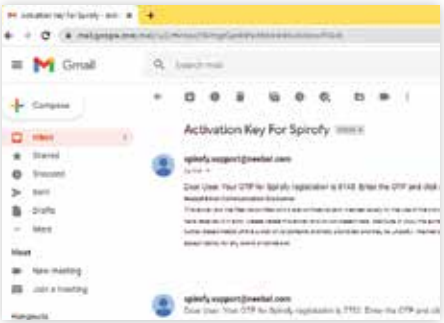
New user

1. Open the downloaded app on your Windows PC. If you are a new user, click on "I am New User".



2. On the new user registration page, fill in the required details, click the Privacy Policy check box and click on "Register". An OTP dialogue box will appear, asking for the OTP sent on the email address you have just added.

3. Check your email address inbox for the OTP email. Also check the spam folder in case OTP email is not in the inbox.



Spirofy™ spirometer

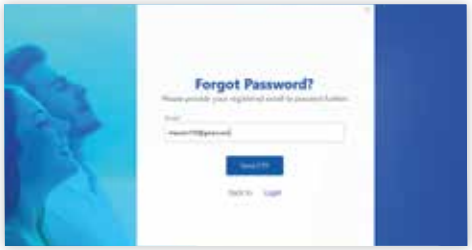
4. Enter the OTP from the email in the dialogue box and click on "Verify". You will see a registration message saying "Successful". After successful registration, you will be taken to the app home screen.

Existing user

1. In case you are an existing user, click on the "I am Existing User" in the screen that appears after opening the app. Login using your registered email address and password.

2. If the information entered is correct, then you will be taken to the app home screen.

3. In case you have forgotten your password, click on "Forgot Password?". Enter your registered email address. An OTP will be sent on that address. Enter the OTP and reset your PIN to login in again.



Adding a device

Unlike the Cipla **Spirofy**™ app for Android and iOS, the **Spirofy**™ Windows app requires a USB dongle* to connect the device with your PC (desktop or laptop).

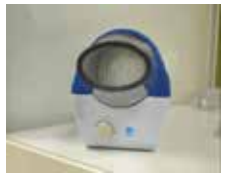
Dongle

** Depending on the **Spirofy™** device model, a USB dongle may or may not be included in the kit.*

1. First, open the **Spirofy**™ Windows app and log in. When the home screen opens up,click on "AddDevice".

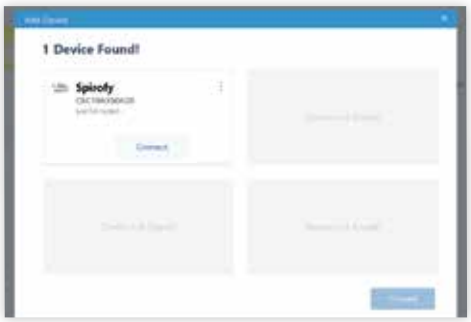
Spirofy™ spirometer

2. A pop-up message will appear, asking you to connect a dongle. Insert the dongle to be used in one of the USB ports of your PC/laptop. Click on "Okay" once successfully inserted. The app will check if a dongle has been connected and move to the next screen.

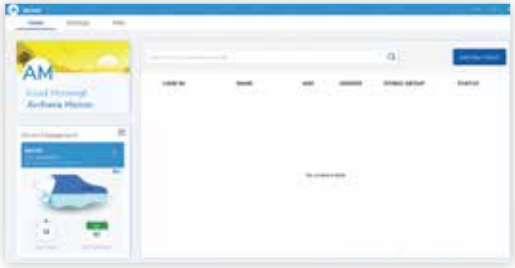


3. The app will prompt you to turn on the **Spirofy**™ device. Switch it ON and click on "Okay" to continue.

4. Ensure that only a single **Spirofy**™ device, the one that is being tested, is switched ON. This is to avoid confusion in identifying the device.
The connected device details should appear on the screen, as seen below. Click on "Connect" to add that device in the app.



5. Confirm that you want to add the device by clicking on “Proceed”. The device will be added and its image will appear in the home screen, as shown below. You can now create a case code and perform spirometry tests for that patient.



Adding a case code

1. In the added device home screen, click on “Add New Patient”.

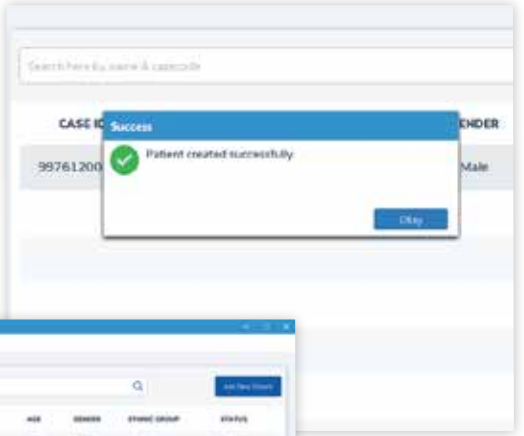
2. Fill in the details of the patient (see image below). Use a working mobile phone number to receive the OTP during case code creation.

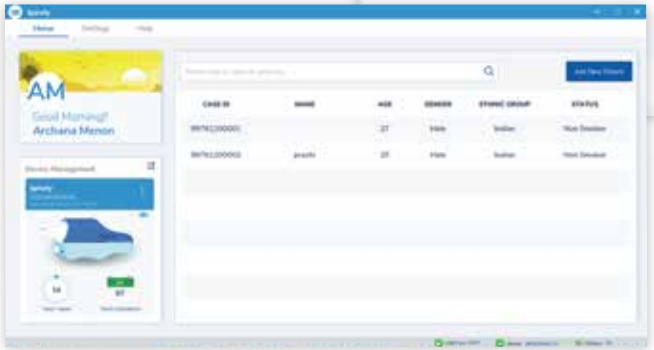
3. The OTP screen will appear as below. Enter the 4-digit OTP and click on “Validate OTP”. You can also change the phone number in case of any error when entering the same earlier.

Spirofy™ spirometer

4. In case the OTP is not received within 30 seconds, click on the check box (as shown below) and manually add the case code.

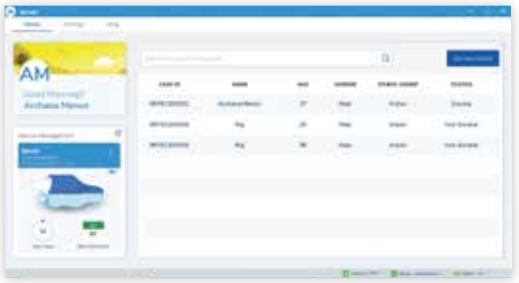
5. The patient case code will be added in the device home screen.



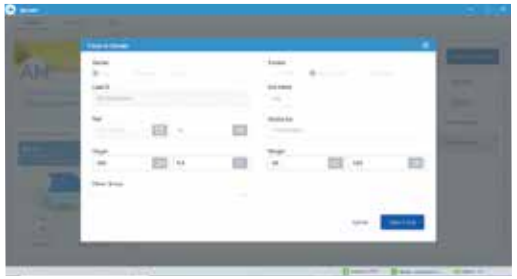


Taking a test

1. Select the patient case code created for the test.

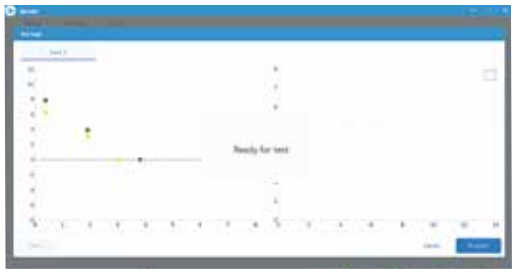


2. Select take a test and continue with the "Pre-Test" test of the patient and after 15 minutes of the pre test you can take the "Post-Test"

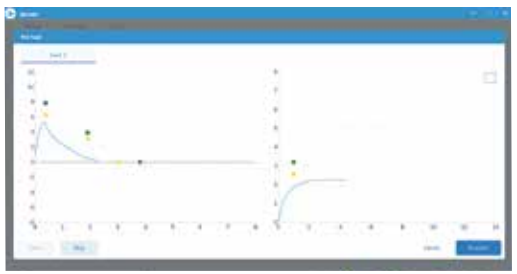


3. Note that a post-test can only be performed for a saved pre-test and only after an interval of 15 minutes following the pre-test.

4. Once on the test page (see below), ask the patient to perform spirometry. For detailed instructions on how to perform spirometry, refer to the 'Performing Spirometry' section.



5. The graph along with the relevant values will appear on the screen. PEFR, FEV1, FVC and FEF25-75 values will also be displayed.



Spirofy™ spirometer

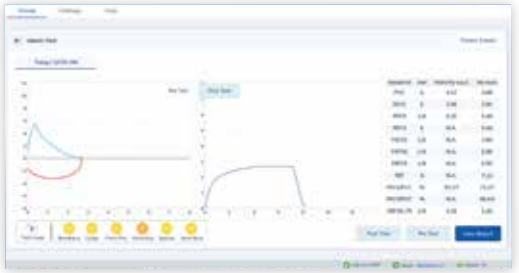
6. Click on the "Retry" button to repeat the test. Select a minimum of three tests and click on "Proceed" to go to the Observation (symptoms and comments) page.

7. You can ask patients for their symptoms observed and click on "Save"

8. After indicating your observations and comments, click once more on "Proceed" to go to the symptoms observed page and then click on "Save" once it is done report generation section would appear.

9. From here, you can generate and print full-size and thermal printer reports.

Generating a test report



1. In the test report section, click on “View Report”.

2. A PDF report will open out, containing details of each of the three spirometry manoeuvres with individual parameters and graphs.

3. You can scroll though the PDF to assess the effort. You can also save the reports in two formats – Spirofy Bluetooth thermal printer* report and standard A4 size report. Click on “Download Report” to save the full PDF in a designated folder.

To take a printout, choose “Print Report”. Then click on “OK”.

** Depending on the **Spirofy™** device model, a **Spirofy™** Bluetooth thermal printer (along with its charging cable and adapter) may or may not be included in the kit.*

4. Open the PDF report on your desktop/laptop via any PDF viewer software.

Spirofy™ spirometer

Performing Spirometry

- In the current COVID 19 pandemic scenario, it is recommended that the operator (and other assistants, if any) wear PPE kits while performing lung function tests OR follow the safety guidelines as laid down by the local authorities.
- Reorganize testing schedules to include extra time for post test cleaning/decontamination procedures of the test equipment and surrounding area. Allow at least 15 minutes to ventilate the room (open windows , closed doors) and for PPE donning and doffing.
- Please also ensure that patients follow the necessary pandemic safety guidelines during clinic visits for the tests.
- It is recommended that the patients should be administered a symptoms screening questionnaire on arrival. Body temperature should b e checked in order to verify if they are likely to have COVID 19 infection OR follow the guidance as laid down by the local authorities.
- Use of masks is recommended for all patients coming for tests.
- Ensure the use of hand sanitizer by all the patients.

Preparation protocol for the operator

- Use a protective mask as per the local policy.
- Eye protection must always be worn, e.g. goggles or a face shield.
- Disposable gloves should be used at all times when testing. These should be discarded after completion of a patient’s tests and after cleaning of the device and the surrounding area.
- Follow hand hygiene protocols as per the local policy, before and after using the gloves.

Preparation protocol for the patient

- At the time of making the appointment, patients should be given the following instructions:
  - They should wear comfortable clothes that allow full expansion ofc hest and abdomen.
  - They should avoid intake of intoxicants for at least 8 hours before spirometry.
  - They should not eat a large meal for at least 2 hours before spirometry and avoid smoking for at least 1 hour before the procedure.
  - They should avoid vigorous exercise for at least 60 minutes before the procedure.
  - They should also be told about medications that need to be stopped before spirometry. The operator must record the type and dosage of any inhaled, oral or injected medication that may alter lung function and when they were last administered. The operator should also record observed signs or symptoms such as cough, wheeze, dyspnoea, or cyanosis.
- Confirm patient identification, age, birth sex, ethnicity, etc.
- Measure weight and height without shoes
- Have the patient assume the correct posture during the test – the patient should be seated erect, with shoulders slightly back and chin slightly elevated.
- A chair with arms (to prevent falling sideways should syncope [sudden loss of consciousness] occur), without wheels, and with a seat height adjustment so that the patient's feet stay flat on the floor should be used. A chair that is lower in height or a raised footstool should be provided for short-statured adults.
- Tissues or paper towels should be offered to help patients deal with nasal/cough/saliva secretions.
- Well-fitting dentures are usually left in place.

Preparing the Spirofy™ device

Please refer to the 'Device Installation' section for the detailed instructions. Some key points are given below:

- Assemble the device using a sterile, unused airway tube.
- Ensure that the device is connected to the app and that the case code is correct.
- Ensure that the **Spirofy™** device is correctly calibrated by checking it in the app calibration window.

- Ensure that the test is done in a quiet, closed environment with minimal to no airflow as it would affect the readings from the **Spirofy™** device.
- Maximize the use of the single-use items and dispose them with care.
- Where reusable items are utilized, they should be managed carefully and should be thoroughly cleaned by following the recommended local infection control policy.
- Strictly follow the regular equipment cleaning protocols as per the local guidelines.

Performing a test

- Hold the **Spirofy™** device next to your cheek, holding it steady, and tap on "Take A Test" on the screen image.
- Once the "Test" screen comes up, proceed with the spirometry.
- Have the patient assume the correct posture. Attach the nose clip, place the **Spirofy™** device mouthpiece in the patient's mouth and then ask the patient to close his/her lips firmly around the mouthpiece. Ensure that there is no accidental exhalation during this process. If an exhalation is detected, the initial inhalation before the test would be recorded and this will result in a bad test.
- Instruct the patient
  - √ to inspire completely and rapidly with a pause of ≤2 seconds at total lung capacity; and,
  - √ to expire with maximum effort until no more air can be expelled, all the while maintaining an upright position.
  - √ Ensure that the patient exhales for a minimum of 6 seconds OR until a beep is heard Repeat these instructions, as necessary, to ensure correct testing.

- Repeat for a minimum of three manoeuvres (usually no more than eight for adults).
- Check FEV1 and FVC repeatability and perform more manoeuvres as necessary.
- Within-manoeuvre acceptability criteria for spirometry:
  - √ An acceptable spirogram should be free of the following visual artefacts:
    - Cough during the first second of exhalation
    - Effort that is not maximal throughout
    - Obstructed mouthpiece
    - Early termination or cut-off
    - Glottis closure that influences the measurement
    - Leak
  - √ Start-of-test criteria: Extrapolated volume <5% of FVC or <150 mL, whichever is greater.
  - √ End-of-test criteria:
    - The volume-time curve shows no change in volume (<25 mL) for at least 1 second, and the subject has tried to exhale for at least 6 seconds OR THE subject cannot or should not continue further exhalation.
- Between-manoeuvre repeatability criteria for spirometry:
  - √ After three acceptable spirograms are obtained, the following criteria should be applied:
    - The two largest FVC values must be within 150 mL of each other*
    - The two largest FEV1 values must be within 150 mL of each other*

    *(*For subjects with FVC ≤1 L, the two largest values must be within 100 mL of each other)*
  - √ If both of these criteria are met, the test session may be concluded.
  - √ If both of these criteria are not met, testing should be continued until
    - both of the criteria are met in the subsequent acceptable spirograms OR a total of eight tests have been performed (optional) OR the subject cannot or should not continue further.
- Within-manoeuvre acceptability criteria for peak expiratory flow manoeuvre:
  - √ No hesitation √ No cough √ No leaks at the mouth
- Between-manoeuvre repeatability criteria for peak expiratory flow manoeuvre:
  - √ At least three manoeuvres should be performed.
  - √ The largest two of three acceptable manoeuvres must be within 0.67 L/(40 L/minute).
  - √ If the above criterion is not met, up to two additional manoeuvres can be performed.

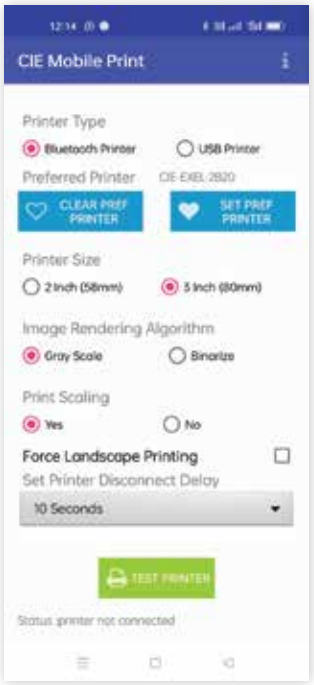
Spirofy™ spirometer

Steps to connect and pair the thermal printer with the phone/tablet (only for android user)

1. Download the CIE Mobile Print app from the Google Play Store & for Apple user you can directly print from the **Spirofy™** application.
2. Open the app. In the window that opens up, go to "Set Printer Disconnect Delay" and set it to 10 seconds". Tap on "OK".
3. Turn ON Bluetooth and location services on your phone/tablet.
4. Switch ON the Spirofy Bluetooth thermal printer by pressing down on the power button. The paper roll will move forward just a bit; the power LED will blink GREEN and the Bluetooth LED will blink BLUE.

5. In the CIE Mobile Print app, select the following settings:

√ Printer Type: Bluetooth Printer
√ Printer Size: 3 inches (80mm)
√ Image Rendering Algorithm: Grey Scale
√ Print Scaling: No
√ Force Landscape Printing: (Leave the box unchecked)
√ Set Printer Disconnect Delay: 10 seconds



6. Tap on “CLEAR PREF PRINTER”. Then tap on “SELECT PREF PRINTER”. Tap on “SCAN RECEIPT PRINTER”. Ensure that only a single thermal printer is switched ON at this point as multiple printers may cause confusion while pairing.
7. Tap on the printer name that is displayed in the format “CIE-EXCEL-####”. The printer is paired with the phone/tablet.
8. Reports can be printed after opening them in the Drive PDF Viewer in Android by tapping the top right button, and selecting “Print”. In the dropdown menu on the print screen, select “ECS/POS Printer”. Ensure that the paper size is 80mm thermal and the number of copies is 1. Tap on the “Printer” icon to print.

Pre-test and post-test

A post-bronchodilator test can be taken for a patient 15 minutes after the pre-test or within 20 hours following the pre-test.

- To take a post-test, click on the case code of the patient and select the “Post-Test” option.
- Follow the same procedure as done for taking a pre-test.

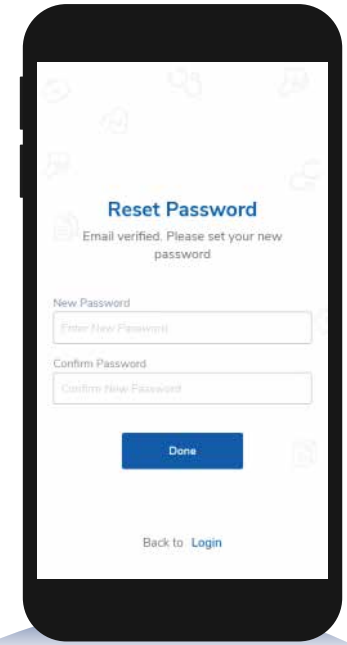
Reconnection of the device

- The last-connected device will be set as the default device for connection.
- To enable the auto-connect feature, open the app and also switch ON Bluetooth and location services on your phone/tablet.
- Switch ON the **Spirofy™** device; the device should auto-connect with the app. On the app home screen, connection status should change from “Disconnected” to “Connected”. If auto-connect fails, restart the device or add it manually in the device management section of the device options menu

Spirofy™ spirometer

Resetting the app. password

In case you forget the app password, don’t worry! Go to the app login page and tap on “Forgot Password?”. Enter your email address. Enter the OTP received via email and set a new password.



Specifications

Product: **Cipla Spirofy™** device

Flow detection principle: Differential pressure pneumotach device

Volume detection: Sampling at 125 Hz

Maximum test duration: 25 seconds

Maximum displayed volume: 7 litres

Maximum displayed flow: 12 L/m

Operating temperature range: 10°–40°C

Operating humidity range: 35–65%

Performance standards: ATS 2005

EMI/EMC standards: IEC 6061

Weight (device + dock): 350 grams

Storage temperature: 25°C

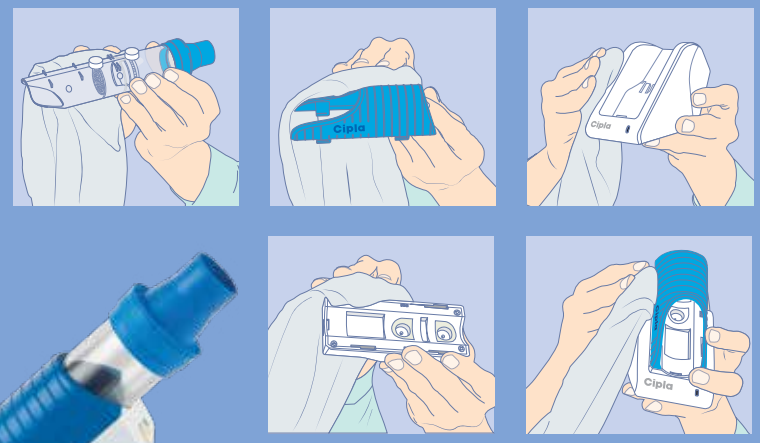
Ambient pressure condition: 850 hPa–1,150 hPa

Storage humidity: 60%

Minimum phone/tablet/Windows PC (desktop/laptop) requirements: iPhone 5s or above, iPad 4 or above, iOS 10 or above, Android OS 8.0 phone/tablet with Quad core processor, 3 GB RAM or above. Intel Core 2 duo or above, AMD FX6300 or above. 4 GB RAM
Windows 7 to Windows 10.

Maintenance of the Device

Periodic cleaning and maintenance of any medical equipment is crucial. Ensure that the **Spirofy™** device is stored in a dust-free environment. Regularly clean the device and the charging dock with a damp cloth, making sure to avoid contact with any exposed electronics such as the charging port, contact pins or the airway tube mounting points. Later, dry the device with a paper towel. Inspect the device periodically and check for any unfamiliar noises, loose panels, etc.



Troubleshooting

This section is divided into three parts: issues related to 1) the **Spirofy™** device hardware; 2) the **Cipla Spirofy™** device app; and, 3) the **Spirofy™** Bluetooth thermal printer hardware. The same information is also available in the 'Help' section of the app. It is strongly recommended that you refer to the app 'Help' section when raising a complaint for any of the issues below.

In case of any doubts or queries, please contact customer care – email at **support.spirofy@cipla.com** or call on 1800 2020 060 (toll-free number).

1. Issues related to the Spirofy™ device hardware

*Please Note: It takes approximately 3 hours for the **Spirofy™** device to get fully charged. Charge the device fully before first use. Ensure that the device is fully charged or charged at least up to 85% before every use. It is recommended that you re-charge the device when the battery level (can be checked on the app) goes down to 30%.*

1.1 Airway tube issues

1.1.1 Airway tube packaging

1.1.1.1 Misprinted/torn/dirty/no packaging

- **Airway tube pouch has a misprint or print is difficult to read:** Check for the expiration date. If visible, then it is okay for use.
- **Expiration date is blurred:** Airway tube should not be used.
- **Packaging is torn:** Check the extent of tearing.If airway tube inside is sealed, then it is okay for use.
- **Packaging is dirty/cloudy from the inside or outside:** Do not use the airway tubes.
- **Airway tubes have no packaging:** Do not use loose, unpacked airway tubes.

1.1.1.2 Airway tube broken/disassembled inside the packaging

- **Airway tube is broken/cracked inside the packaging:** Do not use a broken or cracked airway tube as it may affect the readings.
- **Airway tube is disassembled inside the packaging:**
  1. In case the airway tubes and other individual parts are broken apart inside the packaging, do not use them.
  2. Contact customer care right away.

1.1.2 Airway tube output/test readings

1.1.2.1 Low

- **Readings are abnormal/lower than expected:**
  1. Remove the airway tube from the device. Place it gently again over the device, align it to the device using the attachment points/filter ports, and push it into place without exerting any excessive force. Re-attach the top slide cover,
  2 Check whetherthe airway tube fits correctly and securely (see section 1.1.3).
  3. Check if the patient is holding the device and performing the test correctly. Check for any leaks from the edges of the mouth due to the patient's lips not being closed firmly around the mouthpiece.
  4. Check that the airway tube is fully intact (see section 1.1.1.2).
  5. Ensure that the **Spirofy™** device battery is fully charged or at least up to 85%.

1.1.2.2 Erratic

- **Readings are not similar in multiple efforts using the same airway tube:**
  1. Make sure that the device has been correctly calibrated (zero flow through the device during calibration) in between tests.
  2. Check if the patient is holding the device and performing the test correctly. Check for any leaks from the edges of the mouth due to the patient's lips not being closed firmly around the mouthpiece.
  3. Make sure that patient does not accidentally spit inside the airway tube while taking the test. Replace the airway tube with a new one in case of spit or excess moisture of any kind.
  4. Check whether the airway tube fits correctly and securely (see section 1.1.3).
  5. Check that the airway tube is fully intact (see section 1.1.1.2).
  6. Ensure that the **Spirofy™** device battery is fully charged or at least up to 85%.

1.1.2.3 High

- **Readings are abnormal/higher than expected:**
  1. Make sure that the device has been correctly calibrated (zero flow through the device during calibration) in between tests.
  2. Check if the patient is holding the device and performing the test correctly. Check for any leaks from the edges of the mouth due to the patient's lips not being closed firmly around the mouthpiece.

3. Make sure that the patient does not accidentally spit inside the airway tube while taking the test. Replace the airway tube with a new one in case of spit or excess moisture of any kind.
4. Check whether the airway tube fits correctly and securely (see section 1.1.3).
5. Check that the airway tube is fully intact (see section 1.1.1.2).
6. Ensure that the **Spirofy™** device battery is fully charged or at least up to 85%.

1.1.3 Airway tube assembly/attachment

1.1.3.1 Loose fit

- **Airway tube assembly is loose:** Assemble the airway tube so that all its parts fit together securely (see section 1.1.1.2).

1.1.3.2 Contact/attachment points/filter port(s) on airway tube missing

- **Airway tube is missing one or both contact points/filter ports:** Do not use the said airway tube. Use a fresh airway tube with both of them in place.

1.1.3.3 Incorrect attachment

- **Airway tube attached incorrectly:** Remove the airway tube and re-attach it over the device such that the mouthpiece is on the side of the power button and LED.

1.2 Other hardware issues

Please Note: *It takes approximately 3 hours for the* ***Spirofy™*** *device to get fully charged. Charge the device fully before first use. Ensure that the device is fully charged or charged at least up to 85% before every use. It is recommended that you re-charge the device when the battery level (can be checked on the app) goes down to 30%*

1.2.1 Bluetooth and location services connection

- **Paired Spirofy™ device not detected in the app:**
  1. Ensure that the **Spirofy™** device to be connected is switched ON. If it is still not detectable, switch the **Spirofy™** device OFF; then switch it ON.
  2. Ensure that the phone/tablet Bluetooth and location services are turned ON.
  3. Ensure that **Spirofy™** device is fully charged or at least up to 85%.
  4. Ensure that **Spirofy™** device is within 6 feet of the phone/tablet.
- **Unpaired Spirofy™ device is not detected in the pairing menu of the application:**
  1. Ensure that the **Spirofy™** device to be connected is switched ON. If it is still not detectable, switch the **Spirofy™** device OFF; then switch it ON.
  2. Ensure that the phone/tablet Bluetooth and location services are turned ON.
  3. Ensure that the **Spirofy™** device is fully charged or at least up to 85%.
  4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.
- **Spirofy™ device gets disconnected in between tests:**
  1. Ensure that not more than 8 tests are performed in one test window. This includes any demo tests or poor attempts.
  2. Ensure that the phone/tablet Bluetooth and location services are turned ON during the tests.
  3. Ensure that **Spirofy™** device is fully charged or at least up to 85%.
  4. Ensure that **Spirofy™** device is within 6 feet of the phone/tablet.

- **Unpaired Spirofy™ device is not detected in the pairing menu of the application:**
  1. Ensure that the **Spirofy™** device to be connected is switched ON. If it is still not detectable, switch the **Spirofy™** device OFF; then switch it ON.
  2. Ensure that the phone/tablet Bluetooth and location services are turned ON.
  3. Ensure that the **Spirofy™** device is fully charged or at least up to 85%.
  4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.
- **Spirofy™ device gets disconnected in between tests:**
  1. Ensure that not more than 8 tests are performed in one test window. This includes any demo tests or poor attempts.
  2. Ensure that the phone/tablet Bluetooth and location services are turned ON during the tests.
  3. Ensure that the **Spirofy™** device to be connected is turned ON during the test.
  4. Ensure that the **Spirofy™** device is fully charged or at least up to 85%.
  5. If the device gets disconnected between tests, the "Retry" button will change to "Connect". Click on it to reconnect the device and continue with the tests.
  6. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

1.2.2 Buttons

- **Power button getting stuck inside:**
  1. The **Spirofy™** power button can get stuck/jammed inside the device if pressed incorrectly or with too much force.
  2. To free the button from the plastic housing, press down the button completely inside the housing.
  3. While it is compressed, align the button such that its edge is not touching the plastic border.
  4. Slowly ease the pressure and release the button to get it back to normal position.
- **Spirofy™ device is not turning ON/LED not glowing BLUE after pressing the button:**
  1. Check the device battery level. Fully charge the device and check the LED again.
  2. Check if the device is detected/connected via the app.
- **Spirofy™ device is not turning ON/LED not glowing BLUE after pressing the button:**
  1. Check the device battery level. Fully charge the device and check the LED again.
  2. Check if the device is detected/connected via the app.

- **Spirofy™ device is not turning ON/LED not glowing BLUE after pressing the button:**
  1. Check the device battery level. Fully charge the device and check the LED again.
  2. Check if the device is detected/connected via the app.

1.2.3 Pressure sensor

- **Readings from the Spirofy™ device are wrong/erratic even after all the corrections/troubleshooting:**
  1. Ensure that the device is fully charged or at least up to 85% and connected to the app.
  2. Ensure that a new airway tube is used, and that the airway and top slide cover are attached in the correct orientation.
  3. Ensure that the device is calibrated and has passed a calibration test as per the instructions in the user guide.

1.2.4 Battery

- **Spirofy™ device battery is not getting charged on the dock:**
  1. Ensure that the dock is functional by connecting it to the power source, using the adapter and charging cable provided. The dock LED should turn GREEN when connected to the power source.
  2. Ensure that the adapter and charging cable are properly attached to the power source and also to the dock.
  3. Check if both the adapter and the charging cable are fully functional (see sections 1.3.3 and 1.3.4).
- **Charged Spirofy™ battery is draining faster than expected, even on standby:**
  1. Ensure that the **Spirofy™** device is switched OFF when not in use.
  2. If the problem still persists, contact customer care.

1.3 Charging dock usability or functionality issues

1.3.1 Charging problem/springs

1.3.1.1 Loose contact

- **Dock LED fluctuating between RED and GREEN, indicating loose contact:**
  1. Press down the **Spirofy™** device on the charging dock lock with a little bit of force.
  2. Check if the dock LED turns from RED to Green.

1.3.1.2 Spring action incorrect

- **Gap observed between the Spirofy™ device and the dock when placed for charging:**
  1. Confirm if there is a loose contact (see instructions given above under section 1.3.1.1).
  2. Continue to use if the **Spirofy™** device is able to charge correctly.
- **Dock LED is RED when the dock is connected to the power source but no device is placed on the dock:**
  Contact customer care.
- **Dock LED is RED when the dock is not connected to the power source and the Spirofy™ device is placed on the dock:**
  Contact customer care.

1.3.2.2 Not working

- **Dock LED is not glowing either RED or GREEN:**
  1. Connect the dock to the power source and switch it ON.
  2. Check if the dock LED turns GREEN.
  3. Place a Spirofy™ device on the dock. The LED should glow either RED or GREEN.

1.3.2.3 Never green

- **Dock LED does not turn GREEN:**
  1. Connect the dock to the power source and switch it ON.
  2. Check if the dock LED turns GREEN.
  3. Place a charged Spirofy™ device on the dock. The LED should glow GREEN.

1.3.3 USB charging cable

1.3.3.1 Loose contact

- **Charging cable connection to the dock is loose:**
  1. Check if the Spirofy™ device is able to charge.
  2. If the charging cable warranty period is over, contact customer care.

1.3.3.2 Connection broken

- **Port on the dock is broken/damaged:**
  Contact customer care.
- **Port on the charging cable is broken/damaged:**
  Contact customer care.

1.3.3.3 Wrong fit

- **Cable received with the device kit does not fit/plug into the port on the dock:**
  Contact customer care.

1.3.3.4 Not received

- **No charging cable was received with the device kit:**
  Contact customer care.

1.3.4 Adapter issues

1.3.4.1 Not received

- **No adapter was received with the device kit:**
  Contact customer care.

1.3.4.2 Overheating

- **Adapter tends to overheat while connected to the power source and charging the device:**
  Contact customer care.

1.3.4.3 Not working

- **The adapter provided in the device kit is not charging the device:**
  Contact customer care.

1.4 Top slide cover issues

1.4.1 Broken/bent locks

- **Any of the four locks on the top slide cover are bent/broken:**
  Contact customer care.

1.4.2 Excess plastic

- **Excess plastic residue on the top slide cover:**

1. Check if you are able to take a test using the device with the top slide cover.

2. If it does not work properly, contact customer care.

1.4.3 Excess force required to lock the top slide cover

- **Difficulty in locking top slide cover over the Spirofy™ device:**

1. Check that the airway tube and the top slide cover are placed in the correct orientation.

2. Attach the top slide cover as per the instructions given in this user manual.

2. Issues related to the Cipla Spirofy™ app

2.1 Log in/server issues

• Unable to create an account/register:

1. Check if you have a working internet connection.
2. Check the spam folder in your email address inbox for the OTP.
3. Check if the app has been granted all of the required permissions.
4. Clear the app from the multitasking menu and launch again.
5. Uninstall and reinstall the app.
6. Restart your phone/tablet and retry.

• Unable to log into an existing account:

1. Check your login credentials.
2. Check if you have a working internet connection.
3. Check if the app has been granted all of the required permissions.
4. Clear the app from the multitasking menu and launch again.
5. Uninstall and reinstall the app.

• Unable to create a case code:

1. Check if you have a working internet connection and mobile network reception.
2. Check if the mobile number submitted is correct and operational.
3. Check if the OTP submitted in the app is correct.

• OTP not received on email:

1. Check if the app and email client have a working, stable and reliable internet connection.
2. Check if the correct email address was submitted in the app.
3. Check the spam folder in your email address inbox for the OTP.

• OTP not received on phone/tablet:

1. Check if the correct mobile number was submitted.
2. Check that the internet connection is working.
3. Check that the mobile number has network reception.

2.2 Plotting graphs/test issues

2.2.1 Graphs

- **Graphs are not getting plotted while taking a test:**

1. Check that the device is connected to the app via Bluetooth and location services.
2. Retry taking the test, making sure that the device is properly calibrated and ensuring zero flow in the airway during calibration.
3. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

- **Lag in plotting of graphs while taking a test:**

1. Do not take more than 8 tests per patient in each test window.
2. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
3. Close any other background apps open on the phone/tablet as they may hamper the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.
5. Restart the app.

- **Plotted graphs are incorrect in nature:**

1. Ensure that the airway tube is correctly attached to the **Spirofy™** device and that the top slide cover is also attached properly.
2. Ensure zero flow through the device during calibration before every test.
3. Ensure that the patient does not cough or spit into the airway tube during a test. Replace the airway tube if cough secretion or saliva is seen.

2.2.2 Calibration

- The **Spirofy™** device is repeatedly failing during 3L calibration:

1. Ensure that the syringe is calibrated as per the manufacturer's guidelines and recommendations.
2. Ensure that a new airway tube is used and is attached correctly to the device.
3. Ensure that the device is attached to the syringe via an appropriate coupling and that the connection is leak-proof.
4. Follow the calibration instructions correctly. Do not plunge the syringe while the device is getting ready for calibration.

- **Graphs are not getting plotted while taking a test:**

1. Check that the device is connected to the app via Bluetooth.
2. Retry taking a test, making sure that the device is properly calibrated and there is zero flow in the airway during calibration.
3. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

2.2 Plotting graphs/test issues

2.2.1 Graphs

• **Graphs are not getting plotted while taking a test:**

1. Check that the device is connected to the app via Bluetooth and location services.
2. Retry taking the test, making sure that the device is properly calibrated and ensuring zero flow in the airway during calibration.
3. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

• **Lag in plotting of graphs while taking a test:**

1. Do not take more than 8 tests per patient in each test window.
2. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
3. Close any other background apps open on the phone/tablet as they may hamper the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.
5. Restart the app.

• **Plotted graphs are incorrect in nature:**

1. Ensure that the airway tube is correctly attached to the **Spirofy™** device and that the top slide cover is also attached properly.
2. Ensure zero flow through the device during calibration before every test.
3. Ensure that the patient does not cough or spit into the airway tube during a test. Replace the airway tube if cough secretion or saliva is seen.

2.2.2 Calibration

• The **Spirofy™** device is repeatedly failing during 3L calibration:

1. Ensure that the syringe is calibrated as per the manufacturer's guidelines and recommendations.
2. Ensure that a new airway tube is used and is attached correctly to the device.
3. Ensure that the device is attached to the syringe via an appropriate coupling and that the connection is leak-proof.
4. Follow the calibration instructions correctly. Do not plunge the syringe while the device is getting ready for calibration.

• **Graphs are not getting plotted while taking a test:**

1. Check that the device is connected to the app via Bluetooth.
2. Retry taking a test, making sure that the device is properly calibrated and there is zero flow in the airway during calibration.
3. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
4. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

- **Lag in plotting of graphs while taking a test:**

1. Turn OFF any power-saving modes on the phone/tablet as they may affect the app performance.
2. Close any other background apps open on the phone/tablet as they may hamper the app performance.
3. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.
4. Restart the app.

- **Plotted graphs are incorrect in nature:**

1. Ensure that the airway is correctly attached to the **Spirofy™** device and that the top slide cover is also attached properly.
2. Ensure zero flow through the device duri ng calibration before every test.

2.3 Retrieval issues (syncing test data or retrieving test data after log out and log in)

- **Unable to see previous data after logging in to account:**

1. Previous data must be synced for it to be visible after logging in again. Ensure that the generated data was synced before logging out of a device.

- **Unable to sync generated data to the cloud:**

1. Ensure that the phone has a working internet connection with sufficiently high speed.
2. Ensure that the **Spirofy™** app is provided with the required permissions.

2.4 Connection issues

Please Note: It takes approximately 3 hours for the device to get fully charged. Charge the device fully before first use. Ensure that the device is fully charged or charged at least up to 85% before every use. It is recommended that you re-charge the device when the battery level (can be checked on the app) goes down to 30%.

2.4.1 Connection issues between device and app due to app

- **App unable to add a new Spirofy™ device:**

1. Ensure that the **Spirofy™** device is fully charged and is switched ON while pairing.
2. Ensure that your phone Bluetooth and location services are switched ON during the pairing process.
3. Ensure that the **Spirofy™** device is within 6 feet of the phone/tablet.

- **App unable to connect to an added Spirofy™ device:**

1. Ensure that the **Spirofy™** device is switched ON and fully charged or at least up to 85%.
2. Ensure that your phone Bluetooth and location services are switched ON.

- **Lost connection between device and app in the middle of the test:**

1. The "Retry" button will change to "Connect".
2. Tap/click "Connect" and wait till it changes back to "Retry" again.
3. Tap/click "Retry" and continue the test.

3. Issues related to the Spirofy Bluetooth thermal printer

Please Note: It takes approximately 3 hours for the printer to get fully charged. Charge the printer fully before first use. Ensure that the printer is fully charged before every use.

3.1 Hardware issues

3.1.1 Printer head issues

- **Not printing anything on given command:**

1. Check the Bluetooth and location services connection.
2. Check proper position/alignment of the paper and of the roller head with the roller.
3. If nothing works, contact customer care.

- **Printer head is shaking back/forth when attaching the roller:**

Contact customer care.

3. Check if any of the four LEDs are lighting up.

- **ON/OFF button not getting pressed:**

Contact customer care.

- **Feed button not working:**

1. Ensure that the printer is fully charged.
2. Check if you are able to switch ON the printer.
3. Check if any of the four LEDs are lighting up.
4. Check if you are able to press the ON/OFF button down.

- **Feed button not getting pressed down:**

Contact customer care.

3.1.3 Printer LEDs

- **Bluetooth BLUE LED not glowing:**

1. Ensure that the printer is fully charged.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.

3. Check if you are able to connect the printer to the phone/tablet via Bluetooth and location services by giving the “Test Printer” command.

4. Try printing a thermal report. If the report is getting printed properly, then only the LED may be damaged.

• RED LED not glowing when error occurs:

1. Ensure that the printer is fully charged.

2. Check if you are able take a test print by holding down the feed button and then pressing the power button.

3. Check if you are able to connect the printer to the phone via Bluetooth and location services by giving the “Test Printer” command.

4. Try printing a thermal report. If the report is getting printed properly, then only the LED may be damaged.

• GREEN LED not glowing after switching printer on:

1. Ensure that the printer is fully charged.

2. Check if you are able take a test print by holding down the feed button and then pressing the power button.

3. Check if you are able to connect the printer to the phone/tablet via Bluetooth and location services by giving the “Test Printer” command.

4. Try printing a thermal report. If the report is getting printed properly, then only the LED may be damaged.

• Charging LED not glowing when connected to the charger:

1. Ensure that the printer is fully charged.

2. Check if you are able take a test print by holding down the feed button and then pressing the power button.

3. Check if you are able to connect the printer to the phone/tablet via Bluetooth by giving the “Test Printer”.

4. Try printing a thermal report. If the report is getting printed properly, then only the LED may be damaged.

3.1.4 Printer plastic head

• Printer plastic head is shaking and does not remain firm while connected to the roller on the printer head:

Contact customer care.

3.1.5 Printer plastic roller head

• Roller head is not firmly fitting onto printer head:

1. Check and ensure that the alignment of the roller head and the printer head is proper.

3.1.6 Printer paper

• Printer paper is not rolling out symmetrically from the printer head while printing:

1. Ensure that the printer is fully charged.

2. Check if you are able take a test print by holding down the feed button and then pressing the power button.

3. Check the PDF file that you are going to print.

4. Ensure that the paper roll alignment is correct.

5. Check that the paper lid is properly closed.

3.1.4 Printer plastic head

- **Printer plastic head is shaking and does not remain firm while connected to the roller on the printer head:**

Contact customer care.

3.1.5 Printer plastic roller head

- **Roller head is not firmly fitting onto printer head:**

1. Check and ensure that the alignment of the roller head and the printer head is proper.

3.1.6 Printer paper

- **Printer paper is not rolling out symmetrically from the printer head while printing:**

1. Ensure that the printer is fully charged.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check the PDF file that you are going to print.
4. Ensure that the paper roll alignment is correct.
5. Check that the paper lid is properly closed.

- **Print is blurred or is printed erratically:**

1. Ensure that the printer is fully charged.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check the PDF file that you are going to print.
4. Ensure that the paper roll alignment is correct.

- **Print is blank:**

1. Ensure that the printer is fully charged.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check the PDF file that you are going to print.
4. Ensure that the paper roll alignment is correct, and the paper roll is installed correctly. Ensure that adequate length of paper roll is available.

3.1.7 Bluetooth Connection

- **Paired printer not getting detected by the Spirofy™ app:**

1. Fully charge the printer and then switch it ON.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check if the printer prints out “Hello Printer” if you tap “Test Printer” from the CIE print app.
4. Remove the printer by tapping “Clear Pref Printer” and try adding it again.
5. Try operating the printer using the CIE Mobile Print app on a phone/tablet of a different model/manufacturer.

- **Unpaired printer not getting detected by the Spirofy™ app:**

1. Fully charge the printer and then switch it ON.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check that the printer is not simultaneously connected to a different phone at the same time.
4. Check if the printer prints out “Hello Printer” if you tap on “Test Printer” in the CIE print app.
5. Remove the printer by tapping “Clear Pref Printer” and try adding it again.
6. Try operating the printer using the CIE Mobile Print app on a phone/tablet of a different model/manufacturer.

- **Bluetooth connection lost during the printing process:**

1. Check if the printer has enough battery power. Fully charge the printer or use it in plugged-in mode.
2. Check if the paper roll has adequate length of paper remaining.
3. Tear off the partially printed report and re-print the report.

In case of any doubts or queries, please contact customer care – email at support.spirofy@cipla.com or call on 1800 2020 060 (toll-free number).

• **Print is blank:**

1. Ensure that the printer is fully charged.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check the PDF file that you are going to print.
4. Ensure that the paper roll alignment is correct, and the paper roll is installed correctly. Ensure that adequate length of paper roll is available.

3.1.7 Bluetooth Connection

• **Paired printer not getting detected by the Spirofy™ app:**

1. Fully charge the printer and then switch it ON.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check if the printer prints out "Hello Printer" if you tap "Test Printer" from the CIE print app.
4. Remove the printer by tapping "Clear Pref Printer" and try adding it again.
5. Try operating the printer using the CIE Mobile Print app on a phone/tablet of a different model/manufacturer.

• Unpaired printer not getting detected by the **Spirofy™** app:

1. Fully charge the printer and then switch it ON.
2. Check if you are able take a test print by holding down the feed button and then pressing the power button.
3. Check that the printer is not simultaneously connected to a different phone at the same time.
4. Check if the printer prints out "Hello Printer" if you tap on "Test Printer" in the CIE print app.
5. Remove the printer by tapping "Clear Pref Printer" and try adding it again.
6. Try operating the printer using the CIE Mobile Print app on a phone/tablet of a different model/manufacturer.

• **Bluetooth connection lost during the printing process:**

1. Check if the printer has enough battery power. Fully charge the printer or use it in plugged-in mode.
2. Check if the paper roll has adequate length of paper remaining.
3. Tear off the partially printed report and re-print the report.

In case of any doubts or queries, please contact customer care – email at support.spirofy@cipla.com or call on 1800 2020 060 (toll-free number).

Contraindications, Warnings, Cautions and Precautions

Contraindications for spirometry

If any of the following have occurred recently, then it may be better to wait till the patient has fully recovered before subjecting the patient to spirometry:

- Unstable cardiovascular status such as myocardial infarction
- Recent thoracic or abdominal surgery
- Recent eye or ear surgery
- Proven or suspected active pulmonary tuberculosis
- Thoracic, abdominal or cerebral aneurysm
- Oral or facial pain exacerbated by the device mouthpiece
- Haemoptysis of known/unknown origin
- Uncontrolled blood pressure
- Acute illnesses that may interfere with the performance of the procedure such as acute respiratory tract infection, nausea, vomiting, chest pain, or abdominal pain

Warnings and Cautions

*The **Spirofy™** device should be used only by trained and qualified personnel.*

In this manual, the following terms are used as specified:

CAUTION:
Possibility of injury or serious damage.

WARNING:
Conditions or practices that could result in injury or damage.

Please Note: Important information with regards to handling the device or facilitating operation of the device.

Please take note of the following before using the device:

CAUTION:
Read this user manual and watch the tutorial videos (scan the QR code given) before use.

WARNING:
The device is not suitable for use in the presence of explosive or flammable gases, flammable anaesthetic mixtures or in oxygen-rich environments.

WARNING:
Use of portable phones or other radio frequency (RF)-emitting equipment near the system may cause unexpected or adverse operation.

CAUTION:
Airway tubes are for single-patient use. If used on more than one patient, there is a risk of cross-infection. Repeat use may degrade materials and lead to an incorrect measurement.

CAUTION:
Do not allow the patient to handle the spirometer when connected to either the power supply for charging or to a personal computer when configuring the unit.

WARNING: The user must not touch any voltage-carrying parts and the patient at the same time.

Please Note: This product should not be disposed of as unsorted waste. Please utilize your local recycling facility for the disposal of this product.

Precautions: IT IS HIGHLY RECOMMENDED THAT YOU READ THE ENTIRE USER MANUAL AND WATCH THE TUTORIAL VIDEOS FULLY **(SCAN THE QR CODE TO DO SO)** BEFORE ATTEMPTING TO TAKE A TEST.

- Do not keep the **Spirofy™** device in a damp place or expose it to extreme temperatures. Avoid exposing the **Spirofy™** device to direct sunlight.
- Avoid operating the spirometer in dusty conditions or near heating appliances or radiators.
- Reusing airway tubes incurs a risk of transmitting diseases from one person to another via saliva. Ensure that a fresh airway tube is used for every test.
- Only use **Spirofy™** certified airway tubes that are approved by Cipla Ltd. Using counterfeit tubes will yield incorrect results and may lead to misdiagnosis.
- Keep the **Spirofy™** device and all its components away from children aged 3 years or below. There is a risk of choking if small parts, such as those used in the airway tube or device, get swallowed accidentally.
- Do not exert excessive physical pressure while attaching the airway tubes to the **Spirofy™** device, and while docking the device for charging as it may damage sensitive hardware components such as the filter ports/attachment points and charging pins.
- Wipe the device regularly with a dry paper towel to keep it clean.
- Refrain from using **Spirofy™** in airplanes or moving vehicles, unless necessary.
- Do not make any modifications to any part of the hardware or open the device as it would void the warranty.
- Use only the charging cable and adapter provided with the device for charging.

List of Abbreviations

BVF	Bacterial and viral filter
COPD	Chronic obstructive pulmonary disease
FVC	Forced vital capacity
FEF25	Forced expiratory flow at 25% of the FVC
FEF50	Forced expiratory flow at 50% of the FVC
FEF75	Forced expiratory flow at75% of the FVC
FEF25-75	Forced expiratory flow between 25 &75% of the FVC
FEV1	Forced expiratory volume in 1 second
FIVC	Forced inspiratory vital capacity
FEV3	Forced expiratory volume in 3 seconds
FEF25	Forced expiratory flow (25% of the pulmonary volume)
FEF50	Forced expiratory flow (50% of the pulmonary volume)
FEF75	Forced expiratory flow (75% of the pulmonary volume)
FEF25-75	Forced expiratory flow (25-75% of the pulmonary volume)
FET	Forced expiratory time
ILD	Interstitial lung disease
LED	Light-emitting diode
MAC	Media access control
PEFR	Peak expiratory flow rate

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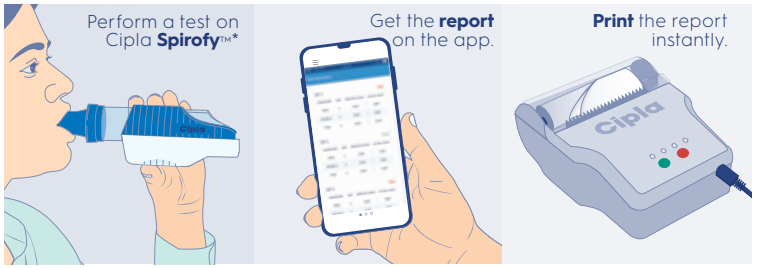

*Test must be performed under medical supervision only.

FOR THE USE OF REGISTERED MEDICAL PRACTITIONERS OR
A HOSPITAL OR A LABORATORY ONLY.

Spirofy™

spirometer

Cipla

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