NxGen

NxGen Pocket Spirometer

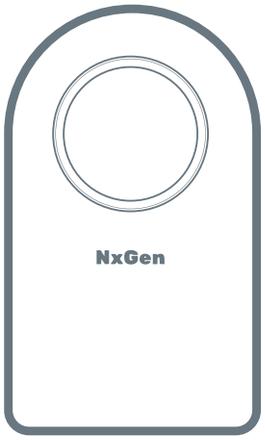
Model – SpiroLite

Instructions for Use

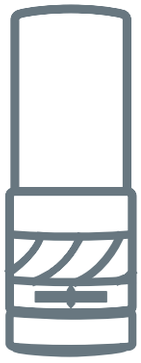
Version: 6.0

WHAT'S IN THE BOX

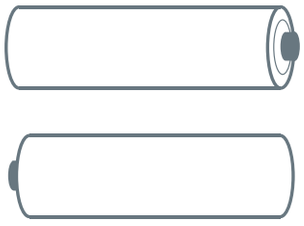
Pouch



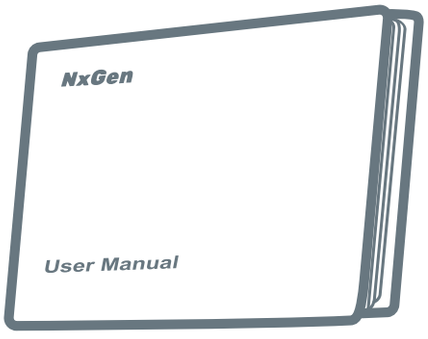
Pocket Spirometer



Turbine



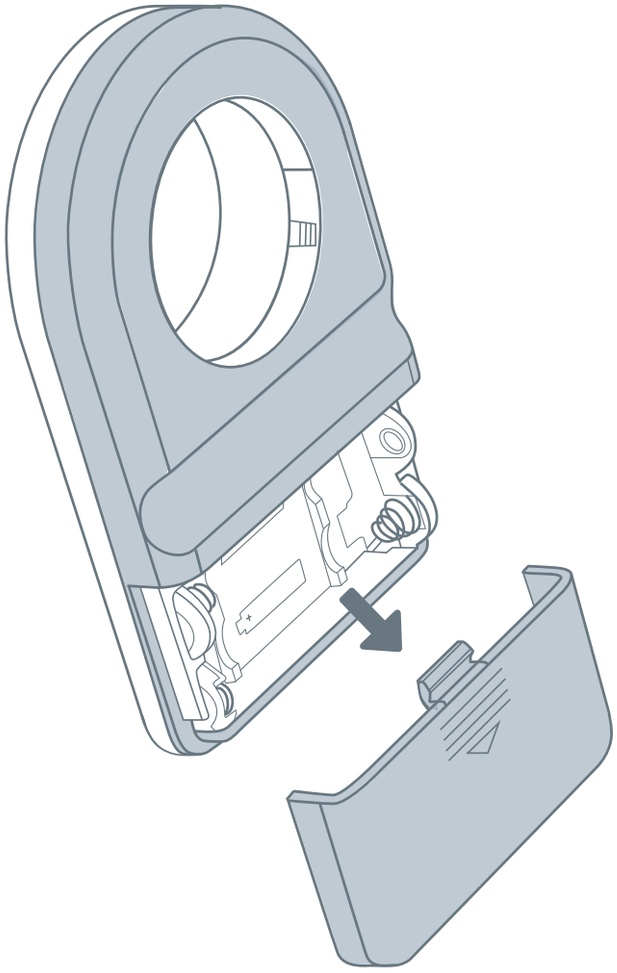
2x AAA Batteries



Instruction Card

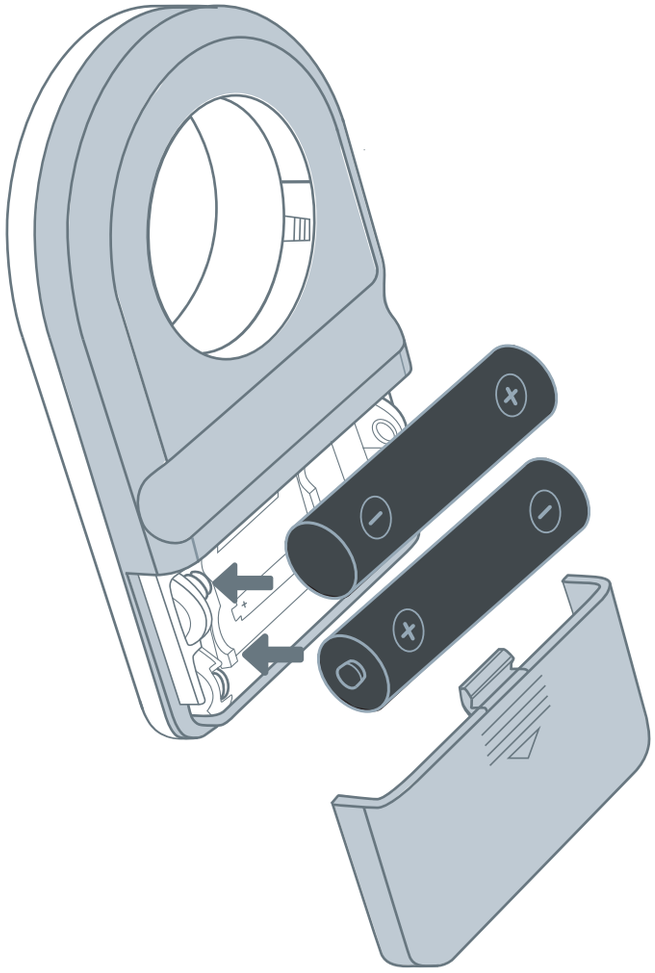
BATTERY INSTALLATION

1



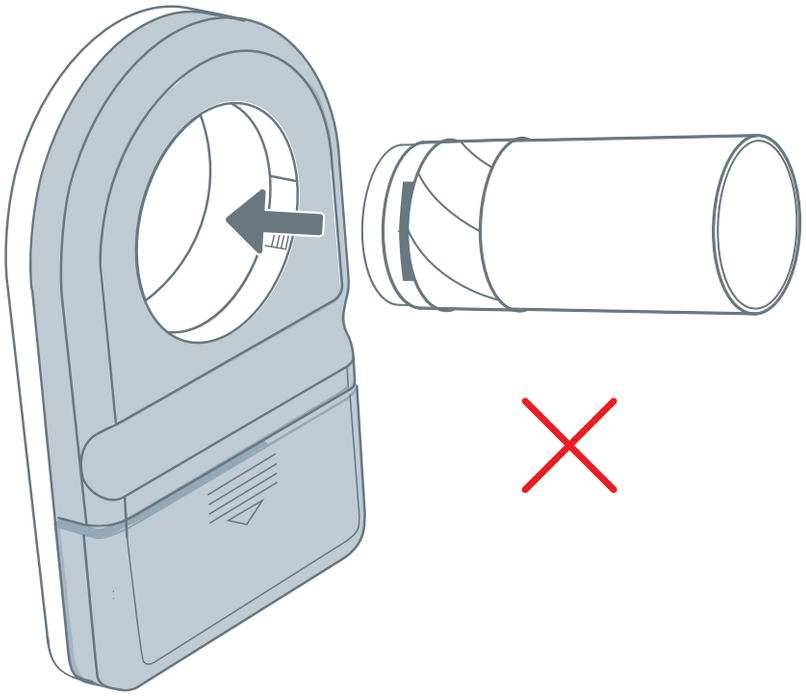
Open the battery latch on the back by gently pushing on the grip and pulling it downward.

2

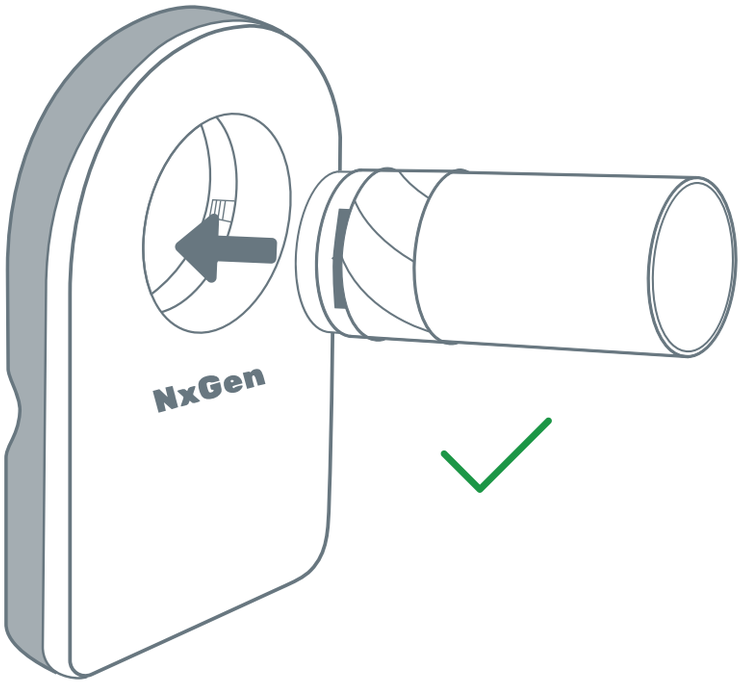


Insert two AAA batteries into the battery compartment, making sure to align them according to the battery label with the correct (+) and (-) signs. Close the battery latch until it clicks into place

TURBINE INSTALLATION

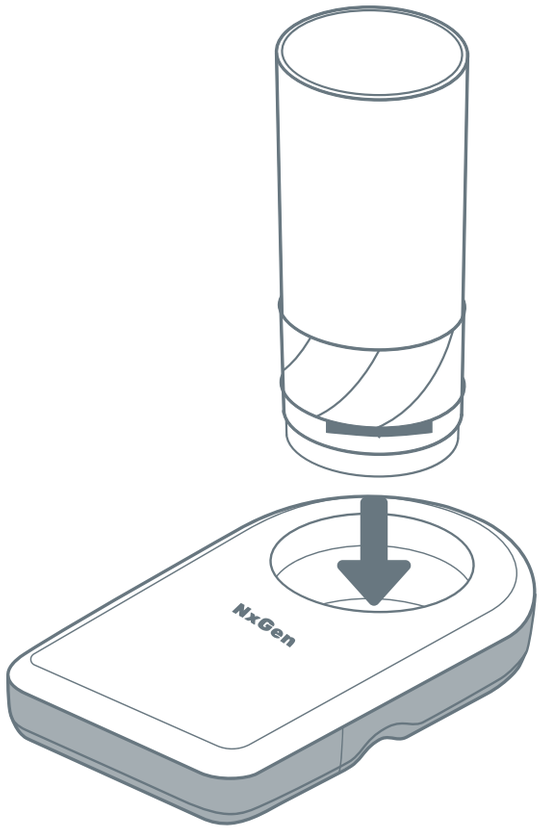


Do not insert the Turbine
from the back side of the Device.



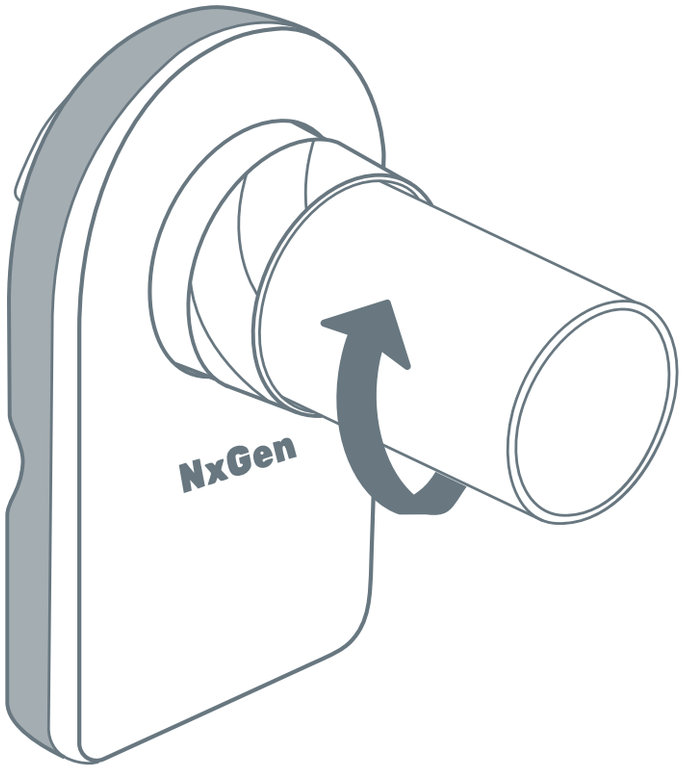
Insert the Turbine only
From Front side as shown as
in above Figure.

1



Insert the Turbine into the device, and gently push until it is fully fitted.

2



Insert the Turbine by pushing it in while rotating it clockwise until it is fully seated.

APP INSTALLATION

To download the NxGen Spirometer App scan the QR code using your mobile device and install the app from the Google Play Store.

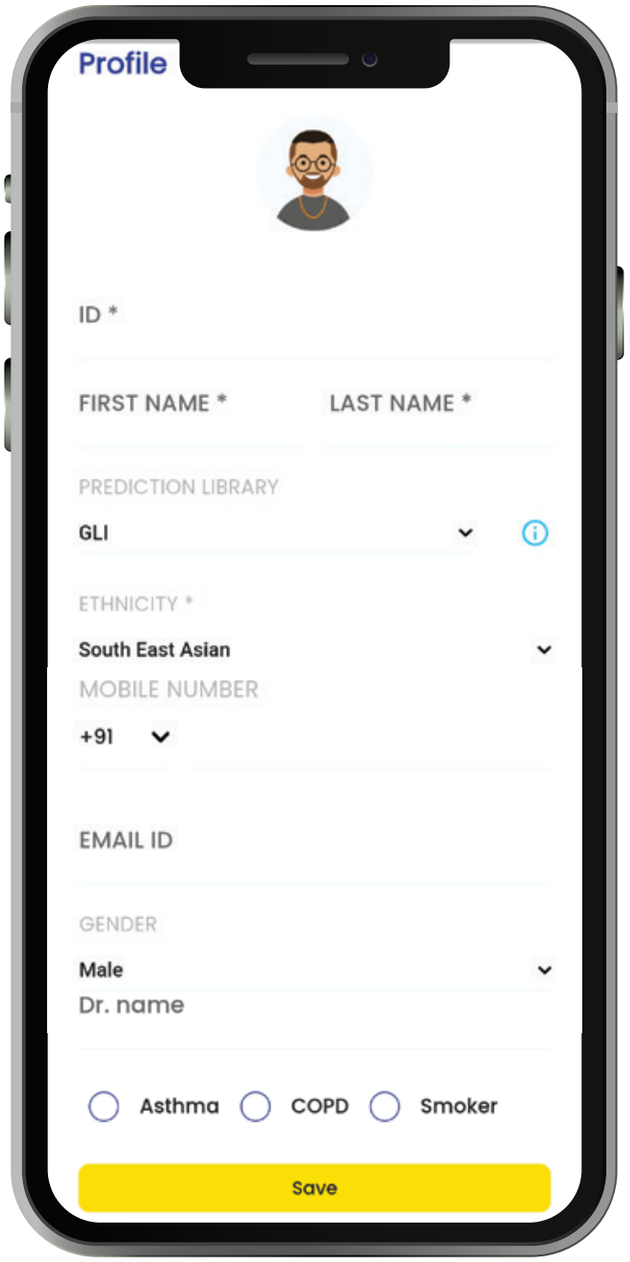
To download the NxGen Spirometer App, scan the QR code using your mobile device and install the app from the Apple App Store.

SETTING UP NXGEN APP AND CONNECTING TO POCKET SPIROMETER DEVICE.

1

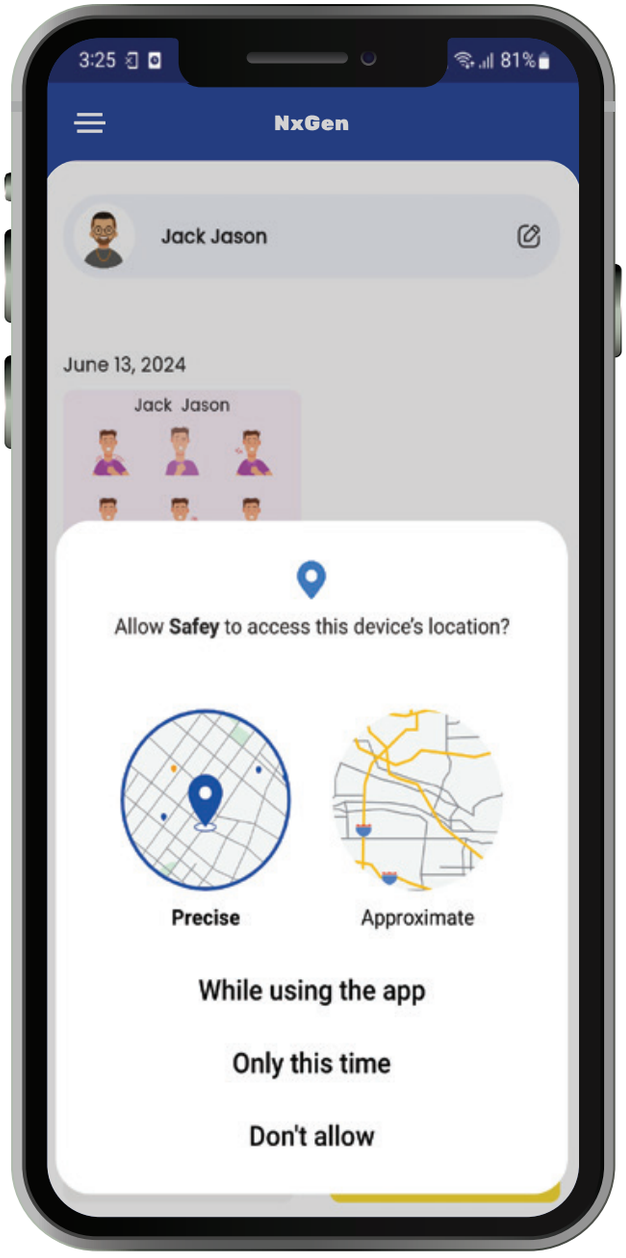
Open The NxGen Spirometer App on your mobile phone and tap “Continue” until you reach the Profile Screen.

2



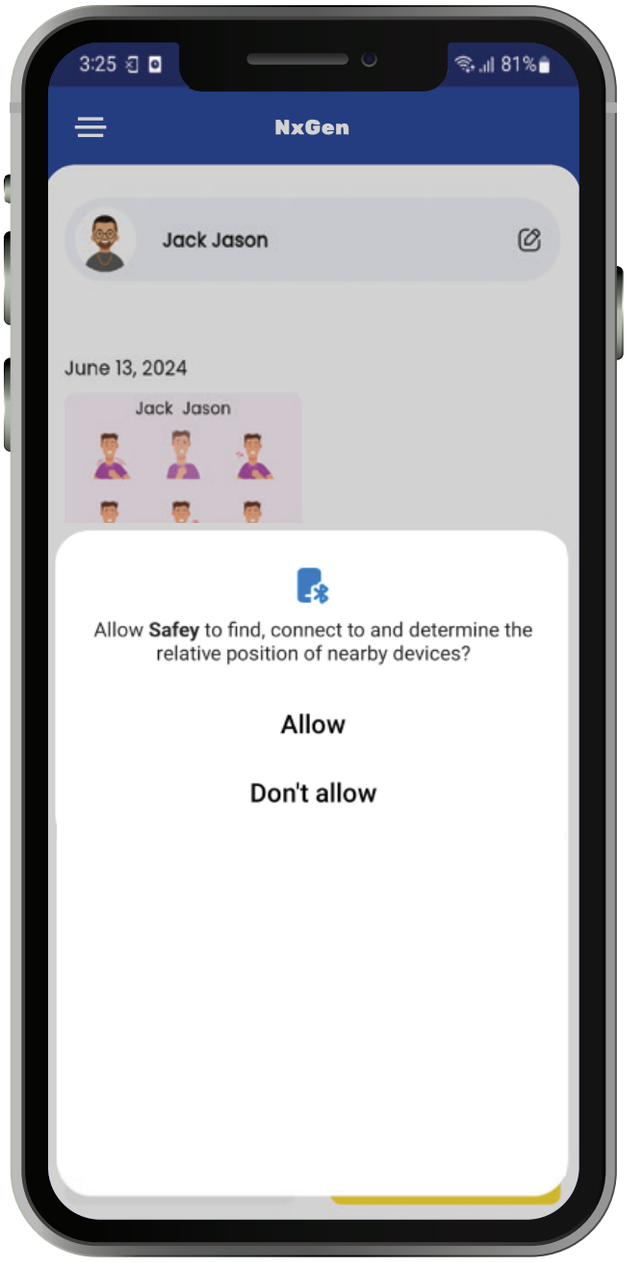
On the Profile Screen, enter the following patient details: name, date of birth, gender, height, ethnicity, and avatar. Once all the information is entered, tap the Save button to create your profile.

3



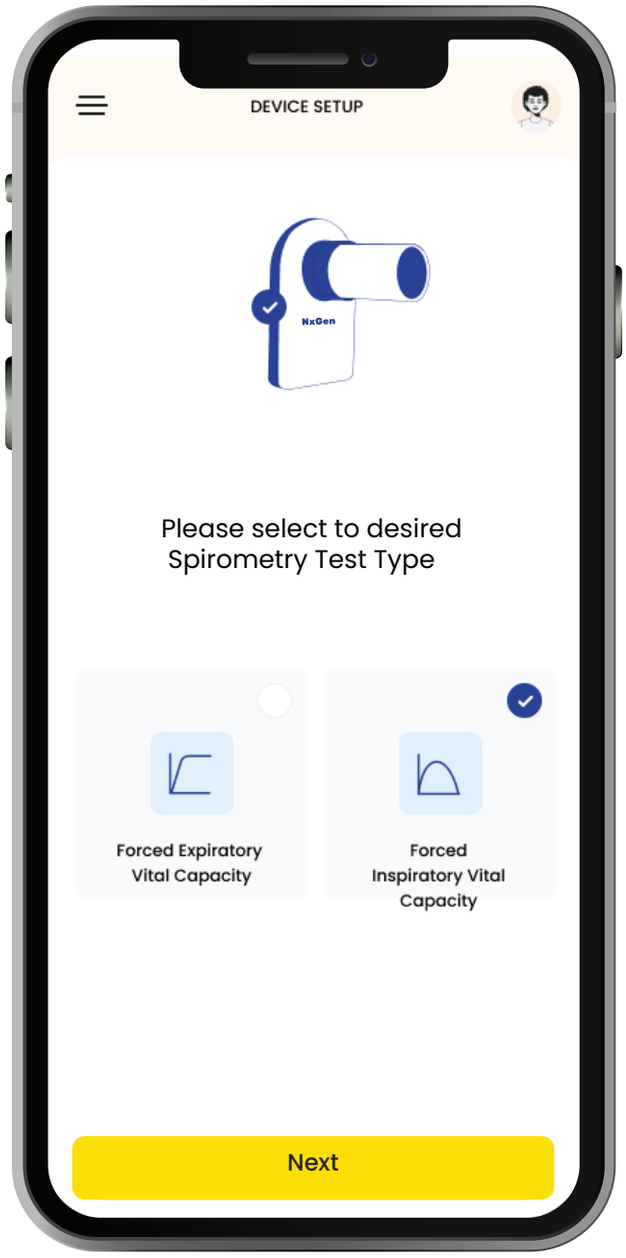
Turn on location services and allow access to your device's location and connections for the NxGen Spirometer App.

4



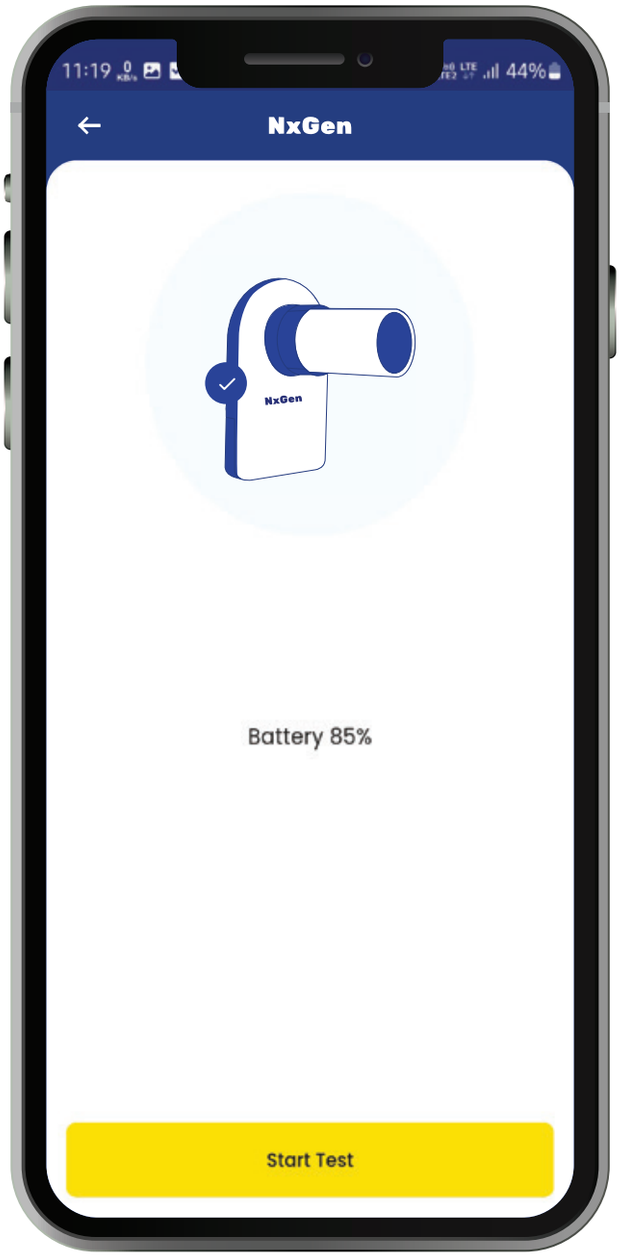
Turn on Bluetooth and grant the NxGen Spirometer App access to your device's Bluetooth connection.

5



Select the Spirometry test type and click Next.

6



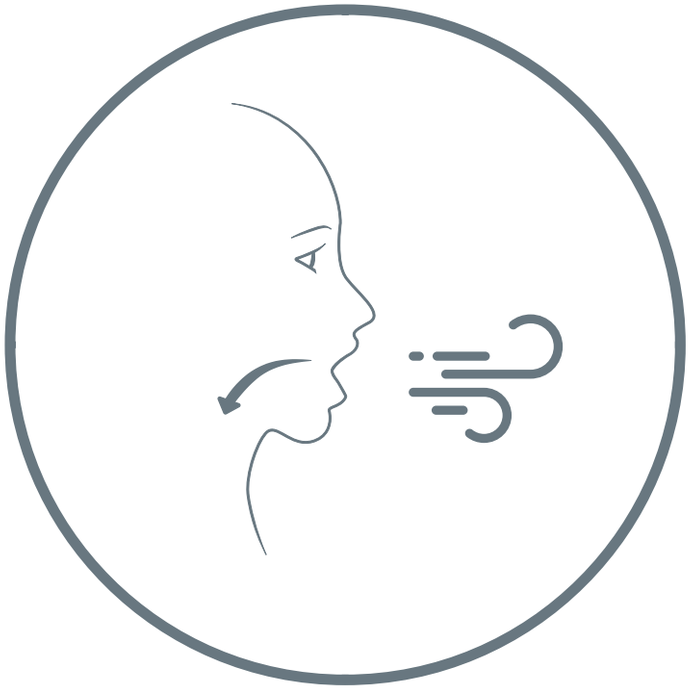
Everything is set up! Press the "Start Test" button to begin the test.

PERFORMING A LUNG FUNCTION TEST

1

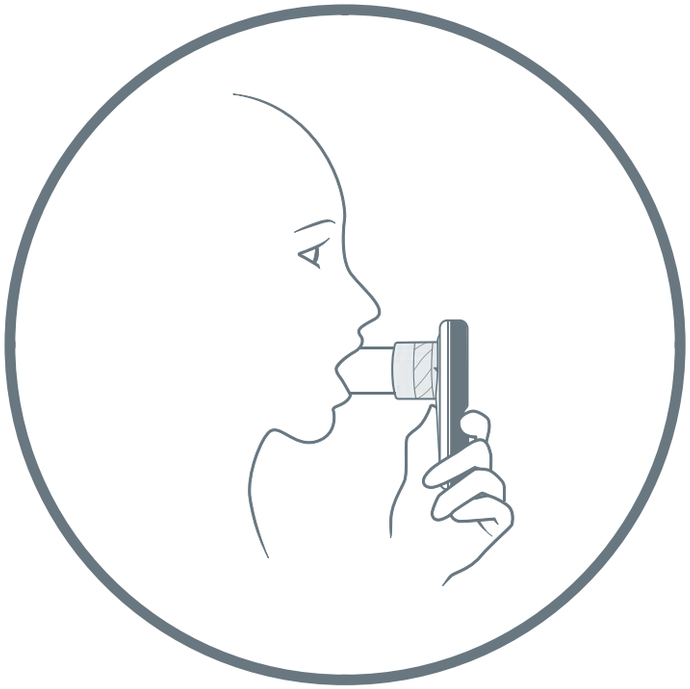
Stand up and relax,
hold the Peak Flow Meter
in your hand.

2



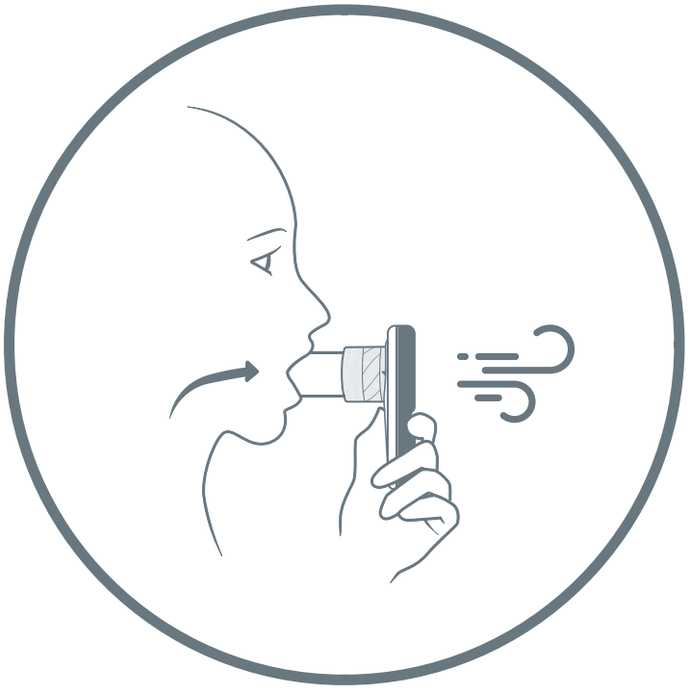
Inhale deeply.
Completely fill your lungs.

3



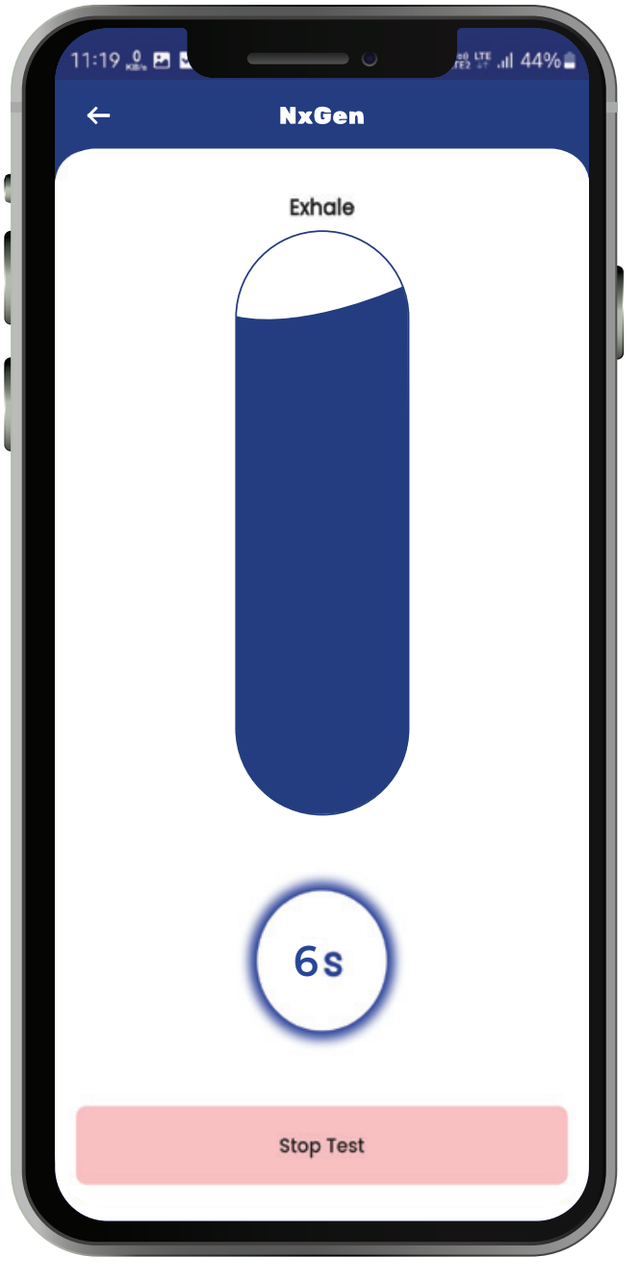
Close your lips around the mouthpiece.

4



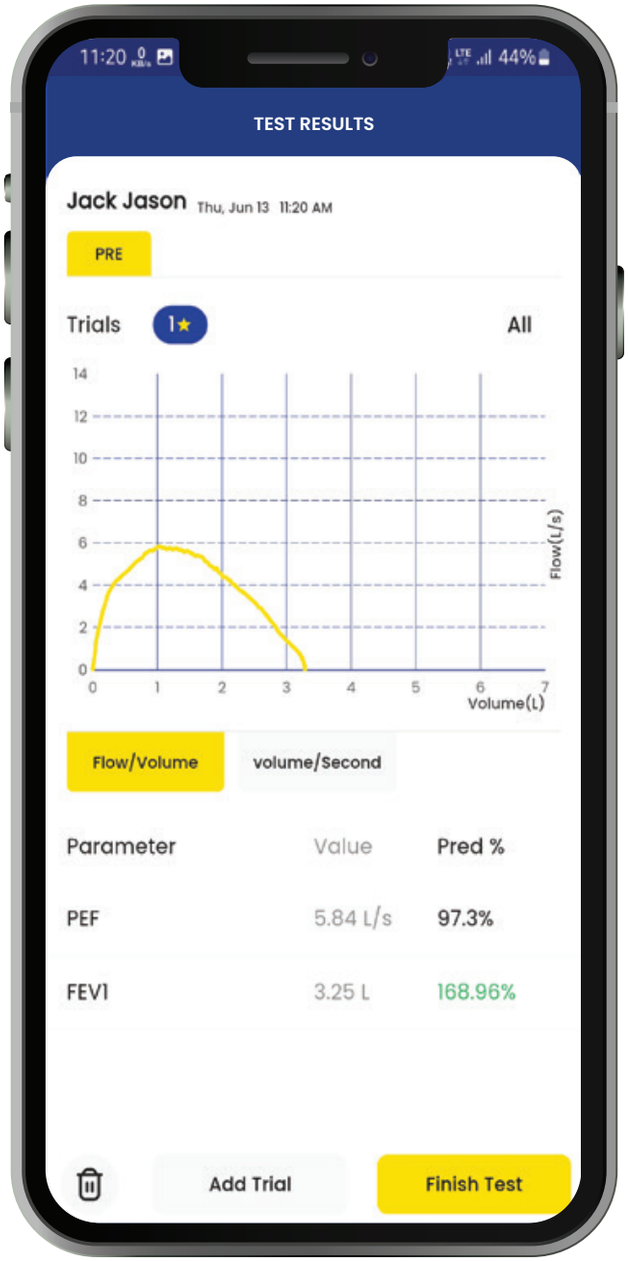
Exhale as much
as you can into the Mouthpiece.

5



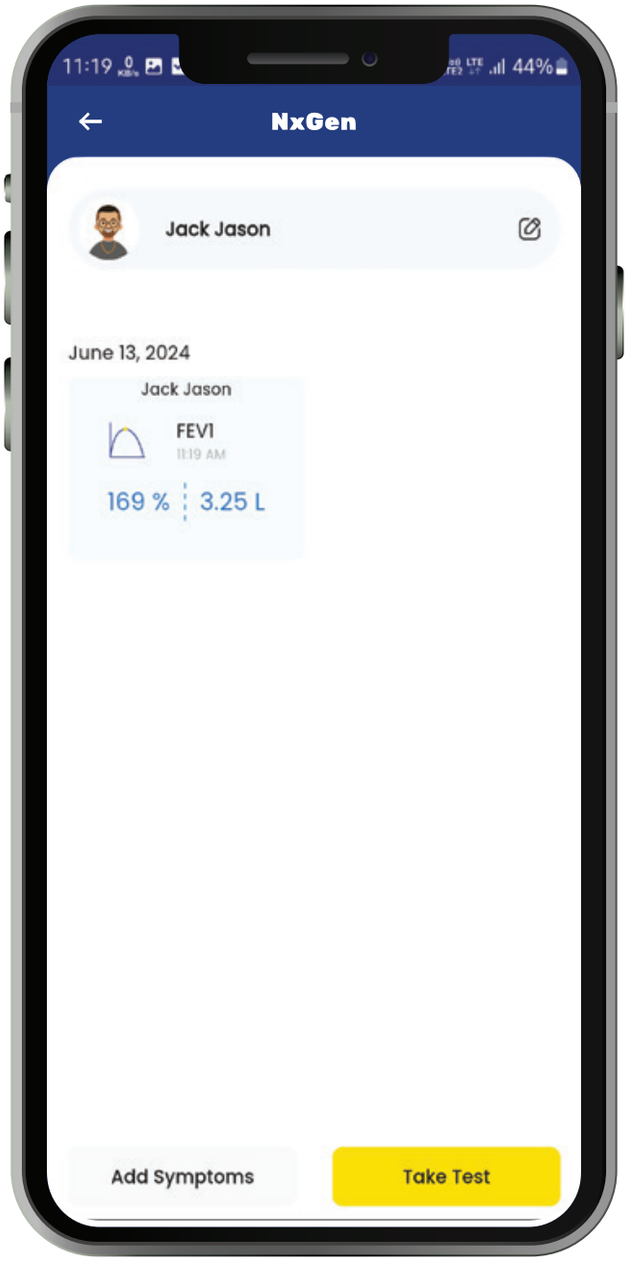
Exhale as hard as you can into
the Turbine upto 6 seconds.

6



Now, click on the Finish Test.

7

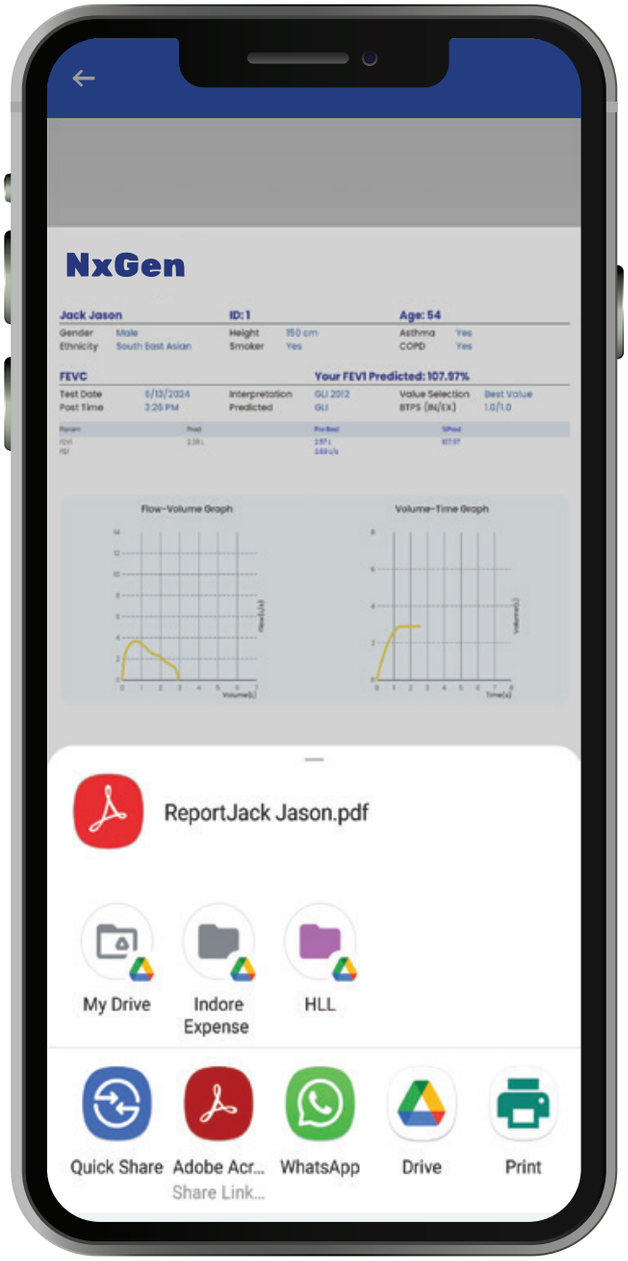


Choose the Test report from the history that you wish to view, share or print.

8

Your final report has been generated successfully. You can now choose to either share it or print it.

9



You may now choose to share your report through Bluetooth, WhatsApp, Drive, Cloud Storage etc.

INTENDED USE

NxGen Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home healthcare environment.

GENERAL INFORMATION

The NxGen Pocket Spirometer is designed for use with the reusable “Safey Turbine”. The word “Turbine” mentioned in the document refers to “Safey Turbine”. During Spirometry tests, the user inhales or exhales into the turbine, which causes a rotor to spin. The NxGen Pocket Spirometer registers the rotor's speed, converts this data, and transmits it via Bluetooth to the NxGen Spirometer App.
Key steps of the Peak Flow Meter include:

1. Attaching the “Turbine”.
2. Pairing with a smartphone via Bluetooth.
3. Conducting tests.
4. Viewing results on the NxGen Spirometer App

Compatible with iOS and Android devices, the NxGen Pocket Spirometer operates on two 1.5V AAA alkaline batteries, which should last six to eight months. Dispose of used batteries as electronic waste and use only alkaline batteries. **Rechargeable batteries are not suitable.**
The Peak Flow Meter measures airflow through the Turbine's helical inlet, which causes a vane to spin. The vane interrupts an infrared beam, and the Pocket Spirometer records these interruptions and time intervals. Data is transmitted to the NxGen Spirometer App, where it is converted into graphs and numbers for analysis by

healthcare professionals. Patients under 16 must be supervised by an adult during use. If the battery is low, the NxGen Spirometer App will provide a warning to replace batteries.
This device aids healthcare professionals in monitoring and managing patient's lung health, facilitating timely clinical interventions and improving patient outcomes.
Download the NxGen Spirometer App from the Google Play Store or Apple App Store developed by Manufacturer (refer to the Packaging for the details of the Manufacturer).

CAUTION

Please read all information in the user manual and product label before using this device.

1. The interpretation of results from tests conducted by the Pocket Spirometer, and any related medical or clinical actions, should be done with the advice of a physician or licensed healthcare professional.
2. NxGen Pocket Spirometer results depend on the effort applied by the user. For optimal results, ensure that your exhalation lasts longer than 6 seconds during the Pocket Spirometer Test.
3. This product must not be disposed of as unsorted waste. Please use local
   Electronic waste recycling facilities for safe disposal.
4. Only use "Safey Turbine" to ensure the accuracy of results generated by the NxGen Spirometer App and to maintain user safety.
5. Do not modify the device.

6. Do not attempt to charge, improperly connect, or dispose of batteries in fire, as there is a risk of leakage or explosion. Follow the manufacturer's instructions for battery use.
7. Do not use the device with your mobile phone while the phone is charging.
8. Dropping the device from a height greater than 6 feet may cause irreparable damage.

PLEASE NOTE: For any questions or clarifications regarding the Pocket Spirometer, contact the manufacturer. Consult a physician or health-care professional immediately for any health-related concerns.

WARNINGS

1. Please ensure that accurate personal details, including height, age, and ethnicity, are registered on the NxGen Spirometer App. These are essential parameters for computing predicted Pocket Spirometer values.
2. In case of signs and symptoms such as chest tightness, shortness of breath, coughing, or wheezing, contact your physician or a licensed healthcare professional immediately.
3. The Turbine is reusable. Using the reusable Turbine between different patients may lead to cross contamination.
4. The user must seal his/her lips around the mouthpiece to ensure there is no leakage of air. Any attempt to insert the mouthpiece deeper inside the mouth or to swallow the mouthpiece can cause serious choking.
5. The instrument is not suitable for use in the presence of explosive or flammable gases, flammable anesthetic mixtures, or in oxygen

rich environments.

6. Keep the device out of reach of children, infants, and pets.
7. In case of any visible physical damage to the product (once removed from its packaging), do not use the device. Contact the manufacturer immediately.
8. The device shall only be used in the operating environment specified in this manual.
9. Do not expose the device to liquids.
10. If you lose the battery latch with the required device specific information, the guarantee will no longer be valid, and the manufacturer cannot provide further support or guarantee the condition or functionality of the product.
11. NxGen Spirometer App Solutions or the Manufacturer does not hold any responsibility for damages caused to the user as a result of not following the instructions carefully.
12. The device should not be treated with toxic chemicals.
13. The device shall be stored under the conditions mentioned in this manual.
14. Do not expose the device to ambient conditions involving extreme temperatures, pressures, or humidity. This can cause a temporary loss of function. However, bringing the device back to standard operating conditions may help regain its basic safety and essential performance.
15. Do not expose the device to extreme vibrations or oscillations.

IMPORTANT NOTES

1. Keep the packaging provided by the manufacturer safe. The product must be returned in the original packaging provided by the manufacturer.
2. Please refer to the manufacturer's contact details for any complaints.
3. Manufacturer reserves the right to update th information in this user manual as required by regulatory bodies.

Use only with iOS and Android devices specified on our website:

https://www.nxgenhealthsolutions.com/compatibledevices.

INDICATIONS OF USE

NxGen Pocket Spirometer is a spirometer intended to be used by a patient under the instruction of a physician to perform basic lung function and spirometry testing for users above 5 years of age in home healthcare environment.

LIMITATIONS OF USE

1. A lung function test should only be carried out when the user is at rest (i.e. does not experience shortness of breath) and in good health, and thus in a suitable condition for the test.
2. An analysis of test results alone is not enough to diagnose a clinical condition. The results of the tests conducted by NxGen Pocket Spirometer and the diagnosis of a clinical condition can only be performed by the physician or licensed healthcare professional.

3. A correct lung function test depends on the user's ability to exhale &or inhale all air completely and as fast as possible. If these fundamental conditions are not met, then the results obtained during testing will not be accurate and the test results are "not acceptable".
4. The acceptability of a test is the responsibility of the user. Special attention should be given when testing the elderly, disabled and children. This device shall be used on a patient with mental stability.
5. The device should never be used when it is possible or probable that the validity of the results may be compromised due to external factors.

CONTRAINDICATIONS

The Pocket Spirometer should never be used when it is possible or probable that the validity of the results may be compromised due to any external factors. Some conditions may pose a relative danger to a patient or affect the validity of performance and results. These include, but are not limited to unstable cardiovascular status, unstable angina, recent myocardial infarction (within one month) or pulmonary embolism, hemoptysis of unknown origin, recent pneumothorax, thoracic, abdominal or cerebral aneurysms, recent thoracic, abdominal or eye surgery, acute disorders such as nausea or vomiting, severe respiratory distress, physical limitations, cognitive impairment, dementia, dyspnea, fatigue, lightheadedness, dizziness, severe breathing problem and coughing.

USER PROFILE

Patients above 5 years of age, more than 10kg and more than 110cm of height shall use the Pocket Spirometer. Patients under 16 years of age shall be assisted by adults.

TURBINE

The NxGen Pocket Spirometer is designed to be used with the Safey Turbine, which is reusable. Before each use, the Turbine and mouth-piece should be cleaned and disinfected according to the instructions in this User Manual.
The integrity and functionality of the Turbine are maintained by:

1. Not holding the Turbine under a jet of water or air.
2. Preventing it from coming into contact with high temperature fluids.
3. Keeping dust or foreign bodies from entering the turbine sensor to avoid malfunction and potential damage. Impurities such as hair, sputum, or threads within the turbine sensor may seriously compromise the accuracy of the measurements.
4. Properly disinfecting the reusable Turbine before each test by following the cleaning instructions mentioned in this User Manual.
5. Using only Safey Turbines. The use of third-party Turbines or mouthpieces will seriously impact the accuracy of the readings and the safety of the patient.
6. Replacing the Turbine when it reaches or exceeds its useful life. Indications that the Turbine has reached or exceeded its useful life include:
    - Visible wear and tear of the Turbine
    - Discoloration or fading of the Turbine

Discard defective Turbines as municipal waste.

CLEANING THE TURBINE

1. The patient should clean the Turbine and mouthpiece according to the instructions below: first before initial use and then after every use.
2. Remove the Turbine and Mouthpiece from their compartment on the Pocket Spirometer by pressing lightly and turning counter-clockwise. It can be helpful to push gently from underneath with one finger.
3. Rinse the Turbine and Mouthpiece by moving them back and forth in clean, tepid water (not hot). Do not place the Turbine under a direct jet of water or use compressed or high-pressure air. Instead, soak the Turbine and Mouthpiece in a container of water. Patients are instructed to clean the Turbine and Mouthpiece after removing them from the plastic film.
4. Soak the Turbine and Mouthpiece in one of the following solutions, following the respective instructions:
5. Home Detergent with 70% Isopropyl Alcohol: Immerse the Mouthpiece and Turbine in a container of water with some detergent. Move them around in the solution to remove any collected impurities. Leave the Turbine and Mouthpiece immersed in the solution for 5 minutes.
6. Remove any remaining impurities from the Turbine and Mouthpiece using a soft-bristle nylon brush.
7. Perform a subsequent rinse step by moving the Turbine and Mouthpiece back and forth in clean, tepid water (not hot). Do not place the Turbine under a direct jet of water. Instead, soak the Turbine and Mouthpiece in a container of water.
8. Shake off the excess water from the Turbine and Mouthpiece and dry them with a non-shedding wipe.

CLEANING THE POCKET SPIROMETER DEVICE

1. To clean the Pocket Spirometer component, soak a non-shedding cloth in one of the provided solutions. Before applying the cloth to the device, wring out the solution to avoid affecting the electrical components. Once the cloth is damp, use it to wipe the device clean, and then dry it with another non-shedding cloth.
2. After cleaning the Turbine/Mouthpiece and Pocket Spirometer, reinsert the Turbine into its compartment. To correctly insert the Turbine, push it into the chamber while rotating it clockwise until it fully snaps into place.

⚠ RISK OF SELF CONTAMINATION

The Turbine is marked as a single-patient use component. To avoid self-contamination, please follow these guidelines:

1. The Turbine should be properly cleaned before each use according to the cleaning instructions provided in this user manual.
2. After cleaning the Turbine, perform a visual inspection to ensure that no visible dust particles, hair, soil, or saliva remain on the Turbine. If contaminants are present, repeat the cleaning process.
3. If, during cleaning, you observe that the Turbine is damaged or has exceeded its intended use life, discard it as municipal waste and use a new Turbine.

⚠ RISK OF CROSS CONTAMINATION

Using the Turbine across multiple patients can cause cross contamination and infection related to such a use.

STORAGE, HANDLING AND MAINTENANCE

1. Handle the Pocket Spirometer carefully and store it in a clean, moisture-free environment. Always ensure that the device is free from dust, contamination, or any particles before use.
2. If the body of the device needs to be cleaned, use only a damp cloth without detergent. The batteries in the Pocket Spirometer are replaceable.
3. If the storage temperature is below 20°C, allow the device to warm up to room temperature before use.
4. If the storage temperature is above 60°C, allow the device to cool down to room temperature before use.
5. Keep the device out of the reach of infants and pets.

TROUBLESHOOTING

In case the device does not perform as intended, or if unexpected outcome is observed, perform the following steps:

1. Ensure that the Turbine is securely inserted into the device by rotating it clockwise until it fits snugly.
2. Verify that the Turbine is stationary before commencing the test.
3. Confirm that the battery has sufficient charge before initiating the test.
4. Ensure that the testing environment is free from excessive wind or bright light.
5. Make sure Bluetooth is activated on your smartphone.
6. If the device malfunctions or fails to connect via Bluetooth, replace the batteries with a new set.

CLASSIFICATION OF THE MEDICAL DEVICE

- The NxGen Pocket Spirometer is classified as Internally Powered ME Equipment, as it relies on 2 AAA batteries. The parts are Type BF Applied Parts, as indicated by 
- the corresponding symbol on the label.
- To protect the medical device from harmful ingress of water or particulate matter, the device has been tested and classified as IP22. This is also indicated on the 

- label with the appropriate symbol.
- No sterilization processes are applicable to the Pocket Spirometer. The NxGen Pocket Spirometer is not intended for use in an oxygen-rich environment. The NxGen Pocket Spirometer is classified as a non-continuous operation device, as it is used for periods of less than 4 minutes to perform tests.

IMPORTANT SAFETY WARNINGS

The NxGen Pocket Spirometer has been examined by an independent laboratory which has certified the conformity of the device to the ISO 60601-1 and guarantees the EMC requirements within the limits set ISO 60601-1-2 and ETSI's EN300328. It is a medical device Class IIA (Two a) product.

The NxGen Pocket Spirometer is constantly controlled during its production; therefore, the product conforms to the essential requirements set by the European Medical Device Regulations 2017/745.

OPERATING ENVIRONMENT

The NxGen Pocket Spirometer has been designed for use in a Home Healthcare Environment.

The NxGen Pocket Spirometer is not intended for use in an operation theatre, in the presence of flammable liquids or anesthetic gases (oxygen or nitrogen). The device is not designed to be used in direct air currents (e.g. wind); sources of heat or cold; direct sunlight or other sources of light or energy; dust, sand or near any other chemical substances.

Home Healthcare Environment
Restaurants, cafes, shops, stores, markets, schools, churches, libraries, outdoors (streets, sidewalks, parks), domiciles (residences, homes, nursing homes), train stations, bus stations, airports, hotels, hostels, pensions, museums, theatres.

ACCESS TO BLUETOOTH

Enable Bluetooth on your mobile device in order to pair with the NxGen Pocket Spirometer device. You can enable Bluetooth in your mobile device settings. Check your device manual for directions.

BLUETOOTH PROXIMITY

Ensure that the NxGen Pocket Spirometer is within Bluetooth proximity of your phone. A connection may be lost if the phone is too far away from the NxGen Pocket Spirometer.

EXPLANATION OF THE SIGNS AND SYMBOLS MARKED ON THE DEVICE LABEL

	Manufacturer Name and address.		Date of manufacturing.
CE	CE Mark – This symbol indicates that the device certifies and conforms to Medical Device Regulations 2017/745.	REF	Manufacturer's Product Reference code.
	The Symbol is used in accordance with IEC 60601-1-2:2014 (Edition 4) for products including radio transmitters and in accordance with EN 300 328.	SN	Serial Number Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Indicates the need for the user to consult the instructions for use.	EC REP	Indicates the authorized representative in the European
	Type BF Applied Part: Device that has conductive contact or medium or long-term contact with the patient in order to fulfill the intended use. Applied Part: The Safey Pocket Spirometer and the Safey Turbine are Type BF Part.	IP22	IP Classification indicates that the device is protected against solid objects over 2.5mm entering the device. It also indicates that it is protected from falling droplets of water if the device is placed at an angle of 15 Degrees from the vertical.
	Waste Electrical and Electronics goods. Do not dispose of as	LOT	Indicates the batch code so that the batch or lot can be identified.
	Non-ionizing electromagnetic radiation		

FIRMWARE & SOFTWARE UPDATE

Under normal use of the device, it is essential to keep both the NxGen Spirometer App and the Pocket Spirometer firmware updated.
When a new version of the NxGen Spirometer App is released, it will be automatically updated for Android users via Google Play and for iOS users via the Apple App Store.
When the Peak Flow Meter is connected to the NxGen Spirometer App, the app will check for available firmware updates and, if necessary, update the Pocket Spirometer firmware via Bluetooth.

NXGEN POCKET SPIROMETER MEASUREMENT PARAMETERS.

The NxGen Pocket Spirometer measures and displays PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second).
The following table contains information that can be used to correctly interpret the Pocket Spirometer values. However, it should be noted that clinical actions such as treatment or prescription of medication based on Pocket Spirometer data should only be performed by a licensed healthcare professional.

Test Parameter	Predicted % Value	Description
PEF	100% - 80%	**Good.** A reading in this zone means that your lung health is under reasonably good control.
PEF	79% - 50%	**Caution:** A reading in this zone may indicate that your respiratory airways are narrowing. Contact your doctor for further advice.
PEF	Below 50%	**Warning:** Severe airway narrowing may be occurring, and immediate action is needed. Contact your doctor immediately.
FEV1	100% - 80%	**Normal:** No action is needed.
FEV1	79% - 70%	**Mildly abnormal.**
FEV1	69% - 60%	**Moderately Abnormal:** Contact your doctor for further advice.
FEV1	Below 60%	**Severe:** Contact your doctor immediately.

IC RADIO FREQUENCY INTERFERENCE STATEMENT

This device contains license-exempt transmitter(s)/ receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

- This device may not cause interference.
- This device must accept any interference, including interference that may cause undesired operation of the device.

The products are compliant with SAR for general population/uncontrolled exposure limits in IC RSS-102 and has been tested in accordance with the measurement methods and procedures specified in IEEE 1528. The transmitter module may not be located with any other transmitter or antenna.

FCC RADIO FREQUENCY INTERFERENCE STATEMENT

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
This equipment generates uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, device may cause harmful interference to radio communications. There is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

a. Reorient or relocate the receiving antenna.
b. Increase the separation between the equipment and receiver.
c. Connect the equipment to an outlet on circuit different from that to which the receiver is connected.
d. Consult the dealer or an experienced radio/TV technician for help.

Manufacturer is not responsible for any radio or communication interference caused by use, other than specified or recommended cables and battery or by unauthorized changes or modifications to this equipment.
Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including interference that may cause undesired operation.
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance.

RF SAFETY INFORMATION

NxGen Pocket Spirometer is designed and tested safe for use in a home healthcare environment. Common consumer electronic devices that transmit in the similar frequency bands used by NxGen Pocket Spirometer (or other wireless radio frequency emitting devices such as RFID) may prevent the device or the mobile app from receiving data. This device generates, uses and radiates radio frequencies. If not installed and used according to the instructions, device can cause harmful interference to radio communication.
If NxGen Pocket Spirometer causes harmful interference to radio or television reception, which can be
determined by turning the equipment off and on, the user is encouraged to correct the interference by increasing the separation between the equipment and the receiver.
WARNING: Avoid using the NxGen Pocket Spirometer in the vicinity of radio transmitters and security systems. The wireless interference from such equipment can degrade the functionality of your Pocket Spirometer.
In case of an electromagnetic disturbance, NxGen Pocket Spirometer may not advertise an available Bluetooth connection or may disconnect if already connected to a smartphone device.
WARNING: Use of this equipment adjacent to, or stacked with, other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NxGen Pocket Spirometer, including cables specified by the manufacturer.
Otherwise, this could result in degradation of the performance of the equipment.
NxGen Pocket Spirometer should not be exposed to devices radiating high electromagnetic frequencies such as MRI, X-Ray, CT Scanner or similar equipment.

ESSENTIAL PERFORMANCE

NxGen Pocket Spirometer shall transmit on Bluetooth and shall be ready to connect to a Bluetooth receiver whenever idle.

ELECTROMAGNETIC COMPATIBILITY INFORMATION

NxGen Pocket Spirometer may be used in environments where there are other electronics functioning in the background. The Electromagnetic emissions from the surrounding NxGen Pocket Spirometer can cause interferences in the functioning of NxGen Pocket Spirometer.

NxGen Pocket Spirometer has been tested safe to be used in such an environment. NxGen Pocket Spirometer has undergone EMC testing as per IEC 60601-1-2:2014.

The device is tested for Emissions and Immunity. Under Emissions testing, it was tested as per CISPR11 (Class B, Group 2).

Under Immunity Testing, the device was tested as per IEC 61000-4-3 (Edition 3.2). There were no deviations or allowances to the tested standards.

GUIDANCE AND MANUFACTURE'S DECLARATION - ELECTROMAGNETIC EMISSIONS & ENVIRONMENT GUIDANCE

NxGen Pocket Spirometer is intended for use in the electromagnetic environment specified below.

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

The customer or the user of the device should assure that it is used in such an environment.

GUIDANCE AND MANUFACTURE'S DECLARATION - ELECTROMAGNETIC IMMUNITY

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-44	± 1 kV for input/output lines	Not Applicable	
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC	<5% U_T+(>95% dip in U_T+) for 0.5 cycle 40% U_T+ (60% dip in U_T+) for 5 cycles 70% U_T+ (30% dip in U_T+) for 25 cycles <5% U_T+(>95% dip in U_T+) for 5 s	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home environment

NOTE: U is the A.C. mains voltage prior to application of the test level.

GUIDANCE AND MANUFACTURE'S DECLARATION - ELECTROMAGNETIC IMMUNITY

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the NxGen Pocket Spirometer including cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d not applicable d= 0,175 VP 80 MHz to 1000 MHz d=0,35 VP 1000 MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	

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

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a) Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy.

To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary such as re-orienting or relocating the device.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE MOBILE COMMUNICATIONS EQUIPMENT AND NXGEN POCKET SPIROMETER

The NxGen Pocket Spirometer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the NxGen Pocket Spirometer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications.

Rated maximum outputpower of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz	80 MHz to 800 MHz d=0.175 VP	800 MHz to 2,5 GHz d= 0.35 VP
0.01	Not Applicable	0.017	0.35
0.01	Not Applicable	0.055	0.110
1	Not Applicable	0.175	0.350
10	Not Applicable	0.550	1.100
100	Not Applicable	0.750	3.500

equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

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

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

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

TECHNICAL FEATURES

Environment of use	Home Healthcare Environment
Measurement method	Infrared Interrupt using a Turbine
Power Supply	2 x 1.5V AAA Alkaline battery
Flow Accuracy	±10% error
Volume Accuracy	±3% error
Operating Conditions	Temperature: 10°C – 40°C Or 50°F – 104°F Humidity: 10% - 90% Altitude: ≤2000m
Conditions of Storage	Temperature: -10°C – 70°C Or 14°F – 158°F Humidity: 10% - 90% Altitude: ≤2000m
Atmospheric Pressure	1000 hPa – 750 hPa
Transportation Conditions	Temperature: -10°C – 70°C Or 14°F – 158°F Humidity:10%-90% Altitude: ≤2000m
Communication	Bluetooth LE
ExpectedservicelifeofThe SafeyPeakFlowMeter	2Years
WirelessFrequency	2.4Ghz
ModulationType	GFSK
MaxOutputPower	2.62dBm
WirelessQualityofService	To take a test, the device shall be connected to a Smart-phone with NxGen Spirometer App. This device uses Bluetooth Low Energy for seamless wireless communication

We are committed to the continuous improvement of our products; therefore, the information in this User Manual will be updated regularly. The Manufacturer assumes no responsibility for any loss or damage to the patient resulting from the use of the device if the instructions outlined in this User Manual are not followed.

Questions, feedback or concerns?

Contact: info@nxgenhealthsolutions.com.

“Breathe Smarter”

Contact Information

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Find the latest version of the Instructions for Use on
www.safeymedicaldevices.com/manuals

Product Name: NxGen Spirometer
Model Number: SpiroLite

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