

EasyOne Air

Operator's Manual V03

1. Preface

1.1. Revision history of the *EasyOne Air* Operator's Manual

Revision date	Version	Description
20 February 2020	V03	Revised version reflecting enhanced cybersecurity requirements
19 February 2019	V02	Updated content, alignment with the Operator's Manuals of other <i>EasyOne</i> products, includes exchanged CE mark due to the transition to a new notified body in the EU
10 April 2018	V1.1	Revised version with minor changes
27 February 2017	V01	Initial release for market launch

Revision history of the *EasyOne Air* Operator's Manual

1.2. Identification and revision of the *EasyOne Air* spirometer

This revision V03 of the *EasyOne Air* Operator's Manual applies to *EasyOne Air* with a serial number greater than 1,000,000 and with a firmware version greater than V1.13.0.

If you are in doubt whether this revision of the Operator's Manual applies to your particular *EasyOne Air* sensor, please contact the *ndd* Servicing Department.

You can find the most recent revision of this Operator's Manual on the *ndd* website.

⇒ Contact information  4
www.ndd.ch
 For the USA: www.nddmed.com

1.3. Version history of the *EasyOne Connect* PC software

A comprehensive version history of *EasyOne Connect* is available on the *ndd* website. Simply search for "version history" on the *ndd* website.

EasyOne Air requires *EasyOne Connect* V3.0 or later.

⇒ www.ndd.ch
 For the USA: www.nddmed.com

1.4. Intended use of the *EasyOne Air* spirometer

The *EasyOne Air* spirometer is intended for prescription use only to conduct diagnostic spirometry testing of adults and pediatric patients over 4 years old. The *EasyOne Air* spirometer is used by general practitioners, specialists, and health care professionals, in hospitals and clinics, in pharmacies, and in clinical settings in occupational medicine.

1.5. Intended audience of this Operator's Manual

This Operator's Manual is intended for general practitioners, specialists, and health care professionals. General practitioners, specialists, and health care professionals are expected to have working knowledge of medical procedures, practices, and terminology as required to conduct or interpret diagnostic spirometry tests.

1.6. Using this Operator's Manual

Read this Operator's Manual prior to operating *EasyOne Air* and *EasyOne Connect*.

Store the Operator's Manual in a safe and easily accessible place.

1.7. Application Notes for further information

You can find further information on specialized topics in Application Notes on the *ndd* website.

⇒ www.ndd.ch

For the USA: www.nddmed.com

1.8. Legal information

For devices sold within the European Economic Area, any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Due to continuing product innovation, specifications in this manual are subject to change without notice.

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PCL[®] is a registered trademark of Hewlett-Packard Development Company, L.P.

Microsoft and *Windows* are either registered trademarks or trademarks of *Microsoft Corporation* in the United States and/or other countries.

1.9. About electromagnetic interference

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 Class B digital apparatus complies with Industry Canada RSS standards.

⇒ For the USA, see 47 Code of Federal Regulations Sec. 15.19(a)(3)
For Canada, see RSS-Gen – General Requirements for Compliance of Radio Apparatus

1.10. Contact information



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1.11. Product registration

Registering *EasyOne Air* facilitates the handling of warranty claims.

To register *EasyOne Air*, go to the *ndd* website.

⇒ www.ndd.ch

For the USA: www.nddmed.com

1.12. Disposal



In the European Union, the product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local WEEE collection facilities to dispose of this product and otherwise observe all applicable requirements.

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2. Safety information

2.1. Classification

In this manual, safety information is classified as follows:

WARNING

WARNING . . .


. . . indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION








CAUTION . . .

. . . indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

2.2. General safety information

Personnel instruction	Make sure that all personnel are familiar with this Operator's Manual and have understood its content.
Electric Shock	<p>Patients and technicians may be exposed to dangerous voltage.</p> <p>Connect only medical-grade power supply released by the manufacturer.</p> <p>To ensure electric safety, connect only equipment, such as printers and networks, that complies with the IEC 60950-1 standard for the electrical safety of IT equipment.</p>
Patient health hazard	<p>Inadequate qualification of personnel who operate <i>EasyOne Air</i> can put the patient's health at risk.</p> <p>The patient may suffer an asthma attack or a bronchospasm while performing spirometry.</p> <p><i>EasyOne Air</i> must only be used by qualified personnel.</p> <p>Do not leave the patient unattended while performing spirometry or in between trials.</p> <p>Intended audience of this Operator's Manual  3</p>
Cross-contamination and adverse reaction	<p>After use, the disposable <i>EasyOne FlowTube</i> can be infectious.</p> <p>Provide means for proper disposal of infectious waste, according to legal requirements.</p>

False diagnosis	<p>Inadequate qualification of the personnel that operates <i>EasyOne Air</i> can lead to false results, false interpretation, and false diagnosis.</p> <p><i>EasyOne Air</i> must only be used by qualified personnel.</p> <p>Intended audience of this Operator's Manual 3</p>
Electric shock	<p>Do not open <i>EasyOne Air</i>.</p>
Fire	<p>Follow the manufacturer's recommendation for proper disposal of the battery. Only use an original battery by the manufacturer.</p> <p>Do not store <i>EasyOne Air</i> close to flammable materials like paper or textiles.</p> <p>Disposal 5</p> <p>List of order numbers and accessories for EasyOne Air 93</p>
False diagnosis	<p><i>EasyOne Air</i> may be damaged when dropped or during transport.</p> <p>Perform an incoming inspection when you first receive <i>EasyOne Air</i>. If you detect any damage, contact your <i>EasyOne Air</i> distribution partner or the <i>n dd</i> Servicing Department.</p> <p>Especially check the battery for visible damage before use.</p> <p>Do not drop <i>EasyOne Air</i>.</p> <p>If <i>EasyOne Air</i> has been dropped, check for correct operation of <i>EasyOne Air</i>.</p> <p>Checking for correct operation of EasyOne Air 86</p>
Fire due to explosive or flammable gases	<p>If used in the vicinity of flammable gases, the plastic case may catch fire and cause burn injuries to the patient.</p> <p>For preventive measures, make sure that the device is not used near flammable gases (for example, anesthetic agents).</p> <p>If not in daily use, remove the battery from <i>EasyOne Air</i> and store the battery in the original packaging.</p>
False diagnosis	<p>Environment conditions outside the range described in the specifications can cause measurement errors.</p> <p>Use <i>EasyOne Air</i> only within the defined environment specifications for temperature, humidity, and atmospheric pressure/altitude.</p> <p>Observe the limits of storage conditions.</p> <p>Setting up the EasyOne Air spirometer 23</p> <p>List of specifications for EasyOne Air 89</p> <p>Configuration of EasyOne Air 72</p> <p>List of specifications for EasyOne Air 89</p> <p>About reactivating EasyOne Air after storage 88</p>
False diagnosis	<p>Setup with wrong environment data can cause false results.</p> <p>Verify the environment data that you have set up.</p>
False diagnosis	<p>Electromagnetic fields from other devices may cause disturbances in <i>EasyOne Air</i>.</p>

False diagnosis	<p>Graphs on the display of <i>EasyOne Connect</i> may be misleading due to unclear curve scaling between different patients.</p> <p>Only conduct result interpretation of curves with a printed report.</p> <p>List of quality messages and quality grades  55</p>
Failed update	<p>An update may fail.</p> <p>Perform backups of the database of <i>EasyOne Air</i> and <i>EasyOne Connect</i> frequently.</p> <p>Performing a backup of EasyOne Air  79</p>
Data loss	<p>Data loss may occur for various other reasons and is generally unpredictable.</p> <p>Backup the database of <i>EasyOne Air</i> frequently.</p> <p>Performing a backup of EasyOne Air  79</p>
False diagnosis	<p>For unforeseen reasons, malfunction of <i>EasyOne Air</i> can lead to false results and false diagnosis.</p> <p>Perform calibration checks periodically.</p> <p>Calibration check  84</p> <p>Checking for correct operation of EasyOne Air  86</p>
Malfunction	<p>Viruses, malware, and other hazardous software on your PC may adversely affect the performance of <i>EasyOne Connect</i>.</p> <p>Install anti-virus software on your PC.</p>
Malfunction	<p>Damaged components can lead to false results.</p> <p>Make sure that no liquid penetrates into <i>EasyOne Air</i>, for example through the battery compartment or the USB port.</p>
Leakage of acids and explosion	<p>Do not connect the battery improperly.</p> <p>Do not throw the battery into fire.</p> <p>Remove the battery from the battery compartment if you do not intend to use <i>EasyOne Air</i> for a longer period.</p> <p>Avoid mechanical shock to the battery.</p> <p>If the rechargeable battery is damaged, liquids from the battery must not get into contact with skin or eyes. In case of contact with skin or eyes, rinse thoroughly with water and consult a physician.</p> <p>Only charge the battery using <i>EasyOne Air</i>, the power supply released by the manufacturer, and the cradle.</p> <p>Follow the manufacturer's recommendation for proper disposal of the battery.</p> <p>About charging the battery of EasyOne Air  86</p> <p>Disposal  5</p>
Malfunction	<p>Servicing must only be carried out by <i>n d d</i> staff or by qualified service personnel of official <i>n d d</i> distributors.</p> <p>Do not open <i>EasyOne Air</i>.</p>

Malfunction	<p>Non-original accessories and disposables, like respiratory tubes, battery, power adapter, or cables can cause malfunction.</p> <p>Only use original accessories and disposables by the manufacturer.</p> <p>List of order numbers and accessories for EasyOne Air 93</p>
False diagnosis	<p>Non-original respiratory tubes can cause measurement error and false results. You must only use <i>EasyOne FlowTube</i> respiratory tubes by the manufacturer <i>ndd</i> to assure accuracy, long-life, and full warranty coverage.</p>
Excessive heat	<p>Prolonged exposure to direct sunlight, for example in cars, or exposure to other sources of heat may cause the battery to explode.</p> <p>Do not store in places that can exceed temperatures of 50°C or 122°F.</p> <p>Remove the battery and store the battery in the original packaging.</p>
Network connection	<p>Connection of <i>EasyOne Connect</i> to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.</p> <p>Subsequent changes to the IT network could introduce new risks and require additional analysis.</p> <p>Changes to the IT network include:</p> <ul style="list-style-type: none"> • changes in the IT network configuration, • connection of additional items to the IT network, • disconnecting items from the IT network, • update of equipment connected to the IT network, and • upgrade of equipment connected to the IT network. <p>It is your responsibility to identify, analyze, evaluate, and control these risks. IEC 80001-1:2010 provides guidance to address these risks.</p>

2.3. Safety information regarding electromagnetic compatibility

Influence by HF surgical equipment	<p>Electrical devices with a high RF power output during intended use (e.g. High frequency (HF) surgical equipment) should not be operated in parallel with <i>EasyOne Air</i>.</p>
Portable wireless communications equipment	<p>Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. can affect <i>EasyOne Air</i>.</p> <p>Keep a distance of at least 30 cm (12 in) to any part of <i>EasyOne Air</i>.</p>
Increased emissions or decreased immunity	<p>Accessories, transducers, and cables other than those specified by the manufacturer or replacement parts for internal components may result in increased emissions or decreased immunity of <i>EasyOne Air</i>.</p>
Proximity to other equipment	<p><i>EasyOne Air</i> should not be used adjacent to or stacked with other equipment. Should close proximity or stacking be unavoidable, however, the configuration in which it is used needs to be watched closely to ensure that the equipment is functioning normally.</p>

Interruption of the USB connection

Electrical fast transient coupling to the USB cable or electrostatic discharge on the device may cause an interruption of the USB connection, which is indicated to the user. After reconnecting, the USB connection will work as expected. There is no harm because the data transmission is secured.

⇒ See Appendix

2.4. About requirements for connections to external devices

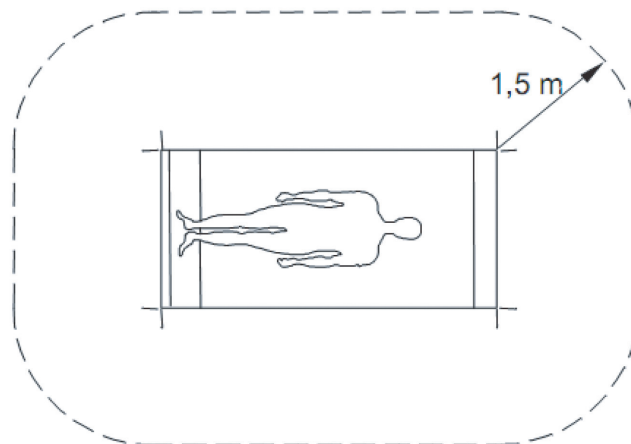
EasyOne Connect is installed on a PC or laptop, to which *EasyOne Air* is connected via the cradle or wirelessly.

The PC or laptop is not part of the equipment supplied by the manufacturer and is considered a requisite accessory that is necessary to use *EasyOne Air* with the PC software *EasyOne Connect*.

In your capacity as the operator of the medical electrical device, you are obliged to ensure that the specific, applicable safety requirements for the operation of a medical-electrical device are complied with.

The following conditions must be met:

- All equipment operated in the patient environment must meet the requirements of IEC 60601-1.
- All equipment set up outside the patient environment must meet the requirements of the applicable IEC or ISO safety standards (e.g. IEC 60950-1).



Patient environment

If devices that do not fulfill the requirements of IEC standard 60601-1 are operated in the patient environment, it must be ensured that the maximum allowed touch currents will not be exceeded.

The following limits are applicable:

- normal condition: 100 μ A
- with interruption of the (not permanently connected) protective earth conductor: 500 μ A

Appropriate measures must be taken if these limits are exceeded.













Suggestions:

- additional protective earth connection of the PC or
- isolating transformer for the PC or
- isolating transformer with built-in power outlet strip for the PC and the devices connected to it

EN 60601-1:2006 specifies the requirements for power outlet strips.

Bear in mind that the touch currents may vary with the system configuration.

2.5. List of equipment icons

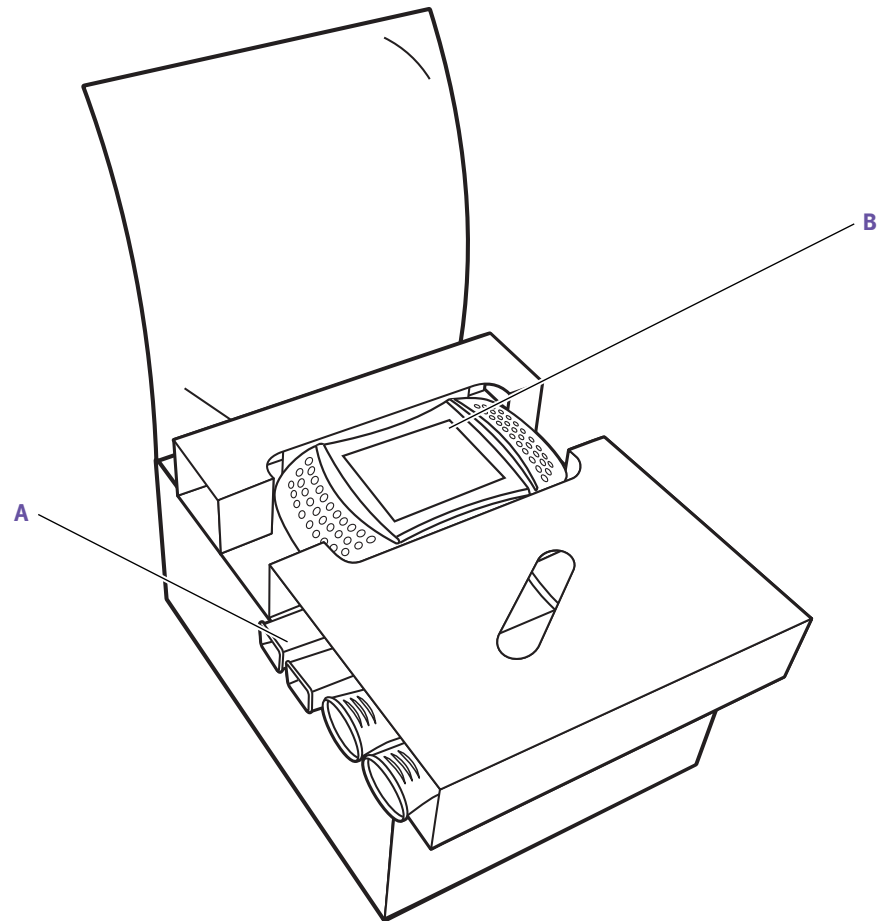
	Read usage instructions
	Follow instructions for use
	Do not reuse, i.e., single-patient use (applicable to the <i>EasyOne FlowTube</i>)
	CE mark including Notified Body Identification Number
	Compliance with additional US and Canadian safety requirements for medical electrical equipment
	Medical electric equipment that includes a radio frequency transmitter and emits non-ionizing radiation
	Manufacturer
	Date of manufacture
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	In the European Union, the product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local WEEE collection facilities to dispose of this product and otherwise observe all applicable requirements.
	Instrument classification: Type BF applied part
	Class II equipment
	For indoor use only

	Universal Serial Bus (USB 1.0/1.1, USB 2.0, max. 100 mA)—standard for data transfer, connecting devices, and battery charging, applies to cables and connectors
	Connection to PC or printer
	Battery
	Battery door open position
	Power ON/OFF (standby mode)
	Connection to power supply
	Fragile—handle with care
	Do not use if package is damaged
	Keep dry
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
	Serial number
	Batch code
	Catalog number
	Medical Device
	Authorized representative in the European Community

3. First-time setup

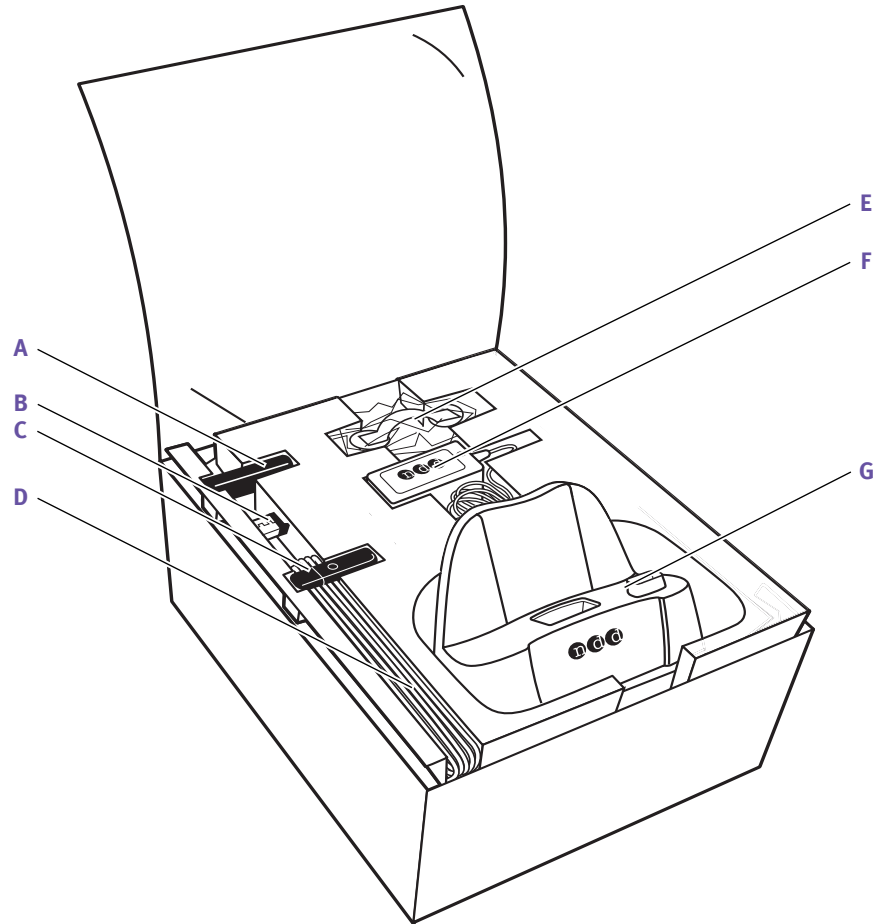
3.1. List of box contents

The box contains the following items:



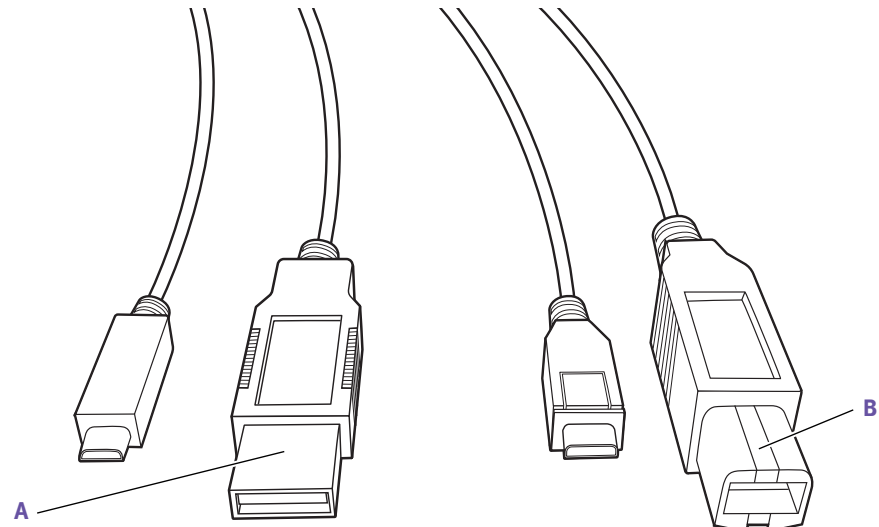
A *EasyOne FlowTube* respiratory tubes **B** *EasyOne Air* spirometer

Box contents – top inlay



- A** Battery
- B** USB Bluetooth adapter
- C** USB flash drive
- D** 2x USB cable
- E** Nose clip
- F** *ndd* power supply
- G** Cradle

Box contents – bottom inlay



A USB cable micro to type A

B USB cable micro to type B

The different USB connectors of the two USB cables

The box contains the following documents:

- The *EasyOne Air* Quick Guide
- Certificate of Stability

The USB flash drive contains the following:

- The *EasyOne Air* Operator's Manual
- The *EasyOne Air* Quick Guide
- Instructional movies
- The *EasyOne Connect* PC software

3.2. About compatible printers

EasyOne Air can print over USB when using the cradle.

To print via the cradle, the printer must support the protocols *Direct PDF*, *Postscript*, or *HP PCL 3 Enhanced*.

EasyOne Connect can use any printer that is installed on your PC. To print using *EasyOne Connect*, connect the printer to your PC and not to the cradle.

- ⇒ [Description of print settings of EasyOne Air](#)  78
- [Setting up the physical components](#)  20
- [Application Note *Printer Compatibility List*](#)
- [Application Notes for further information](#)  3

3.3. Setting up the physical components

⚠ WARNING

ELECTRIC SHOCK

Patients and technicians may be exposed to dangerous voltage.

Connect only medical-grade power supply released by the manufacturer.

To ensure electric safety, connect only equipment, such as printers and networks, that complies with the IEC 60950-1 standard for the electrical safety of IT equipment.

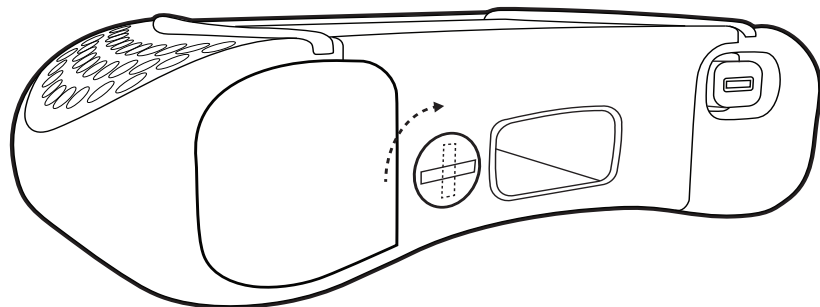
⚠ CAUTION

ELECTRIC SHOCK, PATIENT HEALTH HAZARD, AND FALSE DIAGNOSIS

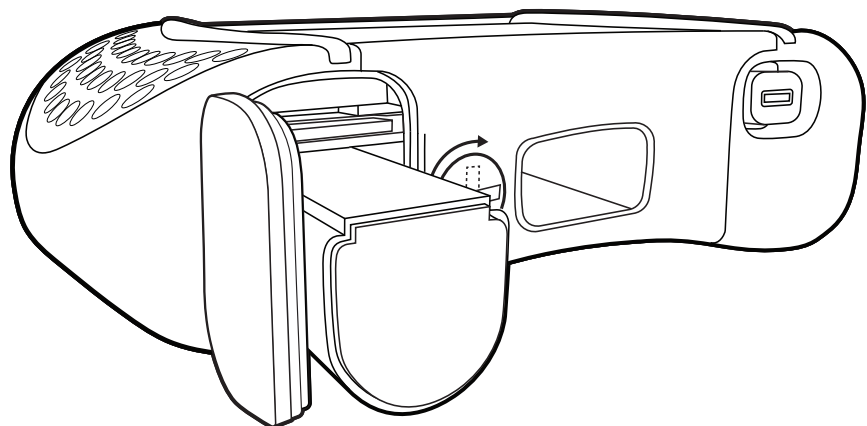
Damage to casing or broken components may expose the patient or technician to dangerous voltage. Small parts from damaged disposables can be ingested or inhaled by the patient. Measurement errors can cause false diagnosis.

Check the device and especially the battery for visible damage before on-site installation and before usage.

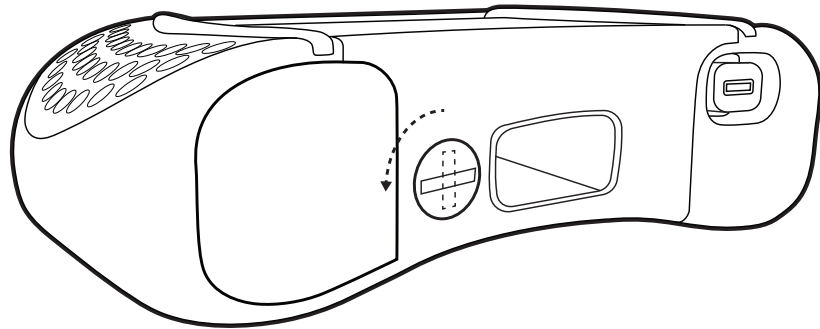
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



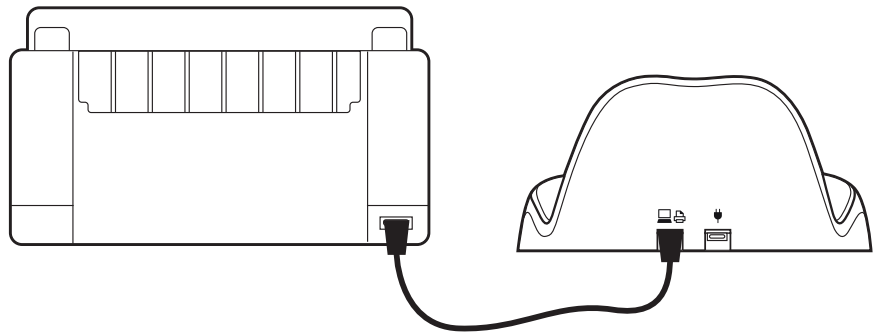
- 2 Insert the battery into the battery compartment of *EasyOne Air*.



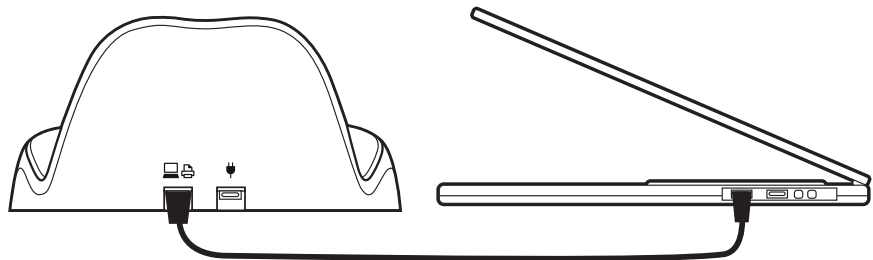
- 3** Close and lock the battery compartment by turning the lock screw counterclockwise.



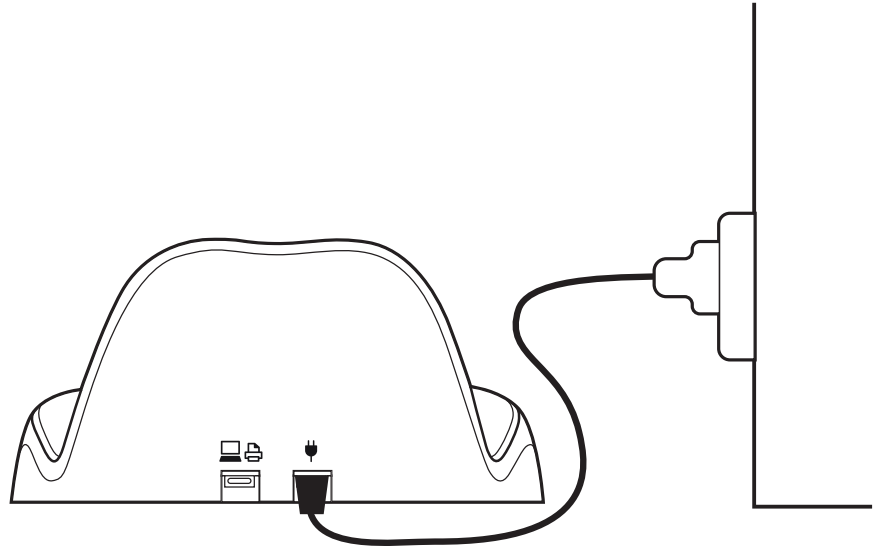
- 4** If you want to connect the cradle to a printer, do the following:
- a)** Connect the smaller plug of the *USB cable micro to type B* to the left USB port of the cradle (marked with the printer/PC icon).
 - b)** Connect the larger plug of the *USB cable micro to type B* to the corresponding USB port of your printer.



- 5** If you want to connect the cradle to a PC, do the following:
- a)** Connect the smaller plug of the *USB cable micro to type A* to the left USB port of the cradle (marked with the printer/PC icon).
 - b)** Connect the larger plug of the *USB cable micro to type A* to a USB port of your PC.
- You can connect the cradle either to a PC or to a printer. If you connect the cradle to a PC, you can use *EasyOne Connect* to print.



- 6** For charging *EasyOne Air*, always connect the *n d d* power supply:
- a)** Plug the *n d d* power supply into a power outlet, which is easily accessible for connection and disconnection.
 - b)** Connect the cable of the *n d d* power supply to the right USB port of the cradle (marked with the plug icon).



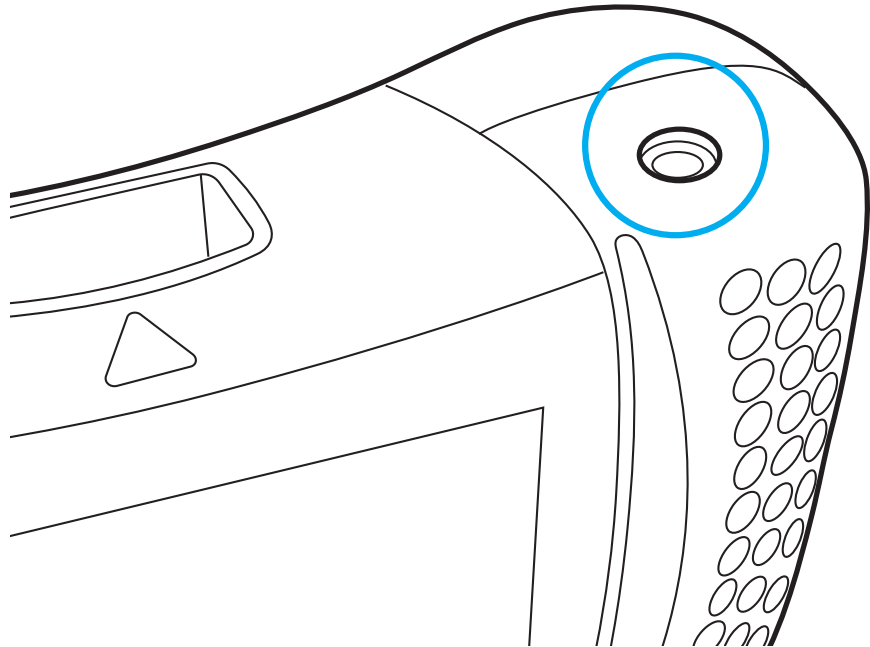
- 7** To disconnect *EasyOne Air* from power supply, do one of the following:
- a)** Unplug the *n d d* power supply from the power outlet.
 - b)** Unplug the cable from the cradle (marked with the plug icon).

⇒ [Setting up the EasyOne Air spirometer](#) 23

3.4. Setting up the *EasyOne Air* spirometer

Prerequisite

- You have set up the physical components
[Setting up the physical components](#) 20
- 1 Turn on *EasyOne Air*.



- ✓ The region selection screen is displayed.
 - 2 Select your region from the world map.
 - ✓ The language selection screen is displayed.
 - 3 Select your language from the language selection list.
 - 4 Select the date and time format.
 - 5 Enter the date and time and choose **Next**.
 - If the battery is removed for more than 8 hours, you need to reenter date and time.
- ⇒ [Configuration of EasyOne Air](#) 72
[Description of print settings of EasyOne Air](#) 78

3.5. Installing or updating the *EasyOne Connect* software on your PC

The procedure for installing *EasyOne Connect* is the same as for updating *EasyOne Connect*.

Prerequisite

- Your PC meets the system requirements for *EasyOne Connect*.
[List of system requirements for EasyOne Connect](#) 93
- Your Windows user has administrator privileges.

CAUTION

FAILED UPDATE

An update may fail unnoticed.

After performing an update, restart *EasyOne Air* and *EasyOne Connect* and perform a calibration check.

[Cybersecurity](#) 37

[Checking for correct operation of EasyOne Air](#) 86

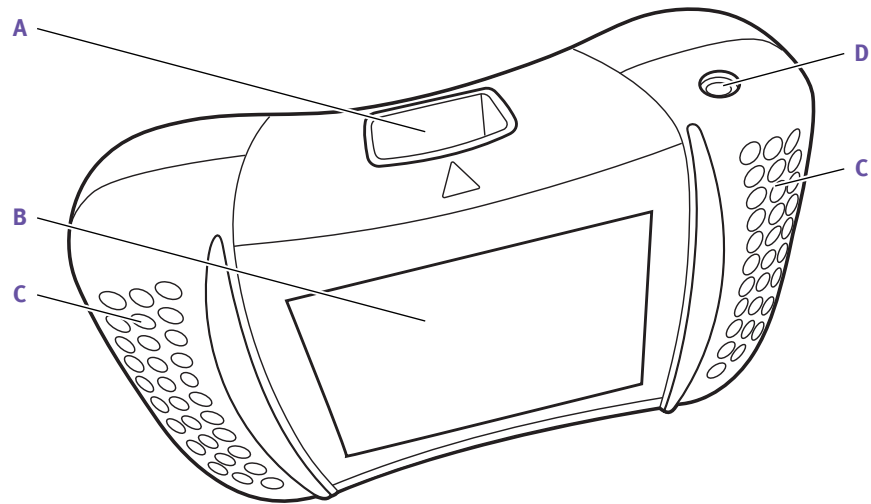
- 1 Connect the USB flash drive from the box contents to your PC.
- 2 In the folder *EasyOne Connect PC Software*, run the installer application.
- 3 Follow the on-screen instructions.

4. Introduction

4.1. Introduction to the *EasyOne Air* spirometer

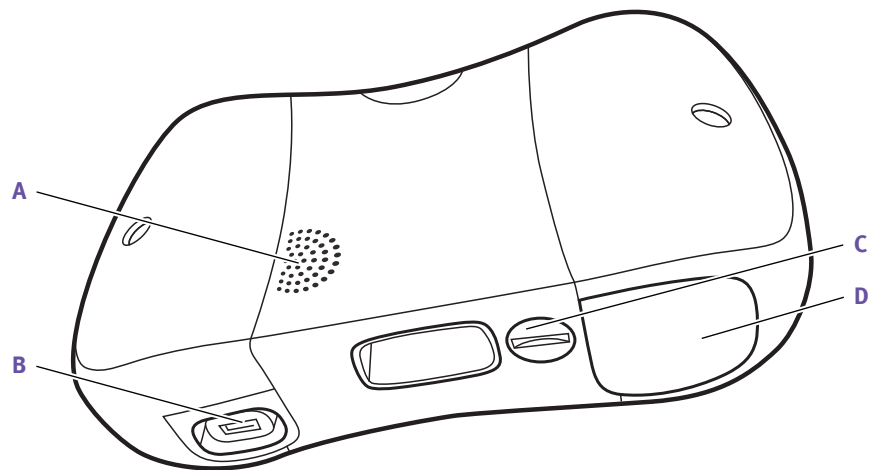
4.1.1. Overview of *EasyOne Air*

The *EasyOne Air* spirometer



- A** *EasyOne FlowTube* holder
- B** Touchscreen
- C** Handles
- D** Power button

Top-view of *EasyOne Air*



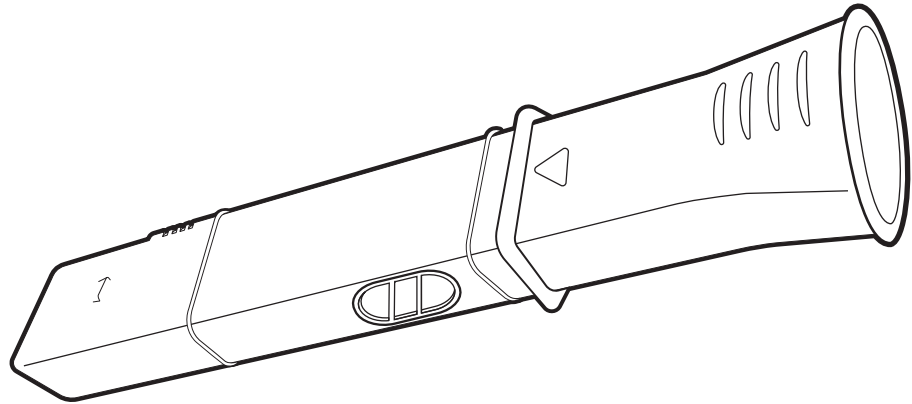
- A** Speaker
- B** USB port to connect to the cradle
- C** Lock screw for battery compartment
- D** Battery compartment

Bottom-view of *EasyOne Air*

When *EasyOne Air* is turned on and not in use, the screensaver and automatic power-off function are activated to save battery power.

You can manually switch off the device by pressing the power button.

The *EasyOne FlowTube* respiratory tube for single-patient use



- The *EasyOne FlowTube* respiratory tube

To ensure hygienic testing, the *EasyOne FlowTube* respiratory tube is a disposable for single-patient use. *EasyOne Air* recognizes the correct position of the *EasyOne FlowTube* in the *EasyOne FlowTube* holder and gives feedback if the *EasyOne FlowTube* is not placed correctly. The *EasyOne FlowTube* is designed to work accurately with the ultrasonic sensor of *EasyOne Air*. For reliable results, use only the original *ndd EasyOne FlowTube*.

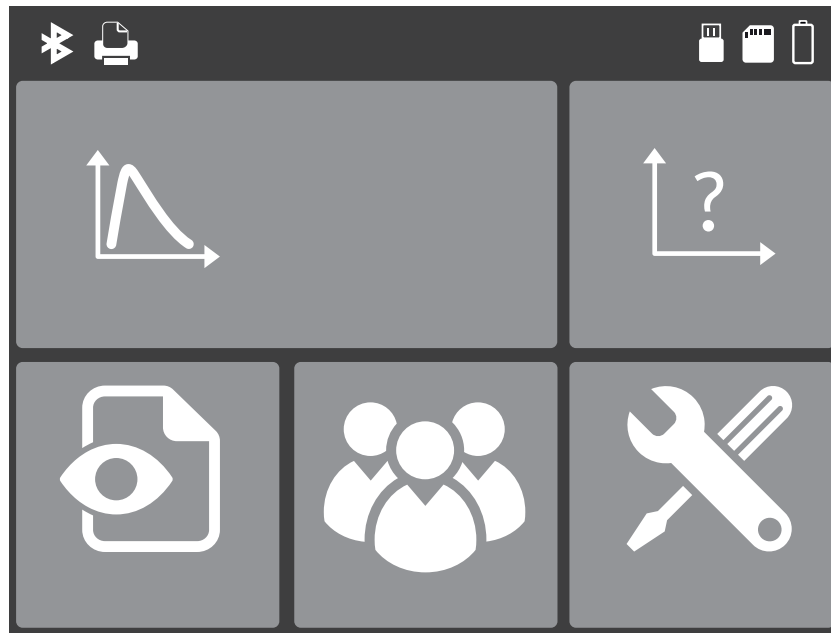
⚠ CAUTION

FALSE DIAGNOSIS

Non-original respiratory tubes can cause measurement error and false results. You must only use *EasyOne FlowTube* respiratory tubes by the manufacturer *ndd* to assure accuracy, long-life, and full warranty coverage.

4.1.2. Overview of the user interface of *EasyOne Air*

The home screen

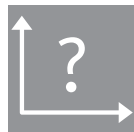


The home screen of *EasyOne Air*

The home screen displays the following icons:



This icon is a shortcut to the most commonly performed test, the FVC test.



In the more menu, you can choose from all available tests.



In the reports menu, you have access to the reports in chronological order.



In the patients menu, you have access to patient data and also to the reports, which are sorted by patient here.



In the tools menu, you can configure *EasyOne Air* and perform calibration checks and have access to settings and database functionalities.



In the orders menu, you have access to orders for spirometry tests from your EMR system.

The patients menu displays the following icons:



With the add patient button, you can add a patient to the database.



With the delete patient button, you can delete a patient from the database.



With the edit patient data button, you can edit patient data.



In the history menu, you have access to patient data and results.



With the export button, you can export patient data and results.

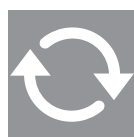
The tools menu displays the following icons:



In the settings menu, you have access to various settings that are listed in the table below.



In the calibration check menu, you can perform calibration checks to verify that *EasyOne Air* is functioning correctly.



In the update menu, you can perform firmware updates.



In the database menu, you can backup, restore and delete the patient database and configurations.



The information menu displays information about the currently installed firmware.



In the user menu, you can configure individual users and their passwords for login.

The settings menu displays the following icons:



In the device settings menu, you have access to device settings, like speaker volume, empirical or metric units settings, date and time settings, or Bluetooth settings.



In the spirometry settings menu, you have access to spirometry settings, like predicted normal values, system interpretation, or the automatic quality control setting.



In the security settings menu, you have access to device security settings such as enabling user/password authentication



In the print settings menu, you can configure the printer that is connected to the cradle.



In the factory reset menu, you can reset the configuration of *EasyOne Air* to its delivery status. However, the patient data will not be deleted.

[Configuration of EasyOne Air](#) 72

The status bar

The status bar on the top of the home screen displays basic status information.

The status bar displays the following icons:



Indicates that Bluetooth is enabled.



Indicates a connection to a printer.



Indicates a connection to a PC.



Indicates that an SD memory card is inserted.



Indicates that charging level of the battery is very low.



Indicates that *EasyOne Air* is connected to the *ndd* power supply and currently charging. But the charging level is still low.



Indicates that *EasyOne Air* is connected to the *ndd* power supply and currently charging. The charging level is at about 50%.



Indicates that *EasyOne Air* is connected to a power supply, but cannot charge.
Check whether *EasyOne Air* is connected to the *ndd* power supply or to a different USB power source.
Only use the *ndd* power supply.



Indicates that the health of the battery is low.
Consider replacing the battery.

The < Back button and the home button



< Back button

In any menu, the < Back button is displayed at the bottom left and the home button at the bottom middle of the touchscreen.

4.2. Overview of features of the *EasyOne Connect* software

EasyOne Connect offers the same features as *EasyOne Air* to perform spirometry, to work with patient data, or to evaluate results, as well as some additional features.

EasyOne Connect is especially helpful to work with patient data and to evaluate results because you can use a full-size PC monitor and keyboard.

If you want to perform spirometry with *EasyOne Air* stand-alone, for example off-site, *EasyOne Connect* enables you to enter all relevant patient data beforehand and synchronize that data to *EasyOne Air*. Then, after you return from performing spirometry, you can synchronize the test results back to *EasyOne Connect* and evaluate the test results, print reports, and archive the data on your PC.

To work efficiently with patient data and orders for spirometry tests, you can link up *EasyOne Connect* with your EMR system.

⇒ [About connectivity and data exchange](#)  36

4.3. List of terms and definitions

Term	Definition
test	<p>Short for spirometry test.</p> <p>A test is an examination that is defined by the breathing maneuver that the patient performs and by the parameters that are calculated from the measured data.</p> <p>For each test, a report exists.</p>
trial	<p>The performing of one breathing maneuver.</p> <p>A trial is part of a test.</p>
parameter	<p>For each trial, parameters are calculated from its curve.</p>
post	<p>Short for post bronchodilator.</p> <p>A post is performed after the patient is treated with a bronchodilator. Prior to the medication, the same test has been performed to be compared with the post.</p>

Terms and definitions

4.4. List of tests and parameters

The following tables give an overview of the relevant tests and parameters. The parameters are established in the professional literature and constitute the results of testing.

Test	Test description	Available parameters
FVC	Forced expiratory vital capacity test	BEV, EOTV, FEF ₁₀ , FEF ₂₅ , FEF ₂₅₋₇₅ , FEF ₂₅₋₇₅ /FVC, FEF ₄₀ , FEF ₅₀ , FEF ₅₀ /FVC, FEF ₆₀ , FEF ₇₅ , FEF ₈₀ , FET, FET ₂₅₋₇₅ , FEV _{.25} , FEV _{.5} , FEV _{.5} /FVC, FEV _{.75} , FEV _{.75} /FVC, FEV ₁ , FEV ₁ /FEV ₆ , FEV ₁ /FVC, FEV ₃ , FEV ₃ /FVC, FEV ₆ , FVC, FVC ₆ , MEF ₂₀ , MEF ₂₅ , MEF ₄₀ , MEF ₅₀ , MEF ₆₀ , MEF ₇₅ , MEF ₉₀ , MMEF, PEF, PEFT, t ₀
FVL	Flow volume loop test	BEV, EOTV, FEF ₁₀ , FEF ₂₅ , FEF ₂₅₋₇₅ , FEF ₂₅₋₇₅ /FVC, FEF ₄₀ , FEF ₅₀ , FEF ₅₀ /FVC, FEF ₆₀ , FEF ₇₅ , FEF ₈₀ , FET, FET ₂₅₋₇₅ , FEV _{.25} , FEV _{.5} , FEV _{.5} /FVC, FEV _{.75} , FEV _{.75} /FVC, FEV ₁ , FEV ₁ /FEV ₆ , FEV ₁ /FVC, FEV ₃ , FEV ₃ /FVC, FEV ₆ , FIF ₂₅ , FIF ₅₀ , FIF ₅₀ /FEV ₅₀ , FIF ₇₅ , FIV _{.25} , FIV _{.5} , FIV ₁ , FVC, FVC ₆ , MEF ₂₀ , MEF ₂₅ , MEF ₄₀ , MEF ₅₀ , MEF ₆₀ , MEF ₇₅ , MEF ₉₀ , MIF ₂₅ , MIF ₅₀ , MIF ₇₅ , MMEF, PEF, PEFT, t ₀
MVV	Maximum voluntary ventilation test	MVV, MVV ₆ , MVV _{time} , Rf
SVC	Slow vital capacity test	ERV, IC, IRV, Rf, VC, VC _{ex} , VC _{in} , VC _{max} , VT

☐ Tests

Parameter	Parameter description	Unit
BEV	Back extrapolated volume	L
BTPS _{ex}	BTPS factor used for expiration	–
BTPS _{in}	BTPS factor used for inspiration	–
EOTV	End of test volume	L
ERV	Expiratory reserve volume	L
FEF ₁₀	Forced expiratory flow at 10% of vital capacity—synonymous with MEF ₉₀	L/s
FEF ₂₅	Forced expiratory flow at 25% of vital capacity—synonymous with MEF ₇₅	L/s
FEF ₂₅₋₇₅	Forced expiratory flow from 25% to 75% of vital capacity—synonymous with MMEF	L/s
FEF ₂₅₋₇₅ /FVC	Ratio of FEF ₂₅₋₇₅ to FVC	1/s
FEF ₄₀	Forced expiratory flow at 40% of vital capacity—synonymous with MEF ₆₀	L/s
FEF ₅₀	Forced expiratory flow at 50% of vital capacity—synonymous with MEF ₅₀	L/s
FEF ₅₀ /FVC	Ratio of FEF ₅₀ to FVC	1/s
FEF ₆₀	Forced expiratory flow at 60% of vital capacity—synonymous with MEF ₄₀	L/s
FEF ₇₅	Forced expiratory flow at 75% of vital capacity—synonymous with MEF ₂₅	L/s
FEF ₈₀	Forced expiratory flow at 80% of vital capacity—synonymous with MEF ₂₀	L/s
FET	Forced expiratory time	s
FET ₂₅₋₇₅	Forced expiratory time between FEF ₂₅ and FEF ₇₅	s
FEV _{.25}	Forced expiratory volume after 0.25 seconds	L
FEV _{.5}	Forced expiratory volume after 0.5 seconds	L

☐ Parameters

Parameter	Parameter description	Unit
FEV ₅ /FVC	Ratio of FEV ₅ to FVC	–
FEV _{.75}	Forced expiratory volume after 0.75 seconds	L
FEV _{.75} /FVC	Ratio of FEV _{.75} to FVC	–
FEV ₁	Forced expiratory volume after 1 second	L
FEV ₁ /FEV ₆	Ratio of FEV ₁ to FEV ₆	–
FEV ₁ /FIV ₁	Ratio of FEV ₁ to FIV ₁	–
FEV ₁ /FVC	Ratio of FEV ₁ to FVC	–
FEV ₁ /VC	Ratio of FEV ₁ to VC (VC taken from SVC test)	–
FEV ₃	Forced expiratory volume after 3 seconds	L
FEV ₃ /FVC	Ratio of FEV ₃ to FVC	–
FEV ₆	Forced expiratory volume after 6 seconds	L
FIF ₂₅	Forced inspiratory flow at 25% of vital capacity—synonymous with MIF ₇₅	L/s
FIF ₅₀	Forced inspiratory flow at 50% of vital capacity—synonymous with MIF ₅₀	L/s
FIF ₅₀ /FEF ₅₀	Ratio of FIF ₅₀ to FEF ₅₀	–
FIF ₇₅	Forced inspiratory flow at 75% of vital capacity—synonymous with MIF ₂₅	L/s
FIV _{.25}	Forced inspiratory volume after 0.25 seconds	L
FIV _{.5}	Forced inspiratory volume after 0.5 seconds	L
FIV ₁	Forced inspiratory volume after 1 second	L
FIVC	Forced inspiratory vital capacity	L
FVC	Forced expiratory vital capacity	L
FVC ₆	Forced expiratory vital capacity after 6 seconds	L
IC	Inspiratory capacity from end of tidal breathing	L
IRV	Inspiratory reserve volume	L
LCI _{ao}	Lung clearance index at airway opening	–
Lung Age	calculated age of the average healthy individual who would perform similar to tested patient on spirometry	Years
MEF ₂₀	Mean expiratory flow at 80% of vital capacity—synonymous with FEF ₈₀	L/s
MEF ₂₅	Mean expiratory flow at 75% of vital capacity—synonymous with FEF ₇₅	L/s
MEF ₄₀	Mean expiratory flow at 60% of vital capacity—synonymous with FEF ₆₀	L/s
MEF ₅₀	Mean expiratory flow at 50% of vital capacity—synonymous with FEF ₅₀	L/s
MEF ₆₀	Mean expiratory flow at 40% of vital capacity—synonymous with FEF ₄₀	L/s
MEF ₇₅	Mean expiratory flow at 25% of vital capacity—synonymous with FEF ₂₅	L/s
MEF ₉₀	Mean expiratory flow at 10% of vital capacity—synonymous with FEF ₁₀	L/s
MIF ₂₅	Mean inspiratory flow at 75% of vital capacity—synonymous with FIF ₇₅	L/s
MIF ₅₀	Mean inspiratory flow at 50% of vital capacity—synonymous with FIF ₅₀	L/s
MIF ₇₅	Mean inspiratory flow at 25% of vital capacity—synonymous with FIF ₂₅	L/s
MMEF	Mean mid-expiratory flow—synonymous with FEF ₂₅₋₇₅	L/s
MVV	Maximum voluntary ventilation	L/min

 Parameters

Parameter	Parameter description	Unit
MVV ₆	Maximum voluntary ventilation for 6 seconds	L/min
MVV _{time}	Duration of the trial in seconds	s
PEF	Peak expiratory flow	L/s
PEFT	Time to peak flow	s
PIF	Peak inspiratory flow	L/s
Rf	Respiratory frequency	1/min
t ₀	Back-extrapolated start time of the trial	s
VC	Vital capacity, from slow expiration	L
VC _{ex}	Expiratory vital capacity, from slow expiration	L
VC _{in}	Inspiratory vital capacity, from slow inspiration	L
VC _{max}	Highest VC value from all trials of one test	L
VT	Tidal volume	L

Parameters

4.5. List of abbreviations

Abbreviation	Full form
ATPS	Ambient temperature pressure saturated—refers to environment conditions, can be converted to BTPS
ATS	American Thoracic Society
BTPS	Body temperature pressure saturated—refers to converted environment conditions, can be converted from ATPS
EHR	Electronic health record—synonymous to EMR, used in EMR systems
EMC	Electromagnetic compatibility
EMR	Electronic medical record—synonymous to EHR, used in EMR systems
EMR system	Computer software for handling electronic medical records
ERS	European Respiratory Society
GDT	Gerätedatentransfer—German EMR standard
GLI	Global Lung Function Initiative
GOLD	Global Initiative for Chronic Obstructive Lung Disease
HIPAA	Health Insurance Portability and Accountability Act
HIS	Hospital information system
HL7	Health Level 7—international EMR standard
LLN	Lower limit of normal
NIOSH	National Institute for Occupational Safety and Health
NLHEP	National Lung Health Education Program
OSHA	Occupational Safety and Health Administration
SD	Standard deviation
SEE	Standard error of the estimate
SSA	Social Security Administration
USB	Universal Serial Bus (USB)—standard for data transfer, connecting devices, and battery charging, applies to cables and connectors

Abbreviations

4.6. About sources for predicted normal values

The available predicted normal values for *EasyOne Air* are updated as required through software updates.

You can find the currently used sources for predicted normal values in the document below.

- ⇒ [Application Note *Reference Predicted Normal Values*](#)
 - [Application Notes for further information](#) 3
 - [Installing or updating the EasyOne Connect software on your PC](#) 24

4.7. About connectivity and data exchange

For data exchange, you can connect *EasyOne* products with the *EasyOne Connect* PC software. In addition, you can interface *EasyOne Connect* and *EasyOne Pro/LAB* with the information system in your hospital or practice.

For further information, please visit the *n dd* website.

- ⇒ www.ndd.ch
For the USA: www.nddmed.com

5. Cybersecurity

EasyOne Air is protected against cyberattacks. However, to maintain security, you must follow the guidelines that are laid out in this chapter.

5.1. About cybersecurity

EasyOne Connect can be installed on regular *Windows* PCs. The operating institution is responsible for installing an antivirus software and a firewall on the PC, for installing critical *Windows* updates regularly, and for keeping the PC otherwise secure. *EasyOne Connect* does not run with *Windows* administrator privileges.

EasyOne Air itself is not directly connected to the network.

EasyOne Connect can be connected to a network for various purposes, but can also function stand-alone without network access. The file-based database is encrypted. Alternatively, it is also possible to connect *EasyOne Connect* to an SQL-server-based database.

5.2. About password policies and password expiration

You can use a combination of user name and password in order to control access to *EasyOne Connect*. It is the responsibility of the operating institution to apply the appropriate password policies (for example, password strength and password renewal intervals).

EasyOne Connect includes functionality for password strength and password expiration requirements. In case user handling is deactivated a default password is used to restrict access to certain functionalities. To comply with security policies, the manufacturer recommends that you activate user handling.

Follow these general recommendations on password strength in case your institution does not have a more specific policy:

- Use a minimum password length of 8 characters.
- Include lower-case and upper-case alphabetic characters, numbers and symbols.
- Generate passwords randomly where feasible.

Follow this general recommendation for a password renewal interval in case your institution does not have a more specific policy:

- Passwords should be renewed after 90 days.

⇒ [About user handling and the default password of EasyOne Connect](#)  82

5.3. About periodical software updates and patches

For secure use, perform software updates regularly and antivirus updates frequently (weekly).

Contact your *EasyOne* distribution partner in order to receive regular notifications of software updates, or visit the *ndd* website for information on updates.

- ⇒ [Installing or updating the EasyOne Connect software on your PC](#) 24
- [About performing a firmware update with EasyOne Air](#) 78
- [Contact information](#) 4

5.4. About backups

For EasyOne Air data backup, refer to the [Application Note *Data Backup Deletion and Restoration in EasyOne Air*](#) on the *ndd* website.

- ⇒ [Application Notes for further information](#) 3

5.5. Escalating in case of a security breach

In case a security breach has been detected in your institution, do the following:

- 1 Immediately disconnect the PC that *EasyOne Connect* is installed on from the network.
 - ☐ After you have disconnected the PC that *EasyOne Connect* is installed on from the network, you can no longer access an SQL server, but you can work temporarily with a file-based database that is stored locally on your PC.
- 2 Follow all other necessary procedures for a security breach as specified by your institution's IT department.
- 3 If you are uncertain whether *EasyOne Air* has been compromised, contact the *ndd* Servicing Department.

5.6. Dealing with a lost or stolen *EasyOne Air* or PC

In case *EasyOne Air* or the PC that *EasyOne Connect* is installed on has been lost or stolen, do the following:

Prerequisite

- The manufacturer strongly recommends that you activate user handling in order to prevent unauthorized persons from accessing the data stored on *EasyOne Air* or in *EasyOne Connect*.

[About the user menu of *EasyOne Air*](#) 81

[About user handling and the default password of *EasyOne Connect*](#) 82

- 1 Immediately report the loss or theft of *EasyOne Air* or of the PC that *EasyOne Connect* is installed on to the *n dd* Servicing Department.
 - ✓ The *n dd* Servicing Department will ensure that your *EasyOne Air* or your installation of *EasyOne Connect* is not unlocked unintentionally by *n dd* staff for anyone else but you.

⇒ [Contact information](#) 4




5.7. Using *EasyOne Air* securely – general guidelines







The internal database of *EasyOne Air* is encrypted. However, the manufacturer strongly recommends that you follow these guidelines at all times, especially in order to be compliant to the *Health Insurance Portability and Accountability Act* (HIPAA)




EasyOne Air enforces strong password rules, laid out in step **1**, due to cybersecurity requirements.



■ To activate user handling for *EasyOne Air*

- 1 To support enhanced cybersecurity requirements, *EasyOne Air* can enforce the following strong password rules. Password must contain:
 - At least 8 characters
 - 1 lower-case letter
 - 1 upper-case letter
 - 1 number or 1 special character

☐ This can be enabled in  >  > 

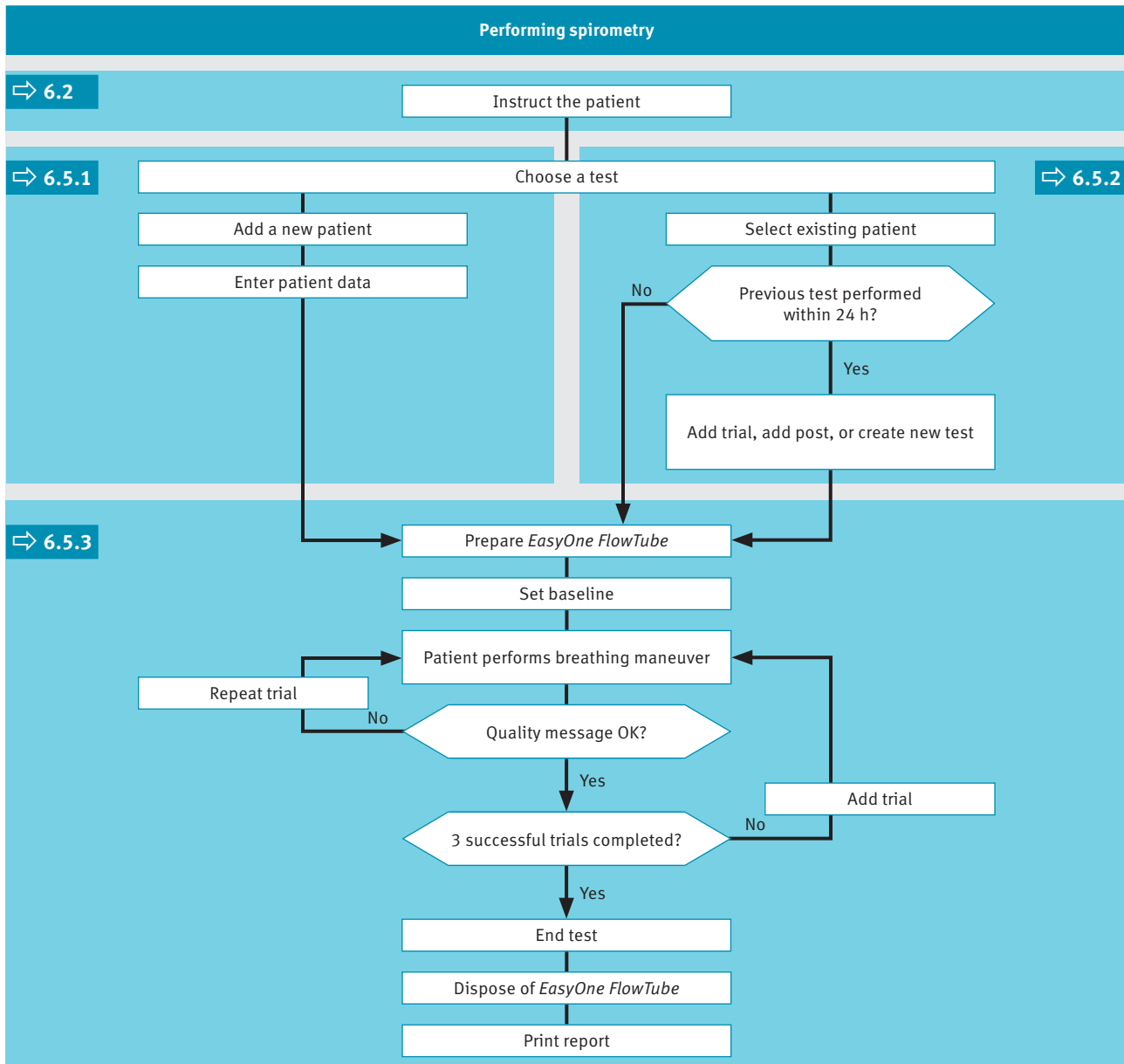
☐ Please exercise caution when enabling this setting, as a lost password cannot be recovered.
 - 2 Activate user handling if unauthorized persons might have physical access to *EasyOne Air*. To activate user handling, do the following:
 - a) Choose  >  > .
 - b) Enter the default user ID *admin*, the default password *8005*, and choose **Login**.
 - c) To add a user, choose  >  > .
 - d) Fill out the following fields: **First Name**, **Last Name**, **User ID**, **Password**, and **UserGroup**. Use the password that you have chosen in step 1.
 - e) Optionally, fill out the other fields.
 - f) Choose **OK**.

✓ User handling is activated. Now, users must log in to use *EasyOne Air*.
 - 3 To prevent unauthorized access when *EasyOne Air* is unattended, specify a time period for automatic power-off:
 - a) Choose  >  > .
 - b) In the **Power-off after** field, specify the time period by using the slider.

✓ After the time period that you have set, *EasyOne Air* powers off and users must log in again.
 - 4 Only use network file transfer (pdf, HL7, XML, etc.) in trusted and secured network environments.
 - 5 In case you use an SQL-server-based database, it is the operating institution's responsibility to use appropriate measures to protect the SQL server as well as the communication channel.
 - ☐ Generally, SQL servers provide functionality for encrypted SSL connections.
 - ☐ The manufacturer does not take responsibility for the cybersecurity of the communication channel or the data storage on the SQL server. The SQL server is considered a third-party product and not within the scope of *EasyOne Air*.
- ⇒ [Description of security settings of EasyOne Air](#)  77
[Configuration of EasyOne Connect](#)  82

6. Performing spirometry

6.1. Overview of the spirometry workflow



General spirometry workflow using *EasyOne Air* stand-alone

⚠ CAUTION**ELECTRIC SHOCK, PATIENT HEALTH HAZARD, AND FALSE DIAGNOSIS**

Damage to casing or broken components may expose the patient or technician to dangerous voltage. Small parts from damaged disposables can be ingested or inhaled by the patient. Measurement errors can cause false diagnosis.

Check the device and especially the battery for visible damage before on-site installation and before usage.

6.2. About preparation of spirometry and instructions for the patient

Preparing the patient

Prepare the patient for testing: The patient should loosen tight clothing, remove dentures, and relax. The patient may sit or stand. If the patient is standing, perform testing in an area free of sharp table edges or counter edges, or have a chair available as there is a slight possibility that the patient faints during the strenuous breathing maneuver of the spirometry test.

Instructing the correct usage of *EasyOne FlowTube*

The patient should seal the lips around the *EasyOne FlowTube* so that there are no leaks. Make sure that the patient is not blocking the opening of the *EasyOne FlowTube* with the teeth or tongue and does not bite down excessively.

Different breathing maneuvers for different tests

This chapter describes the overall process of performing spirometry with the FVC test as an example. The different spirometry tests differ only in the breathing maneuver that the patient has to perform. The overall process of performing spirometry is the same.

Therefore, to perform the other spirometry tests, familiarize yourself with the other breathing maneuvers.

Carefully watch the patient

It is your responsibility to watch the patient for signs of distress. After several trials, let the patient take a break. If it is not possible to obtain an adequate number of good trials, even after repeated attempts, you should let the patient rest, depending on how the patient feels, or stop the measurement entirely. After a break, you can still pick up a test and add trials, or print the report.

Animation program for children

If you use *EasyOne Connect* in combination with *EasyOne Air*, an animation program for children is available. The animation is available for the FVC test, the FVL test and the SVC test. You can choose between three animations: balloon, cake, and monkey.

When the animation program is activated, the manufacturer recommends disabling the manual test stop and working with the automatic test stop. You can configure manual or automatic test stop under **Utilities > Configuration > Test > General > Test Procedure**.

- ⇒ [Breathing maneuvers for all available tests](#) 58
- [Avoiding contamination while performing spirometry](#) 62

6.3. About quality messages for trials and quality grades for tests

Quality messages

To obtain reliable results, an acceptable quality of the trials is necessary. The quality of a trial depends on cooperation of the patient and this, in turn, depends on the quality of your instructions. To facilitate giving good instructions to the patient, an automatic quality control function displays feedback prompts. After each trial, a message on the screen informs you whether the trial is acceptable or not. If the trial is not acceptable, the message will guide you on how to coach the patient to do better.

When you see the **Test complete** message, you do not need to conduct further trials.

Quality grades

A quality grading from *A* to *F* is displayed at the end of the test. It provides information on the overall quality of the test. You should keep performing trials with the patient until the quality grade is an *A* or a *B*. Only after several trials, when the patient is exhausted and if the patient has already had a break, a quality grade *C* is sufficient.

- ⇒ [List of quality messages and quality grades](#) 55

6.4. About posts and bronchodilation



A test and a post are performed together to determine the response to bronchodilating asthma medication.

After performing an FVC test or an FVL test, the patient is treated with a bronchodilator. Approximately 10 to 20 minutes after the medication, when the bronchodilator shows effect, the test is repeated as a post. The results of the previous test and the post are then compared on the result screen and on the test protocol. Posts can only be added to an existing test within 24 hours.

6.5. Performing spirometry using *EasyOne Air* stand-alone

6.5.1. Choosing a test and adding a new patient

If you wish to register the patient to be tested immediately before conducting the test, you can start by manually adding a new patient.

- 1 If you want to perform an FVC test, choose .
 - ✓ The patient selection list is displayed.
- 2 If you want to perform any other test, do the following:
 - a) Choose .
 - b) Choose one of the test icons.
- 3 Select **<Add Patient>**.
 - ✓ A dialog is displayed.
 - ☐ The dialog consists of several steps.
- 4 **CAUTION!** False diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results. Enter patient data meticulously. Double-check that you have entered the patient data correctly.

In each step, enter the requested data and choose **Next >**.

- 5 In the last step, choose **Finish**.
- 6 Optionally, enter additional information about the patient.

⇒ [Performing a complete test using EasyOne Air stand-alone](#)  46

6.5.2. Choosing a test and selecting an existing patient



If you test a patient that you have tested before or if you have transferred patient data onto *EasyOne Air* from *EasyOne Connect* on your PC, start by selecting an existing patient.

Prerequisites

- Previously, you have manually added the patient to *EasyOne Air*.
- Or, you have transferred patient data onto *EasyOne Air* from *EasyOne Connect* on your PC.

[Working with patient data and reports on EasyOne Air](#) 64

[Copying patient data between EasyOne Air and EasyOne Connect](#) 69

- 1 If you want to perform an FVC test, choose .
 - ✓ The patient selection list is displayed.
 - 2 If you want to perform any other test, do the following:
 - a) Choose .
 - b) Choose one of the test icons.
 - ✓ The patient selection list is displayed.
 - 3 Select a patient.
 - ✓ If the patient has performed a test within the previous 24 hours, the question window is displayed. Proceed with step 4.
 - If the patient has not performed a test before or not within the previous 24 hours, step 4 does not apply.
 - 4 If the question window is displayed, do one of the following:
 - a) To add a trial to the existing test, choose **Add Trial**.
 - b) To add a post to the existing test after administering a bronchodilator, choose **Add Post**.
 - c) To create a new test that is unrelated to the existing test, choose **Create new**.
- ⇒ [Performing a complete test using EasyOne Air stand-alone](#) 46

6.5.3. Performing a complete test using *EasyOne Air* stand-alone

Required materials

- A new *EasyOne FlowTube* for each patient
- For an FVL test, an MVV test, or an SVC test, a nose clip is required.

Prerequisites

- For the FVL test, the MVV test, and the SVC test, you have entered the environment temperature within 1°C or 1.8°F accuracy.
- You have chosen a test and added a new patient.
- Or you have chosen a test and selected an existing patient.
- You are wearing disposable gloves.
- You have instructed the patient on how to perform the test before you start with the test.

[Choosing a test and adding a new patient](#) 44

[Choosing a test and selecting an existing patient](#) 45

[Specific lung function tests for the USA](#) 99

⚠ WARNING

PATIENT CROSS-CONTAMINATION

If you reuse the *EasyOne FlowTube*, contamination from an infected patient can be deposited on the *EasyOne FlowTube*. The contamination from an infected patient can later be passed on to the next patient who is tested.

You cannot clean or disinfect the *EasyOne FlowTube* in any way. The *EasyOne FlowTube* is for single-patient use only.

Always replace the *EasyOne FlowTube* with a new one between patients or when performing spirometry on yourself.

Only use an original *EasyOne FlowTube* by the manufacturer.

PATIENT HEALTH HAZARD

Performing spirometry can cause an asthma attack or bronchospasm.

If the patient is on medication, check the contraindications for the medication.

⚠ CAUTION

PATIENT HEALTH HAZARD

Pulmonary function tests require maximum effort on the part of the patient and may lead to dizziness.

Make sure the patient cannot be injured by objects in the vicinity if the patient falls.

Watch the patient for signs of dizziness and support the patient if necessary.

Do not leave the patient unattended during a test.

The *EasyOne FlowTube* is a single-patient-use disposable and hygienically packaged. Visually check the wrapper of a new *EasyOne FlowTube* for defects.

If the wrapper of the *EasyOne FlowTube* has a defect, discard the *EasyOne FlowTube*, take another *EasyOne FlowTube*, and visually check the wrapper of the new *EasyOne FlowTube* again for defects.

Visually check the *EasyOne FlowTube* for defects before use and between trials.

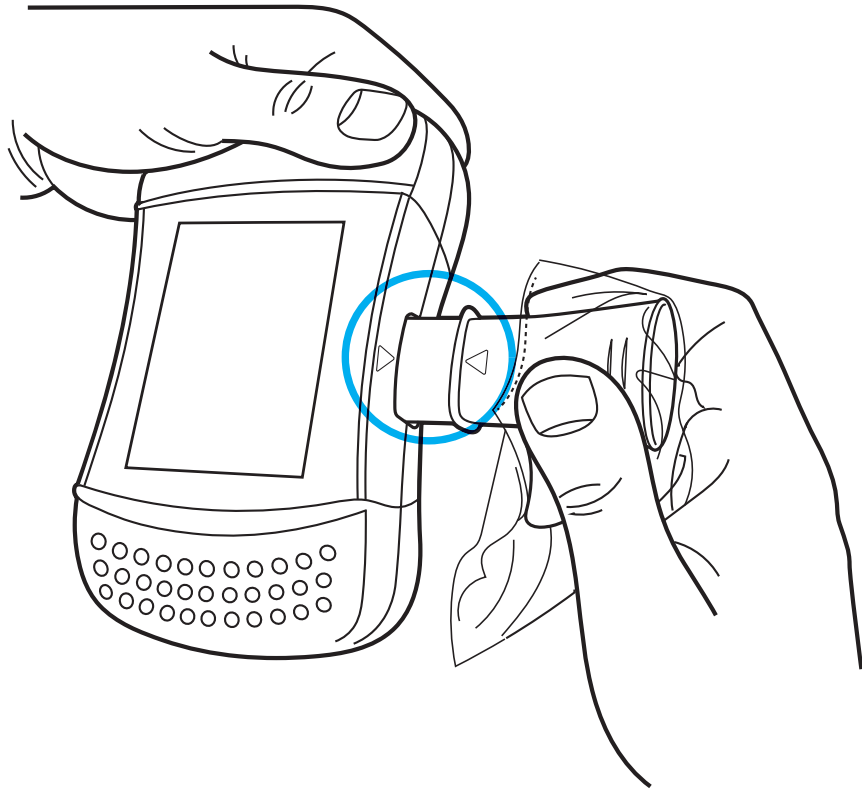
Before you use *EasyOne Air* with the patient, make sure that there are no obvious or wet residues on *EasyOne Air* from prior cleaning.

■ To prepare the test

- 1 Partly unwrap the *EasyOne FlowTube*.
 - ☐ For hygiene reasons, grip the partly unwrapped *EasyOne FlowTube* only with the wrapper at the mouthpiece. Do not touch the *EasyOne FlowTube*.



- 2 Fully insert the *EasyOne FlowTube* into the *EasyOne FlowTube* holder as depicted below, but keep the partly unwrapped wrapper on the mouthpiece of the *EasyOne FlowTube*.
 - ☐ The shape of the *EasyOne FlowTube* and the *EasyOne FlowTube* holder guide the orientation of the *EasyOne FlowTube*. You can only insert the *EasyOne FlowTube* fully if it is positioned correctly.
 - ☐ When you insert the *EasyOne FlowTube*, avoid direct sunlight as it can interfere with the automatic recognition of the *EasyOne FlowTube*.



- 3 Choose **Start test**.
 - ✓ The sensor starts buzzing and the user action required window is displayed for setting the baseline.

- 4 To set the baseline, seal off one end of the *EasyOne FlowTube* with the wrapper to avoid air flow.



- 5 Choose **OK**.
 - ✓ The **Please wait...** message is displayed while the baseline is set.
 - ✓ After the baseline has been set, a signal sounds, and the **BLAST OUT...** message is displayed.
- 6 Remove the wrapper from the *EasyOne FlowTube*.
- 7 If you want to perform an FVL test, an MVV test, or an SVC test, attach the nose clip to the patient's nose.
- 8 Hand *EasyOne Air* to the patient.
- 9 Tell the patient to breathe at rest.
 - ☐ The following procedure **To perform the FVC breathing maneuver** represents the breathing maneuver for the FVC test as an example. If you want to perform any other test, replace the procedure **To perform the FVC breathing maneuver** with the breathing maneuver for the required test.

[Breathing maneuvers for all available tests](#) 58

■ To perform the FVC breathing maneuver

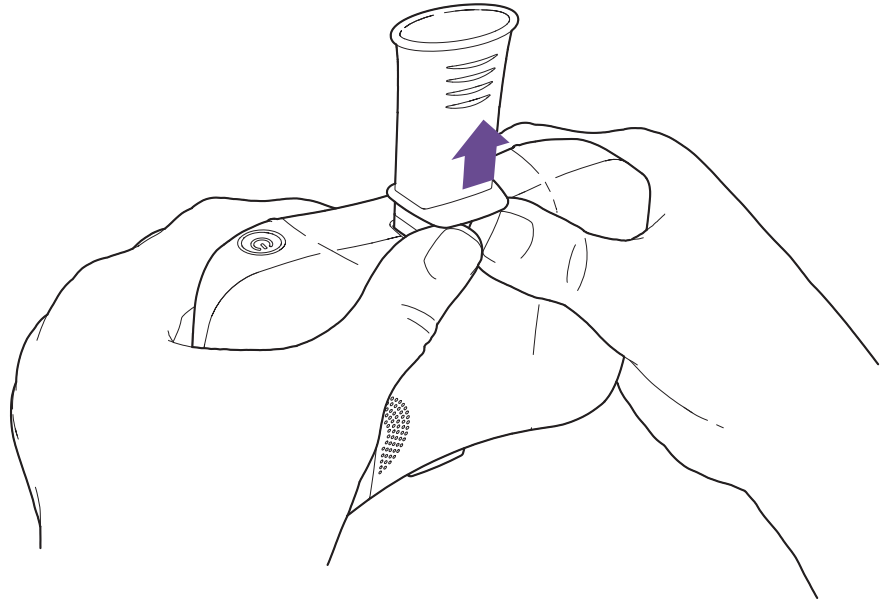
- 1 Tell the patient to fill the lungs completely.
- 2 Tell the patient to take the *EasyOne FlowTube* into the mouth and to seal the lips around the *EasyOne FlowTube*.
 - ☐ The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne FlowTube*.
- 3 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
 - ☐ While the patient performs the breathing maneuver, a feedback sound indicates the effort of the patient. The harder the patient exhales, the faster the feedback sound is repeated. When the patient exhales more slowly towards the end, the feedback sound also gets slower.
 - ✓ At the end of the trial, another feedback sound indicates whether the trial is acceptable or not.
- 4 Tell the patient to take the *EasyOne FlowTube* out of the mouth and to breathe normally again.
 - ✓ If the trial is acceptable, the green quality message is displayed.
 - ✓ If the trial is not acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

■ To add trials



- 1 If you want to look at the details of this trial, choose **Data**.
 - ✓ The report screen is displayed.
- 2 Choose **Next**.
- 3 Repeat the previous procedure **To perform the FVC breathing maneuver** and this procedure **To add trials** until a green acceptability message is displayed.
 - ☐ After the third and every following trial, a red or a green acceptability message is displayed with the quality grade for the test.
 - ✓ After three acceptable trials, the test ends automatically and a green acceptability message is displayed.
- 4 Choose **Data**.
 - ✓ The report screen is displayed.
- 5 Choose **End session**.

■ To end the test

- 1 To remove the *EasyOne FlowTube*, do the following:
 - a) Grip *EasyOne Air* with both hands, with the backside of *EasyOne Air* facing towards you and with the *EasyOne FlowTube* pointing up.
 - b) Press against the protruding lip of the *EasyOne FlowTube* with both thumbs and push the *EasyOne FlowTube* out.
 - c) Do not touch the *EasyOne FlowTube* anywhere else than at the protruding lip.
 - d) Drop the *EasyOne FlowTube* directly into a waste container.



- 2 **WARNING!** Patient cross-contamination and infection of the technician: Always wear disposable gloves. Between patients, always exchange disposable gloves, clean *EasyOne Air*, and disinfect hands. / Electric shock, failure of *EasyOne Air*, and false diagnosis: Make sure that no fluid penetrates the *EasyOne FlowTube* holder or the inside of *EasyOne Air* while cleaning. To clean *EasyOne Air*, do not fully dip *EasyOne Air* into any fluid. To clean *EasyOne Air* and to disinfect your hands after each patient, do the following:
 - a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions under [Hygiene and cleaning](#) 62 and wipe the handles and the display of *EasyOne Air*.
 - b) Put down *EasyOne Air*.
 - c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.
- 3 If you want to print the report immediately, choose **Print**.
 - ✓ A progress bar is displayed that indicates the progress of the print-out.

- 4 Choose **End**.
 - ✓ The home screen is displayed.
- ⇒ [List of cleaning solutions for EasyOne Air](#)  63
[About compatible printers](#)  19

6.6. Performing spirometry using *EasyOne Connect* in combination with *EasyOne Air*

6.6.1. Connecting *EasyOne Air* to *EasyOne Connect*




To use *EasyOne Connect* in combination with *EasyOne Air*, you need to connect *EasyOne Air* to your PC over Bluetooth.

Prerequisite

- On your PC, Bluetooth is enabled.
 - A USB Bluetooth adapter is supplied with *EasyOne Air* in case your PC does not have Bluetooth built-in.

[List of box contents](#)  17

If *EasyOne Air* is directly connected to a PC over USB, performing tests is not possible. Leakage currents could harm the patient. Connect *EasyOne Air* to your PC wirelessly, only.

- 1 On *EasyOne Air*, choose  >  > .
- 2 Select the **Bluetooth** check box and keep the menu open.
 - ✓ *EasyOne Air* is discoverable over Bluetooth by other devices.
- 3 On your PC, navigate to the Bluetooth menu to add Bluetooth devices.
 - Where to find the Bluetooth menu varies between the versions of *Microsoft Windows*. For assistance, open the *Control Panel* in any *Windows* version and press the *F1* key.
 - ✓ In the list of available devices, you see “*EasyOne Air*” followed by its serial number.
- 4 On your PC, select *EasyOne Air* for pairing.
- 5 Exchange the Bluetooth pairing key as advised by your PC and by *EasyOne Air*.
 - ✓ Your PC and *EasyOne Air* are now paired. Whenever Bluetooth is enabled on both devices and both devices are within range, your PC and *EasyOne Air* reconnect automatically.

6.6.2. Performing a bronchial provocation test using *EasyOne Connect* in combination with *EasyOne Air*

Bronchial provocation tests are performed by administering increasing doses of an airway irritant. The reaction of the respiratory system to these substances is measured. For example, Mannitol and Methacholine are available as provocative agents for a number of protocols.

Required materials

- A new *EasyOne FlowTube* for each patient
- A nose clip

Prerequisites

- You have configured the appropriate protocol for provocation tests.
- You have added the patient data to the database of *EasyOne Connect*.
- Or the patient data is already in the database of *EasyOne Connect*.
- You are wearing disposable gloves.
- You have instructed the patient on how to perform the test before you start with the test.

[About preparation of spirometry and instructions for the patient](#)  42

[Performing the breathing maneuver for the FVL test](#)  59

WARNING

PATIENT HEALTH HAZARD

Performing provocation tests can cause an asthma attack or bronchospasm. Familiarize yourself with appropriate medication documentation, guidelines, procedures, and contraindications as to when to stop further testing.

If the patient is on medication, check the contraindications for the medication.

The following must be available on short notice: a physician that is trained in the treatment of acute bronchospasm, appropriate medication counteracting the provocative agent, and resuscitation equipment.

Do not leave the patient unattended during a provocation test.

CAUTION

PATIENT HEALTH HAZARD

Pulmonary function tests require maximum effort on the part of the patient and may lead to dizziness.

Make sure the patient cannot be injured by objects in the vicinity if the patient falls.

Watch the patient for signs of dizziness and support the patient if necessary.

Do not leave the patient unattended during a test.

⚠ CAUTION

PATIENT CROSS-CONTAMINATION

If you reuse the *EasyOne FlowTube*, *DLCO barriette*, or *FRC barriette*, contamination from an infected patient can be deposited on the *EasyOne FlowTube*, on the *DLCO barriette*, or on the *FRC barriette*. The contamination from an infected patient can later be passed on to the next patient who is tested.

You cannot clean or disinfect the *EasyOne FlowTube*, the *DLCO barriette*, or the *FRC barriette* in any way. The *EasyOne FlowTube*, the *DLCO barriette*, and the *FRC barriette* are for single-patient use only.

Always replace the *EasyOne FlowTube*, the *DLCO barriette*, and the *FRC barriette* with a new one between patients or when performing lung function test on yourself.

Only use an original *EasyOne FlowTube*, *DLCO barriette*, and *FRC barriette* by the manufacturer.

The procedure **To perform the FVC breathing maneuver** represent the breathing maneuver for the FVC test. If you use the FVL test for forced spirometry, replace the procedure **To perform the FVC breathing maneuver** with the breathing maneuver for the FVL test.

[Breathing maneuvers for all available tests](#) 58

You can configure whether to use the FVC test or the FVL test for forced spirometry under **Utilities > Configuration > Test > FVC/FVL > Type**.

The *EasyOne FlowTube* is a single-patient-use disposable and hygienically packaged. Visually check the wrapper of a new *EasyOne FlowTube* for defects.

If the wrapper of the *EasyOne FlowTube* has a defect, discard the *EasyOne FlowTube*, take another *EasyOne FlowTube*, and visually check the wrapper of the new *EasyOne FlowTube* again for defects.

⇒ [About interpreting results](#) 54

6.7. About interpreting results

Quality grades are included in all results and indicate a result's reliability. The quality grades range from *A* to *F*. Their interpretation differs depending on the test. See [List of quality grades for tests](#) 56.

On the printed report, parameters that are below the lower limit of normal (LLN) are marked with an asterisk (*). Unacceptable trials are struck through. In addition to the marks, *EasyOne Air* and *EasyOne Connect* offer an automatic interpretation aid.

It is possible to deactivate the automatic quality grading function and the system interpretation function.

⇒ [List of tests and parameters](#) 32

[List of quality messages and quality grades](#) 55

[Configuration](#) 72

6.8. List of quality messages and quality grades

6.8.1. About quality messages and quality grades

End-of-Test criteria, quality criteria, and quality grading are based upon the published standards [1], [4], [13], [14], and [15].

Quality grading is based on the sources [4], [13], [14], and [15].

The main articles [2] and [3] do not numerically define the minimum expiratory peak flow time (PEFT) that is required for an acceptable test. For *EasyOne Air*, 160 ms is used.

⇒ [List of bibliographic references](#)  94

6.8.2. Quality messages for trials

Immediately after a trial, quality messages help you to give feedback to the patient as to whether the trial has been acceptable or not. If the trial has not been acceptable, a recommendation on how to improve is displayed.

Displaying quality messages for trials

To display the quality message for a trial, choose the trial rank from the parameter table on the result screen (**Patients > select patient > History > select test**). The trial ranks are given in numbers 1, 2, 3, etc. and may be crossed out.

For a list of all quality messages, see the Application Note *EasyWarePro Message Numbers* on the *ndd* website.

⇒ [Application Notes for further information](#)  3

6.8.3. List of quality grades for tests

Quality grades help you as the operator to assess the quality of a completed test.

Quality grades for the FVC test, the FVL test, and the OSHA test

Rating	Criteria	Result reliability
A	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV ₁ and FVC values is equal to or less than 100 mL (80 mL if FVC <1.0 L) (for age 6 and under: 80 mL or 8% of FVC or FEV ₁ whichever is greater)	Reliable result
B	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV ₁ and FVC values is equal to or less than 150 mL (100 mL if FVC <1.0 L) (for age 6 and under: 100 mL or 10% of FVC or FEV ₁ whichever is greater)	Reliable result
C	At least 2 acceptable trials AND the difference between the best two FEV ₁ and FVC values is equal to or less than 200 mL (150 mL if FVC <1.0 L) (for age 6 and under: 150 mL or 15% of FVC or FEV ₁ whichever is greater)	Reliable result
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'C'. Quality message: <i>Result not reproducible</i>	Result might have clinical utility. Interpret with caution.
D (2)	Only one acceptable trial Quality message: <i>Only one acceptable trial</i>	Result might have clinical utility. Interpret with caution.
F	No acceptable trial available	Result should not be used.

[About the OSHA test](#)  99

Quality grades for the SSA test

Rating	Criteria	Result reliability
A	At least 3 acceptable trials AND the difference between the best two FEV ₁ and FVC values is equal to or less than 100 mL	Reliable result
B	At least 3 acceptable trials AND the difference between the best two FEV ₁ and FVC values is equal to or less than 100 mL or 5% of FVC or FEV ₁ , respectively.	Reliable result
F	No acceptable trial available	Result should not be used.

[About the SSA test](#)  100

Quality grades for the SVC test

Rating	Criteria	Result reliability
A	At least 3 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.	Reliable result
B	At least 2 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.	Reliable result
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'B'.	Result might have clinical utility. Interpret with caution.
D (2)	Only one acceptable trial	Result might have clinical utility. Interpret with caution.
F	No acceptable trial available	Result should not be used.

7. Breathing maneuvers for all available tests

7.1. About breathing maneuvers for all available tests

The overall process of performing spirometry is the same for all spirometry tests. The tests differ in the breathing maneuver that the patient must perform.

⇒ [Performing spirometry](#) 41

7.2. Performing the breathing maneuver for the FVC test

The forced expiratory vital capacity test is the most commonly used spirometry test. During the breathing maneuver, the patient must exhale with a forceful, maximum effort.

- 1 Tell the patient to breathe at rest.
- 2 Tell the patient to fill the lungs completely.
- 3 Tell the patient to take the *EasyOne FlowTube* into the mouth and to seal the lips around the *EasyOne FlowTube*.
 - ☐ The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne FlowTube*.
- 4 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
- 5 Tell the patient to take the *EasyOne FlowTube* out of the mouth and to breathe normally again.
 - ✓ If the trial is acceptable, the green quality message is displayed.
 - ✓ If the trial is not acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

⇒ [Performing spirometry](#) 41

7.3. Performing the breathing maneuver for the FVL test

With the flow volume loop test, a deep inhalation directly follows the exhalation maneuver.

Required material

- A nose clip

Prerequisite

- For this test, you must enter the environment temperature within 1°C or 1.8°F accuracy.
- 1 Tell the patient to breathe at rest.
 - 2 Tell the patient to fill the lungs completely.
 - 3 Tell the patient to take the *EasyOne FlowTube* into the mouth and to seal the lips around the *EasyOne FlowTube*.
 - The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne FlowTube*.
 - 4 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
 - 5 Tell the patient to keep the *EasyOne FlowTube* in the mouth, to breathe in, and to continue inhaling until the lungs are completely filled again.
 - 6 Tell the patient to take the *EasyOne FlowTube* out of the mouth and to breathe out again.
 - ✓ If the trial has been acceptable, the green quality message is displayed.
 - ✓ If the trial has not been acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

⇒ [Performing spirometry](#) 41

7.4. Performing the breathing maneuver for the MVV test

With the maximum voluntary ventilation test, the patient fully inhales and fully exhales repeatedly.

Required material

- A nose clip

Prerequisite

- For this test, you must enter the environment temperature within 1°C or 1.8°F accuracy.

- 1 Tell the patient to breathe at rest.
- 2 Tell the patient to fully exhale.
- 3 Tell the patient to take the *EasyOne FlowTube* into the mouth and to seal the lips around the *EasyOne FlowTube*.
 - The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne FlowTube*.
- 4 Tell the patient to fully inhale and fully exhale repeatedly for an uninterrupted period of at least 12 seconds.
- 5 Tell the patient to take the *EasyOne FlowTube* out of the mouth and to breathe normally again.

⇒ [Performing spirometry](#)  41

7.5. Performing the breathing maneuver for the SVC test

The slow vital capacity test serves to determine the vital capacity and the lung volumes. This test does not require great effort on part of the patient.

Required material

- A nose clip

Prerequisite

- For this test, you must enter the environment temperature within 1°C or 1.8°F accuracy.
- 1 Tell the patient to breathe at rest.
 - 2 Tell the patient to take the *EasyOne FlowTube* into the mouth and to seal the lips around the *EasyOne FlowTube*.
 - The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne FlowTube*.
 - 3 Tell the patient to continue breathing at rest.
 - Typically, three to five breaths are required.
 - ✓ *Tidal Breathing* is displayed.
 - 4 When *Start test ...* is displayed and when the steady-tidal acoustic signal sounds, tell the patient to fully inhale and fully exhale.
 - Instead, the patient can also fully exhale first and then fully inhale.
 - The patient can take this deep breath slowly and does not need to force it.
 - 5 Tell the patient to take the *EasyOne FlowTube* out of the mouth and to breathe normally again.
 - ✓ If the trial is acceptable, the green quality message is displayed.
 - ✓ If the trial is not acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

⇒ [Performing spirometry](#) 41

8. Hygiene and cleaning

8.1. Avoiding contamination while performing spirometry

When handling the *EasyOne FlowTube*, you must be careful not to contaminate the next *EasyOne FlowTube* or *EasyOne Air*.

The wrapped *EasyOne FlowTube* is hygienically wrapped and for single-patient use only. You must use a new *EasyOne FlowTube* for each patient.

WARNING

PATIENT CROSS-CONTAMINATION

If you reuse the *EasyOne FlowTube*, contamination from an infected patient can be deposited on the *EasyOne FlowTube*. The contamination from an infected patient can later be passed on to the next patient who is tested.

You cannot clean or disinfect the *EasyOne FlowTube* in any way. The *EasyOne FlowTube* is for single-patient use only.

Always replace the *EasyOne FlowTube* with a new one between patients or when performing spirometry on yourself.

Only use an original *EasyOne FlowTube* by the manufacturer.

- 1 To protect yourself and to avoid infection of patients, wear disposable gloves.
- 2 Never touch the *EasyOne FlowTube* directly, but partly unwrap the wrapper and grip the *EasyOne FlowTube* with the wrapper still around the mouthpiece.
- 3 Keep the wrapper while the patient is performing the breathing maneuver.
- 4 After the patient has completed the breathing maneuver, grip the *EasyOne FlowTube* with the wrapper again and dispose of the *EasyOne FlowTube* together with the wrapper.

5 WARNING! Patient cross-contamination and infection of the technician: Always wear disposable gloves. Between patients, always exchange disposable gloves, clean *EasyOne Air*, and disinfect hands. / Electric shock, failure of *EasyOne Air*, and false diagnosis: Make sure that no fluid penetrates the *EasyOne FlowTube* holder or the inside of *EasyOne Air* while cleaning. To clean *EasyOne Air*, do not fully dip *EasyOne Air* into any fluid.

To clean *EasyOne Air* and to disinfect your hands after each patient, do the following:

- a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions under [Hygiene and cleaning](#) 62 and wipe the handles and the display of *EasyOne Air*.
- b) Put down *EasyOne Air*.
- c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.

⇒ [Calibration check](#) 84

8.2. List of cleaning solutions for *EasyOne Air*

Do not use just any cleaning solution for *EasyOne Air*. Only use the listed cleaning solutions.

CAUTION

ELECTRIC SHOCK, FAILURE OF *EASYONE AIR*, AND FALSE DIAGNOSIS

Make sure that no fluid penetrates the inside of *EasyOne Air* while cleaning.

To clean *EasyOne Air*, do not immerse *EasyOne Air* in any fluid.

To clean *EasyOne Air* from environmental dirt, you can use a damp cloth.

After each patient, clean *EasyOne Air*. You can use a soft cloth with a cleaning solution according to the following list.

The cradle may be cleansed with the same cleaning solution.

- 70 percent isopropyl alcohol solutions or
- Solutions that contain formaldehyde (only for use outside the USA) or
- Solutions that contain chlorine (e.g. Sani-Cloth Germicidal Disposable Wipes, EPA Reg# 9480-4)

9. Working with patient data and reports

CAUTION

FALSE DIAGNOSIS

The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results.


Enter patient data meticulously.


Double-check that you have entered the patient data correctly.

9.1. Working with patient data and reports on *EasyOne Air*

9.1.1. Adding a patient to the database on *EasyOne Air*



1 Choose .

2 Choose .

✓ The add patient dialog is displayed.



3 **CAUTION!** False diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results. Enter patient data meticulously. Double-check that you have entered the patient data correctly.

In each step, enter the requested data and choose **Next >**.


4 In the last step, choose **Finish**.

9.1.2. Editing patient data on *EasyOne Air*



- 1 Choose .
- 2 Choose .
✓ The patient selection list is displayed.
- 3 Select a patient.
- 4 Choose a list item.
- 5 **CAUTION!** False diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results. Enter patient data meticulously. Double-check that you have entered the patient data correctly.



Edit the entry and, if applicable, choose **OK**.

 Note that these changes only apply to sessions going forward and not to previous sessions.

- 6 Choose **OK**.
- 7 Choose the home button.

9.1.3. Deleting a patient from the database on *EasyOne Air*



- 1 Choose .
- 2 Choose .
✓ The patient selection list is displayed.
- 3 Select a patient and confirm the message that is displayed.
✓ The selected patient data is deleted.

9.1.4. Exporting data from *EasyOne Air*

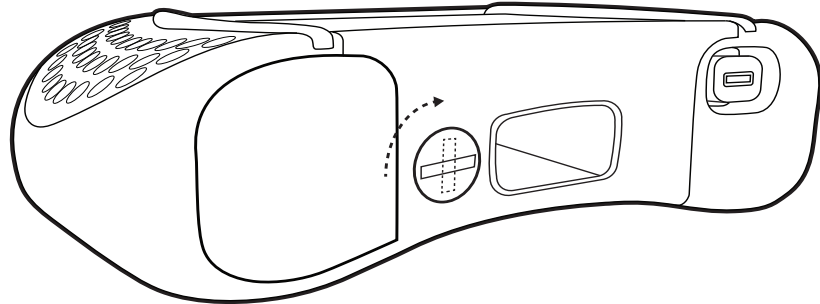


You can export data including reports to the SD memory card.

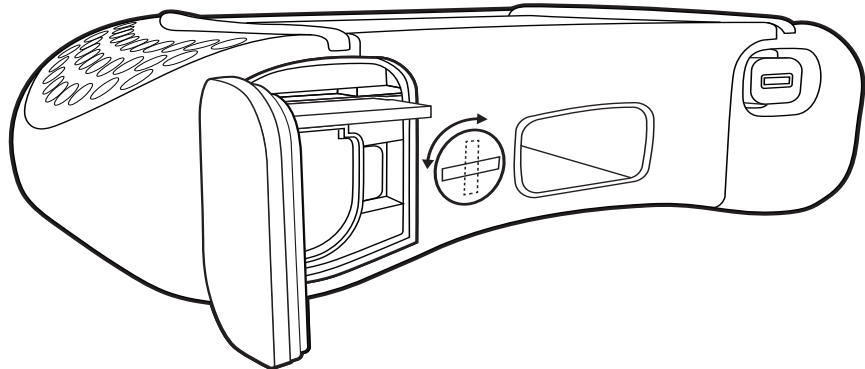
Required material

- An SD card

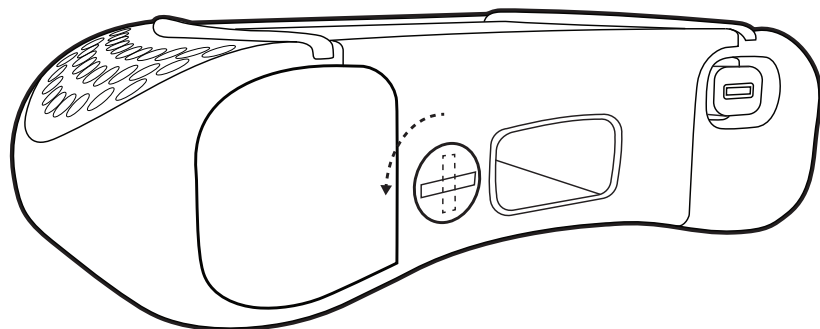
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



- 2 Insert the SD memory card into the SD card slot.




- 3 Close and lock the battery compartment by turning the lock screw counterclockwise.



- 4 Choose > .

- 5 Tap and hold on the patient record that you want to export.
 - ✓ A pop-up window is displayed.
- 6 In the pop-up window, choose **Export**.
 - ✓ The patient record is saved to the SD card.
- 7 Remove the SD card.

9.1.5. Viewing and printing reports on *EasyOne Air*

- 1 Choose .
 - ✓ The test selection list is displayed.
- 2 Select a test.
 - ✓ The report screen is displayed.
- 3 To enlarge, tap on the combined volume-time curve and flow-volume curve or on the parameter table.
- 4 To reduce, tap again on the combined volume-time curve and flow-volume curve or on the parameter table.
- 5 If you want to print the report, do the following:
 - a) Dock *EasyOne Air* to the cradle that is connected to a printer.
 - b) Choose **Print**.
 - ✓ A progress bar is displayed, which indicates the progress of the print-out.

9.2. Working with patient data and reports in *EasyOne Connect*

CAUTION

FALSE DIAGNOSIS

The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results.

Enter patient data meticulously.

Double-check that you have entered the patient data correctly.

9.2.1. Merging two patient data records with *EasyOne Connect*

If, for example, two data records of the same patient were acquired with different tests or if different spellings of a patient's name exist, you can merge these two data records into one.

Prerequisite

The two data records must have an identical date of birth.

1 Choose **Patients**.

2 Select one of the two data records.

3 Drag and drop that data record onto the second data record by doing the following:

a) Right-click the first data record and keep the mouse button pressed.

b) Move the data record across the screen onto the second data record.

c) While the first data record is above the second, release the mouse button.

✓ If the dates of birth of the two data records match, a confirmation window is displayed.

✓ If the dates of birth of the two data records do not match, a warning is displayed. In this case, you cannot merge these two data records.

4 To finish, confirm the message.

9.2.2. Copying patient data between *EasyOne Air* and *EasyOne Connect*

Usually, you perform spirometry with *EasyOne Air* stand-alone. But it can be more convenient to enter patient data, to evaluate results or to archive patient data and results with *EasyOne Connect* on your PC. For this purpose, you can create patient records in *EasyOne Connect* and copy patient records onto *EasyOne Air*. After you have performed spirometry, you can copy patient data and results from *EasyOne Air* to *EasyOne Connect*.

⚠ CAUTION

DATA LOSS

With the current firmware version V1.5.x, patient data and results cannot be merged if the patient data and results exist both on *EasyOne Air* and in *EasyOne Connect*. If any patient data for the same patient exists on *EasyOne Air* and in *EasyOne Connect*, the patient data and results in *EasyOne Connect* can be overwritten by *EasyOne Air*.

Do not copy incomplete test results from *EasyOne Air* to *EasyOne Connect*, then change patient data or add trials, and copy data from *EasyOne Air* to *EasyOne Connect* again.

Instead, first complete tests with *EasyOne Air* before you copy patient data and results to *EasyOne Connect*.

Make changes to existing patient data on *EasyOne Air* only.

Use *EasyOne Connect* only

to create new patient records without results yet for sending to *EasyOne Air*

to evaluate results,

to print reports,

to archive patient data and results,

or to send patient data and results from *EasyOne Connect* to your EMR system.

EASYONE AIR MAY FREEZE

If *EasyOne Air* is connected to your PC via USB and if there are also electromagnetic fields from other electrical devices nearby, *EasyOne Air* may freeze.

To restart *EasyOne Air*, turn *EasyOne Air* off and on again.

■ To copy patient data and results from *EasyOne Air* to *EasyOne Connect*


- 1 On your PC, launch *EasyOne Connect*.
- 2 Turn on *EasyOne Air*.
- 3 Put *EasyOne Air* into the cradle.
 - ✓ Patient data and results are copied from *EasyOne Air* to *EasyOne Connect*.
 - ✓ *EasyOne Connect* displays a message whether the copying has been successful.
 - ☐ You can remove *EasyOne Air* from the cradle, or you can proceed with the next procedure to create and send new patient records from *EasyOne Connect* to *EasyOne Air*.

■ To create and send a new patient record from *EasyOne Connect* to *EasyOne Air*

- 1 In *EasyOne Connect*, choose **Patients**.
- 2 Choose **New**.
- 3 **CAUTION!** False diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results. Enter patient data meticulously. Double-check that you have entered the patient data correctly.

Fill out those fields that are marked with an asterisk (*).

- ☐ You cannot complete adding patient data without filling out these fields.

- 4 In all other fields, enter additional patient data if necessary.
- 5 Choose **OK**.
- 6 Select the patient record that you just have created.
- 7 Choose  **EasyOne**.
 - ✓ The selected patient record is send to *EasyOne Air*.
 - ✓ *EasyOne Connect* displays a message whether the sending has been successful.
 - ☐ You can remove *EasyOne Air* from the cradle, or you can repeat steps **2** to **7** to create and send additional patient records.

⇒ [About connectivity and data exchange](#)  36

9.2.3. About the trend view with *EasyOne Connect*

The trend view visualizes an increase or a decline of individual parameters. This view facilitates the comparison of different measurements over time.

From the history screen (**Patients > select patient > History**), choose **Trend**. The trend screen displays two curves, one for the absolute values and one for the percentage of predicted normal values.

At the bottom of the trend screen, you can select four parameters to be displayed at the same time.

9.2.4. Assessing tests retrospectively with *EasyOne Connect*

Retrospectively, you can manually override the acceptability of trials and the ranking of trials. This means that you can mark trials that the system judged acceptable as unacceptable and vice versa. Also, you can change the trial ranking (rank 1, 2, 3, and so forth).

- 1 From any result screen in the parameter table, choose the **Trial Rank** field for the particular trial.
 - ✓ An overlay window is displayed.
- 2 To mark the selected trial as acceptable or unacceptable, select or deselect the **Acceptable** check-box.
 - ✓ If you have not activated user handling, the login window is displayed.
 - ✓ If you have activated user handling, the test comment window is displayed. In this case, proceed with step 4.
- 3 If the login window is displayed, enter your user ID.
 - ✓ The selected trial is marked as either acceptable or unacceptable.
- 4 To change the ranking, choose **Highest Ranked**.
 - ☐ You can only set the rank to 1 (highest). To set the rank of other trials to 2, 3, and so forth, you must subsequently set the rank to 1 for all trials. The last trial that you set to rank 1 is rank 1. The second last trial that you set to rank 1 is rank 2, and so forth.
- 5 To close the overlay window, choose **x**.

⇒ [About user handling and the default password of EasyOne Connect](#) 82

10. Configuration

⚠ CAUTION

FALSE DIAGNOSIS

Wrong configuration settings can cause incorrect diagnostic calculations.

Be aware that wrong configuration settings can affect the predicted values, the system interpretation, and the displayed result values.

Verify the configuration settings.

10.1. Configuration of *EasyOne Air*



You can configure *EasyOne Air* in the tools menu.

10.1.1. Configurations in the settings menu of *EasyOne Air*



10.1.1.1. Description of system settings of *EasyOne Air*



On this screen, you can choose basic settings for *EasyOne Air*.

Setting	Purpose
Speaker volume	To set the speaker volume
Key click	To enable sound for audible click feedback
System Time	To set the time
System Date	To set the date
Date format	To set the format of the date
Time format	To set the format of the time
Language	To set the language
Brightness	To set the brightness of the touchscreen
Screensaver after	To set the time, after which the screensaver is enabled

Description of system settings

10.1.1.2. Description of spirometry settings of *EasyOne Air*



Predicted normal values setting

Predicted normal values are based on the latest scientific publications. Therefore, the predicted normal values are subject to change. These changes are delivered to you via software updates.

Updated information is published in an Application Note on the *ndd* website.

[Application Note *Reference Predicted Normal Values*](#)

[Application Notes for further information](#)  3

[List of bibliographic references](#)  94

Best trial/best value selection

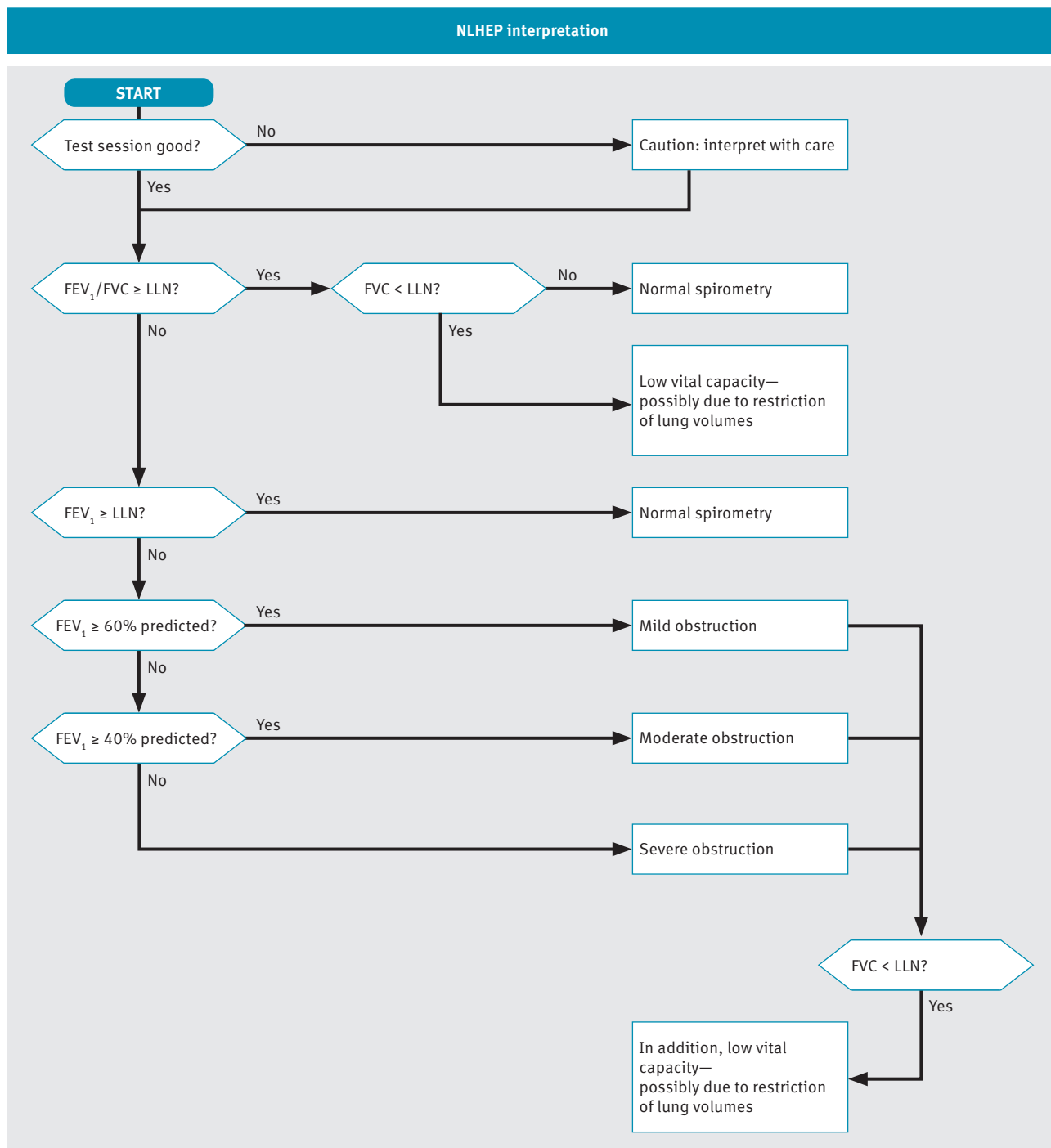
If you choose the **Best Trial** option, the complete best trial is selected for assessing the quality of the test and for assessing the interpretation. The trial with the largest sum of FVC and FEV₁ is selected, as suggested by ATS and ERS.

If you choose the **Best Value** option, the best single, relevant values are selected from different trials for assessing the quality of the test and for assessing the interpretation. This compiled column shows, for example, the largest FVC (or FEV₆) and the largest FEV₁ from all acceptable tests (unless all tests are unacceptable). Other parameters are taken from the best trial (also defined by the largest sum of FEV₁ and FVC).

System Interpretation

Choose from the interpretation standards NLHEP, GOLD/Hardie, and NICE, or disable automatic interpretation.

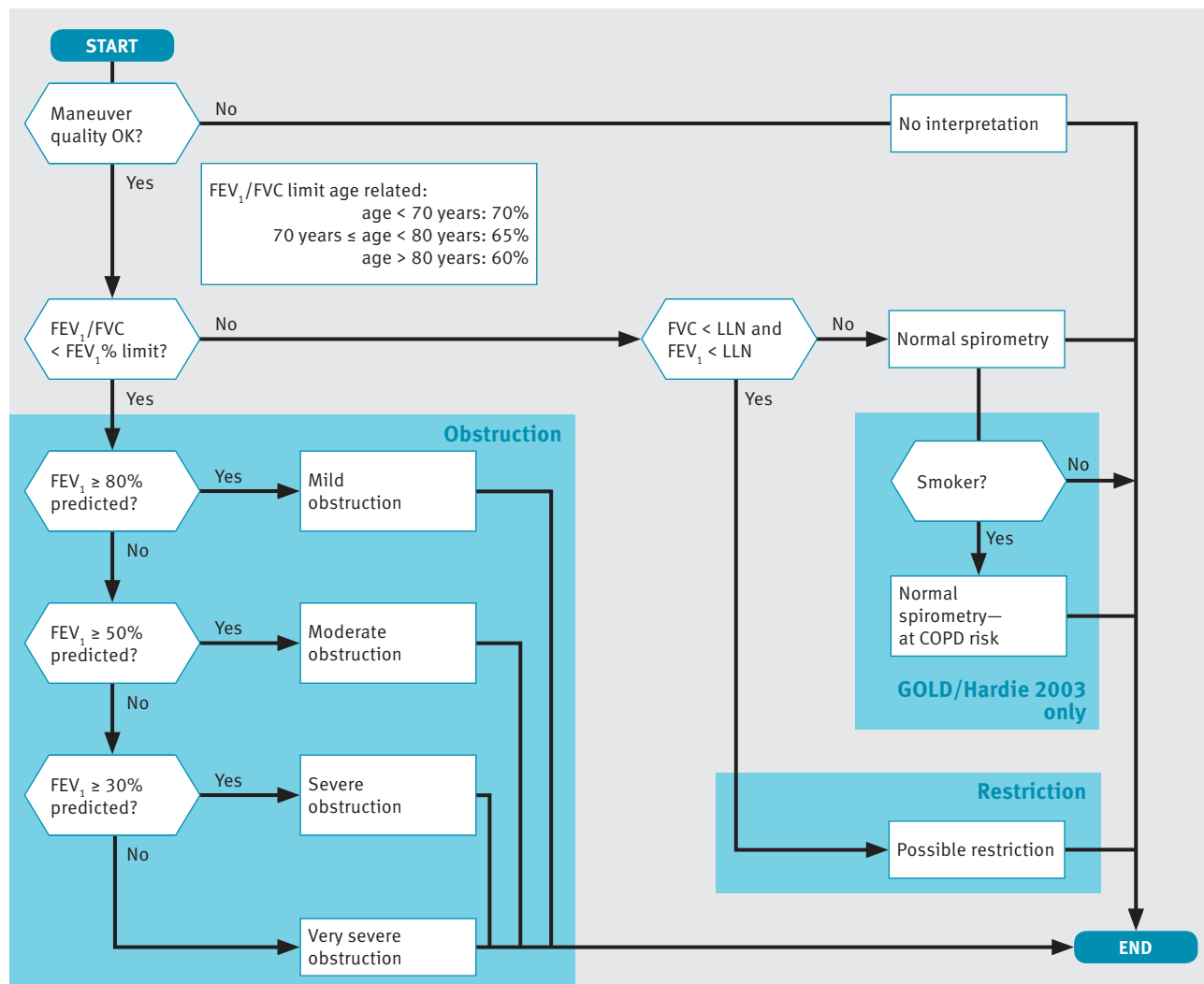
The default setting is GOLD/Hardie.



NLHEP interpretation algorithm

The diagram above shows how the interpretation for NLHEP is determined, according to Ferguson (2000/NLHEP) [4].

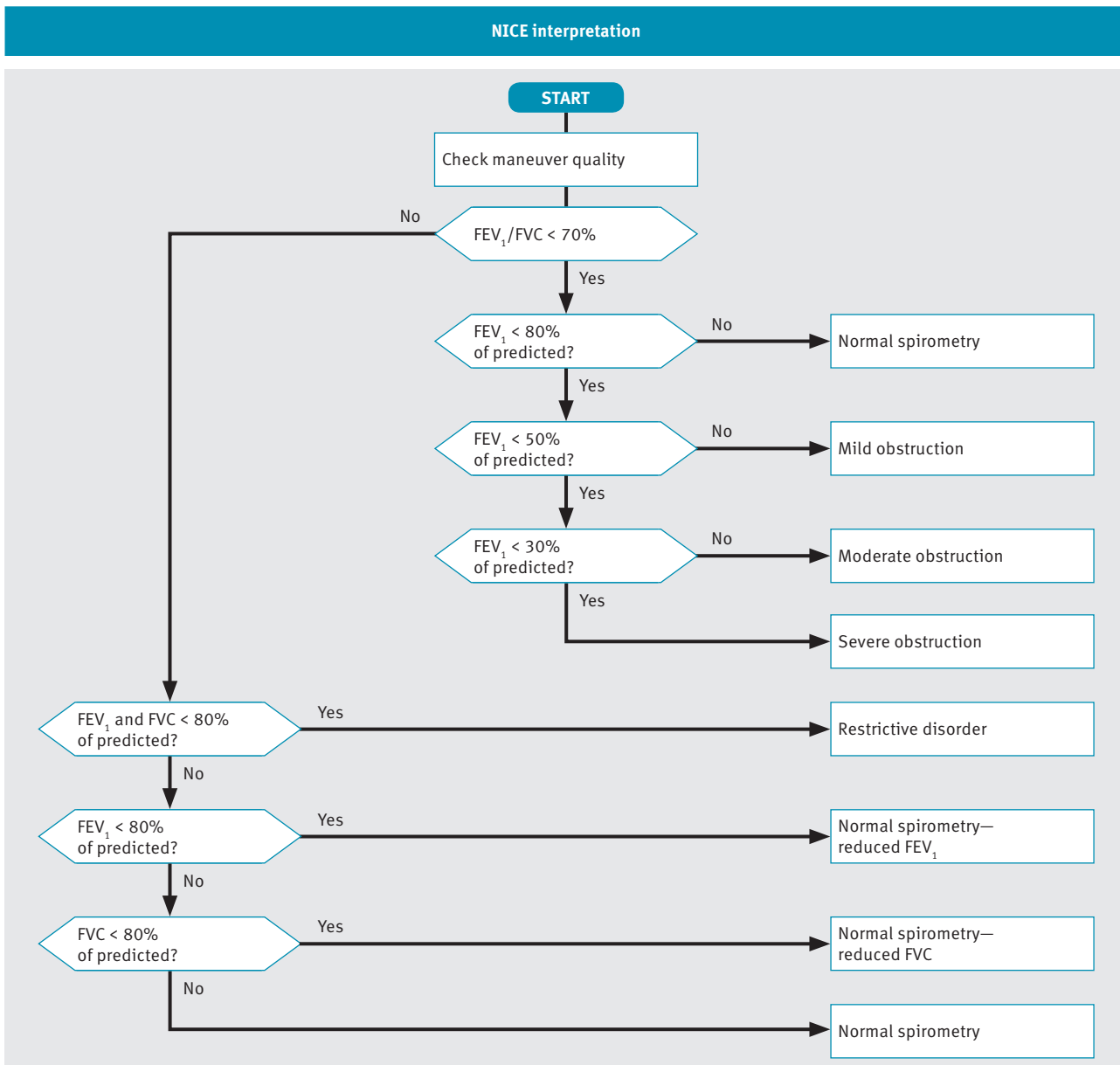
GOLD/Hardie Interpretation 2003 & 2008



□ GOLD/Hardie interpretation algorithm

The diagram above shows how the interpretation for GOLD/Hardie 2003 and GOLD/Hardie 2008 is determined, according to GOLD (2003) [11] and Hardie (2002) [12].

The smoker status is not part of the GOLD/Hardie standard of 2008, only of 2003.



NICE interpretation algorithm

The diagram above shows how the interpretation for NICE is determined. The NICE interpretation is mainly used in the UK.

Ethnic correction

Some studies for predicted values take into account the differences between certain ethnic groups. However, most studies that are used for spirometry were conducted on Caucasian subjects and are therefore most appropriate for use with Caucasian patients.

When entering patient information, you are presented with a list of options for four ethnic groups. In this setting, you can define the corrections for these ethnic groups. The adjustment is made to the values for Caucasian patients.

There is an exception to this function. If specific values are available for the chosen group of predicted values and the chosen ethnic group, they will be used instead of the correction entered here.

The American Thoracic Society's publication, *Lung Function Testing: Selection of Reference Values and Interpretative Strategies* [8], provides guidance on the subject of ethnic correction. This paper recommends using 88% of the Caucasian values when testing African patients and provides general guidance in selecting adjustments for other ethnic groups.


[List of bibliographic references](#)  94

10.1.1.3. Description of security settings of *EasyOne Air*



On this screen, you can configure the following security-related settings.

Setting	Purpose
User logon required	To enforce user name/password authentication
Enforce strong password	Passwords must include: At least 8 characters 1 lower-case letter 1 upper-case letter 1 number or 1 special character
Power-off after	To set the time after which <i>EasyOne Air</i> will be powered off
Disable PDF printing	Disable the print to PDF function

 Description of security settings

[⇨ Cybersecurity](#)  37




10.1.1.4. Description of print settings of *EasyOne Air*



You can determine basic settings for printouts when using *EasyOne Air* and the cradle. There are more comprehensive configuration options available for printouts when using *EasyOne Connect*.

Setting	Purpose
Printer	To select a physical printer or a virtual PDF printer (saves a PDF file)
Printer page format	To select the page format in imperial or metric dimensions
Data	To set whether one or three trials are included on the printout, corresponding to the best trial/best value selection in the spirometry settings
Curve	To set which curves are included on the printout, corresponding to the <i>Data</i> setting above
Custom header	To specify four lines of text on the printout, for customizing the printout for your institution

Description of print settings

- ⇒ [Best trial/best value selection](#)  73
- [About compatible printers](#)  19
- [Setting up the physical components](#)  20

10.1.2. About performing a firmware update with *EasyOne Air*

To perform a firmware update, refer to the Application Note *Updating the Software on EasyOne Air* on the *ndd* website.

CAUTION

FAILED UPDATE

An update may fail unnoticed.

After performing an update, restart *EasyOne Air* and *EasyOne Connect* and perform a calibration check.

[Cybersecurity](#)  37

[Checking for correct operation of EasyOne Air](#)  86

- ⇒ [Application Notes for further information](#)  3
- www.ndd.ch
- For the USA: www.nddmed.com

10.1.3. Performing a backup of *EasyOne Air*



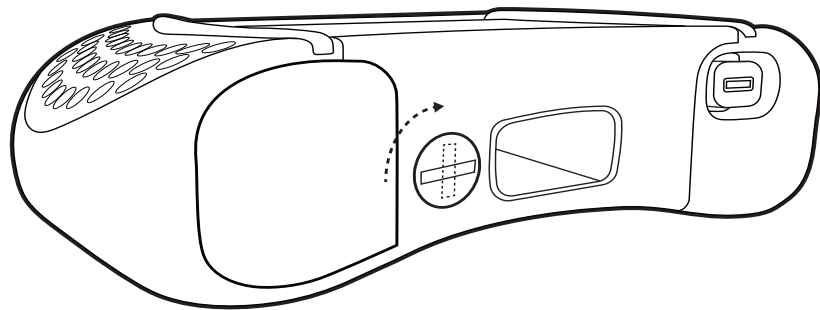
Required material

- An SD memory card with at least 2 GB of free space

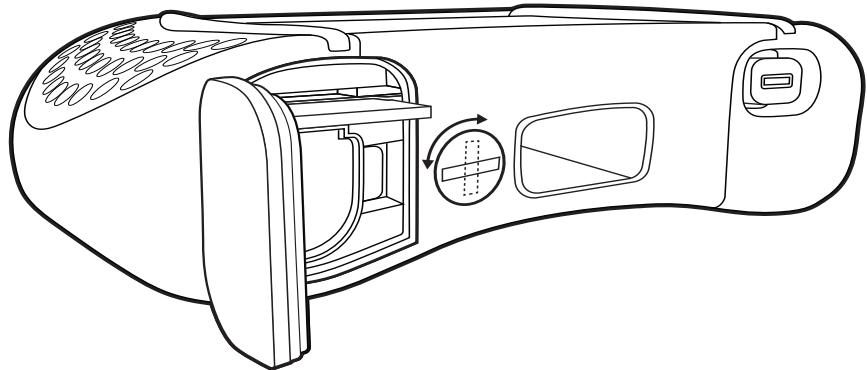
To archive a copy of the complete database (including patient data and results) and of the configuration settings, perform backups regularly. You can also use the backup to set up another *EasyOne Air* with the same database and configuration settings.

For each backup, the manufacturer recommends to use one SD memory card with 2 GB storage capacity.

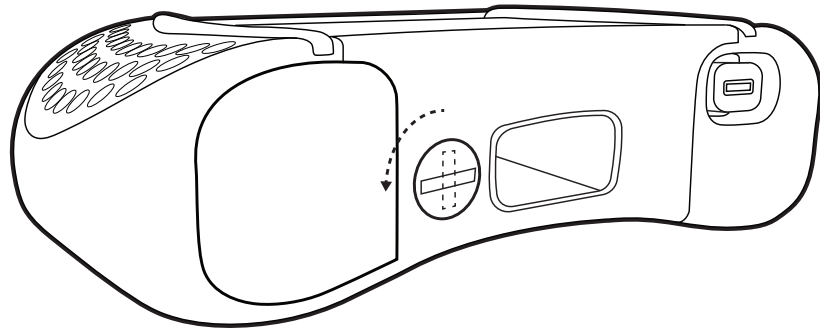
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.






- 2 Insert the SD memory card into the SD card slot.



- 3 Close and lock the battery compartment by turning the lock screw counterclockwise.



- 4 Choose  >  > .
✓ A message is displayed that asks whether you want to encrypt the backup with a password.
- 5 Do one of the following:
 - a) To encrypt the backup with a password, choose **Set password** and enter the password in the following window.
 - b) To proceed without setting a password, choose **No password**.

10.1.4. About the information menu of *EasyOne Air*



The information menu displays the firmware version of *EasyOne Air*.

10.1.5. About the user menu of *EasyOne Air*




Inactive user handling

If user handling is inactive, all menus and settings are exposed. Sensitive changes, for example deleting patient data, require authentication.

The default user name / password is: *admin / 8005*

Active user handling

If user handling is active, users must login. User accounts can be password-protected.

Security policies, like password strength and password expiration, must be handled by the operating institution, for example the hospital or practice. *EasyOne Air* provides the option to enforce strong password rules. See [Description of security settings of EasyOne Air](#)  77.

If user accounts are password-protected, users are only prompted for their password once for login. For sensitive changes, like deleting patient data, users are not prompted for their passwords again.

Instead, logs include the respective user. Therefore, sensitive changes can be traced back to individual users.

User groups

There are two user groups: *Administrator* and *Technician*. *Administrator* users have full access and privileges to all menus and functions of *EasyOne Connect*. *Technician* users have restricted access and privileges.

At least one user has to remain as an *Administrator* user. *Administrator* users have access to the configuration of user handling and to the EMR configuration.

⇒ [Cybersecurity](#)  37

[Description of security settings of EasyOne Air](#)  77

10.2. Configuration of *EasyOne Connect*

[Utilities > Configuration](#)

10.2.1. About user handling and the default password of *EasyOne Connect*

[Utilities > Configuration > General > User Handling](#)

Inactive user handling

If user handling is inactive, all menus and settings are exposed. Sensitive changes, for example deleting patient data, require authentication.

The default user name / password is: *admin / 8005*

Active user handling

If user handling is active, users must login. User accounts can be password-protected.

Security policies, such as password strength and password expiration, must be handled by the operating institution, for example the hospital or practice. To comply with such security policies, the manufacturer recommends that you activate user handling.

If user accounts are password-protected, users are only prompted for their password once for login. For sensitive changes, like deleting patient data, users are not prompted for their passwords again.

Instead, logs include the respective user. Therefore, sensitive changes can be traced back to individual users.

User groups

There are two user groups: *Administrator* and *Technician*. *Administrator* users have full access and privileges to all menus and functions of *EasyOne Connect*. *Technician* users have restricted access and privileges.

At least one user has to remain as an *Administrator* user. *Administrator* users have access to the configuration of user handling and to the EMR configuration.

⇒ [About connectivity and data exchange](#)  36

10.2.2. Activating user handling and administering user accounts

- 1 Choose **Utilities > Configuration > General > User Handling**.
 - 2 Enter the default user name / password and choose **Login**.
 - ☐ The default user name / password is: *admin / 8005*
 - 3 To activate user handling, select the **User Handling** check box.
 - 4 To add a user, do the following:
 - a) Choose **Add**.
 - b) Enter a user ID.
 - c) Enter additional information as required.
 - d) Choose **OK**.
 - 5 To edit a user, do the following:
 - a) Select an existing user.
 - b) Edit information as required.
 - c) Choose **OK**.
 - 6 To delete a user, do the following:
 - a) Select an existing user.
 - b) Choose **Delete**.
 - c) Confirm the following message.
 - 7 To save the changes, choose **OK**.
 - 8 To discard the changes, choose **Cancel**.
- ⇒ [About user handling and the default password of EasyOne Connect](#) 82

11. Calibration check

Calibration check is a preventive inspection to ensure that *EasyOne Air* calibration has not been adversely affected. Calibration check is different from calibration and is the procedure used to validate that *EasyOne Air* is within calibration limits. Routine calibration by users is not required.

⚠ CAUTION

FALSE DIAGNOSIS

For unforeseen reasons, malfunction of *EasyOne Air* can lead to false results and false diagnosis.

Perform calibration checks periodically.

[Calibration check](#)  84

[Checking for correct operation of EasyOne Air](#)  86

MALFUNCTION

Calibration of *EasyOne Air* is not possible. You can merely check *EasyOne Air* for correct calibration.

Do not attempt to repair *EasyOne Air* yourself. A third-party service must not attempt to repair *EasyOne Air* either.

Do not open or remove the casing.

If a calibration check fails, contact only your *EasyOne* distribution partner or the *ndd* Servicing Department for repairs.

[Contact information](#)  4

11.1. Performing a calibration check with *EasyOne Air*

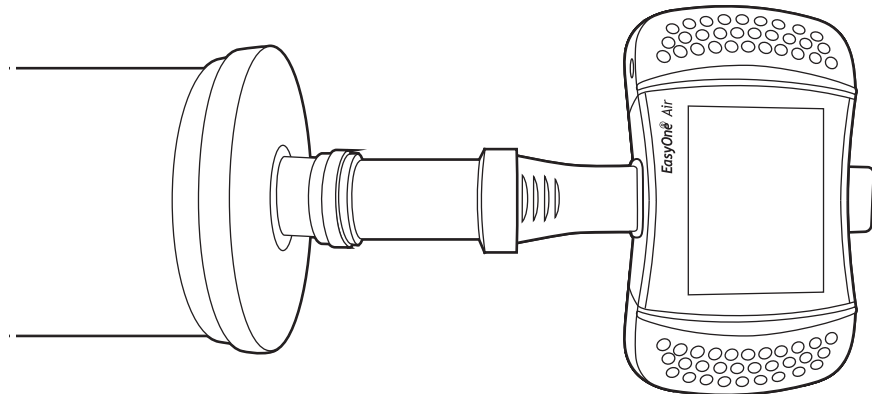




Required materials

- A calibration syringe (separately available)
 - An *EasyOne FlowTube* cal check adapter (separately available)
 - An *EasyOne FlowTube*
- 1 To assure that the temperature inside the syringe and the room temperature are the same, push and draw the piston five times.
 - A temperature difference may lead to a failed calibration check.
 - Do not warm the body of the calibration syringe with your hands.
 - 2 Push the piston of the calibration syringe all the way in.
 - 3 Unwrap the *EasyOne FlowTube*.

- 4 Insert the *EasyOne FlowTube* into *EasyOne Air*.
 - ☐ The shape of the *EasyOne FlowTube* and the *EasyOne FlowTube* holder guide the orientation of the *EasyOne FlowTube*. You can only insert the *EasyOne FlowTube* fully if it is positioned correctly.
- 5 Attach the *EasyOne FlowTube* cal check adapter to the calibration syringe.
 - ☐ To avoid any temperature differences, fixate the syringe with two fingers at the one end of the syringe only.
- 6 Attach the nozzle of the *EasyOne FlowTube* cal check adapter to the *EasyOne FlowTube* and make sure that the piston is fully inserted.

The *EasyOne FlowTube* snaps into the nozzle of the *EasyOne FlowTube* cal check adapter.



- 7 Choose  >  > **Single flow**, **Multi flow**, or **Linearity** and confirm the message that is displayed.
- 8 Wait for the baseline to be set.
- 9 Pull the piston all the way out as slow or as fast as required by the flow level that is displayed.
- 10 Push the piston all the way in again with the same speed.
- 11 To end the maneuver, pull the piston briefly again.
 - ✓ If the maneuver was not acceptable, you need to repeat steps 9 to 11.
 - ✓ If you have chosen **Single flow** before and the maneuver was acceptable, the calibration check is completed.
 - ✓ If you have chosen **Multi flow** or **Linearity** before and the maneuver was acceptable, proceed with step 12.
- 12 If you have chosen **Multi flow** or **Linearity** before and the previous maneuver was acceptable, perform the next maneuvers according to the messages that are displayed.
 - ✓ If a maneuver was not acceptable, you need to repeat steps 9 to 11.
 - ✓ If all maneuvers were acceptable, the calibration check is completed.

⇒ [List of troubleshooting solutions](#)  86
[Contact information](#)  4

12. Servicing and troubleshooting

12.1. About charging the battery of *EasyOne Air*

The rechargeable battery of *EasyOne Air* lasts for an entire working day.

To charge *EasyOne Air*, always use the cradle and an original power supply released by the manufacturer.

⇒ [Setting up the physical components](#) 20

12.2. Checking for correct operation of *EasyOne Air*

- 1 Perform a calibration check.
- 2 Perform a spirometry test on yourself or on another known subject.
- 3 Check the results of steps 1 and 2 for plausibility.
 - a) If the results of steps 1 and 2 are plausible, *EasyOne Air* is operating correctly.
 - b) If the results of steps 1 and 2 are not plausible, troubleshoot.
 - c) If you are not able to remedy the defect, contact your *EasyOne* distribution partner or the *n d d* Servicing Department.

⇒ [Calibration check](#) 84
[Performing spirometry](#) 41
[List of troubleshooting solutions](#) 86
[Contact information](#) 4

12.3. List of troubleshooting solutions

If you encounter problems operating *EasyOne Air*, consult the table below.

Problem	Possible cause	Solution
<i>EasyOne Air</i> cannot be switched on.	Battery is dead.	Replace the battery.
	You did not press and hold the ON/OFF key for at least 2 seconds.	Press and hold the ON/OFF key for at least 2 seconds.
When the <i>EasyOne Air</i> is switched on, you hear three consecutive tones as a warning signal.	The spirometer is defective.	Consult your <i>EasyOne</i> distribution partner or the <i>n d d</i> Servicing Department.
When <i>EasyOne Air</i> is switched on, you see the following message on the display: "Self-test failed"	The spirometer is possibly defective.	Turn the spirometer off and on. Try again. If you receive the same message again, contact your <i>EasyOne</i> distribution partner or the <i>n d d</i> Servicing Department.

☐ Troubleshooting solutions

Problem	Possible cause	Solution
Every time you switch <i>EasyOne Air</i> on, you are prompted to enter Date etc.	The internal battery of <i>EasyOne Air</i> is defective.	Consult your <i>EasyOne</i> distribution partner or the <i>ndd</i> Servicing Department.
When you start a test, you see the following message: “Please insert <i>EasyOne FlowTube</i> correctly”	The <i>EasyOne FlowTube</i> is not correctly positioned.	Ensure the <i>EasyOne FlowTube</i> is inserted correctly and fully pushed in.
<i>EasyOne Air</i> is outside of $\pm 3.5\%$ when conducting the calibration check.	The <i>EasyOne FlowTube</i> is not correctly positioned.	Insert the <i>EasyOne FlowTube</i> correctly.
	You have not used an <i>ndd</i> adapter.	Use the <i>EasyOne FlowTube</i> cal check adapter.
	There are leaks in the syringe connection.	Check the connections.
	The specified syringe volume does not correspond to the actual syringe volume.	Choose the correct syringe volume under “Configuration”.
The curve is missing on the printout.	The ink cartridge of your printer is empty.	Replace the cartridge.
	In the configuration of your <i>EasyOne Air</i> , a black and white printer is selected, but you actually use a color printer.	Go to “Configuration”, then “Report Settings” and select the right printer.
When printing a report, the printer prints meaningless characters, or the printer does not respond.	A wrong printer type has been selected in the settings.	Set the correct printer.
	The printer cable is not correctly connected or is defective.	Switch off the spirometer and printer. Check all plug connections.
	The printer is not switched on or is not ready.	Ensure that the printer is switched on and also has paper. Switch the printer off and back on again.
	<i>EasyOne Air</i> is not correctly positioned on the base unit.	Insert <i>EasyOne Air</i> correctly into the base unit.
If <i>EasyOne FlowTube</i> is not inserted correctly or if the <i>EasyOne FlowTube</i> detection is not working correctly.	An <i>EasyOne FlowTube</i> was inserted while <i>EasyOne Air</i> was switched on the instrument, or the <i>EasyOne FlowTube</i> was not inserted correctly.	Try again with the <i>EasyOne FlowTube</i> inserted correctly. If you receive the same message again, contact your <i>EasyOne</i> distribution partner or the <i>ndd</i> Servicing Department.
Wireless connection to external device is not working correctly.	Bluetooth is not enabled, or distance is too far, or Bluetooth is already connected to another device.	Enable Bluetooth (configuration), make sure device is close enough (within 5 meters or 16.4 feet), check setup.

☐ Troubleshooting solutions






- ⇒ [List of quality messages and quality grades](#) 55
- [Contact information](#) 4

12.4. About reactivating *EasyOne Air* after storage

After storing *EasyOne Air* for longer than approximately 8 hours without the battery, you must reactivate *EasyOne Air*.

Make sure that *EasyOne Air* has been stored under the specified storage conditions. If *EasyOne Air* has not been stored under correct conditions, or if you cannot verify the conditions, do not proceed. Contact your *EasyOne* distribution partner or the *n d d* Servicing Department.

To reactivate *EasyOne Air*, you must setup *EasyOne Air* like you did for the first-time setup.

- ⇒ [List of specifications for EasyOne Air](#)  89
- [About charging the battery of EasyOne Air](#)  86
- [Setting up the EasyOne Air spirometer](#)  23
- [Checking for correct operation of EasyOne Air](#)  86
- [Contact information](#)  4

12.5. Exporting logging information

EasyOne Connect can export logging information. The *n d d* Servicing Department or your own technical staff may require logging information to determine the source of a problem.

- 1 Choose **Utilities > Export Data**.
- 2 Select **Logging Information** and deselect all other check boxes.
- 3 Choose **Export**.
- 4 Select a location in your file system where you to save the log file, for example, a USB flash drive.
- 5 Choose **OK**.
 - ✓ A confirmation is displayed when the export has been successful.


- ⇒ [Contact information](#)  4

13. Specifications and bibliography




13.1. List of specifications for *EasyOne Air*

Size		87 × 155 × 36 mm (3.4 × 6.1 × 1.4 in)
Weight	without battery	302 g (11 oz)
	with battery	356 g (13 oz)
Measuring accuracy	Volume	±2% or 0.050 L
	Flow, except PEF	±2% or 0.020 L/s
	PEF	±5% or 0.200 L/s
	MVV	±5% or 5 L/min
Measuring resolution	Volume	1 mL
	Flow	4 mL/s
Measuring range	Volume	±12 L
	Flow	±16 L/s
Resistance		0.3 cm H ₂ O/L/s at 16 L/s
Measurement principle		Ultrasonic transit-time measurement
Display		88.9 mm (3.5 in) diagonal size, 320 × 240 pixels, LCD
Input method		Touchscreen
Test storage capacity		Up to 10,000 tests
Languages		English, French, German, Spanish, Italian, Danish, Dutch, Swedish
Data Management		<i>EasyOne Connect</i> PC software
Printing option		Direct to printer or with <i>EasyOne Connect</i> PC software
Export/EMR		HL7, XML, GDT (with <i>EasyOne Connect</i> PC software)
Hardware interface		USB 1.0/1.1, USB 2.0 (max. 100 mA), Bluetooth
Age range for patients		Spirometry >4 years
Respiratory tube		Disposable <i>EasyOne FlowTube</i> respiratory tube
Power supply		Rechargeable lithium-ion battery, USB power supply
Voltage (<i>EasyOne Air</i>)	Input	4.5 V to 5.5 V
Power consumption (<i>EasyOne Air</i>)		Up to 7.5 W
<i>ndd</i> power supply	Output voltage	5 V DC
	Output current	Up to 1400 mA
	Nominal input voltage	100 V to 240 V AC, 50 Hz to 60 Hz
	Nominal input current	160 mA to 80 mA
Appliance class		Class II

Specifications for *EasyOne Air*

Instrument classification		Type BF applied part (the surface of the <i>EasyOne Air</i> enclosure) Powered internally with a lithium-ion battery Short usage time, less than 10 minutes Not intended to be used in the presence of oxygen-rich environments
Mode of operation		Continuous operation
Wireless connection	Type	Bluetooth: v2.1 + EDR, v3.0 + HS, v4.0
	Modulation	Bluetooth: GFSK, DQPSK, 8DPSK
	QoS	WMM and WMM Power Save Support
	Frequency band	Bluetooth: 2.402 GHz to 2.480 GHz
	Transmit power	Bluetooth: 15 dBm (class-1)
	Receive sensitivity	Bluetooth: -94dBm
	Contains transmitter module	FCC ID: XF6-RS9113SB IC ID: 8407A-RS9113SB
Storage and transport conditions	Temperature	-20°C to 50°C (-4°F to 122°F)
	Relative humidity	5% to 90%
	Atmospheric pressure	500 hPa to 1060 hPa
	Battery	removed battery
Operating conditions	Temperature	0°C to 40°C (32°F to 104°F) At 40°C (104°F) room temperature, the surface temperature of the applied part of <i>EasyOne Air</i> can reach up to 44.7°C (112.5°F).
	Relative humidity	5% to 90%
	Atmospheric pressure	700 hPa to 1060 hPa
Certifications and standards	International standards	IEC 60601-1 Medical electrical equipment. General requirements for basic safety and essential performance
		IEC 60601-1-2 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests
		IEC 62304 Medical device software – Software life cycle processes
		IEC 62366 Medical devices. Application of usability engineering to medical devices
	ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes	
ISO 14971 Medical devices. Application of risk management to medical devices		
ISO 26782 Anesthetic and respiratory equipment. Spirometers intended for the measurement of time forced expired volumes in humans		
ISO 23747 Anesthetic and respiratory equipment. Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans		
EU	CE marked, EC declaration of conformity, see on the <i>n d d</i> website under “Certificates”	
US	FDA 510(k) market clearance	
Associations and institutes	ATS/ERS 2005, NIOSH, OSHA	
Life time		7 years

Specifications for *EasyOne Air*

- ⇒ List of tests and parameters  32
- Application Note *Reference Predicted Normal Values*
- Application Notes for further information  3
- Contact information  4

13.2. List of specifications for the lithium-ion battery of *EasyOne Air*

CAUTION

RISK OF PERSONAL INJURY

- Do not expose the battery to fire or dispose of the battery in fire.
- Do not put the battery in a charger or equipment with wrong terminals connected.
- Do not short circuit.
- Avoid excessive physical shock or vibration.
- Do not disassemble or deform the battery.
- Do not immerse in water.
- Do not use the battery in combination with any other batteries.
- Keep out of the reach of children.
- Only charge the battery when inside of *EasyOne Air* and in conjunction with the cradle and the power supply provided by the manufacturer.
- Never use a modified or damaged *EasyOne Air*, cradle, or power supply.
- Store the battery in a cool, dry and well-ventilated area.
- Dispose of the battery in accordance with local regulations. Regulations vary for different countries.

RISK OF FIRE AND BURNS

- Do not open, crush, heat above 50°C/122°F, or incinerate.
- Follow the instructions in this Operator's Manual.

Manufacturer		CTU Ltd. Second Floor Zhongxing Industrial Zone Chuang Ye Rd. Nanshan Shenzhen 518054 China
Type	Original	Lithium-ion Battery Pack 1ICR1865
	New	Lithium-ion Battery Pack 1ICR19/66
Weight	Type 1ICR1865	54 g (1.9 oz)
	Type 1ICR19/66	59 g (2.1 oz)
Rated capacity	Type 1ICR1865	3400 mAh, 12.24 Wh
	Type 1ICR19/66	3000 mAh, 10.80 Wh
Rated voltage		3.6 V DC
Battery life		100 tests with a full battery charge

 Specifications for the lithium-ion battery of *EasyOne Air*

The following standard conditions are identical to the conditions of *EasyOne Air*. Storage, transport, and operation under these conditions is safe.

Standard storage and transport conditions	Temperature	-20°C to 50°C (-4°F to 122°F)
	Relative humidity	5% to 90%
	Atmospheric pressure	500 hPa to 1060 hPa
	Battery	removed battery
Standard operating conditions	Temperature	0°C to 40°C (32°F to 104°F)
	Relative humidity	5% to 90%
	Atmospheric pressure	700 hPa to 1060 hPa

The following optimized conditions prolong the life expectancy of the battery.

Optimized environmental conditions	Temperature	23±5°C (73.4±9°F)
	Humidity	45% to 75% relative humidity
	Atmospheric Pressure	860 hPa to 1060 hPa
Optimized operating conditions while charging and discharging	Charging	0°C to 45°C (32°F to 113°F) 45% to 85% relative humidity
	Discharging	-20°C to 60°C (-4°F to 140°F) 45% to 85% relative humidity
Optimized storage periods and storage conditions resulting in no less than 80% recoverable capacity of the initial capacity	Storage period ≤1 month	-20°C to 60°C (-4°F to 140°F) 45% to 85% relative humidity
	Storage period ≤3 months	-20°C to 45°C (-4°F to 113°F) 45% to 85% relative humidity
	Storage period ≤1 year	-20°C to 20°C (-4°F to 68°F) 45% to 85% relative humidity

Icons on the battery		The battery complies with the requirements of applicable EC directives of the European Union.
		Consult instructions for use.
		Caution, consult accompanying documents.
	Europe only	In the European Union, the product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local WEEE collection facilities to dispose of this product and otherwise observe all applicable requirements.
		The battery was certified for the US market by <i>SGS CSTC Standards Technical Services Co., Ltd.</i> , Shanghai in project number 710351.
		Batch code

☐ Specifications for the lithium-ion battery of *EasyOne Air*

	Manufacturer
	Catalog number

Specifications for the lithium-ion battery of *EasyOne Air*

13.3. List of order numbers and accessories for *EasyOne Air*

Item	Intended region	Order number
<i>EasyOne Air</i> US	USA, Canada, and Latin America	2500-2A
<i>EasyOne Air</i> International	Rest of the world	2500-2INT
<i>EasyOne FlowTube</i> box of 50 pcs.	Worldwide	5050-50
<i>EasyOne FlowTube</i> box of 200 pcs.	Worldwide	5050-200
<i>EasyOne FlowTube</i> box of 500 pcs.	Worldwide	5050-500
<i>ndd</i> calibration syringe 3 L with <i>EasyOne FlowTube</i> cal check adapter	Worldwide	2030-2
<i>EasyOne FlowTube</i> cal check adapter	Worldwide	5030-2
<i>EasyOne Air</i> USB cable B–micro (cradle to printer)	Worldwide	2500-50.1sp
<i>EasyOne Air</i> bluetooth dongle	Worldwide	2500-50.2sp
<i>EasyOne Air</i> battery pack	Worldwide	2500-50.4sp
<i>EasyOne Air</i> power supply with adapters	Worldwide	2500-50.5sp
<i>EasyOne Air</i> cradle	Worldwide	2500-50.11sp

Order numbers and accessories for *EasyOne Air*

13.4. List of system requirements for *EasyOne Connect*

To install *EasyOne Connect*, make sure that your PC *EasyOne Connect* meets the following system requirements:

Operating system	Microsoft Windows 7, Microsoft Windows 8 and 8.1 (32 bit and 64 bit), Microsoft Windows 10 (32 bit and 64 bit)
Hard disk capacity	1 GB (software) 4 GB (database)
RAM	2 GB

System requirements for *EasyOne Connect*

13.5. List of bibliographic references

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⇒ [Application Note Reference Predicted Normal Values](#)

[Application Notes for further information](#)  3

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A. Appendix

A.1. Specific lung function tests for the USA

The following tests are only available with US regional settings.

A.1.1. About the OSHA test

The OSHA test is intended for occupational testing and meets certain standardization requirements. The OSHA test is only available with US regional settings.

From the test menu in *EasyOne Connect*, choose the OSHA test.

On *EasyOne Air*, choose the OSHA test from the more menu.

The patient performs the same breathing maneuver as for the FVC test.

Reports meet the requirements of the following institutions and standards:

- Occupational Safety and Health Administration (OSHA)
- National Institute for Occupational Safety and Health (NIOSH)
- Cotton Dust standard (29 CFR: 1910.1043 Appendix D)
- Predicted values for adults according to Knudson (1976)

The default configuration for predicted values for adults is NHANES III. To use predicted values for adults according to Knudson (1976), you need to change the configuration in the following menu:

 >  >  > **Predicted set 1**

According to these requirements, the reports contain the following information:

- The best three tests and volume-time curves are saved and printed.
- The curves are printed in large, in validation size.
- There is no clinical interpretation displayed or printed.

⇒ [Performing spirometry](#)  41

[Performing the breathing maneuver for the FVC test](#)  58

[Application Note Reference Predicted Normal Values](#)

[Application Notes for further information](#)  3

A.1.2. About the SSA test

The SSA test is intended to test for social security disabilities. The SSA test is only available with US regional settings.

The patient performs the same breathing maneuver as for the FVC test. Merely the quality grades for the SSA are different from the quality grades for the FVC test.

- ⇒ [Performing spirometry](#) 41
- [Performing the breathing maneuver for the FVC test](#) 58
- [Quality grades for the SSA test](#) 56

A.2. Electromagnetic Compatibility (EMC)

A.2.1. General

A.2.1.1. Environment

See:

- ⇒ [Intended use of the EasyOne Air spirometer](#) 3

A.2.1.2. EMC conformance

EasyOne Air is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 3rd edition (see the following tables) and IEC 60601-1-2:2014 4th edition (according clause 7 and 8.9, tables 4 to 9). *EasyOne Air* is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the information given in tables below.

A.2.2. Safety information

See:

- ⇒ [Safety information regarding electromagnetic compatibility](#) 13

A.2.3. Compliant cables and accessories

WARNING

INCREASED EMISSIONS OR DECREASED IMMUNITY

The use of accessories, transducers and cables other than those specified may result in increased emission or decreased immunity performance of the equipment or system.

The table below lists cables, transducers, and other applicable accessories with which the manufacturer claims EMC compliance.

Accessories that do not affect EMC compliance are not included in the following list.

USB cable micro to type A, shielded, 1.8 m

USB cable micro to type B, shielded, 1.8 m

ndd power supply 5.0 V DC

Accessories with which the manufacturer claims EMC compliance

⇒ [List of box contents](#)  17

A.2.4. Wireless module

EasyOne Air contains a wireless module for Bluetooth communication.

See *Wireless connection* in:

⇒ [List of specifications for EasyOne Air](#)  89

A.2.5. Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions

EasyOne Air is intended for use in the electromagnetic environment specified below. The user of *EasyOne Air* should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	<i>EasyOne Air</i> uses RF energy for its internal function. Additionally, the EUT contains a Radio Bluetooth and BLE module, which complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF emissions CISPR 11	Class B	<i>EasyOne Air</i> 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 IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Emission table for IEC 60601-1-2 3rd and 4th edition

A.2.6. Electromagnetic immunity


The following tables are guidelines according to the 3rd edition of the medical standard IEC 60601-1-2.

Guidance and manufacturer's declaration – electromagnetic Immunity

EasyOne Air is intended for use in the electromagnetic environment specified below. The user of *EasyOne Air* should assure that it is used in such an environment.

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (0.5 cycles) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	<5% U_T (0.5 cycles) 40% U_T (5 cycles) 70% U_T (25 cycles) <5% U_T for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Electromagnetic immunity

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of the <i>EasyOne Air</i>, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p> $d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 0.7\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following icon:</p> 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	
			<p>Note: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>^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 <i>EasyOne Air</i> is used exceeds the applicable RF compliance level above, the <i>EasyOne Air</i> should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the <i>EasyOne Air</i>.</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>

Electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and *EasyOne Air*

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 0.35\sqrt{P}$	$d = 0.7\sqrt{P}$
0.01 W	0.12 m	0.035 m	0.07 m
0.1 W	0.38 m	0.11 m	0.22 m
1 W	1.2 m	0.35 m	0.70 m
10 W	3.8 m	1.1 m	2.2 m
100 W	12 m	3.5 m	7.0 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Note: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.			

Recommended separation distances between portable and mobile RF communications equipment and *EasyOne Air*