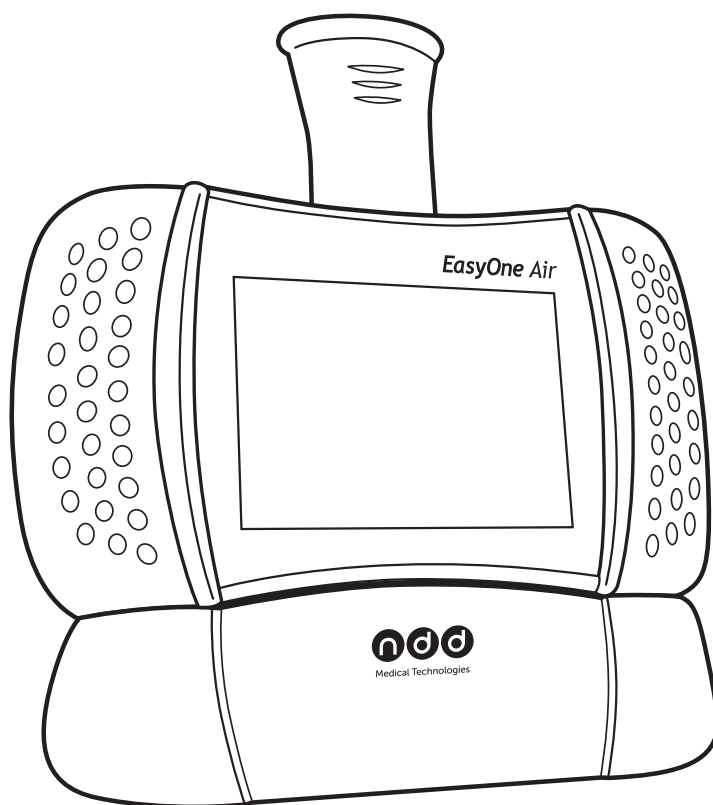




EasyOne Air

Operator's Manual V08

1. Preface

1.1. Using this Operator's Manual

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

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

Before printing out pages from this Operator's Manual, consider the environmental impact.

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

This revision V08 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 V1.21.x or higher.

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

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

⇒ nddmed.com/ea/downloads

1.3. Version history of **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.

This revision V08 of the **EasyOne Air** Operator's Manual refers to the software version **EasyOne Connect** V3.9.5.x or higher.

⇒ nddmed.com/ea/downloads

1.4. Intended use/ Indications for use of **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. Clinical benefit

The **EasyOne Air** allows for improved patient management with accurate lung function measurement and an early diagnosis of lung disease.

1.6. Patient population

- Adults and children over the age of 4 years.
- General ability to perform a lung function test maneuver and to follow instructions.

1.7. User profile

The intended users are general practitioners, specialists and health care professionals (e.g. physicians, respiratory therapists or nurses) in primary care, hospitals, pharmacies or occupational medicine. The users are expected to have working knowledge of medical procedures, practices, and terminology as required to conduct or interpret diagnostic spirometry tests. The device is operated by the user and only handed over to the patient for the performance of a test. The patients are instructed on how to perform a test by the user.

1.8. Use environment

EasyOne Air is a portable, hand-held device. **EasyOne Air** will mainly be used inside the physician's offices and hospitals. Conducting of spirometry outside of a building is possible because the device is portable. However, the normal usage will happen inside a building.

1.9. Indications and contraindications

EasyOne Air is indicated to support the diagnosis and management of lung diseases (e.g. COPD, asthma) and to monitor lung function.

EasyOne Air does not have any absolute contraindications.

For safe handling of the **EasyOne Air**, please read the chapter on safety information and adhere to the risk information in this Operator's Manual.

 [Safety information 11](#) 

Performing spirometry can be physically demanding. The prescription of **EasyOne Air** is the responsibility of a healthcare professional, who is required to perform a comprehensive evaluation of the benefits and risks for each individual patient. Carefully read the chapter:

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

1.10. Revision history of **EasyOne Air** Operator's Manual

Revision date	Version	Description
28 January 2025	V08	Revised version reflecting new packaging content and improved explanations and clarity across multiple chapters for better understanding.
27 November 2023	V07	Minor updates for European Medical Device Regulation 2017/745 (MDR) compliance
18 July 2023	V06	Revised version reflecting, software update to be aligned with ERS/ATS technical standard on interpretive strategies for routine lung function tests 2021 and European Medical Device Regulation 2017/745 (MDR) updates
30 November 2021	V05	Integration of <i>EasyOne</i> Filter and minor general changes
15 April 2021	V04	Implementation of spirometry standard 2019
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

1.11. Application Notes for further information

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

⇒ nddmed.com/eoa/downloads

1.12. Legal information

Any serious incident that occurs in connection with the device must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient resides.

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.

⇒ Find all *ndd* patents here:
nddmed.com/legal/patents

1.13. Contact information



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1.14. Authorized representatives

ndd's authorized representatives can be found here: nddmed.com/rep.

1.15. Technical support

ndd is committed to providing first-class technical support. Please use the support request form on our website to open a case with our support team or call us directly at one of the numbers below:

International support: Tel: +41 (0) 44 512 65 10

US/Canada/LATAM support: Tel: +1 978 470 0923 Option 1

1.16. Product registration

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

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

⇒ nddmed.com/registration

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2. Safety information



Particular attention must be paid to the following safety information consisting of warnings and cautions. If safety messages are ignored, users might suffer serious or fatal injury.

2.1. Personnel instruction and qualification

Patient health risk

Allowing uninstructed or inadequately qualified personnel to operate **EasyOne Air** can lead to erroneous results, interpretations, or diagnoses, putting the patient's health at risk. The patient might suffer a bronchoconstriction while performing spirometry.

- Make sure that all personnel are familiar with this Operator's Manual and have understood its content.
- **EasyOne Air** must only be used by qualified personnel.

 [User profile 3](#)

Allergic and anaphylactic reaction

If an allergic person's skin comes into contact with cleaning solutions, battery solution, the spirometer's casing or a broken display, it might lead to an allergic or anaphylactic reaction.

- To avoid contact with cleaning solutions via skin or inhalation of fumes, make sure that there is no obvious or wet residue left on the device and always wipe the spirometer dry after cleaning.
- If skin or eyes come into contact with battery fluid or liquid crystal from the display, rinse the affected areas with water and seek medical assistance.
- In case of a known allergy to polymer based materials contact *ndd* to provide you with further information regarding material.

2.2. IT and connection to other devices

Data loss

Data loss might occur due to a failed update or for various other reasons and is generally unpredictable.

- Perform backups of the database of **EasyOne Air** and **EasyOne Connect** frequently.

 [Performing a backup 83](#)

Malfunction due to virus

Viruses, malware, and other hazardous software on your PC might adversely affect the performance of **EasyOne Connect**.

- Install anti-virus software on your PC.

Network connection

Connection of **EasyOne Connect** to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties.

Subsequent changes to the IT network could introduce new risks and require additional analysis. Changes to the IT network include:

- 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.

- Identify, analyze, evaluate, and control these risks. IEC 80001-1 provides guidance to address these risks.

Leakage currents

Patients and technicians might be exposed to leakage currents when connecting **EasyOne Air** to defective electric equipment. It is the operator's responsibility to ensure electric safety. Therefore, strictly adhere to the following:

- To ensure electric safety, connect only equipment, such as power supply units, PCs, printers and networks that comply with either IEC 62368-1, IEC 60601-1, or equivalent standards for electrical safety.

2.3. Compatible components or services

Cross-contamination and adverse reaction

Disposable breathing mouthpieces (**EasyOne FlowTube**) or other disposable components are designed for single patient use only. If one and the same breathing mouthpiece is used for several patients, cross-contamination can occur.

- Use a new disposable breathing mouthpiece (**EasyOne FlowTube**) or component for each patient.

Erroneous results due to wrong components

Non-original components like batteries can cause malfunction of the device and non-original disposables, like breathing mouthpieces, can cause erroneous results.

- Only use original components and disposables by the manufacturer.
[List of order numbers for **EasyOne Air** and its components 118](#)

Malfunction due to wrong servicing

Wrong services or repairs not carried out by *ndd* or qualified personnel can lead to malfunctions.

- Servicing must only be carried out by *ndd* staff or by qualified service personnel of official *ndd* distributors.
- Do not try to repair **EasyOne Air** yourself.
- Do not open **EasyOne Air**.

2.4. Fire, heat and explosion

Fire due to battery short circuit

Batteries have to be disposed of properly. If the batteries get close to or come into contact with liquids, aluminum foil, etc. during disposal, they might catch fire due to a short circuit.

- Do not throw the battery into fire.
- Follow the manufacturer's recommendation for proper disposal of the battery.

 [Disposal 111](#) 

Leakage of acids and explosion

Wrong handling of batteries can lead to leakage of acids and explosion.

- Avoid mechanical shock to the battery.
- If the rechargeable battery is damaged, liquids from the battery must not come into contact with skin or eyes. If a battery has leaked, put on protective gloves and clean the battery compartment with a dry cloth. If skin or eyes come into contact with battery fluid, rinse the affected areas with water and consult a physician.
- Only charge the battery with a power supply or PC that complies with either IEC 62368-1, IEC 60601-1, or equivalent standards for electrical safety.

 [List of specifications for the power supply unit 117](#) 

- Follow the manufacturer's recommendation for proper disposal of the battery.

 [Disposal 111](#) 

Fire due to defect

A defect in the batteries might lead to overheating and fire.

- Check the battery for any visible damage before use.
- Only use an original battery provided by the manufacturer.

Fire due to explosive or flammable gases

If used in the vicinity of flammable gases, the plastic case might catch fire and cause burn injuries to the patient.

- For preventive measures, make sure that the device is not used near flammable gases (for example, anesthetic agents).
- When storing the device for a longer period of time, remove the battery and store the battery in the original packaging.

2.5. Environment, storage, transport

Measurement errors

Environment, storage or transport conditions outside the range described in the specifications can cause measurement errors.

- Use **EasyOne Air** only within the defined environment, storage and transport specifications for temperature, humidity, and atmospheric pressure/altitude.
- Do not use **EasyOne Air** immediately after removing it from an extreme storage environment, even if it was stored under conditions still within the specified range of environmental conditions.
- Allow enough time for the device to acclimatize to the ambient environment where patient testing takes place after removing it from storage.
- Observe the limits of storage conditions.

 [List of specifications 112](#)

 [Reactivation after storage 110](#)

Malfunction or insufficient hygiene

EasyOne Air, **EasyOne FlowTube**, compatible components or their wrapper might be damaged when dropped or during transport. If **EasyOne Air** has been dropped or damaged, this can lead to malfunctions. If the **EasyOne FlowTube** has been dropped or damaged, this can lead to malfunctions or render the **EasyOne FlowTube** unusable due to unfulfilled hygienic standards.

- Perform an incoming inspection of all components when you first receive **EasyOne Air**. If you detect any damage, contact your *ndd* distribution partner or the *ndd* servicing department.
- Especially check the battery for visible damage before use. If you detect any damage, contact your *ndd* distribution partner or the *ndd* servicing department.
- Do not drop **EasyOne Air**, **EasyOne FlowTube** or other compatible components.
- If **EasyOne Air** has been dropped, check for correct operation of **EasyOne Air**.
 [Checking for correct operation 106](#)
- If the **EasyOne FlowTube** or other compatible components have been dropped, check for correct operation or tears in the wrapper.
- If you detect tears in the wrapper of single use components (e.g., **EasyOne FlowTube**), dispose of the single use component and use a new one.

Excessive heat during storage

When storing the device, prolonged exposure to direct sunlight, for example in cars, or exposure to other sources of heat might cause the battery to explode.

- Do not store in places that can exceed temperatures of 50°C or 122°F.
- When storing the device for a longer period of time, remove the battery and store the battery in the original packaging.

2.6. Safety information regarding electromagnetic compatibility

Impact of HF surgical equipment	Electrical devices with a high RF (radio frequency) power output (e.g., high frequency (HF) surgical equipment) can influence the operation of EasyOne Air. 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 EasyOne Air.
Portable wireless communications equipment	Portable wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies, etc. can affect EasyOne Air. Keep a distance of at least 30 cm (12 in) to any part of EasyOne Air.
Increased emissions or decreased immunity	Use of components (incl. battery, cables etc.) and replacement parts other than those specified by the manufacturer can result in increased emissions or decreased immunity of EasyOne Air. Do not use components other than those specified by the manufacturer.
Proximity to other equipment	Proximity to other equipment can influence the operation of EasyOne Air. - Do not use EasyOne Air adjacent to or stacked with other equipment. - Should close proximity or stacking be unavoidable: closely watch the configuration in which it is used to ensure that the equipment is functioning normally. - Should the device be stuck in freeze mode, restart your EasyOne Air.
Interruption of the USB connection	Electrical fast transient coupling to the USB cable or electrostatic discharge on the device might 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. Do not interrupt the USB connection data transmission.

⇒  [Appendix - Electromagnetic compatibility \(EMC\) 120](#) 

2.7. 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.

Notice

Notice . . .

- . . . indicates a hazardous situation which, if not avoided, will result in damage to the device.

2.8. Requirements for connections to external devices

Caution

Malfunction

Wrongly connected devices can lead to a communication malfunction, which can lead to missing test data and erroneous diagnosis.

- Make sure to follow the manufacturer's instructions for setting up **EasyOne Air**.

 [First-time setup 21](#) ↗

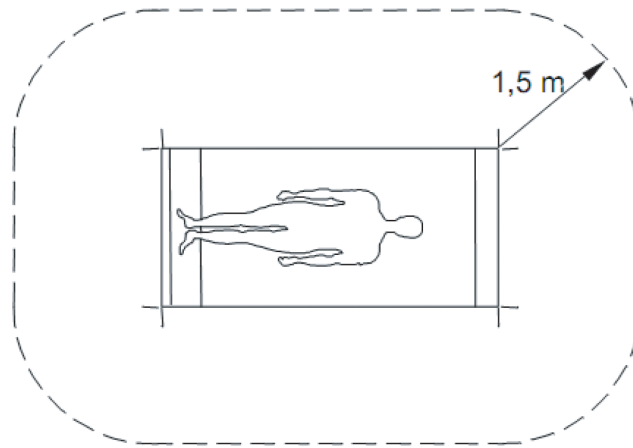
To access all functions of **EasyOne Air**, connect the device to the software **EasyOne Connect**. **EasyOne Connect** is installed on a PC or laptop, to which **EasyOne Air** is connected via its cradle or wirelessly via Bluetooth.

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's environment must meet the requirements of IEC 60601-1.
- All equipment set up outside the patient's environment must meet the requirements of the applicable IEC or ISO safety standards (e.g. IEC 62368-1).



☐ 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:

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

IEC 60601-1 specifies the requirements for power outlet strips.

Bear in mind that the touch currents might vary depending on the system configuration.

⇒ Minimum specifications for PC and printer:

 [List of system requirements 118](#)

 [Compatible printers 23](#)

2.9. List of equipment icons



Consult instructions for use



Follow instructions for use



Do not reuse, i.e., single-patient use (applicable to the **EasyOne FlowTube**)



CE mark including Notified Body Identification Number



Complies with the provisions of the applicable EU regulations



Compliance with additional US and Canadian safety requirements for medical electrical equipment



United Kingdom Conformity Assessed



Medical electric equipment that includes a radio frequency transmitter and emits non-ionizing radiation



Manufacturer



Date of manufacture



Country of manufacture: Switzerland

Rx ONLY

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



The product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local Waste of Electrical and Electronic Equipment (WEEE) collection facilities to dispose of this product and otherwise observe all applicable requirements.



Instrument classification: Type BF applied part



Universal Serial Bus (USB 1.0/1.1, USB 2.0, max. 100 mA), standard for connecting devices and data transfer, 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



Global trade item number



Batch code



Catalogue number



Medical Device



Authorized representative in the European Community



Authorized representative in the United Kingdom



Unique Device Identifier



Indication for **EasyOne FlowTube** insertion



Minimal compatible software



Expiration date

2.10. List of used symbols in Operator's Manual

- ⇒ Followed by a cross-reference at the end of a chapter
- ↗ Indicates a cross-reference
- ☞ Introduces a cross-reference to a paragraph
- Introduces a cross-reference to a graphic
- ▢ Introduces a cross-reference to a table
- ▣ Followed by "Prerequisite" (i.e. What requirements have to be fulfilled before performing an action)
- 📄 Followed by additional information
- ✓ Followed by the result of an action

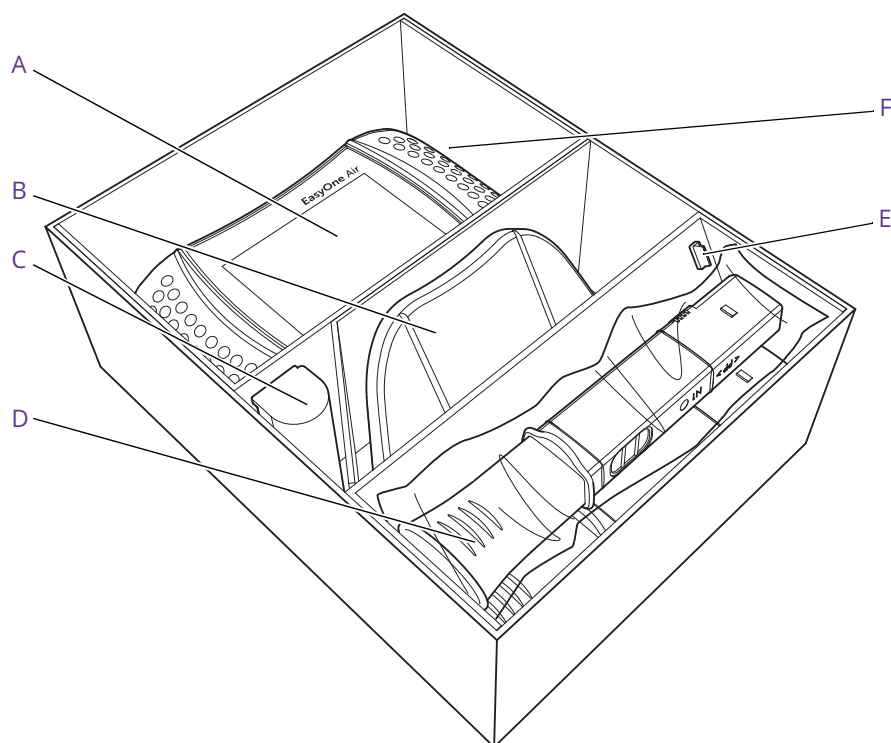
2.11. Terminology used on label

Support	Contact for technical support
Patents	Website to access all <i>ndd</i> relevant patents
Including	This package includes the following...
Rechargeable	Rechargeable battery
Contains	This device contains...

3. First-time setup

3.1. List of box contents

The box contains the following items:



A **EasyOne Air** spirometer

B Cradle

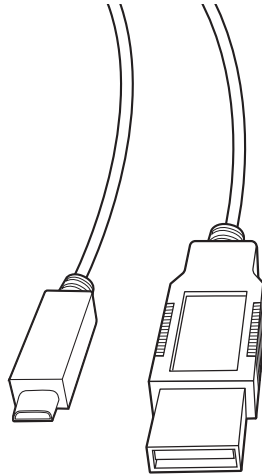
C Battery

☐ Box contents

D **EasyOne FlowTube** breathing mouthpiece

E USB Bluetooth adapter

F USB cable (below **EasyOne Air**)



- ☐ USB cable micro to type A

The box contains the following documents:

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

3.2. Installing or updating **EasyOne Connect** software on your PC

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

Prerequisites

- ☐ Your PC meets the system requirements for **EasyOne Connect**.
 [List of system requirements 118](#)
 - ☐ Your Windows user has administrator privileges.
- 1 Go to the *n d d* website via noddmed.com/ea/downloads or via the QR-Code on the Quick Guide and download **EasyOne Connect** to your PC.
 - 2 Install **EasyOne Connect** on your PC.
 - 3 Follow the on-screen instructions.

3.3. Compatible printers

EasyOne Air can print via USB when using the cradle.

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

 [Print settings 82](#)

 [Setting up the physical components 24](#)

Application Note *Printing with EasyOne Air*:

 [Application Notes for further information 4](#)

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

⇒ For installing printers, online help of Microsoft Windows
[Operator's Manual of your printer](#)

3.4. Setting up the physical components

Warning

Electric shock, patient health hazard, and erroneous diagnosis

If the packaging is exposed to environmental conditions outside of those specified by the manufacturer it might damage the casing. A damaged casing or broken components in general might expose the patient or technician to dangerous voltage. If a disposable component is damaged small parts of it could be ingested or inhaled by the patient and lead to choking. Measurement errors can lead to erroneous diagnoses.

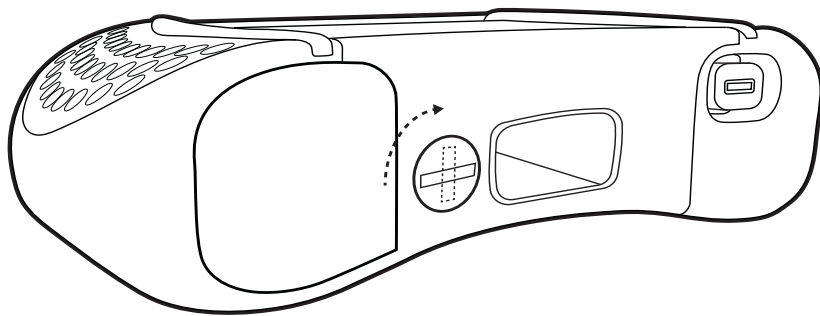
- Check the device, compatible components and especially the battery for visible damage before on-site installation and before use.

Leakage currents

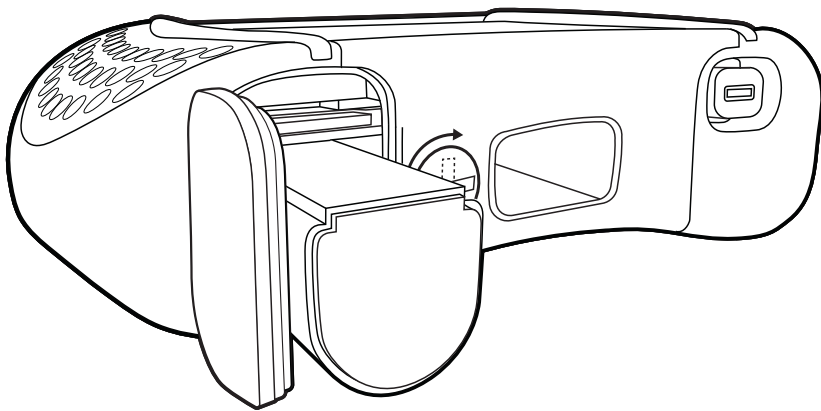
Patients and technicians might be exposed to leakage currents when connecting **EasyOne Air** to defective electric equipment. It is the operator's responsibility to ensure electric safety. Therefore, strictly adhere to the following:

- To ensure electric safety, connect only equipment, such as power supply units, PCs, printers and networks, that comply with either IEC 62368-1, IEC 60601-1, or equivalent standards for electrical safety.

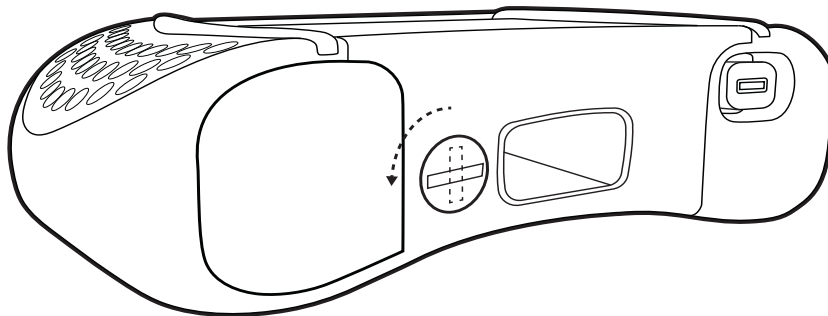
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



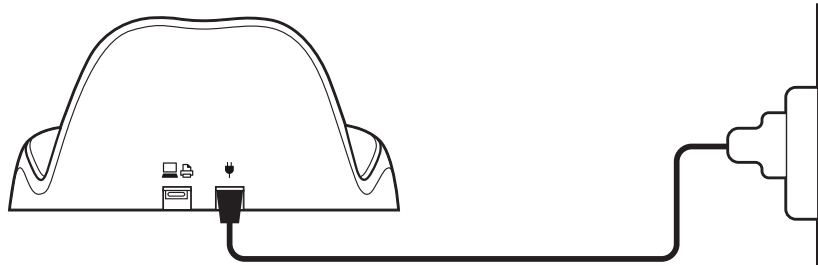
- 2 Insert the battery into the battery compartment of **EasyOne Air**.



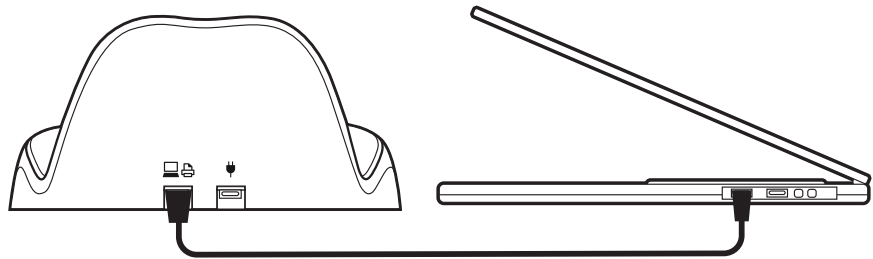
- 3 Close and lock the battery compartment by turning the lock screw counterclockwise.



- 4 To charge **EasyOne Air**, connect the cradle to a power source:
- To a power supply unit:
Plug the power supply into a power outlet which is easily accessible for connection and disconnection, and into the micro USB with the symbol  on the cradle.
 [List of specifications for the power supply unit 117](#)
 - To a PC:
Connect the larger plug of the *USB cable micro to type A* to a USB port powered by a computer. This setup allows to connect to **EasyOne Connect** at the same time.

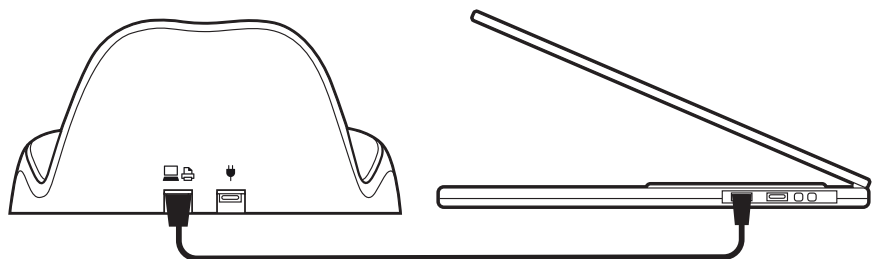


☐ Charging **EasyOne Air** on a power supply unit (a)

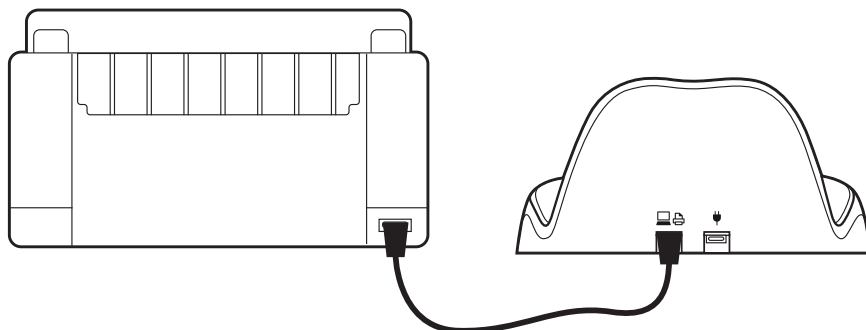


☐ Charging **EasyOne Air** on a PC (b)

- 5 To transfer data to a PC, connect the cradle to a PC, doing the following:
- 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).
 - Connect the larger plug of the *USB cable micro to type A* to a USB port of your PC.



- 6 To connect the cradle to a printer, do the following:
 - a) Connect the cradle to a printer using the micro USB port of the cable.
-  An USB cable micro type B can be ordered from *ndd*.
-  [List of order numbers for **EasyOne Air** and its components 118](#) 



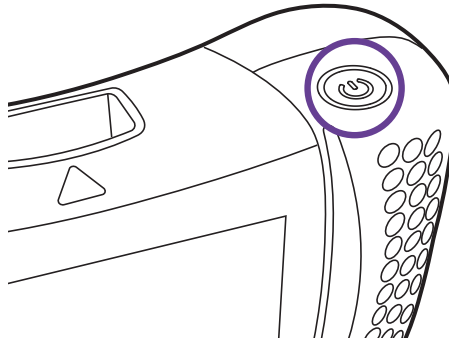
- 7 To disconnect **EasyOne Air** from the power supply, do one of the following:
 - a) Unplug the power supply from the power outlet.
 - b) Unplug the cable from the cradle (marked with the  symbol).

3.5. Preparation for first-time use

Prerequisite

- ❑ You have set up the physical components
[❏ Setting up the physical components 24](#)

- 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.
 - ❏ If the battery is removed for more than 8 hours, you need to reenter date and time.
 - 6 Select the printer type.
 - 7 Select the ATS/ERS spirometry standard.
 - 8 Select the bronchodilator response type (BDR).
 - 9 Select the use of an inline filter.
 - 10 Choose **Next**.
- ⇒ [❏ Configuration of **EasyOne Air 79**](#)
[❏ Print settings 82](#)

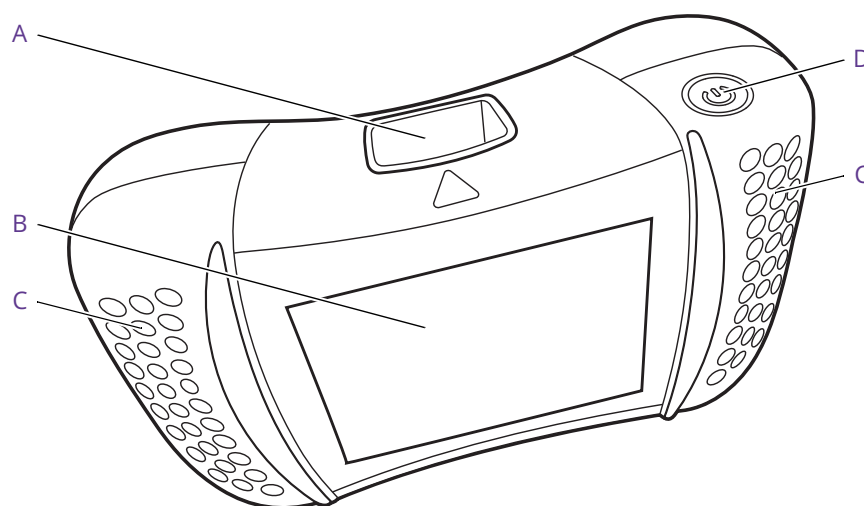
4. Introduction

The **EasyOne Air** uses digital ultrasonic flow measurement technology to conduct air flow measurements. It can be used as a stand-alone, enabling users to display, save and analyze patient data directly on the device.

EasyOne Air can also be used in combination with **EasyOne Connect** for further functions like user-specific test protocols, data management or import of external test data.

4.1. Overview of **EasyOne Air**

The **EasyOne Air** spirometer



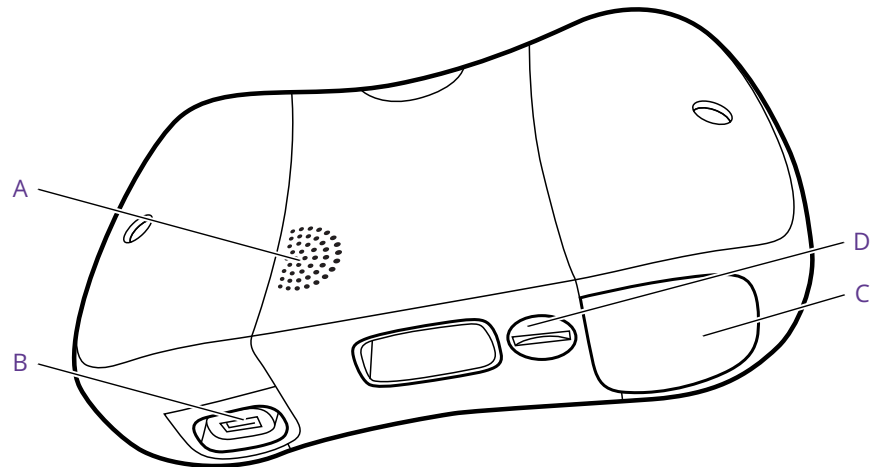
A **EasyOne FlowTube** holder

B Touchscreen

C Handles

D Power button

□ Top-view of **EasyOne Air**



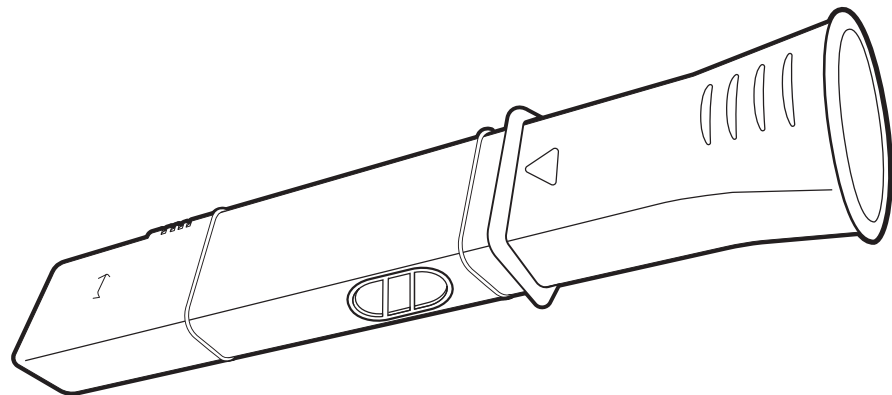
- | | |
|-----------------------|--------------------------------------|
| A Speaker | B USB port to connect to the cradle |
| C Battery compartment | D Lock screw for battery compartment |

☐ 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** breathing mouthpiece for single-patient use



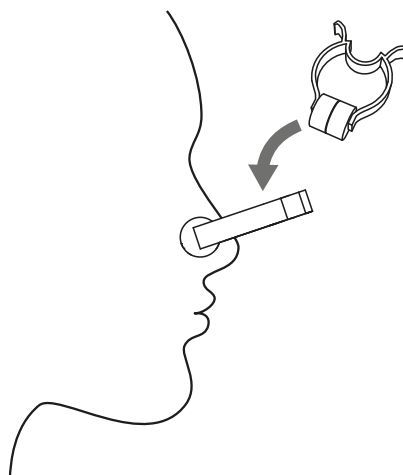
☐ The **EasyOne FlowTube** breathing mouthpiece

To ensure hygienic testing, the **EasyOne FlowTube** breathing mouthpiece 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**Erroneous diagnosis**

Non-original breathing mouthpieces can cause measurement errors and erroneous results.

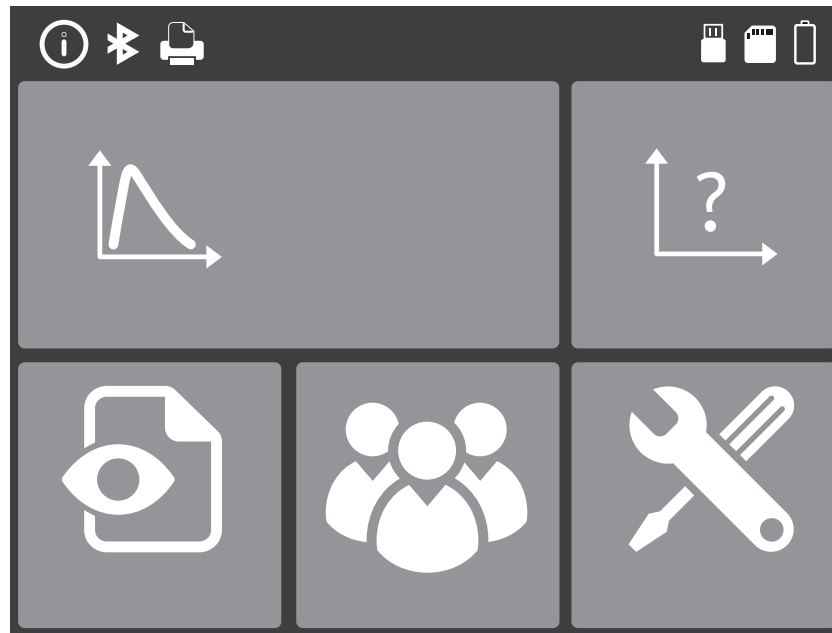
- Use only **EasyOne FlowTube** breathing mouthpieces provided by the manufacturer *ndd* to ensure accuracy, long-life, and full warranty coverage of the lung function device.

Nose clip

We recommend using the nose clip during tests to avoid air escaping through the nose.

4.2. Overview of the user interface

The home screen

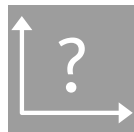


□ The home screen of **EasyOne Air**

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 names.



In the tools menu, you can configure **EasyOne Air**, perform calibration checks, 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 recalculate button, you can recalculate patient data and results.

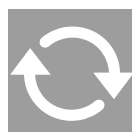
The tools menu displays the following icons:



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 back up, restore and delete the patient database and configurations.



The information menu displays information about the currently installed firmware.

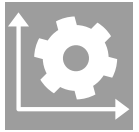


In the user menu, you can configure individual users and their passwords for login.

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.



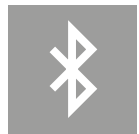
In the security settings menu, you have access to device security settings such as enabling user/password authentication.



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.



In the Bluetooth menu, you can find general information about the Bluetooth function, set a Bluetooth key as well as activate or deactivate Bluetooth.

 [Configuration of **EasyOne Air** 79](#)

The status bar

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

The status bar displays the following icons:



Indicates information about technical support and access to the operator's manual.



Indicated that Bluetooth is enabled.



Indicates that Bluetooth is connected.



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 a power source and currently charging. But the charging level is still low.



Indicates that **EasyOne Air** is connected to a power source and currently charging. The charging level is at about 50%.



Indicates that **EasyOne Air** is connected to a power source that is too low in wattage to charge.

 [List of troubleshooting solutions 107](#)



Indicates a poor battery condition.
Consider replacing the battery.

The < Back button and the home button



 < Back button

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

4.3. Overview of features of **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.

⇒  [Connectivity and data exchange 40](#)

4.4. List of terms and definitions

Term	Definition
test	Short for spirometry test.
	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.
	A test comprises one or more trials. At least three trials are recommended, but not required.
	For each test, a report is generated.
trial	The performing of one breathing maneuver.
	A trial is part of a test.
parameter	For each trial, parameters are calculated from its curve.
post	Short for post bronchodilator.
	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.

 Terms and definitions

4.5. List of tests and parameters

The following tables give an overview of the relevant tests and parameters in **EasyOne Connect**. The parameters are established in the professional literature and constitute the results of testing. The parameters on the **EasyOne Air** standalone device are fixed (currently up to 14).

Test	Test description	Available parameters
FVC	Forced expiratory vital capacity test	ATI, BEV, EOTV, FEF ₁₀ , FEF ₂₅ , FEF ₂₅₋₇₅ , FEF _{25-75_6} , FEF ₄₀ , FEF ₅₀ , FEF ₅₀ /FVC, FEF ₅₀ /VC _{max} , FEF ₆₀ , FEF ₇₅ , FEF ₇₅₋₈₅ , FEF ₈₀ , FET, FET ₂₅₋₇₅ , FEV _{.25} , FEV _{.5} , FEV _{.5} /FVC, FEV _{.75} , FEV _{.75} /FEV ₆ , FEV _{.75} /FVC, FEV _{.75} /VC _{max} , FEV ₁ , FEV ₁ /FEV ₆ , FEV ₁ /FVC, FEV ₁ /FVC ₆ , FEV ₁ /VC, FEV ₁ /VC _{max} , FEV ₁ Q, FEV ₃ /FVC, FEV ₃ /VC _{max} , FEV ₃ , FEV ₆ , FVC, MEF ₂₀ , MEF ₂₅ , MEF ₄₀ , MEF ₅₀ , MEF ₆₀ , MEF ₇₅ , MEF ₉₀ , MMEF, MTC ₁ , MTC ₂ , MTC ₃ , MTCR, PEF, PEFT, t ₀ , VC, VC _{max}
FVL	Flow volume loop test	ATI, BEV, CVI, E ₅₀ /I ₅₀ , EOTV, FEF ₁₀ , FEF ₂₅ , FEF ₂₅₋₇₅ , FEF _{25-75_6} , FEF ₄₀ , FEF ₅₀ , FEF ₅₀ /FVC, FEF ₅₀ /VC _{max} , FEF ₆₀ , FEF ₇₅ , FEF ₇₅₋₈₅ , FEF ₈₀ , FET, FET ₂₅₋₇₅ , FEV _{.25} , FEV _{.5} , FEV _{.5} /FVC, FEV _{.75} , FEV _{.75} /FEV ₆ , FEV _{.75} /FVC, FEV _{.75} /VC _{max} , FEV ₁ , FEV ₁ /FEV ₆ , FEV ₁ /FIV ₁ , FEV ₁ /FIVC, FEV ₁ /FVC, FEV ₁ /VC, FEV ₁ /VC _{max} , FEV ₃ /FVC, FEV ₃ /VC _{max} , FEV ₁ Q, FEV ₃ , FEV ₆ , FIF ₂₅ , FIF ₂₅₋₇₅ , FIF ₅₀ , FIF ₅₀ /FEV ₅₀ , FIF ₇₅ , FIV _{.25} , FIV _{.5} , FIV ₁ , FIVC, FVC, MEF ₂₀ , MEF ₂₅ , MEF ₄₀ , MEF ₅₀ , MEF ₆₀ , MEF ₇₅ , MEF ₉₀ , MIF ₂₅ , MIF ₅₀ , MIF ₇₅ , MMEF, MMIF, MTC ₁ , MTC ₂ , MTC ₃ , MTCR, PEF, PEFT, PIF, t ₀ , VC, VC _{max}
MVV	Maximum voluntary ventilation test	MVV, MVV ₆ , MVV _{time} , Rf, VC _{ext} , VT
SVC	Slow vital capacity test	ERV, IC, IRV, Rf, VC, VC _{ex} , VC _{in} , VC _{max} , VT

☐ Tests

Parameter	Parameter description	Unit
ATI	VC _{max} -FVC/ VC _{max}	%
BEV	Back extrapolated volume	L
BTPS _{ex}	BTPS factor used for expiration	–
BTPS _{in}	BTPS factor used for inspiration	–
CVI	Ratio of FEV _{.5} to FIV _{.5}	–
E ₅₀ /I ₅₀	Ratio of FEF ₅₀ to FIF ₅₀	–
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_6}	FEF ₂₅₋₇₅ based on FEV ₆ instead of FVC	L/s
FEF ₄₀	Forced expiratory flow at 40% of vital capacity—synonymous with MEF ₆₀	L/s

☐ Parameters

Parameter	Parameter description	Unit
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 ₅₀ /VC _{max}	Ratio of FEF ₅₀ to VC _{max}	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 ₇₅₋₈₅	Forced expiratory flow from 75% to 85% of vital capacity	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
FEV _{.75}	Forced expiratory volume after 0.75 seconds	L
FEV _{.75} /FEV ₆	Ratio of FEV _{.75} to FVC ₆	–
FEV _{.75} /FVC	Ratio of FEV _{.75} to FVC	–
FEV _{.75} /VC _{max}	Ratio of FEV _{.75} to VC _{max}	–
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 /FVC ₆	Ratio of FEV ₁ to FVC ₆	–
FEV ₁ /VC _{max}	Ratio of FEV ₁ to VC _{max}	–
FEV ₁ /VC	Ratio of FEV ₁ to VC	–
FEV ₁ /VC _{ext}	Ratio of FEV ₁ to VC _{ext}	–
FEV ₁ Q	FEV ₁ quotient, ratio of FEV ₁ to 0.5 L (male) or 0.4 L (female)	–
FEV ₃	Forced expiratory volume after 3 seconds	L
FEV ₃ /FVC	Ratio of FEV ₃ to FVC	–
FEV ₃ /VC _{max}	Ratio of FEV ₃ to VC _{max}	–
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 ₂₅₋₇₅	Forced inspiratory flow at 25% to 75% of vital capacity —synonymous with MMIF	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

Parameters

Parameter	Parameter description	Unit
IC	Inspiratory capacity from end of tidal breathing	L
IRV	Inspiratory reserve volume	L
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
MMIF	Mean mid-inspiratory flow—synonymous with FIF ₂₅₋₇₅	L/s
MTC ₁	$(FEF_{75} - FEF_{50}) * 4 / FVC$	1
MTC ₂	$(FEF_{50} - FEF_{25}) * 4 / FVC$	1
MTC ₃	$FEF_{25} * 4 / FVC$	1
MTCR	Ratio of MTC ₁ to MTC ₃	1
MV	Maximum voluntary ventilation	L/min
MV ₆	Maximum voluntary ventilation for 6 seconds	L/min
MV _{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, FT	+ /flow tidal added Respiratory frequency/flow tidal	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 _{ext}	Vital capacity from another test	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

4.6. List of abbreviations

Abbreviation	Full form
ATPS	Ambient temperature pressure saturated—refers to environment conditions, can be converted to BTPS
ATS	American Thoracic Society
BDR	Bronchodilator response
BTPS	Body temperature pressure saturated—refers to converted environment conditions, can be converted from ATPS
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
GOLD	Global Initiative for Chronic Obstructive Lung Disease
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
SSL	Secure Sockets Layer
SQL	Structured Query Language
USB	Universal Serial Bus (USB)—standard for data transfer, connecting devices, and battery charging, applies to cables and connectors
XML	Extensible Markup Language

☐ Abbreviations

4.7. 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 4](#) ↗

4.8. Connectivity and data exchange

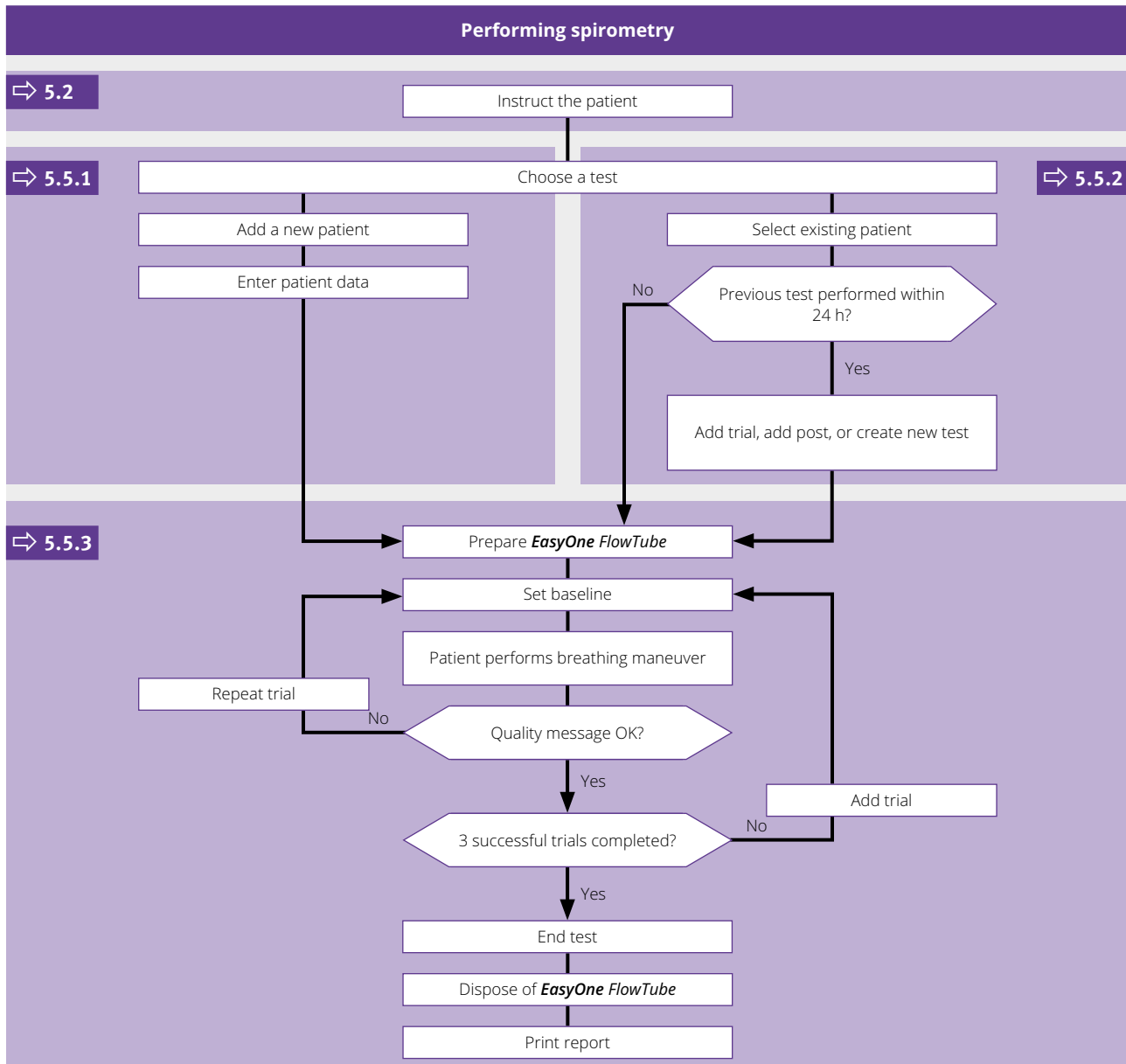
For data exchange, you can connect *EasyOne* products with the **EasyOne Connect** PC software. In addition, you can interface **EasyOne Connect** with the information system in your hospital or practice.

For further information, please visit the *ndd* website.

⇒ nddmed.com/eoc

5. Performing spirometry

5.1. Overview of the spirometry workflow



□ General spirometry workflow using **EasyOne Air** stand-alone

5.2. Preparation of spirometry and instructions for the patient

Warning

Health hazard

As a healthcare professional it is your responsibility to assess the suitability of the patient to perform a spirometry test. Therefore, before performing a test, consider if the patient has or suspects having any of the relative contraindications below:

- Increase in myocardial demand or changes in blood pressure (e.g., Acute myocardial infarction within 1 week, systemic hypotension or severe hypertension, significant atrial/ventricular arrhythmia, noncompensated heart failure, uncontrolled pulmonary hypertension, acute cor pulmonale, clinically unstable pulmonary embolism, history of syncope related to forced expiration/cough)
- Increase in intracranial/intraocular pressure (e.g., cerebral aneurysm, brain surgery within 4 weeks, recent concussion with continuing symptoms, eye surgery within 1 week)
- Increase in sinus and middle ear pressures (e.g., sinus surgery or middle ear surgery or infection within 1 week)
- Increase in intrathoracic and intraabdominal pressure (e.g., presence of pneumothorax, thoracic surgery within 4 weeks, abdominal surgery within 4 weeks, late-term pregnancy)
- Infection control issues (e.g., active or suspected transmissible respiratory or systemic infection, including tuberculosis or physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding)

Patient cross-contamination

Contaminants from an infected patient might be deposited on the **EasyOne FlowTube**. If you reuse the **EasyOne FlowTube**, the contaminants from an infected patient might 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 intended for single-patient use only.

- Always replace the **EasyOne FlowTube** with a new one before testing a new patient.
 - Only use an original **EasyOne FlowTube** by the manufacturer.
-

⚠ Caution**Exhaustion**

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

- Watch the patient for signs of distress or dizziness and support the patient if necessary.
 - Make sure the patient is seated and cannot be injured by objects in the vicinity if the patient faints.
 - Do not leave the patient unattended during a test.
 - If more than 8 consecutive trials have failed, take a break or end the test session.
 - Discontinue the test session if the patient is unwell or feels pain, even if after repeated maneuvers the quality criteria are not met.
-

Erroneous diagnosis and (exercise-induced) bronchoconstriction

It is the responsibility of the healthcare professional that the following requirements are given to the patient at the time of making the appointment. On arrival, all of these points must be checked, and any deviations from them must be recorded.

To avoid acute bronchoconstriction, problems in coordination, potential exercise-induced bronchoconstriction, or external restrictions on lung function, the following activities should be avoided before lung function testing:

- The patient must not smoke and/or vape and/or use the water pipe within 1 h before testing.
 - The patient must not consume intoxicants within 8 h before testing.
 - The patient must not perform vigorous exercise within 1 h before testing.
 - The patient must not wear clothing that substantially restricts full chest and abdominal expansion.
-

Bronchoconstriction

When performing a spirometry test, there is always the possibility that bronchoconstriction is triggered.

- In case of known respiratory conditions the patient shall keep the dilator/medication close.
 - Stop the spirometry test if the patient feels unwell, pain or if bronchoconstriction is induced.
-

Preparing the patient

Prepare the patient for testing: The patient should loosen tight clothing, remove dentures, and relax. The patient should sit down as the breathing maneuvers of a spirometry test can be strenuous.

Providing instructions for using the **EasyOne FlowTube**

The patient should seal the lips around the **EasyOne FlowTube** so that there are no leaks. To ensure a faultless operation of the spirometer, make sure that the patient does not block the opening of the **EasyOne FlowTube** with their teeth or tongue, does not bite down excessively and does not spit or cough into the **EasyOne FlowTube**.

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 patients

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

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](#).

Recommended number of trials per test

Typically, the patient needs to perform 3 consecutive trials per test that meet the respective acceptance criteria. In general, 8 consecutive trials is a practical upper limit for most adults. When testing children, more than 8 consecutive trials might be required because completing a full breathing maneuver can be more challenging for children than for adults.

⇒  [Breathing maneuvers for all available tests 61](#) ↗

 [Cleaning and disinfecting 67](#) ↗

5.3. 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 for the FVC and the FEV1 parameter according to the 2019 standard

Instead of giving one grade to the entire test session, the FVC and the FEV1 parameters are graded separately according to the rules laid out in the table below. FVC and FEV1 from one test session can have different gradings.

Quality grades according to the 2005 standard

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 grades for tests 59](#)

5.4. 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. Posts can only be added to an existing test within 24 hours.

Post according to the ERS/ATS technical standard on interpretive strategies 2022

The results of the previous % predicted parameter and the post are then compared on the result screen and on the test protocol [18].

Post according to the ATS/ERS 2005 standard

The results of the previous test and the post are then compared on the result screen and on the test protocol.

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

EasyOne Air can be used without connection to **EasyOne Connect** as a stand-alone. Test data conducted with **EasyOne Air** as a stand-alone can be copied to **EasyOne Connect** afterwards.

If **EasyOne Air** is connected to another device (e.g., a PC, printer, power supply, or the cradle) performing a test is not possible.

5.5.1. 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 .
- 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! Erroneous diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause erroneous 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 49** 

5.5.2. 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 74](#) 

 [Copying patient data between EasyOne Air and EasyOne Connect 76](#) 

- 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 49](#) 

5.5.3. 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 recommended.

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 have instructed the patient on how to perform the test before you start with the test.

 [Choosing a test and adding a new patient 47](#)

 [Choosing a test and selecting an existing patient 48](#)

 [Appendix - Information for the USA 133](#)

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

If the **EasyOne FlowTube** or its wrapper have been damaged, discard the **EasyOne FlowTube**, take another **EasyOne FlowTube**, and visually recheck.

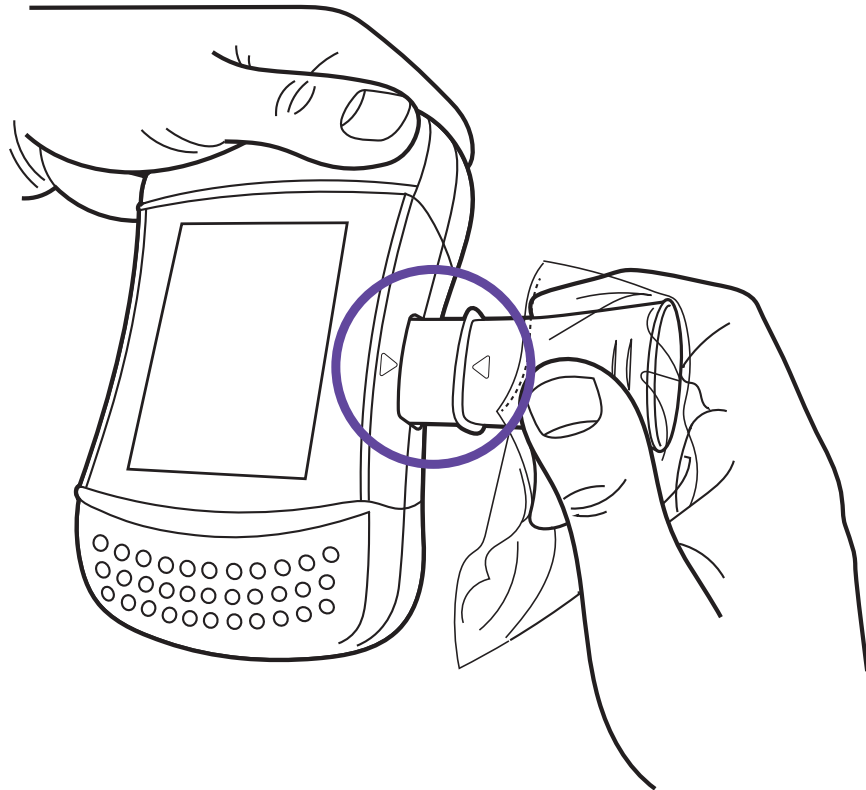
Visually check the **EasyOne FlowTube** for damage before use and between trials.

■ To prepare the test

- 1 Partly unwrap the **EasyOne FlowTube**.
 - ☐ For hygienic reasons, make sure that the wrapper remains on the mouthpiece. Never touch the **EasyOne FlowTube** directly but use the wrapper as a protective foil while handling 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.
 - ❑ Avoid direct sunlight as it can interfere with the automatic recognition of the **EasyOne FlowTube**.



- 3 Caution!
Check the environmental settings. If they are incorrect, adjust the values.
 - ❑ The temperature must always be recorded with an accuracy of ± 1 °C. In situations where the ambient air temperature is changing rapidly (>3 °C in <30 min), continuous temperature corrections might be necessary.
- 4 Choose **Start test**.
 - ✓ The sensor starts buzzing and the **User action required...** window is displayed for setting the baseline.

- 5 Caution! Performing the baseline setting incorrectly could lead to erroneous test results.
To set the baseline, seal off one end of the **EasyOne FlowTube** with the wrapper to avoid air flow.



- 6 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.
- 7 Remove the wrapper from the **EasyOne FlowTube**.
- 8 If you want to perform an FVL test, an MVV test, or an SVC test, attach the nose clip to the patient's nose.
- 9 Hand **EasyOne Air** to the patient.
- ☐ 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 61](#) ↗

■ 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 their tongue or teeth, bite down excessively on the **EasyOne FlowTube** or spit or cough into it.
- 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 status of the maneuver. The harder the patient exhales, the faster the feedback sound is repeated. When the patient has less air to exhale and the flow gets slower 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,  is displayed.
 - ✓ If the trial is usable,  is displayed, along with suggestions on how to improve the breathing maneuver.
 - ✓ If the trial is not usable,  is displayed, along with suggestions on how to improve the breathing maneuver.
- 5 Repeat the steps 1-4 until the button that previously informed the user to add a trial shows **End Test**.
 - ☐ In case **End Test** does not appear, go to **Data** and choose **End Test** there.

■ To check trial details

- 1 If you want to look at the details, choose **Data** after one or two acceptable trials or choose **End Test** after three acceptable trials.
✓ The report screen is displayed.
- 2 Choose the respective field.

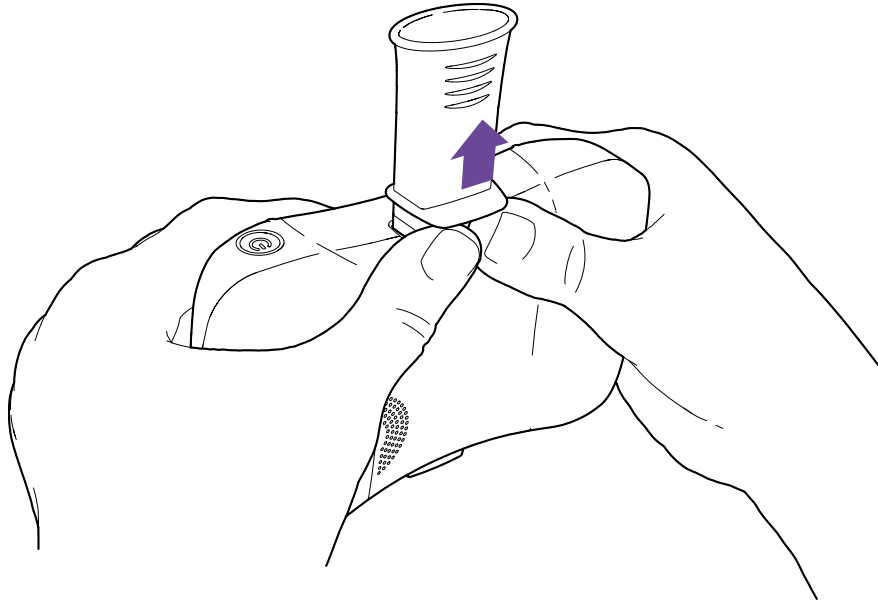


- A Big view of the selected curves
- B Trial or session quality
- C Delete trial or session
- D Print report
- E Symsten interpretation or comments
- F All available parameters including LLN and the three trials

☐ Stylized graphic of the report screen

■ To end the test

- 1 To remove the **EasyOne FlowTube**, do the following:
 - a) Grip **EasyOne Air** with both hands, with the back 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! Possible cross-contamination and infection of patients and staff. Clean the **EasyOne Air** after each test session and especially after each patient by wiping the surfaces that have been touched with a soft cloth and one of the cleaning solutions specified.
To clean and disinfect **EasyOne Air** after each patient, do the following:
 - ☐ Make sure that no fluid penetrates the **EasyOne FlowTube** holder or the inside of **EasyOne Air** while cleaning and disinfecting.
 - a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions and wipe the handles and the display of **EasyOne Air**.
[Hygiene and cleaning 65](#)
 - b) Put **EasyOne Air** in the cradle.
 - c) Properly disinfect your hands following the hygiene procedure of your healthcare institution.
 - ☐ In case of visible dirt wash your hands before disinfecting them.
- 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 and disinfecting solutions 67](#)
- ⇒ Application Note *Printing with **EasyOne Air***
 - [Application Notes for further information 4](#)

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

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

If **EasyOne Air** is connected to another device (e.g., a PC, printer, power supply, or the cradle) performing a test is not possible.

5.6.1. Connecting **EasyOne Air** to **EasyOne Connect**

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 21](#)

- 1 On **EasyOne Air**, choose  >  > .
- 2 Select the **Bluetooth** check box and keep the menu open.
 - ✓ **EasyOne Air** is discoverable via Bluetooth by other devices.
- 3 Select **Bluetooth key** in the menu and enter your user password (e.g. admin password: 8005).
- 4 Define a Bluetooth pairing key of your choice (e.g. 2023).
- 5 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.
- 6 On your PC, select **EasyOne Air** for pairing.
- 7 Enter the Bluetooth pairing key as instructed by your PC.
 - ✓ 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.
 - ☐ More information on the Bluetooth connection:
 - [List of troubleshooting solutions 107](#)

5.6.2. Performing a bronchial provocation test

Bronchial provocation tests are only available when using **EasyOne Connect**. 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.

Caution

Bronchoconstriction

Performing provocation tests can cause a bronchoconstriction.

- Provocation tests should only be conducted by trained physicians.
- 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 bronchospasms, appropriate medication counteracting the provocative agent, and resuscitation equipment.

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 have instructed the patient on how to perform the test before you start with the test.

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

 [FVL test 62](#)

The procedure **To perform the FVC breathing maneuver** represents 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 61](#)

You can configure whether to use the FVC test or the FVL test for forced spirometry under [Utilities > Configuration > Test > FVC/FVL > Type](#).

5.7. Interpreting results

Only conduct result interpretation of curves with a printed report as graphs on the display of **EasyOne Connect** might be misleading due to unclear curve scaling between different patients.

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.

 [List of quality grades for tests 59](#)

On the printed report, parameters that are below the lower limit of normal (LLN) are marked with an asterisk (*) if printed from **EasyOne Connect** or with  if printed directly from **EasyOne Air/Cradle**. Unacceptable trials are struck through in **EasyOne Connect** and not displayed on **EasyOne Air**.

Spirometry Standard 2019: Automatic quality grading function is always activated and is therefore not configurable.

Spirometry Standard 2005: It is possible to deactivate the automatic quality grading function and the system interpretation function.

⇒  [List of tests and parameters 37](#)

 [Quality messages and quality grades 59](#)

 [Configuration 79](#)

5.8. Quality messages and quality grades

End-of-Test criteria, quality criteria, and quality grading are based upon the published standards [1], [4], [13], [14], [15], and [17]. Quality grading is based on the sources [4], [13], [14], [15], and [17]. 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 118](#)

5.8.1. 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.

For a list of all quality messages, see:

⇒ Application Note **EasyOne Connect Message Numbers**

 [Application Notes for further information 4](#)

5.8.2. 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 and the FEV1 parameter according to the 2019 standard.

Instead of giving one grade to the entire test session, the FVC and the FEV1 parameters are graded separately according to the rules laid out in the table below. FVC and FEV1 from one test session can have different gradings.

Grade	Criteria	Result reliability
A	At least 3 acceptable values AND the difference between the two largest values is equal to or less than 150 mL (for age 6 and under: 100 mL or 10% of the highest value, whichever is greater)	Reliable result
B	2 acceptable values AND the difference between the two largest values is equal to or less than 150 mL (for age 6 and under: 100 mL or 10% of the highest value, whichever is greater)	Reliable result
C	At least 2 acceptable values AND the difference between the two largest values is equal to or less than 200 mL (for age 6 and under: 150 mL or 10% of the highest value, whichever is greater)	Reliable result
D	At least 2 acceptable values AND the difference between the two largest values is equal to or less than 250 mL (for age 6 and under: 200 mL or 10% of the highest value, whichever is greater)	Result might have clinical utility. Interpret with caution.
E	1 acceptable value OR, at least 2 acceptable values but the results are not reproducible according to 'D'.	Result might have clinical utility. Interpret with caution.
U	0 acceptable AND at least 1 usable value	Result might have clinical utility. Interpret with caution.
F	0 acceptable and 0 usable value	Result should not be used.

Quality grades for the FVC test, the FVL test, and the OSHA test according to the 2005 standard

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 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.

 [OSHA test 133](#)

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.

 [SSA test 134](#)

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	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.

6. 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](#) 

6.1. 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 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 their tongue or teeth, bite down excessively on the **EasyOne FlowTube** or spit or cough into it.
- 3 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
- 4 Tell the patient to take the **EasyOne FlowTube** out of the mouth and to breathe normally again.

  [Performing spirometry 41](#) 

 [Performing spirometry using **EasyOne Air stand-alone** 47](#) 

6.2. FVL test

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

Recommended 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 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 their tongue or teeth, bite down excessively on the **EasyOne FlowTube** or spit or cough into it.
 - 3 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
 - 4 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.
 - 5 Tell the patient to take the **EasyOne FlowTube** out of the mouth and to breathe normally again.
- ⇒  [Performing spirometry 41](#) ↗
-  [Performing spirometry using **EasyOne Air stand-alone** 47](#) ↗

6.3. MVV test

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

Recommended 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 take the **EasyOne FlowTube** into the mouth and to seal the lips around the **EasyOne FlowTube**.
 - ☐ The patient must not block the opening with their tongue or teeth, bite down excessively on the **EasyOne FlowTube** or spit or cough into it.
 - 2 Tell the patient to fully inhale and fully exhale repeatedly for an uninterrupted period of at least 12 seconds.
 - 3 Tell the patient to take the **EasyOne FlowTube** out of the mouth and to breathe normally again.
- ⇒  [Performing spirometry 41](#) ↗
-  [Performing spirometry using **EasyOne Air** stand-alone 47](#) ↗

6.4. 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.

Recommended 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 take the **EasyOne FlowTube** into the mouth and to seal the lips around the **EasyOne FlowTube**.
 - ☐ The patient must not block the opening with their tongue or teeth, bite down excessively on the **EasyOne FlowTube** or spit or cough into it.
 - 2 Tell the patient to continue breathing at rest.
 - ☐ Typically, three to five steady or at least ten breaths are required.
 - ✓ *Tidal Breathing* is displayed.
 - 3 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.
 - 4 Tell the patient to take the **EasyOne FlowTube** out of the mouth and to breathe normally again.
- ⇒  [Performing spirometry 41](#) ↗
-  [Performing spirometry using **EasyOne Air stand-alone** 47](#) ↗

7. Maintenance

7.1. Hygiene and cleaning

Before testing a new patient or after completing a test session, clean and, if appropriate, disinfect the spirometer by following the instructions in this chapter.

Warning

Patient cross-contamination

Contaminants from an infected patient might be deposited on the **EasyOne FlowTube**. If you reuse the **EasyOne FlowTube**, the contaminants from an infected patient might 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 intended for single-patient use only.

- Always replace the **EasyOne FlowTube** with a new one before testing a new patient.
 - Only use an original **EasyOne FlowTube** by the manufacturer.
-

Anaphylactic reaction

When the patient comes into contact (via skin or inhalation of fumes) with residues of a cleaning or disinfection solution, it could lead to an anaphylactic reaction.

- After cleaning and disinfection, there should be no obvious or wet residue left on the device. Wipe the spirometer only with a damp (not wet) cloth and wipe it with a dry cloth after cleaning.
-

Fire and erroneous diagnosis

Liquids penetrating the device may damage components and lead to malfunction.

- Make sure that no liquids and no cleaning or disinfecting solutions penetrate the device by using only a damp (not wet) cloth to clean the spirometer.
-

Caution

Erroneous diagnosis or bronchoconstriction

The label could be damaged and left unreadable if overly aggressive cleaning or disinfecting solutions outside the specified range are used to clean or disinfect the spirometer. If the label on your device is not readable anymore, the user cannot react in case of a recall or contact the manufacturer. This could lead to late or erroneous diagnosis. If diagnosed wrongly, a patient might suffer a bronchoconstriction.

- Only use the cleaning and disinfecting solutions specified below.
-

Handling breathing mouthpieces and filters

When handling the breathing mouthpiece (e.g., **EasyOne FlowTube**) and, if applicable, the **EasyOne Filter FT**, you must be careful not to contaminate the next **EasyOne FlowTube**, **EasyOne Filter FT**, or **EasyOne Air** that you work with. The wrapped **EasyOne FlowTube** and **EasyOne Filter FT** are hygienically packaged and intended for single-patient use only. You must use a new **EasyOne FlowTube** or **EasyOne Filter FT** for each new patient that you test.

Handling the spirometer

The spirometer must always be cleaned and disinfected before testing a new patient. Also, clean and then disinfect the spirometer whenever it appears visibly soiled. To clean and disinfect the spirometer, no disassembly, reassembly, or use of special accessories is necessary.

7.1.1. List of cleaning and disinfecting solutions

Notice

Invalidation of warranty

The use of disinfectants other than those specified may result in irreversible damage for which *ndd* cannot be held responsible. Therefore, note that the use of incompatible cleaning or disinfecting solutions will invalidate the product warranty.

- To ensure that your warranty remains valid, always follow the cleaning and disinfection guidelines provided by *ndd*.

Recommended cleaning and disinfecting solutions

- Alcohol-based disinfectants
- Hydrogen-peroxide-/H₂O₂-based disinfectants
- Quaternary-ammonium-based disinfectants
- Chlorine-based disinfectants

If you are unsure which cleaning or disinfecting solutions you can use, show this list to your local pharmacy or ask the *ndd* service department.

7.1.2. Cleaning and disinfecting

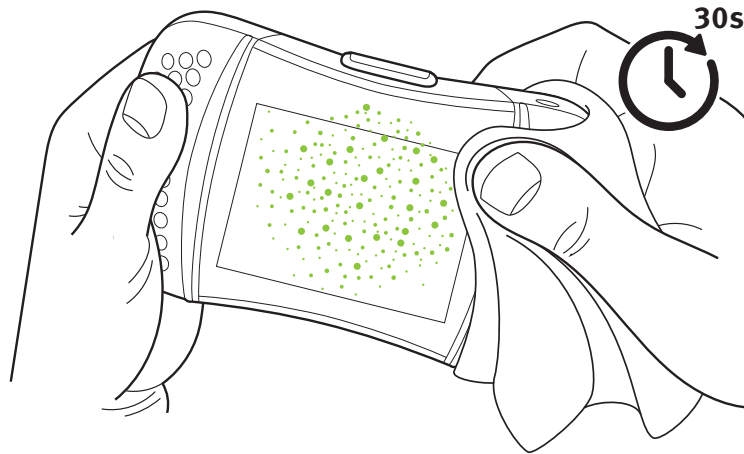
Prerequisites:

- You have turned the spirometer off.
- You have removed the breathing mouthpiece (e.g., **EasyOne FlowTube**).
- You have consulted the cleaning/disinfectant's instructions for further information, e.g., regarding personal protection. You have disinfected and, if needed, washed your hands thoroughly.
- You have verified that the **EasyOne Air** is not connected to a power outlet or to a printer (either directly or via Cradle).

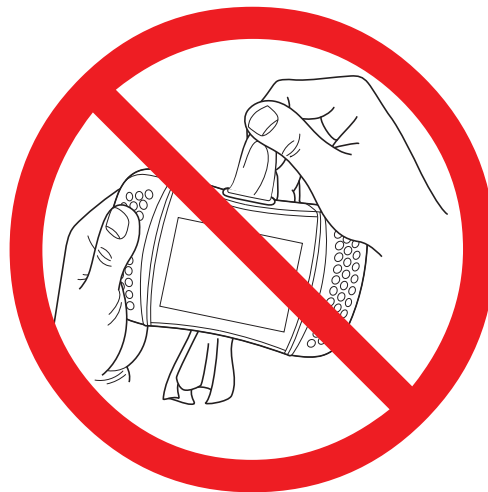
■ Cleaning and disinfecting the spirometer

- 1 To thoroughly clean and disinfect the spirometer, wipe it with the cleaning and disinfection wipe as specified.

- ☐ [List of cleaning and disinfecting solutions 67](#)
- ☐ Perform the procedure with gentle pressure.
- ☐ Wipe all external surfaces of the device for at least 30 seconds (or for contact time specified by wipe manufacturer, whichever is longer)



- ☐ Do not clean or disinfect the inside (**EasyOne FlowTube** holder) of the device. The **EasyOne FlowTube** avoids cross-contamination between patients, by making sure that no air escapes the breathing mouthpiece inserted into the spirometer. For further information contact the *ndd* servicing department.

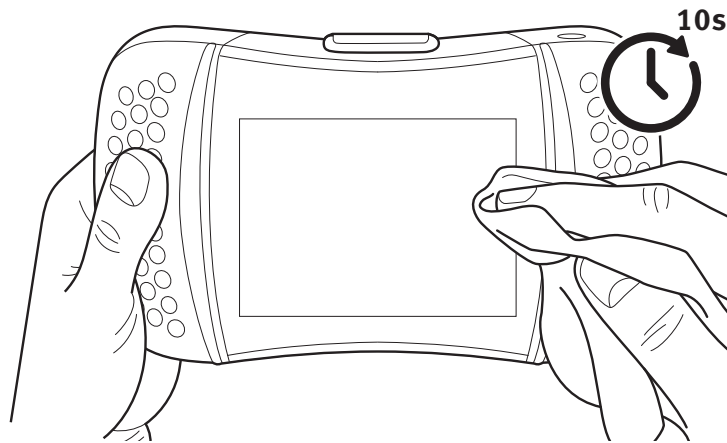


- 2 Check if the cradle has to be cleaned and disinfected.
 - a) If the cradle has had contact to potentially contaminated parts or **EasyOne Air** has not been disinfected before placing it in the cradle, follow the same steps for cleaning and disinfecting the spirometer.
 - b) If the cradle has not had contact with potentially contaminated parts and the **EasyOne Air** has been disinfected before placing it into the cradle, disinfection of the cradle is not needed.

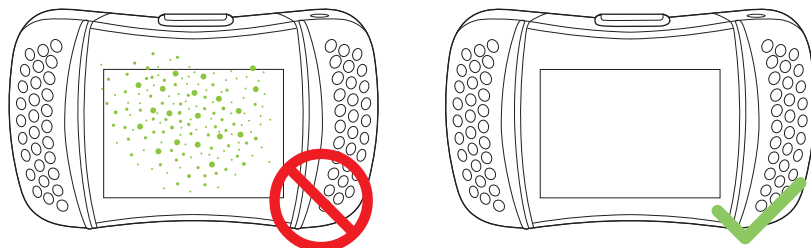
- 3 Discard the used wipes.
- 4 Repeat step 1 and 2 with a **new** fresh wipe to ensure the spirometer is thoroughly cleaned and disinfected.
 - ❑ Never rinse the spirometer.



- 5 Use a soft, non-linting cloth to dry all surfaces of the device for at least 10 seconds.



- 6 Visually check the device after cleaning and disinfection. Repeat procedure in case of residual soil.



- 7 Check if **EasyOne Air** and cradle are completely dry before placing **EasyOne Air** in the cradle.

7.2. Cybersecurity

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

Caution

Health hazard

Loss or manipulation of clinical data could lead to wrong medical treatment as a result of wrong or missing test results. Follow the outlined cybersecurity best practices to avoid data loss or manipulation of clinical data.

- Password policy
- Updates of cybersecurity patches released by *ndd*
- Database backup
- Escalation in case of a security breach
- Dealing with a lost or stolen device
- Responsibility of user to install and maintain an anti-virus program on the PC that runs **EasyOne Connect**
- In case of any uncertainties, contact the *ndd* servicing department.

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.

7.3. Password policies and password expiration

You can use a combination of user name and password in order to control access to **EasyOne Air** and/or **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 Air includes functionality for password strength. **EasyOne Connect** furthermore includes functionality for 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.

⇒  [User handling and the default password 86](#)

7.4. Periodical software updates and patches

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

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

⇒  [Installing or updating **EasyOne Connect** software on your PC 22](#)

 [Firmware update 82](#)

 [Contact information 5](#)

7.5. Backups

For **EasyOne Air** data backups, refer to:

⇒ [Application Note Data Backup Deletion and Restoration in **EasyOne Air**](#)

 [Application Notes for further information 4](#)

7.6. Escalating in case of a security breach

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

- 1 Immediately disconnect **EasyOne Air** from the network.
 - ❏ After you have disconnected **EasyOne Air** from the network, you can no longer access an SQL server, but you can work temporarily with a file-based database that is stored only on **EasyOne Air**.
- 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.

7.7. 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**.
 - ❏ [User menu 85](#)
 - ❏ [User handling and the default password 86](#)
 - 1 Immediately report the loss or theft of **EasyOne Air** or of the PC that **EasyOne Connect** is installed on to the *ndd* servicing department.
 - ✓ The *ndd* servicing department will ensure that your **EasyOne Air** or the **EasyOne Connect** installed on your PC is not unlocked unintentionally by *ndd* staff for anyone else but you.
- ⇒ [Contact information 5](#)

7.8. Safe use – 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 with 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 or forgotten 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 **User Group**. 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**.

⇒  [Security settings 81](#) 

 [Configuration of **EasyOne Connect** 86](#) 

8. Working with patient data and reports

Caution

Erroneous diagnosis

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

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

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

EasyOne Air can be used as a stand-alone for handling patient data, performing spirometry and evaluating reports.

8.1.1. Adding a patient to the database



- 1 In each step, enter the requested data and choose **Next**.
- 2 In the last step, choose **Finish**.

8.1.2. Editing patient data



- 1 Select a patient.
- 2 Choose a list item.
- 3 Edit the entry and, if applicable, choose **OK**.
 - ☐ Note that these changes only apply to future sessions.
- 4 Choose **OK**.
- 5 Choose the home button.

8.1.3. Recalculating patient data and results

EasyOne Air can recalculate predicted values using a different publication and updated patient data.



- 1 Select a patient.
- 2 Choose a test.
- 3 Choose the changes to be recalculated
- 4 Choose .

8.1.4. Deleting a patient from the database



- 1 Select a patient and confirm the message that is displayed.
 - ✓ The selected patient data is deleted as well as all tests this patient performed.

8.1.5. Viewing and printing reports

- 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.
 - ❏ When exporting patient and spirometry test data to any external drives/storages, data safety lies in the responsibility of the operator.

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

EasyOne Air can be used in combination with **EasyOne Connect** on your PC. This facilitates the handling of patient data and evaluation of results. Data acquired on **EasyOne Air** and **EasyOne Connect** is interchangeable.

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

Usually, you perform spirometry with **EasyOne Air** stand-alone. But to enter patient data, to evaluate results or to archive patient data and results it can be more convenient to use **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**.

However, data loss can occur if any patient data for the same patient exists on **EasyOne Air** and in **EasyOne Connect**. In this case the patient data and results in **EasyOne Connect** could be overwritten by **EasyOne Air**. Therefore, only make changes to existing patient data on **EasyOne Air**. Use **EasyOne Connect** only to create new patient records, 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.

■ To copy patient data and results

- 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 as to 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

- 1 In **EasyOne Connect**, choose **Patients**.
- 2 Choose **New**.
- 3 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 have just created.
- 7 Choose **EasyOne**.
 - ✓ The selected patient record is sent to **EasyOne Air**.
 - ✓ **EasyOne Connect** displays a message as to 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.

⇒  [Connectivity and data exchange 40](#)

8.2.2. Merging two patient data records

If, for example, two data records of the same patient were acquired with different tests or if different spellings of a patient, 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.

8.2.3. Trend view

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.

8.2.4. Assessing tests retrospectively

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 **< Trial X** or **Trial X >** to switch between the trials.
- 5 To close the overlay window, choose **×**.

⇒  [User handling and the default password 86](#)

9. Configuration

The configuration settings affect the predicted values, the system interpretation and therefore the shown results.

9.1. Configuration of **EasyOne Air**



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

This chapter explains the navigation of **EasyOne Air**. In the following cases, **EasyOne Connect** behaves in the same way as the **EasyOne Air** firmware. Possible exceptions are mentioned.

 [Configuration of **EasyOne Connect 86**](#) ↗

9.1.1. System settings



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

Setting	Purpose
Language	To set the language
System date	To set the date
System time	To set the time
Inline filter	To set inline filter
Date format	To set the format of the date
Time format	To set the format of the time
Height unit	To set the height unit
Weight unit	To set the weight unit
Temperature unit	To set the temperature unit
Pressure unit	To set the pressure unit
Speaker volume	To set the speaker volume
Key click	To enable sound for audible click feedback
Brightness	To set the brightness of the touchscreen
Screensaver after	To set the time, after which the screensaver is enabled

 Description of system settings

9.1.2. Spirometry settings



Setting	Default		Cross- reference
ATS/ERS standard	ATS/ERS 2019	ATS/ERS 2005 ATS/ERS 2019	Applied Spirometry Standard 95
Preferred type of test	FVC	FVC, Tidal FVC, OSHA, SSA Disability, FVL, Tidal FVL, MVV, SVC	Preferred Test Type 96
Predicted set 1	Dependent on selected region	Complete list of References for Predicted Normal Values	Predicted normal values setting 90
Predicted set 2	Dependent on selected region	Complete list of References for Predicted Normal Values	Predicted normal values setting 90
System interpretation	GOLD/Hardie 2008	None GOLD/Hardie 2003 GOLD/Hardie 2008 GOLD 2003 GOLD 2008 NLHP NICE NICE 2010 OSHA Best Practice (2013)	System Interpretation 91
BDR % Change after	ERS/ATS 2022	ATS/ERS 2005 ERS/ATS 2022	
Beep during maneuver	ON	On Off	-
Best value selection (Available only when ATS/ERS 2005 is enabled)	Best value	Best value Best trial	Best Value selection 89 or Best Trial selection 89
Automatic QC (Available only when ATS/ERS 2005 is enabled)	ON	On: QC-Grades are displayed and trial acceptability can not be overridden. Off: QC-Grades are not displayed and trial acceptability can be overridden	-
Patient ID format	Numbers only	Numbers only Alphanumeric	-
Graphic selection	FV&VT curve	FV&VT curve FV curve only VT curve only	-
Show % of Predicted values for ratio parameters	OFF	On Off	General 90
Show Predicted range	OFF	On Off	Predicted graph 98

 Description of spirometry settings

Setting	Default		Cross- reference
Lung Age calculation	OFF	On Off	Print Lung Age 98
PEF unit	L/s	L/s, L/min	-
Syringe volume	3.0 L	Adjustable, requires authentication, See: Inactive user handling	Syringe Volume 97
Eth. corr Asian	100%	Adjustable	Adjusting result values based on ethnicity 94
Eth. corr African	88%	Adjustable	Adjusting result values based on ethnicity 94
Eth. corr Hispanic	100%	Adjustable	Adjusting result values based on ethnicity 94
Eth. corr Other	100%	Adjustable	Adjusting result values based on ethnicity 94
Reported parameter	BEV	BEV FEV0.5	-

 Description of spirometry settings

9.1.3. Security settings



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

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

 Description of security settings

[⇨ !\[\]\(dbf3ea362ea469475b8e07955c584a31_img.jpg\) Cybersecurity 70](#)

9.1.4. Print settings



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
Color print	To select or deselect color print
Data selection	To set whether one or three trials are included on the printout, corresponding to the best value (ATS/ERS 2019) or either best value or best trial (ATS/ERS 2005) based on spirometry settings.
Curve selection	To set which curves are included on the printout, corresponding to the <i>Data</i> setting above
Graph selection	To select between the graphs: small FV and VT, large FV, large VT, large FV and VT
Show last cal-check	To select or deselect showing last cal-check
Margin adjust	To set the top and left margin
Custom header	To specify four lines of text on the printout, to customize the printout for your institution

 Description of print settings

⇒  [Best Value selection 89](#) 

 [Setting up the physical components 24](#) 

⇒ Application Note *Printing with **EasyOne Air***

 [Application Notes for further information 4](#) 

9.1.5. Firmware update

To perform a firmware update, refer to:

⇒ Application Note *Updating the Software on **EasyOne Air***

 [Application Notes for further information 4](#) 

9.1.6. Performing a backup



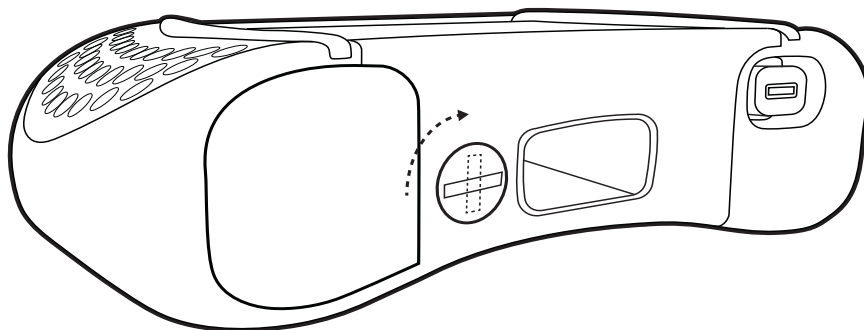
Required material

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

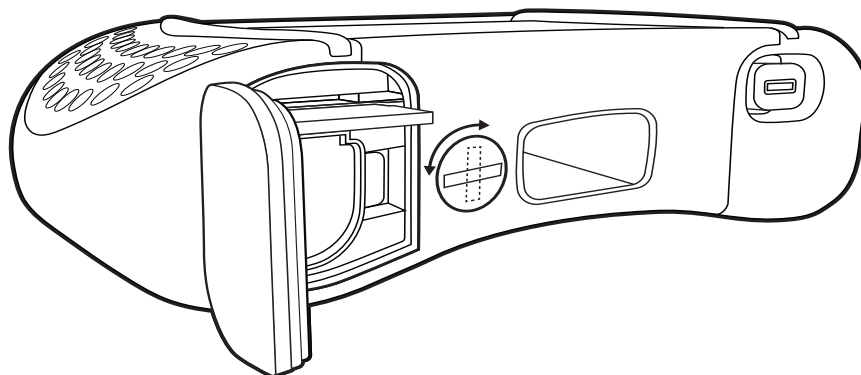
To archive a copy of the complete database (including patient data and results) and of the configuration settings, perform backups regularly. You can also use the backup to set up another **EasyOne Air** with the same database and configuration settings.

For each backup, the manufacturer recommends using an SD memory card with 2 GB storage capacity.

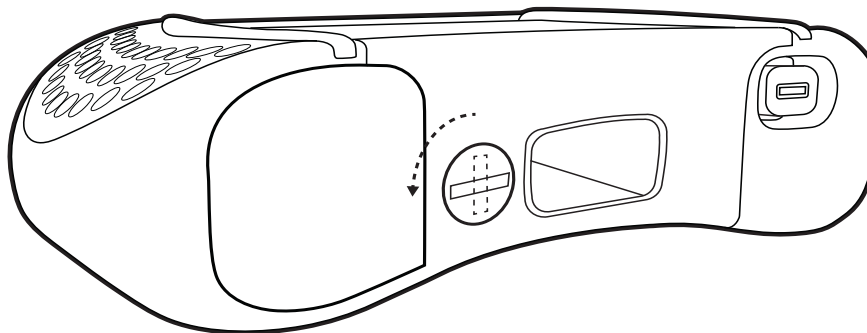
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



- 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**.

9.1.7. Information menu



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

- Firmware version
- Firmware build
- Bootloader version
- Hardware version
- Serial number
- Battery level
- Battery health
- Battery serial number
- Battery version
- Pressure
- Temperature
- Humidity
- Database usage
- Exchange
- System
- Heap Usage kB
- Open source license

9.1.8. User menu



EasyOne Air provides the option to enforce strong password rules.

- ⇒  [Cybersecurity 70](#)
-  [Security settings 81](#)
-  [User handling and the default password 86](#)

9.2. Configuration of **EasyOne Connect**

The configuration settings affect the predicted values, the system interpretation and therefore the shown results.

9.2.1. Saving or discarding configuration changes

You can change the configuration in different tabs and sub-tabs. After you have changed the configuration, choose the **OK** button, which is visible on all screens.

To discard any changes to the configuration, choose the **Cancel** button. The previous configuration stays in effect.

9.2.2. User handling and the default password

Go to **Utilities > Configuration > General > User Handling**.

Inactive user handling

If user handling is inactive, all menus and settings are exposed, except for sensitive changes (e.g., 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 be an *Administrator* user. *Administrator* users have access to the configuration of user handling and to the EMR configuration.

⇒  **Connectivity and data exchange 40** 

9.2.3. 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**.
- ⇒  **User handling and the default password 86** ↗

9.2.4. Description of general configurations for **EasyOne Connect**

Go to [Utilities > Configuration > General](#).

9.2.4.1. Header

You can set your own headers and your own graphic file, for example the name and the logo of your institution, to be displayed in the main menu and to be printed on reports.

The graphic file can be of any common file type, for example *.bmp or *.jpg, with a resolution of 260x80 pixels or smaller. To select or change the graphic file, choose **Browse**. To remove the graphic file, choose **Remove**.

9.2.4.2. Storage

Element	Description
Field	To display the file system path of the currently active database file.
New button	To create a new empty database—you must choose between a local file-based database or an SQL-server-based database.
Select button	In a new window, to select a different database file or connect EasyOne Connect as a database client to a database server. SQL database servers are supported.
Import button	To import a second database file into the currently active database—both databases are merged. Entries that exist in both databases are not duplicated.
Backup button	To save a copy of the currently active database file.
Load Configuration button	To load a configuration file—a configuration file can contain settings, for example for predicted normal values, report headers, or user handling. Be aware that loading a configuration overrides the current configuration settings!
Change database password	The password of the database can be changed. Once the password is changed, the manufacturer can not recover the password. Make sure, to remember the password. Otherwise the data cannot be accessed anymore.

 Storage configuration

⇒  [Connectivity and data exchange 40](#)

⇒ Application Note *EasyConnect Database Connection*

 [Application Notes for further information 4](#)

9.2.4.3. System Settings

Element	Description
Length Unit options	To choose between metric and imperial units.
Temperature Unit options	To choose between metric and imperial units.
Weight Unit options	To choose between metric and imperial units.
Hb Unit options	Regarding hemoglobin, to choose between the SI unit and the traditionally used unit.
Pressure Unit options	To choose between alternative units.
Language options	To choose a language independent of the language of your Microsoft Windows installation.
Show all Test/Device Settings check box	To display settings for EasyOne Connect .
Patient Entry options	To choose between different entry formats for the patient's age.

☐ System Settings

The default configurations in this tab are determined by your language settings and by your regional settings in *Microsoft Windows*.

9.2.5. Test configurations

Go to [Utilities > Configuration > Test](#).

9.2.5.1. General

Best Value selection

If you choose the **Best Value** option, the best single, relevant values are selected from different trials to assess the quality of the test and 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).

If you have selected the 2019 spirometry standard, the **Best Value selection** is fixed for forced spirometry tests (FVC and FVL) and cannot be changed.

Best Trial selection

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

If you have selected the 2019 spirometry standard, the selection is fixed to **Best Value selection**.

If you have selected the 2005 spirometry standard, you can choose between the two selection options **Best Value selection** and **Best Trial selection**.

Curve Overlay

To select which trials are to be displayed in the flow-volume curve and the volume-time curve on the test result screens, choose the corresponding check box.

By default, + **Session Best** and + **Pre Best** are selected.

Test Procedure

If you deselect **Manual Test Stop**, you enable automatic test stop.

By default, **Manual Test Stop** is selected.

General

To display on the test result screens a comparison of the best trial/bestvalue and the predicted values as percentage values also for the post, choose **Show % predicted column for post tests**.

To display the percentage predicted values for ratio parameter (for example %Pred FEV₁/FVC), choose **Show % predicted for ratio parameter**.

To display ratio parameters (for example FEV₁/FVC) as a percentage (for example 78%) instead of a decimal ratio (for example 0.78), choose **Show ratio parameter in %**.

By default, both check boxes are deselected.

To set the maximum number of trials for forced and slow spirometry enter a value between 1 and 99 in the text field **Limit number of trials (1...99): Spirometry**. The default value is 99. The text fields **DLCO** and **MBW** do not apply to the **EasyOne Connect** PC software, but to the firmware of EasyOne Pro/LAB only. A change of the values **DLCO** and **MBW** is without effect for the **EasyOne Connect** PC software.

Select Z-Score Column and/or predicted Column to display the Z-Score and/or predicted values.

9.2.5.2. Predicted

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:

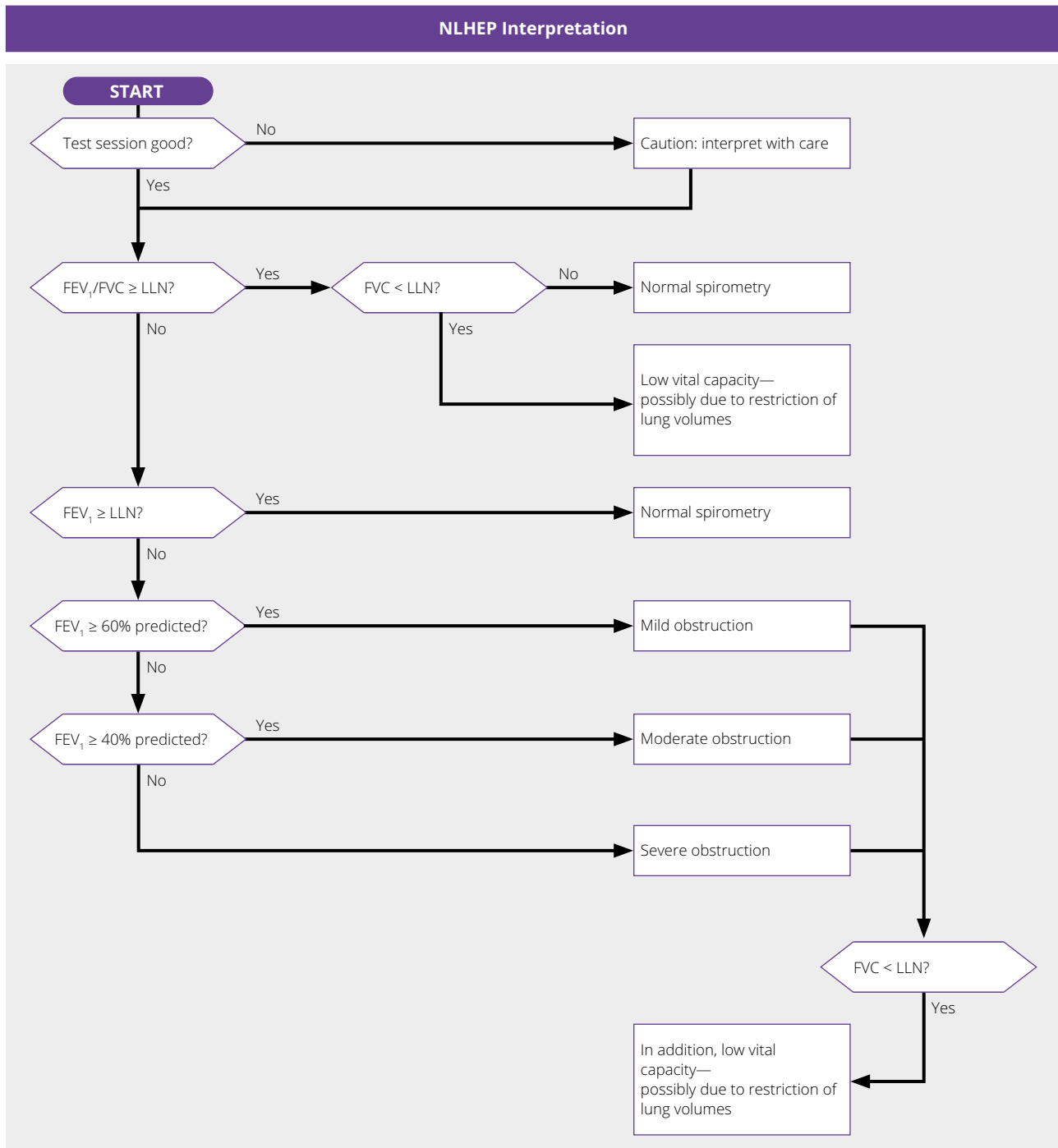
 [Application Notes for further information 4](#)

 [List of bibliographic references 118](#)

System Interpretation

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

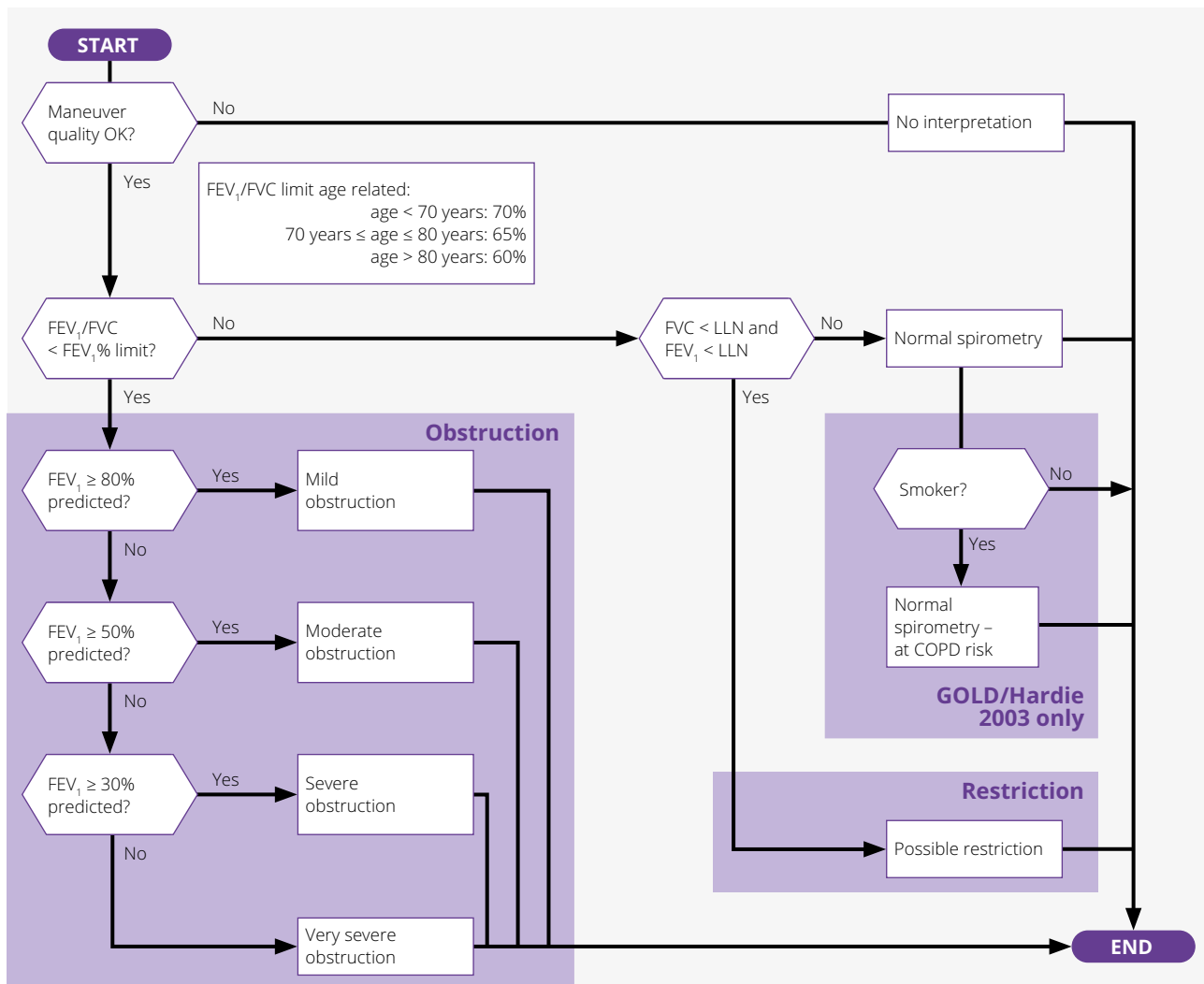
The default setting is GOLD/Hardie.



☐ 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

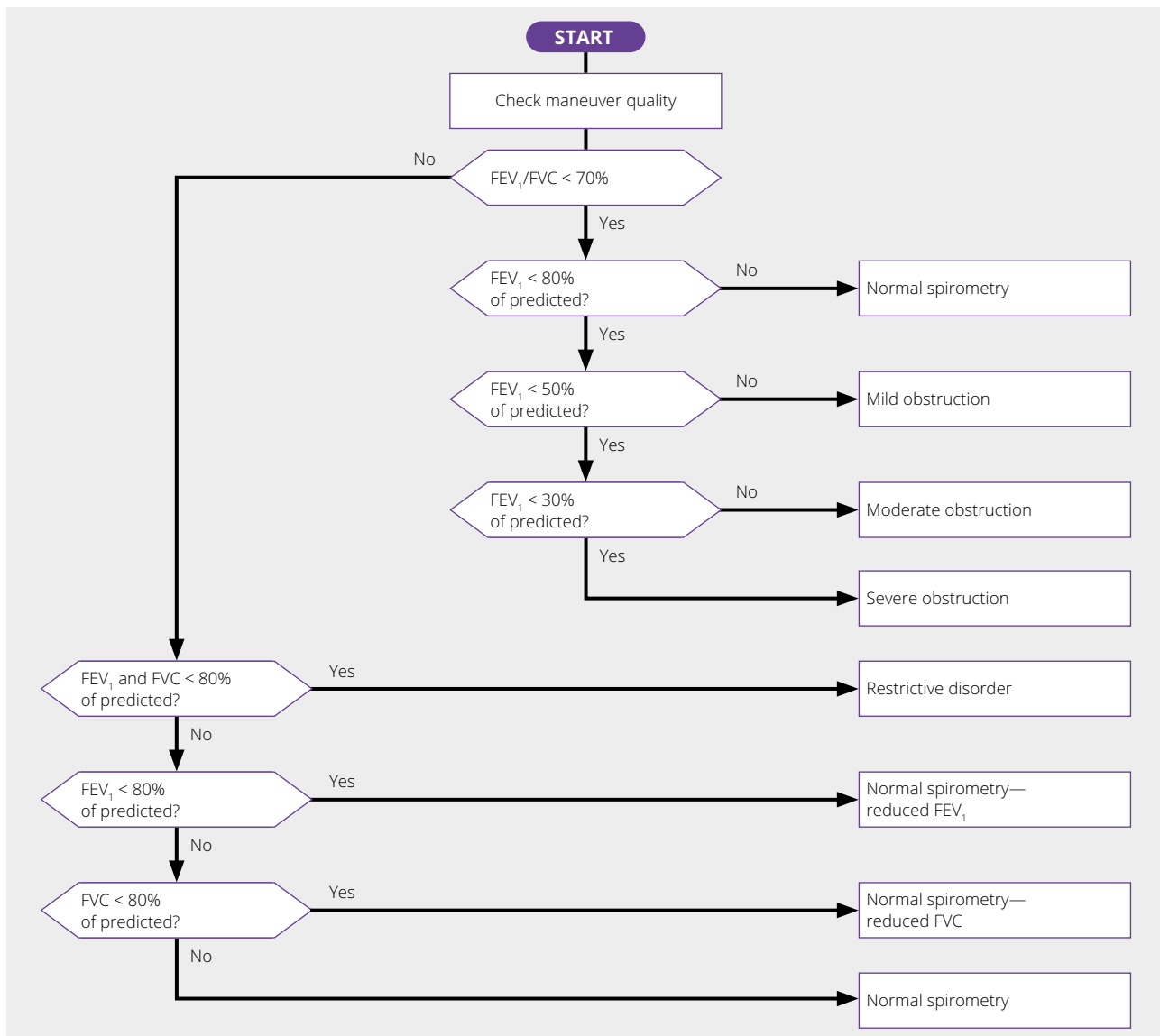


□ GOLD/Hardie interpretation algorithm

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



□ NICE interpretation algorithm

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

Adjusting result values based on ethnicity

When entering patient information, you are presented with a list of options for four ethnic groups. Some studies for predicted values take into account the physiological differences between certain ethnic groups.

Historically, differences in lung function observed between populations have been attributed to the combination of genetic and environmental influences on the growth and development of the lungs. Consequently, the ATS and ERS previously recommended population-specific reference equations, often summarized as race/ethnicity specific reference equations. However, this approach likely underestimates the impact that social determinants have on lung health, and the use of race/ethnic specific equations may obscure true disparities in lung health. The reasons for observed differences in lung function between people around the world are multifactorial and not fully understood. There are ongoing efforts to elucidate the geographical, environmental, genetic, and social determinants of health that play a role in explaining these observed differences. Until high quality evidence is available to inform more accurate and precise interpretation of lung function, the ATS and ERS have recommended race-neutral approaches to interpret lung function measures. Irrespective of which reference equation is used, interpretation of lung function measurements requires careful consideration of an individual's symptoms and medical history when used to make clinical, employment, and insurance decisions [18].

⇒  [List of bibliographic references 118](#)

9.2.5.3. Recalculating predicted values of previous test results

EasyOne Connect can recalculate predicted values using a different publication. This procedure affects all records in the database. Therefore, exporting the database as a backup is recommended prior to changing all records.

Prerequisite

- ☐ You have exported the database as a backup.

- 1 Choose **Utilities > Configuration > Test > Predicted**.
- 2 From the **Predicted** drop-down lists, choose the required publication.
- 3 Choose **Update Tests**.
 - ✓ If you have not activated user handling, the login window is displayed.
 - ✓ If you have activated user handling, the information window is displayed. In this case, proceed with step 5.
- 4 If the login window is displayed, enter your user ID.
 - ✓ The information window is displayed.
- 5 In the information window, review and confirm the selected changes.
 - ✓ All records in the database are updated.

9.2.5.4. FVC/FVL

Applied Spirometry Standard

You can select either the **ATS/ERS Standardization of Spirometry 2005** or the **ATS/ERS Standardization of Spirometry 2019 Update** to be applied to evaluate the FVC and FVL test results. Changing the standard will impact the acceptability criteria of the FEV1 and FVC parameters, and the quality grades of the FVC and FVL tests.

Note that switching from one standard to another does not affect the evaluation of existing tests.

Additionally, you can select whether the post bronchodilator test is calculated according to “% Change compliant with ERS/ATS 2022” or not. If not, the post test is calculated according to ATS/ERS Standardization of Spirometry 2005.

 [Posts and bronchodilation 46](#)

Preferred Test Type

First, the setting **FVC, Ex. only** or **FVL, Ex./In.** determines whether the bronchial provocation test is performed using an FVC test or an FVL test.

Second, if you have integrated **EasyOne Connect** with your EMR system and if you use the GDT plug-in, the setting **FVC, Ex. only** or **FVL, Ex./In.** is also relevant. With this setting, you can configure which test of the two is initiated when the EMR system requests forced spirometry.

To allow the patient to breathe regularly through the **EasyOne FlowTube** before the breathing maneuver, choose **Tidal Breathing**. This check box is only available when **Manual Test Stop** is selected under **Utilities**

> **Configuration > Test > General > Test Procedure.**

 [Test Procedure 90](#)

FVC Selection

This setting is only available if **ATS/ERS Standardization of Spirometry 2005** is selected.

If you choose the **FVC** option, the measurement continues until the end of test criteria are met or until you end the test manually. With this setting, all the intermediate flow values, e.g. MEF_{25} , FEF_{25-75} , are reported.

If you choose the **FEV₆** option, the measurement stops after six seconds. With this setting, none of the intermediate flow values, e.g. MEF_{25} , FEF_{25-75} , are reported.

For diagnostic purposes, the FVC value is comparable with the FEV₆ value. The advantage of choosing the **FEV₆** option is that the FVC test only takes the fixed duration of six seconds and is less demanding for the patient (see Ferguson (2000/NLHEP) [4]). The disadvantage is that the intermediate flow values, e.g. MEF_{25} , FEF_{25-75} , cannot be reported.

 [List of bibliographic references 118](#)

Parameter

To select which diagnostic parameters to include on the test result screens and on the printed reports, choose **Select FVC** and **Select FVL**.

9.2.5.5. SVC

Parameter

To select which diagnostic parameters to include on the test result screens and on the printed reports, choose [Select](#).

Type

To make regular breathing mandatory before the breathing maneuver, choose [Tidal Breathing Required](#).

9.2.5.6. MVV

Parameter

To select which diagnostic parameters to include on the test result screens and on the printed reports, choose [Select](#).

9.2.5.7. CalCheck

Syringe Volume

Calibration syringes are available in various sizes. You can choose the volume of the calibration syringe from the drop-down list.

Type Selection

One test with three trials is required for the Single Flow calibration check. For the Multi Flow calibration check, three tests comprising three trials, each with different flow rates, are required.

Reported Graph

You can select which type of curve you prefer for the calibration check report.

9.2.5.8. Provocation

Protocol

Different protocols for the provocation test are available using Mannitol and Methacholine as provocative agents.

Choose the protocol from the drop-down list.

9.2.6. Configuration for the device

Go to [Utilities > Configuration > Device](#).

Inline filters

You can select whether to work with an inline filter or not and can select from the drop down menu the corresponding filter.

9.2.7. Configurations for the report

Go to [Utilities > Configuration > Report](#).

General

You can select whether to:

- display the time when the trial was performed
- show the range of normal (Z-Score graph)
- If you have selected the 2019 spirometry standard - show the Parameter Acceptability (bold is acceptable, normal is usable, strikethrough is not usable)
- highlight abnormal results or not
- select the preferred color (in case the function is enabled)

Trending

You can select whether to display the trending (print table) with absolute, % predicted values and Z-Scores on the report

Print Lung Age

You can choose to print the lung age on reports. When the calculated lung age is lower than the patient's actual age, the patient's actual age is displayed.

To display the lung age only for smokers, choose [Smoker only](#) from the drop-down list. You can set a patient's smoker status when you add patient data to the database or edit patient data.

To always display the lung age, choose [On](#).

To never display lung age, choose [Off](#).

The default configuration is [Smoker only](#).

Predicted graph

To visualize predicted values in the flow-volume curve and the volume-time curve on the test result screens and on the printed reports, choose [Show predicted points](#) and [Show predicted range](#).

XML Export

You can select whether you would like to include curve data and trials values or not.

Layout

The layout editor allows for customization of the reports' layout.

For details, contact your *ndd* distribution partner or the *ndd* servicing department.

 [Contact information 5](#) 

9.2.8. Configurations for environment conditions

Go to [Utilities > Configuration > Environment](#).

The environment conditions are required to accurately calculate the diagnostic parameters from the raw sensor data.

If you select the check box, you are prompted every two hours to enter the environment conditions when performing spirometry.

From the environment conditions, the ATPS values (Ambient Temperature Pressure Saturated), which describe the conditions for the spirometer, are calculated. The ATPS values are converted to BTPS values (Body Temperature Pressure Saturated), which describe the body conditions of the patient.

If you choose one of the following tests, you are prompted for the current environment conditions:

- FVL test
- MVV test
- SVC test
- Provocation test (if the FVL test is configured for the provocation test)

10. Calibration check

The **EasyOne Air** spirometer uses the patented TrueFlow technology which allows for accurate, robust, and calibration-free spirometry testing over the lifetime of the device. Nevertheless, regular calibration checks can be performed as recommended by ATS/ERS or other technical standards.

A calibration check is a preventive inspection to ensure that **EasyOne Air** calibration has not been adversely affected. In case the spirometer has been dropped, a calibration check determines whether it still works correctly. A calibration check is different from calibration and is the procedure used to validate that the spirometer is within calibration limits.

The calibration check should be performed with the same setting as used for the patient (breathing mouthpieces, filter, etc.).

If a calibration check fails, contact your *ndd* distribution partner or the *ndd* servicing department for repairs. 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.

 [Contact information 5](#) 

Caution

Erroneous diagnosis

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

- Perform calibration checks periodically.

 [Calibration check 100](#) 

 [Checking for correct operation 106](#) 

10.1. Performing a calibration check

Required materials

- ☐ A calibration syringe with an accuracy of ± 0.015 L or $\pm 0.5\%$ of the full scale (separately available)
For appropriate intervals between checks of the syringe accuracy, refer to the labelling of the syringe.
- ☐ An **EasyOne FlowTube** cal check adapter (separately available)
- ☐ An **EasyOne FlowTube**

Prerequisite

- ☐ You have configured the correct syringe volume.

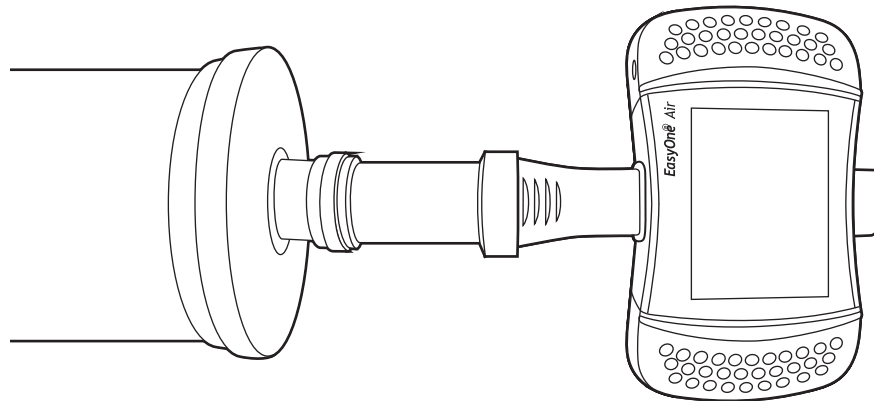


The ultrasonic sensor of **EasyOne Air** does not require calibration. Only unforeseeable reasons can lead to a malfunction that affects results. In these cases, you can determine whether the **EasyOne Air** operates normally with a simple calibration check. Therefore, a regular calibration check is recommended to ensure the reliability of the tests. The American Thoracic Society (ATS) recommends that calibration must be checked periodically.

If you do not reach $\pm 3.0\%$ accuracy, troubleshoot. If you are not able to remedy the defect, contact your *ndd* distribution partner or the *ndd* servicing department.

- 1 Push and draw the piston five times.
 - ☐ This step is necessary to ensure that the temperature inside the syringe and the room temperature are the same. A temperature difference might lead to a failed calibration check.
 - ☐ Therefore also be careful not to warm the body of the calibration syringe with your hands.
- 2 Unwrap the **EasyOne FlowTube**.
- 3 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.
- 4 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.

- 5 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.



- 6 Choose  >  > **Single flow**, **Multi flow**, or **Linearity**.
 - 7 Confirm the message that is displayed.
 - 8 Wait for the baseline to be set.
 - 9 Push the piston of the calibration syringe all the way in.
 - 10 Pull the piston all the way out as slowly or as fast as required by the flow level that is displayed.
 - 11 Push the piston all the way in again with the same speed.
 - 12 To end the maneuver wait shortly or pull the piston briefly again.
 - ✓ If the maneuver was not acceptable, you need to repeat steps 8 to 11.
 - ✓ If you chose **Single flow** before and the maneuver was acceptable, the calibration check is completed.
 - ✓ If you chose **Multi flow** or **Linearity** before and the maneuver was acceptable, proceed with step 12.
 - 13 If you chose **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 8 to 11.
 - ✓ If all maneuvers were acceptable, the calibration check is completed.
- ⇒  [List of troubleshooting solutions 107](#) 
-  [Contact information 5](#) 

10.2. Biological quality control

In order to perform a biological quality control the **EasyOne Connect** software is required.

Biological quality control is an alternative to a calibration check. With biological quality control, you regularly perform tests on healthy subjects.

Overview

The American Thoracic Society (ATS) recommends that calibration be checked every day. Accordingly, biological quality control must also be performed every day.

It is practical to choose subjects in your practice or hospital who are available long-term.

If you suspect a problem with **EasyOne Air**, you can perform a test promptly on one of the known subjects and see whether the results fall within the expected range or not.

Detailed description

FEV₁, FVC, and FEV₆ are the spirometry parameters used for biological quality control. The software will establish a baseline mean value (precision range) for each known subject and sensor from trials repeated daily for 20 days.

This baseline will then be used to trend all subsequent biological quality control tests for that known subject and sensor. Immediate quality feedback will be provided by the software in accordance with the quality criteria for biological quality control. This quality feedback alerts you when the collected parameters deviate too far from the trend.

The biological quality control data will be plotted against time. The biological quality control reference lines will be mean (precision range), upper limit and lower limit. The upper and lower limits are +/- 2 standard deviations (SD).

 [Performing spirometry 41](#) 

10.3. Performing and assessing biological quality control

To perform biological quality control, you perform a simple FVC test or FVL test with your known subject. To be able to compare the measurements of a known subject with previous measurements, you can use the biological quality control functionality of **EasyOne Connect**.

Prerequisite

- ☐ You have one or more known subjects in your organization that are available long-term.

■ To perform biological quality control

- 1 Choose **Utilities > Calibration Check > Biological Quality Control**.
- 2 If you test the subject for the first time, do the following:
 - a) Choose **Add New BioCal Subject**.
 - b) Choose **New**.
 - c) Enter the required data and choose **OK**.
 - d) From the patient selection list, select the subject that you have just added.
 - e) Choose **Add Selected Subject**.
- 3 If you test a known subject that you have tested before, select the known subject from the BioCal subject selection list.
- 4 Choose **Add New Test**.
- 5 Choose a test.
- 6 Perform the test like a regular spirometry test.

■ To assess the biological quality control

- 1 From the BioCal subject selection list, select the known subject.
- 2 To view a visualization of the parameters over time, choose **Graph**.
- 3 Evaluate the quality criteria for biological quality control.
- 4 To print a report, choose the reports button.



⇒  [Performing spirometry 41](#) ↗

10.4. List of quality criteria for biological quality control

For each parameter (FEV₁, FVC, FEV₆) an individual quality criterion is calculated. Additionally the lowest grade of all parameters is reported.

Quality criterion	Limitation	Additional limitation
BA	–	–
BB	1 value outside ± 2 SD	–
BC	1 value outside ± 3 SD	–
BD	≥ 4 values outside ± 1 SD	only consecutive values on same side of mean
	≥ 2 values outside ± 2 SD	only consecutive values on same side of mean
	> 1 value outside ± 3 SD	–
	≥ 10 values, consecutive values on same side of mean	–
BF		–

☐ Specifications of quality criteria for biological quality control

11. Servicing and troubleshooting

11.1. Charging the battery

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

To charge **EasyOne Air**, always use the cradle and the USB micro cable provided by the manufacturer. The USB micro cable can either be connected directly to a computer for power supply and data exchange (plug with symbols computer and printer) or can be connected to a power supply.

- ⇒  [Setting up the physical components 24](#)
-  [List of specifications for the power supply unit 117](#)

11.2. Checking for correct operation

- 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 *ndd* distribution partner or the *ndd* servicing department.

- ⇒  [Calibration check 100](#)
-  [Performing spirometry 41](#)
-  [List of troubleshooting solutions 107](#)
-  [Contact information 5](#)

11.3. List of troubleshooting solutions

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

Problem	Possible cause	Solution
EasyOne Air 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 EasyOne Air is switched on, you hear three consecutive acoustic signals as a warning.	The spirometer is defective.	Consult your <i>ndd</i> distribution partner or the <i>ndd</i> servicing department.
When EasyOne Air 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>ndd</i> distribution partner or the <i>ndd</i> servicing department.
Every time you switch EasyOne Air on, you are prompted to enter Date etc.	The internal battery of EasyOne Air is defective.	Consult your <i>ndd</i> distribution partner or the <i>ndd</i> servicing department.
When you start a test, you see the following message: "Please insert EasyOne FlowTube correctly"	The EasyOne FlowTube is not correctly positioned.	Ensure the EasyOne FlowTube is inserted correctly and fully pushed in.
EasyOne Air is outside of $\pm 3.0\%$ when conducting the calibration check.	The EasyOne FlowTube is not correctly positioned.	Insert the EasyOne FlowTube correctly.
	You have not used an <i>ndd</i> adapter.	Use the EasyOne FlowTube 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 Tools > Settings > Spirometry .
The curve is missing on the printout.	The ink cartridge of your printer is empty.	Replace the cartridge.
	In the configuration of your EasyOne Air , a black and white printer is selected, but you actually use a color printer.	Go to Tools > Settings > Print 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.
	EasyOne Air is not correctly positioned on the base unit.	Insert EasyOne Air correctly into the base unit.
The EasyOne FlowTube detection is not working correctly.	An EasyOne FlowTube was inserted while EasyOne Air was switched on, or the EasyOne FlowTube was not inserted correctly.	Try again with the EasyOne FlowTube inserted correctly. If you receive the same message again, contact your <i>ndd</i> distribution partner or the <i>ndd</i> servicing department.

 Troubleshooting solutions

Problem	Possible cause	Solution
EasyOne Air cannot be found on the computer	Operating system is Window 10 or 11	For Windows 10: Follow the path Windows > Settings > Device > Bluetooth and other devices . Then click Bluetooth . For Windows 11: Follow the path Windows > Settings > Bluetooth & Device . Then click View more devices > Device settings > Bluetooth devices discovery . Click Advanced .
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.
PC does not recognize Bluetooth dongle	The PC already has a built-in Bluetooth adapter which may conflict with the dongle provided with EasyOne Air .	Remove the Bluetooth dongle and check if this resolves the problem. If not, re-start your PC and EasyOne Air .
	No Bluetooth is available in Windows. There is no Bluetooth icon or section in the Windows settings menu.	Plug in the Bluetooth dongle provided with EasyOne Air . After the installation, check if a Bluetooth icon or section is available in the Windows settings menu.

☐ Troubleshooting solutions

Problem	Possible cause	Solution
No connection to EasyOne Connect	There is an issue related to the Bluetooth dongle.	Disconnect and reconnect the dongle. Try to connect again. Unpair the spirometer and pair it again (Windows > Settings > Bluetooth > Remove device/Add device). Enter your secret pairing key. Try to connect again.
	The pairing information is not valid anymore because: it has been deleted on EasyOne Air (e.g., by restoring the factory default settings or deleting the database). The Bluetooth device has been removed in Windows. Or a Windows update has invalidated the information.	On PC: Remove the Bluetooth device (Settings > Bluetooth > Remove Device). On EasyOne Air : Remove the PC connection (Tools > Settings > Bluetooth). Then click and hold shortly on BT Connections at the bottom of the list. Pair EasyOne Air again (Windows > Settings > Bluetooth > Add a device).
	EasyOne Air is outside of range.	Make sure the device is within about 10 meters, or 33 feet of the PC. Reduce the number of obstacles between the two devices (thick walls, metal planes, grids, etc.). Also ensure that the Bluetooth dongle is not blocked so that it can transmit and receive easily.
	The spirometer is already connected to another PC (Bluetooth icon visible on spirometer, EasyOne Connect shows no Bluetooth connection).	Close EasyOne Connect on the other PC(s). On the other PC(s), unpair the spirometer (Windows > Settings > Bluetooth > Remove Device).
	Bluetooth has been disabled on spirometer (no Bluetooth icon visible in status bar).	Activate Bluetooth (Tools > Settings > Bluetooth).
	There is an unrecognized device in the Windows device manager. Example: a missing "ASMedia XHCI" controller (in fact a USB3 driver) can prevent the PC from connecting via Bluetooth.	Install the device driver from the mainboard manufacturer's website.
Connection between EasyOne Air and EasyOne Connect intermittently drops	After a spirometer firmware update or an EasyOne Connect software update, there is no connection or only a faulty connection between EasyOne Connect and the spirometer.	On PC: Remove the Bluetooth device (Settings > Bluetooth > Remove Device). On PC: Pair EasyOne Air again (Windows > Settings > Bluetooth > Add a device).
	The spirometer is already connected to a PC (Bluetooth icon visible on spirometer and EasyOne Connect shows ...)	Log in to your PC as administrator. Disable the power save mode on Bluetooth driver (Windows > Device Manager). Select Bluetooth . Then either go to Properties of Generic Bluetooth Radio (USB dongle) or to the built-in Bluetooth interface (e.g., Qualcomm Atheros QCA61x4 Bluetooth 4.1). Go to Power Management and disable Allow the computer to turn off this device to save power .

☐ Troubleshooting solutions

Problem	Possible cause	Solution
EasyOne Air firmware appears to be very slow.	Too many test reports are stored on the device.	Do a back up of the test reports (e.g. synchronize with EasyOne Connect or do a database export to an SD card and delete test reports. Backups 71
EasyOne Air is not charging.	EasyOne Air is connected to a power source that is too low in wattage to charge.	Change power source (e.g. USB power supply).

Troubleshooting solutions

- ⇒ [Quality messages and quality grades 59](#)
- [Contact information 5](#)
- ⇒ Application Note **EasyOne Air with Bluetooth**
- [Application Notes for further information 4](#)

11.4. Reactivation after storage

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

Do not use **EasyOne Air** immediately after removing it from an extreme storage environment, even if it was stored under conditions still within the specified range of environmental conditions. Allow enough time for the device to acclimatize to the ambient environment where patient testing takes place after removing it from storage. The time required for the device to warm up from the minimum storage temperature to that needed for use is 30 minutes. The time required between uses to cool down from the maximum storage temperature to that needed for use is 30 minutes. These time requirements assume an ambient temperature of 20°C.

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 *ndd* distribution partner or the *ndd* servicing department.

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

- ⇒ [List of specifications 112](#)
- [Charging the battery 106](#)
- [Preparation for first-time use 28](#)
- [Checking for correct operation 106](#)
- [Contact information 5](#)

11.5. Exporting logging information

EasyOne Connect can export logging information. The *ndd* servicing department or your own technical staff might 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 to save the log file, for example, a USB flash drive.
- 5 Choose **OK**.
 - ✓ A confirmation message is displayed when the export has been successful.

⇒  [Contact information 5](#)

11.6. Disposal

Warning

Cross-contamination

If a used **EasyOne FlowTube** is not disposed of after a test session, it could be reused accidentally for another patient. This could lead to cross-contamination.

- Always dispose of any used **EasyOne FlowTube**.



The **EasyOne Air** should not be disposed of as unsorted municipal waste. Please make use of your local Waste of Electrical and Electronic Equipment (WEEE) collection facilities to dispose of this product and otherwise observe all applicable requirements.

Please remember to recycle all packaging material and make sure that the plastic waste is treated in waste management facilities and not released into the environment.

Dispose of lithium batteries according to local and national guidelines.

12. Specifications and bibliography

12.1. List of specifications

Description	Parameter	Value
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	±2% or 0.020 L/s (except PEF) PEF: +- 5% or 0.2 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		<1.5 cm H ₂ O/L/s at 14 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		Working with EasyOne Connect PC software: Chinese, Croatian, Danish, Dutch, English, Finnish, French, French (Canada), German, Italian, Japanese, Norwegian, Portuguese, Portuguese (Brazil), Russian (simplified), Russian, Spanish, Swedish, Turkish, Vietnamese Working with EasyOne Air Standalone: English, Danish, Dutch, French, German, Italian, Norwegian, Polish, Portuguese, Russian, Spanish, Swedish
Data Management		EasyOne Connect PC software
Printing option		Direct to printer or with EasyOne Connect PC software
Export/EMR		HL7, XML, GDT (with EasyOne Connect PC software)
Hardware interface		USB 1.0/1.1, USB 2.0 (max. 100 mA), Bluetooth
Age range for patients		Spirometry ≥4 years
Mouthpiece		Disposable EasyOne FlowTube breathing mouthpiece
Power supply		Rechargeable lithium-ion battery, USB power supply
Voltage (EasyOne Air and Cradle)	Input	4.5 V to 5.5 V
Power consumption EasyOne Air		Up to 7.7 W
Power EasyOne Air Cradle	Output	4.5 V to 5.5 V up to 1.4 A

☐ Specifications for **EasyOne Air**

Description	Parameter	Value
Determination of time zero (According to ATS/ERS 2019)		The device uses the measured values to count back to time zero
Appliance class		Class II
Instrument classification		Type BF applied part (the surface of the EasyOne Air enclosure). Powered internally with a lithium-ion battery. Short usage time, less than 10 minutes. Not intended to be used in oxygen-rich environments. USB cables can come into contact with the patient but are not defined as applied part.
Mode of operation		Continuous operation
Wireless connection	Type	Bluetooth v2.1 + EDR, BT 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: Typical BT Transmit Power: 17dBm
	Bluetooth profile	Bluetooth: SPP (Serial Port Protocol)
	Receive sensitivity	Bluetooth: -94dBm
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 EasyOne Air can reach up to 44.7°C (112.5°F).
	Relative humidity	5% to 90%
	Atmospheric pressure	700 hPa to 1060 hPa

☐ Specifications for **EasyOne Air**

Description	Parameter	Value
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>ndd</i> website under “Certificates”
	US	FDA 510(k) market clearance
	Associations and institutes	ERS/ATS 2022, ATS/ERS 2019 and 2005, SSA Disability, NIOSH, OSHA
Life time		7 years

☐ Specifications for **EasyOne Air**

- ⇒ [☐ List of tests and parameters 37](#)
- ☐ [Contact information 5](#)
- ⇒ [Application Note Reference Predicted Normal Values](#)
- ☐ [Application Notes for further information 4](#)

12.2. List of specifications for the lithium-ion battery

Warning

Risk of personal injury and fire

Wrong handling of batteries can lead to fire or explosion.

- 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.
 - Keep the battery away from other metal parts to avoid short circuits.
 - 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 that complies with either IEC 62368-1, IEC 60601-1, or equivalent standards for electrical safety.
 - 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.
 - Do not open, crush, heat above 50°C/122°F, or incinerate.
 - Follow the instructions in this Operator's Manual.
-

Description	Parameter	Value
Manufacturer of battery pack		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 time		100 tests with a full battery charge. Note that battery lifetime can be reduced by high humidity and temperatures.
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

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

Description	Parameter	Value
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
		Manufacturer
		Catalog number

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

12.3. List of specifications for the power supply unit

Description	Value
Output voltage	5 V DC
Output current	max. 2500 mA
Standard	Need to comply with IEC 62368-1 standard or equivalent and/or IEC60601-1 standard for electrical safety.

☐ Output voltage/current and certification

12.4. List of order numbers for **EasyOne Air** and its components

Item	Intended region	Order number
EasyOne Air	International	2500-2
EasyOne FlowTube box of 50 pcs.	International	5050-50
EasyOne FlowTube box of 200 pcs.	International	5050-200
EasyOne FlowTube box of 500 pcs.	International	5050-500
<i>ndd</i> calibration syringe 3 L with EasyOne FlowTube cal check adapter	International	2030-2
EasyOne FlowTube cal check adapter	International	5030-2
EasyOne Air USB cable B-micro (cradle to printer)	International	2500-50.1sp
EasyOne Air Bluetooth dongle	International	2500-50.2sp
EasyOne Air battery pack	International	2500-50.4sp
EasyOne Air power supply with adapters	International	2500-50.5sp
EasyOne Air cradle	International	2500-50.11sp
EasyOne Filter FT of 100 pcs.	International	2091-422
Nose Clip box of 25 pcs.	International	3000-50.21

☐ Order numbers for **EasyOne Air** and its components

12.5. List of system requirements

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

Component	System requirement
Operating system	Microsoft Windows 10 (32 bit and 64 bit), Windows 11 (64 bit)
Hard disk capacity	1 GB (software) 4 GB (database)
RAM	2 GB

☐ System requirements for **EasyOne Connect**

12.6. List of bibliographic references

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- [2] Occupational Health and Safety Administration (OSHA). *Pulmonary Function Standards for Cotton Dust*. 29 CFR: 1910.1043 Appendix D.
- [3] *Social Security Administration Disability (SSD) Guidelines*. CFR404: Appendix 1 to Subpart P.
- [4] Ferguson et al. *Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program*. Chest Journal, Vol 117, 2000, pp 1146–1161.

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- [13] Miller et al. *ATS/ERS Task Force: Standardization of Lung Function Testing*. Numbers 1 to 5, European Respiratory Journal, Vol 26, 2005, pp 153–161, 319–338, 511–522, 720–735, 948–968.
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- [16] American Thoracic Society Recommendations for a Standardized Pulmonary Function Report. American Journal of Respiratory and Critical Care Medicine, Vol 196, 2017, pp 1463–1472
- [17] Graham, Steenbruggen, Miller, et al. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. American Journal of Respiratory and Critical Care Medicine, Vol 200, Iss 8, 2019, pp e70–e88.
- [18] Stanojevic, Sanja, et al. "ERS/ATS technical standard on interpretive strategies for routine lung function tests." European Respiratory Journal 60.1 (2022).

⇒ Application Note *Reference Predicted Normal Values*

 Application Notes for further information 4

A. Appendix - Electromagnetic compatibility (EMC)

A.1. General

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 might 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):

Note: "Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

⇒ www.fcc.gov

For Canada, see RSS-Gen — General Requirements for Compliance of Radio Apparatus:

⇒ www.ic.gc.ca

Environment

 Intended use/ Indications for use of **EasyOne Air spirometer 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.

Safety information

 Safety information regarding electromagnetic compatibility 15 

Compliant cables and components

Warning

Increased emissions or decreased immunity

The use of components, transducers and cables other than those specified by the manufacturer might result in increased emission or decreased immunity performance of the equipment or system.

- The table below lists cables, transducers, and other applicable components with which the manufacturer guarantees EMC compliance.

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

EMC compliant cables and components

USB cable micro to type A, shielded, 1.8 m

USB cable micro to type B, shielded, 1.8 m

Power supply 5.0 V DC, compliant with IEC 62386-1 or equivalent and/or IEC 60601-1

 [List of specifications for the power supply unit 117](#)

 Components with which the manufacturer guarantees EMC compliance

 [List of box contents 21](#)

Wireless module

EasyOne Air contains a wireless module for Bluetooth communication.

 [List of specifications 112](#)

A.2. 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 ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	EasyOne Air 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	EasyOne Air 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.3. 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 ensure 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	Portable and mobile RF communications equipment should be used no closer to any part of the EasyOne Air, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$ $d = 0,35\sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = 0,7\sqrt{P} \text{ 800 MHz to 2.5 GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference might occur in the vicinity of equipment marked with the following icon: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.7 GHz	

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

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

* These immunity test standards have been tested with the *ndd* power supply (optionally available)  [List of order numbers for **EasyOne Air** and its components 118](#) 

^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 **EasyOne Air** is used exceeds the applicable RF compliance level above, the **EasyOne Air** should be observed to verify normal operation. If abnormal performance is observed, additional measures might be necessary, such as re-orienting or relocating the **EasyOne Air**.

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

 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 might 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**

B. Appendix - Optional use with *EasyOne Filter FT*

In the following the **EasyOne Filter** will also be referred to as filter.

B.1. Intended use/ Indications for use

The **EasyOne Filter** is intended to be used in combination with *ndd* breathing mouthpieces to reduce bacteria, viruses and other particulates from the patient's exhaled air while performing flow measurements, such as spirometry tests.

The **EasyOne Filter** is a single-use device and intended for single-patient use only.

B.2. Compatible software

Required software of the associated device:

- **EasyOne Air** firmware V1.18 or higher
- **EasyOne Connect** software V3.9.3.x or higher

B.3. Safety information

Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the member state in which the user and/or patient resides.

Malfunction

For reliable results, use only the original **EasyOne Filter** and make sure that you have a filter compatible software available on your spirometry device. The **EasyOne Filter** and its wrapper might be damaged when dropped or during transport.

- Only use a new, hygienically packaged filter.
- Visually check the filter and its wrapper for damage, e.g. sharp edges or broken wrapper, before use.
- If you detect any damage, dispose of the filter and use a new one.

Environmental conditions

Environmental conditions outside the range specified by the manufacturer can cause measurement errors.

- Use, store, and transport the **EasyOne Filter** only within the specified environmental conditions.

 [List of Specifications 132](#)

Cross-contamination

If operators do not follow hygienic procedures, operators and patients might be infected with pathogens from other patients.

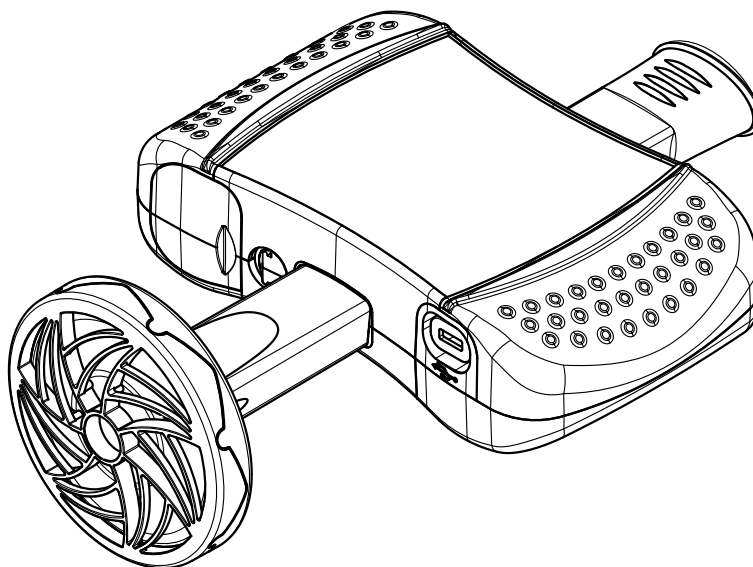
- Follow all applicable hygienic procedures.
[📖 Cleaning and disinfecting 67](#)
- Always exchange the filter before testing a new patient.
- Dispose of the filter after use.

Erroneous diagnosis

For unforeseen reasons, malfunction of the spirometry device can lead to inaccurate results and erroneous diagnosis. To make sure the configuration is set properly

- Perform calibration checks periodically.

B.4. Overview of **EasyOne Filter**



The filter can optionally be attached at the distal end of the **EasyOne FlowTube** to filter pathogens from the exhaled air. Cross contamination is prevented by using the devices and mouthpieces as instructed in this manual.

[📖 Intended use/ Indications for use of **EasyOne Air spirometer 2**](#)

The filter is designed to work accurately with the **EasyOne FlowTube** breathing mouthpiece. If the correct configuration is selected, the measurements of relevant spirometry parameters are not affected.

To ensure hygienic testing, the filter is a disposable single-use device and intended for single-patient use only.

B.5. Performing a test

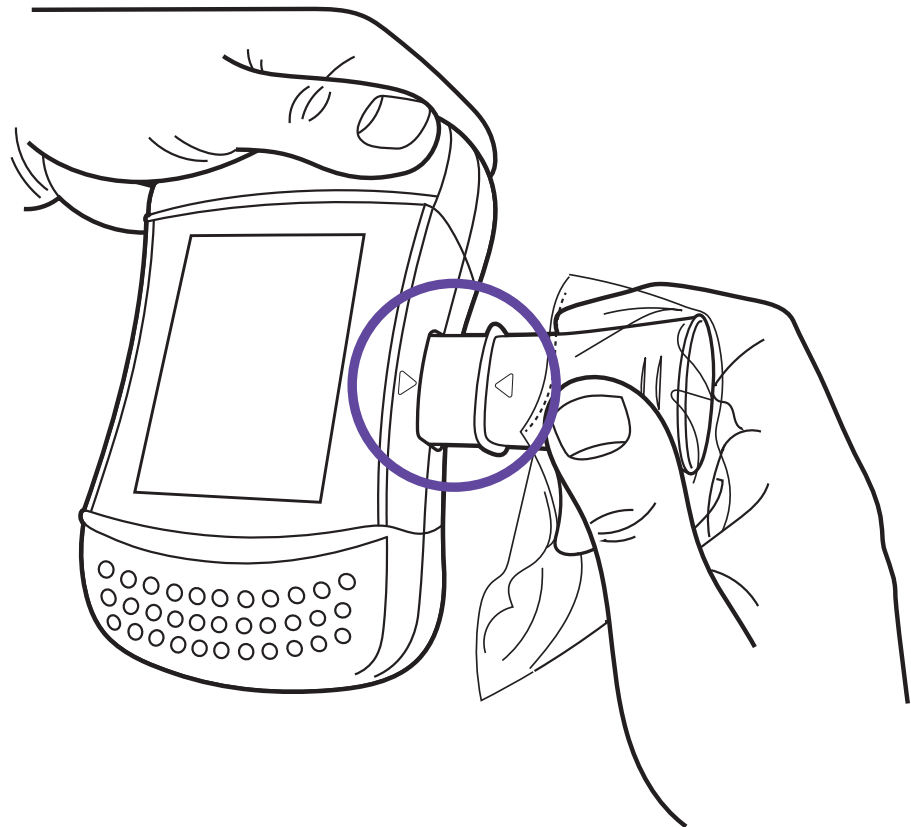
To perform a test using a filter, follow the instructions below while attaching the filter. To perform the test, refer to [Performing spirometry 41](#).

Prerequisites

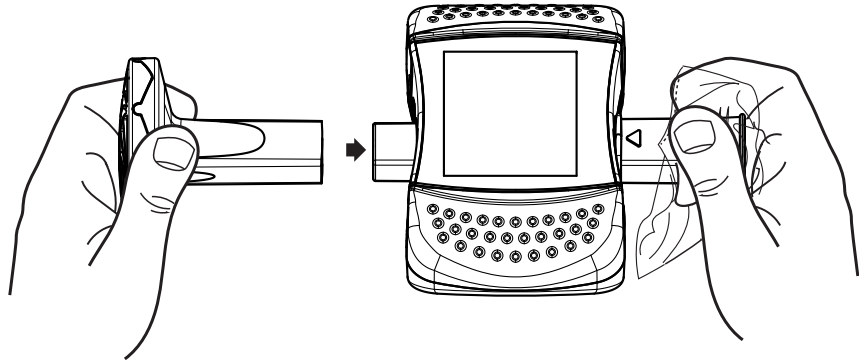
- ☐ You have configured the use with filters.
[Configuration 130](#)
- ☐ You have checked for further prerequisites.
[Overview of the spirometry workflow 41](#)

■ To attach the filter

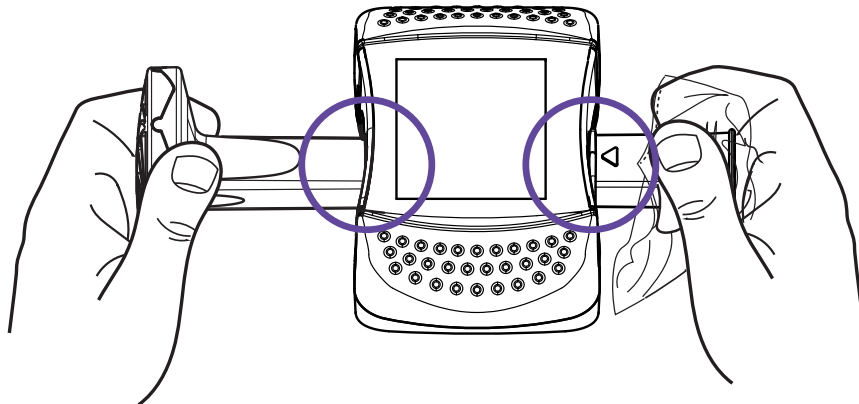
- 1 Unpack the filter.
- 2 Partly unwrap the **EasyOne FlowTube**.
 - ☐ For hygiene reasons, grip the partly unwrapped **EasyOne FlowTube** only with the wrapper at the mouthpiece. Do not touch the **EasyOne FlowTube**.



- 3 Keeping the partly unwrapped wrapper on the mouthpiece of the **EasyOne FlowTube**, fully insert the **EasyOne FlowTube** into the **EasyOne FlowTube** holder.



- ❑ The shape of the **EasyOne FlowTube** and the **EasyOne Air** guide the orientation of the **EasyOne FlowTube**. You can only insert the **EasyOne FlowTube** fully if it is positioned correctly.
- 4 Hold the **EasyOne Air** and the wrapped **EasyOne FlowTube** with one hand, and attach the filter at the end of the **EasyOne FlowTube**.



- 5 Ensure that the **EasyOne FlowTube** and the filter are fully inserted.
 - a) If the **EasyOne FlowTube** is not fully inserted, gently press against the filter and the **EasyOne FlowTube proximal end (mouthpiece)** until the filter and the **EasyOne FlowTube** are fully inserted.
 - b) Check again if the **EasyOne FlowTube** and the filter are fully inserted.
- 6 Make sure that the wrapper protects the mouthpiece of the **EasyOne FlowTube** until you hand the **EasyOne Air** to the patient.

■ To perform a test

- 1 Check for further prerequisites.
 [Overview of the spirometry workflow 41](#) ↗
- 2 Ensure that the filter use is enabled.
 [Configuration 130](#) ↗
- 3 When choosing a test on the user interface, the [Inline Filter Confirmation](#) window is displayed. Confirm the use of a filter.
 -  If the first trial or test of one session were performed with a filter, all consecutive trials or tests of the same session must be performed with a filter.
 -  If the first trial or test of one session were performed without a filter, all consecutive trials or tests of the same session must be performed without a filter.
- 4 Perform the test.
 [Performing spirometry 41](#) ↗

■ To end a test

- 1 Remove the filter.
- 2 Warning! Cross-contamination
 Directly dispose of the filter after use. The filter is a disposable for single-patient use. It is not intended to be cleaned.

B.6. Configuration

You can set the use of filters as a default for performing tests and calibration checks. However, the user has to confirm the use of a filter before every test and calibration check.

■ To configure the use of **EasyOne Air** with **EasyOne Filter**

- 1 Choose  >  >  > [Inline Filter](#)
- 2 Select **EasyOne Filter FT**

■ To configure the use of **EasyOne Connect** with **EasyOne Filter**

- 1 Choose [Utilities](#) > [Configuration](#) > [Device](#) > [Inline Filters](#).
- 2 Choose your spirometry device which is to be used with a filter.
- 3 Select the [Use Inline Filter](#) check box.
- 4 From the [Select inline filter configuration](#) drop-down list, choose the filter.
- 5 Choose [Save](#).
 -  The [Import inline filter configuration](#) function is only for *ndd* maintenance purposes.

B.7. Calibration check

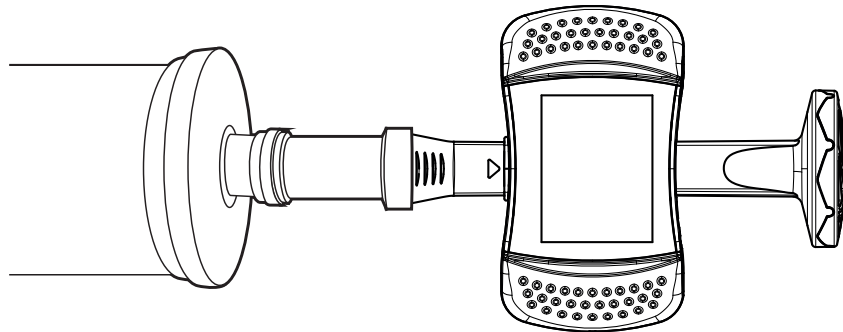
If you generally perform tests using filters, you have to perform a calibration check using a filter.

Prerequisites

- ❑ You have configured the use with filters.
[Configuration 130](#)
- ❑ You have checked for further prerequisites.
[Performing a calibration check 101](#)

■ To perform a calibration check

- 1 Follow the instructions to the point where the device is connected to the calibration syringe.
[Performing a calibration check 101](#)
- 2 Attach the filter at the end of the **EasyOne FlowTube**.



- 3 Ensure that the **EasyOne FlowTube** and the filter are fully inserted.
 - a) Align the arrow on the **EasyOne FlowTube** with the arrow on the **EasyOne Air**.
 - b) If the **EasyOne FlowTube** and/or the filter are not fully inserted, gently press against both until the **EasyOne FlowTube** and the filter are fully inserted.
 - c) Check again if **EasyOne FlowTube** and filter are fully inserted.
- 4 Continue following the calibration instructions.
[Performing a calibration check 101](#)

B.8. List of Specifications

Description	Parameter	Value
Age range for patients	Spirometry ≥ 4 years	
Operating conditions	Temperature	0 to 40°C (32 to 104°F)
	Relative humidity	5% to 80%
	Atmospheric pressure	620 to 1060 hPa
Storage and transport conditions	Temperature	-20 to 40°C (-4 to 104 °F)
	Relative humidity	5% to 80%
	Atmospheric pressure	400 to 1060 hPa
Life time	See expiration date printed on the filter wrapper	
Filter efficiency (BFE)		$\geq 99.999\%$

☐ List of Specifications

C. Appendix - Information for the USA

The following tests are only available with US regional settings.

C.1. 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 a larger scale.
- There is no clinical interpretation displayed or printed.

⇒  [Performing spirometry 41](#) ↗

 [FVC test 61](#) ↗

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

 [Application Notes for further information 4](#) ↗

C.2. SSA test

The SSA test is intended to test for social security disabilities. The SSA test is only available with US regional settings. Before performing an SSA test calibration has to be checked.

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](#) 
-  [FVC test 61](#) 
-  [Quality grades for the SSA test 60](#) 
-  [Performing a calibration check 101](#) 

