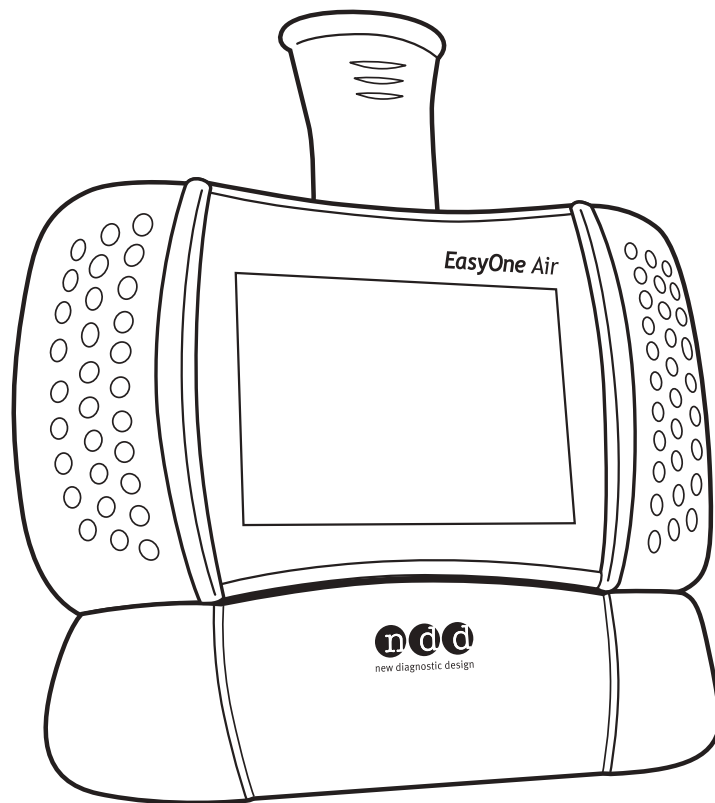




EasyOne Air

Operator's Manual V1.1

1 Preface

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

Revision date	Version	Description
10 April 2018	V1.1	Revised version with minor changes
27 February 2017	V01	Initial release for market launch

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

1.2 Identification and revision of the *EasyOne Air* spirometer

This revision V1.1 of the *EasyOne Air* Operator's Manual applies to *EasyOne Air* with a serial number greater than 1,000,000 and with a firmware version greater than V1.9.0.

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

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

⇒ [Contact information, 4](#) 
 On www.ndd.ch
 For the US, on www.nddmed.com

1.3 Version history of the *EasyOne Connect* PC software

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

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

⇒ On www.ndd.ch
 For the US, on www.nddmed.com

1.4 Intended use of the *EasyOne Air* spirometer

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

1.5 Intended audience of this Operator's Manual

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

1.6 Using this Operator's Manual

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

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

1.7 Application Notes for further information

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

⇒ <http://AppNotes.ndd.ch>
For the US <http://AppNotes.nddmed.com>

1.8 Legal information

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

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ndd, *ndd new diagnostic design* and *EasyOne* are registered trademarks of ndd Medizintechnik AG.

Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

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

Wi-Fi® is a registered trademark of Wi-Fi Alliance.

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

1.9 About electromagnetic interference

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

For the US, see 47 Code of Federal Regulations Sec. 15.19(a)(3)

This Class B digital apparatus complies with Industry Canada RSS standards.

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

1.10 Contact information



ndd Medizintechnik AG
Technoparkstrasse 1
CH-8005 Zurich, Switzerland
Tel: +41 44 445 2530
Fax: +41 44 445 2531
www.ndd.ch

ndd Medical Technologies
300 Brickstone Square, Suite 604
Andover, MA 01810, USA
Tel: +1 978 470 0923
Fax: +1 978 470 0924
www.nddmed.com

1.11 Product registration

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

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

⇒ <http://reg.ndd.ch>

For the US <http://reg.nddmed.com>

1.12 Disposal



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

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2 Safety information

2.1 Classification

In this manual, safety information is classified as follows:

WARNING

WARNING ...

... indicates a hazard. If not avoided, the hazard can result in death or serious injury.

CAUTION

CAUTION ...

... indicates a potential hazard. If not avoided, the hazard may result in minor injury and/or product/property damage.

2.2 General safety information

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

Fire	Follow the manufacturer's recommendation for proper disposal of the battery. Only use an original battery by the manufacturer. Do not store <i>EasyOne Air</i> close to flammable materials like paper or textiles. Disposal, 4 ↗ List of order numbers and accessories for EasyOne Air, 131 ↗
False diagnosis	<i>EasyOne Air</i> may be damaged when dropped or during transport. Perform an incoming inspection when you first receive <i>EasyOne Air</i>. If you detect any damage, contact your <i>EasyOne Air</i> dealer or the <i>ndd</i> Servicing Department. Especially check the battery for visible damage before use. Do not drop <i>EasyOne Air</i>. If <i>EasyOne Air</i> has been dropped, check for correct operation of <i>EasyOne Air</i>. Checking for correct operation of EasyOne Air, 122 ↗
Fire due to explosive or flammable gases	If used in the vicinity of flammable gases, the plastic case may 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). If not in daily use, remove the battery from <i>EasyOne Air</i> and store the battery in the original packaging.
False diagnosis	Environment conditions outside the range described in the specifications can cause measurement errors. Use <i>EasyOne Air</i> only within the defined environment specifications for temperature, humidity, and atmospheric pressure/altitude. Observe the limits of storage conditions. Setting up the EasyOne Air spirometer, 24 ↗ List of specifications for EasyOne Air, 125 ↗ Configuration of EasyOne Air, 93 ↗ List of specifications for EasyOne Air, 125 ↗ About reactivating EasyOne Air after storage, 124 ↗
False diagnosis	Setup with wrong environment data can cause false results. Verify the environment data that you have set up.
False diagnosis	Electromagnetic fields from other devices may cause disturbances in <i>EasyOne Air</i>.
False diagnosis	Graphs on the display of <i>EasyOne Connect</i> may be misleading due to unclear curve scaling between different patients. Only conduct result interpretation of curves with a printed report. About interpreting results, 72 ↗ List of quality messages and quality grades, 73 ↗

Failed update	An update may fail. Perform backups of the database of <i>EasyOne Air</i> and <i>EasyOne Connect</i> frequently. Performing a backup of EasyOne Air, 102
Data loss	Data loss may occur for various other reasons and is generally unpredictable. Backup the database of <i>EasyOne Air</i> frequently. Performing a backup of EasyOne Air, 102
False diagnosis	For unforeseen reasons, malfunction of <i>EasyOne Air</i> can lead to false results. Perform calibration checks periodically. Calibration check, 118 Checking for correct operation of EasyOne Air, 122
Malfunction	Viruses, malware, and other hazardous software on your PC may adversely affect the performance of <i>EasyOne Connect</i>. Install anti-virus software on your PC.
Malfunction	Damaged components can lead to false results. Make sure that no liquid penetrates into <i>EasyOne Air</i>, for example through the battery compartment or the USB port.
Leakage of acids and explosion	Do not connect the battery improperly. Do not throw the battery into fire. Remove the battery from the battery compartment if you do not intend to use <i>EasyOne Air</i> for a longer period. Avoid mechanical shock to the battery. If the rechargeable battery is damaged, liquids from the battery must not get into contact with skin or eyes. In case of contact with skin or eyes, rinse thoroughly with water and consult a physician. Only charge the battery using <i>EasyOne Air</i>, the power supply released by the manufacturer, and the cradle. Follow the manufacturer's recommendation for proper disposal of the battery. About charging the battery of EasyOne Air, 122 Disposal, 4
Malfunction	Servicing must only be carried out by <i>ndd</i> staff or by qualified service personnel of official <i>ndd</i> distributors. Do not open <i>EasyOne Air</i>.
Malfunction	Non-original accessories and disposables, like respiratory tubes, battery, power adapter, or cables can cause malfunction. Only use original accessories and disposables by the manufacturer. List of order numbers and accessories for EasyOne Air, 131
False diagnosis	Non-original respiratory tubes can cause measurement error and false results. You must only use <i>EasyOne Flow Tube</i> respiratory tubes by the manufacturer <i>ndd</i> to assure accuracy, long-life, and full warranty coverage.

Excessive heat	Prolonged exposure to direct sunlight, for example in cars, or exposure to other sources of heat may cause the battery to explode. Do not store in places that can exceed temperatures of 50°C or 122°F. Remove the battery and store the battery in the original packaging.
Network connection	Connection of <i>EasyOne Connect</i> to an IT network that includes other equipment could result in previously unidentified risks to patients, operators, or third parties. 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. It is your responsibility to identify, analyze, evaluate, and control these risks. IEC 80001-1:2010 provides guidance to address these risks.

2.3 Safety information regarding electromagnetic compatibility

Influence by HF surgical equipment	Electrical devices with a high RF power output during intended use (e.g. High frequency (HF) surgical equipment) should not be operated in parallel with <i>EasyOne Air</i>.
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 <i>EasyOne Air</i>. Keep a distance of at least 30 cm (12 inches) to any part of <i>EasyOne Air</i>.
Increased emissions or decreased immunity	Accessories, transducers, and cables other than those specified by the manufacturer or replacement parts for internal components may result in increased emissions or decreased immunity of <i>EasyOne Air</i>.
Proximity to other equipment	<i>EasyOne Air</i> should not be used adjacent to or stacked with other equipment. Should close proximity or stacking be unavoidable, however, the configuration in which it is used needs to be watched closely to ensure that the equipment is functioning normally.
Interruption of the USB connection	Electrical fast transient coupling to the USB cable or electrostatic discharge on the device may cause an interruption of the USB connection, which is indicated to the user. After reconnecting, the USB connection will work as expected. There is no harm because the data transmission is secured. ⇒ See Appendix

2.4 About requirements for connections to external devices

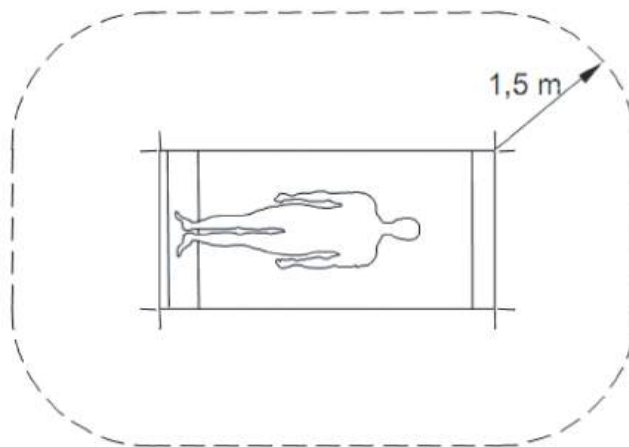
EasyOne Connect is installed on a PC or laptop, to which *EasyOne Air* is connected via the cradle or wirelessly.

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

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

The following conditions must be met:

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



☐ Patient environment

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

The following limits are applicable:

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

Appropriate measures must be taken if these limits are exceeded.

Suggestions:

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

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

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

2.5 List of equipment icons



Follow instructions for use



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



CE marked per the Medical Device Directive 93/42/EEC since 2008



Product certification for the USA and Canada



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



Manufacturer

Rx only

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



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



Instrument classification: Type BF applied part



Universal Serial Bus (USB)—standard for data transfer, connecting devices, and battery charging, applies to cables and connectors



Battery

SN

Serial number

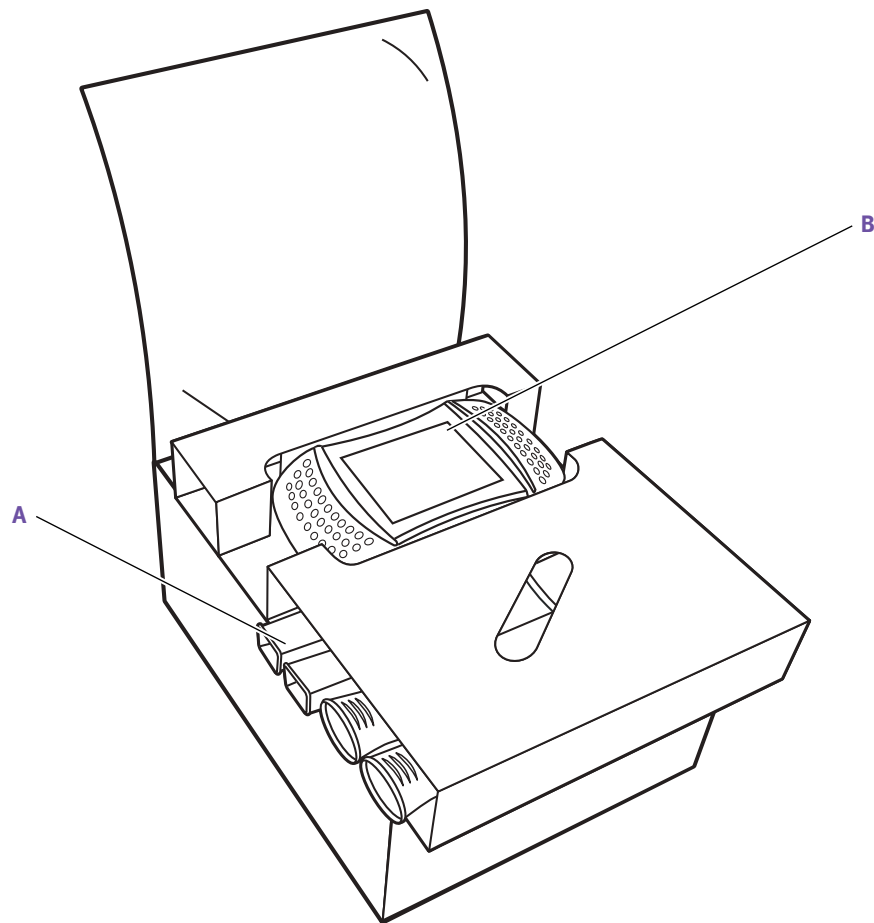
Lot

Batch code

3 First-time setup

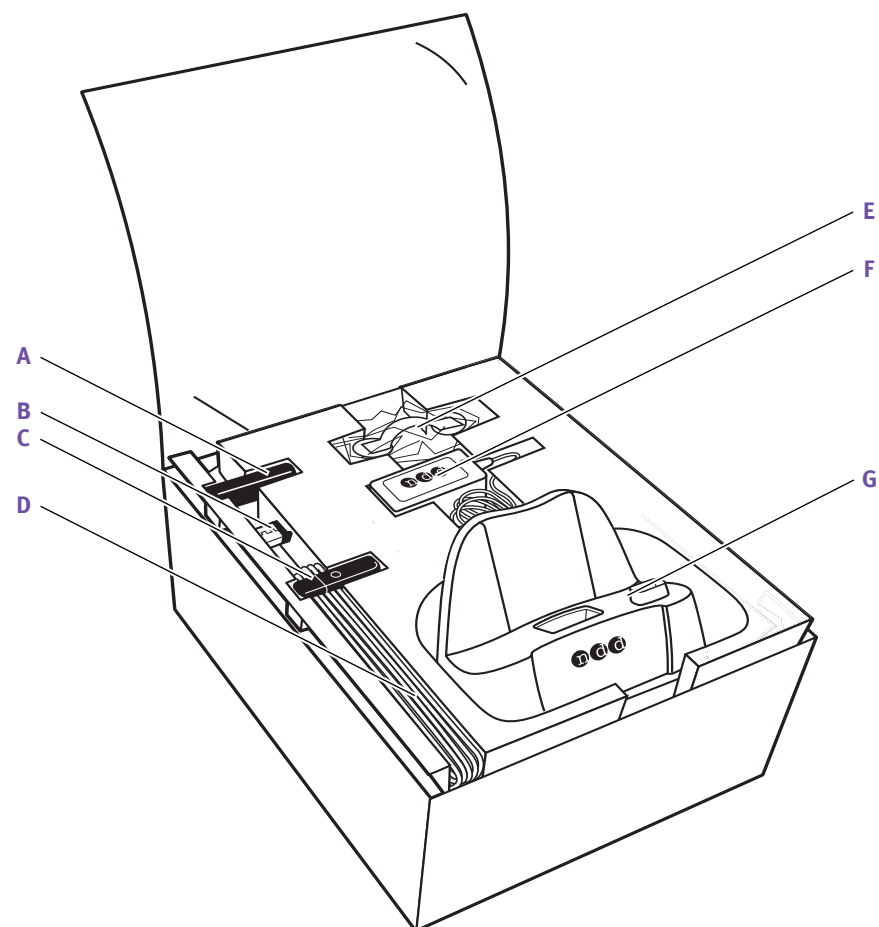
3.1 List of box contents

The box contains the following items:



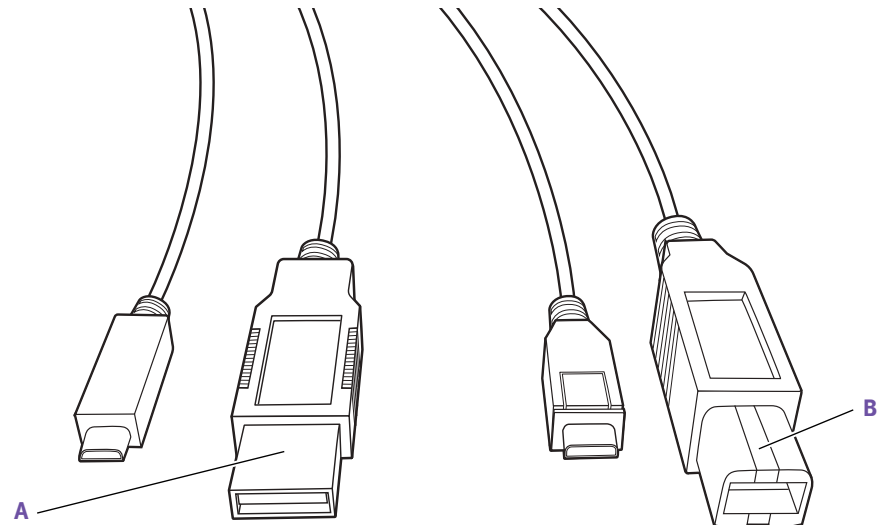
A *EasyOne Flow Tube* respiratory tubes **B** *EasyOne Air* spirometer

☐ Box contents – top inlay



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

☐ Box contents – bottom inlay



A USB cable micro to type A

B USB cable micro to type B

☐ The different USB connectors of the two USB cables

The box contains the following documents:

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

The USB flash drive contains the following:

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

3.2 About compatible printers

EasyOne Air can print over USB when using the cradle.

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

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

- ⇒ [Description of print settings of EasyOne Air, 100](#)
- [Setting up the physical components, 20](#)
- [Application Note *Printer Compatibility List*](#)
- [Application Notes for further information, 3](#)

3.3 Setting up the physical components

⚠ WARNING

ELECTRIC SHOCK

Patients and technicians may be exposed to dangerous voltage.

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

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

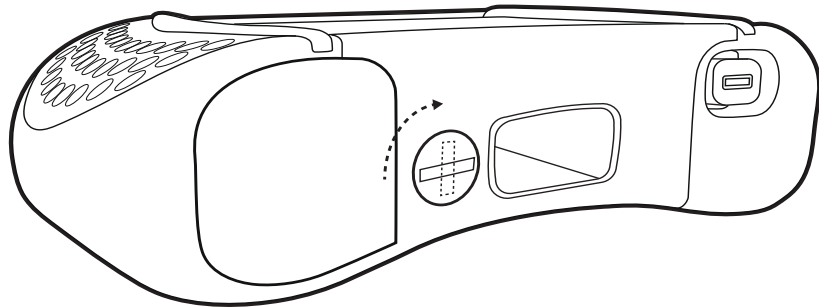
⚠ CAUTION

ELECTRIC SHOCK, PATIENT HEALTH HAZARD, AND FALSE DIAGNOSIS

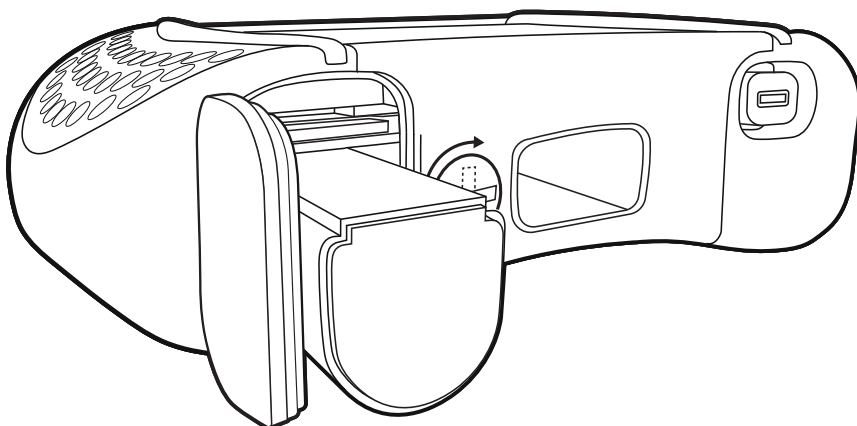
Damage to casing or broken components may expose the patient or technician to dangerous voltage. Small parts from damaged disposables can be ingested or inhaled by the patient. Measurement errors can cause false diagnosis.

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

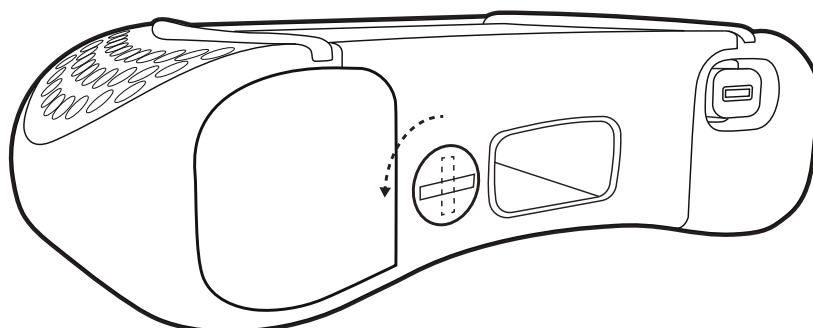
- 1 Unpack *EasyOne Air* and the battery.
- 2 Unlock and open the battery compartment by turning the lock screw clockwise.



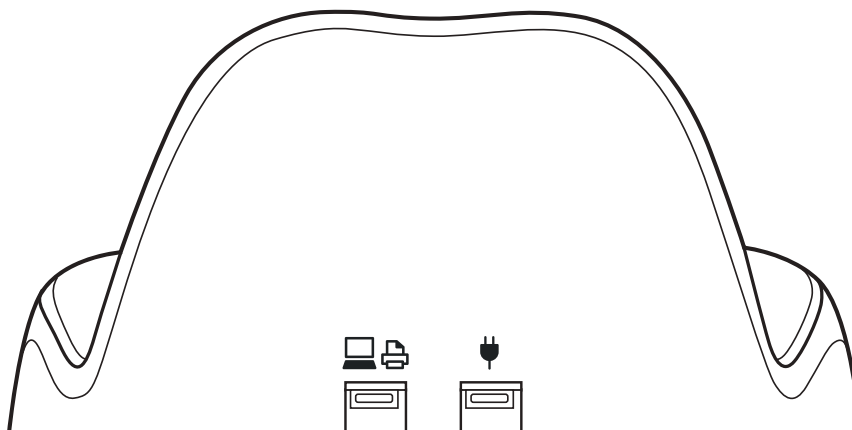
- 3 Insert the battery into the battery compartment of *EasyOne Air*.
 - 📄 The battery fits easily into the compartment. If the battery does not seem to fit, check the correct insert direction. Do not apply force.



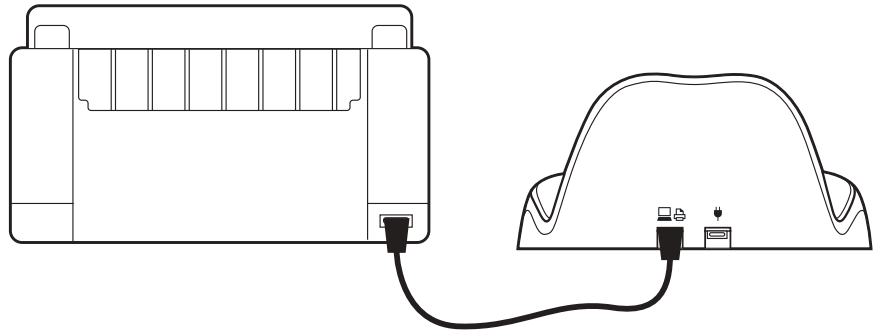
- 4 Close and lock the battery compartment by turning the lock screw counterclockwise.



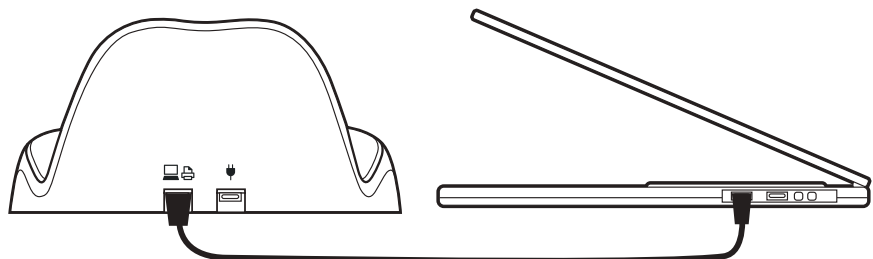
- 5 Unpack the cradle and the USB cables.
- 6 Turn the cradle around so that the back of the cradle is facing towards you.



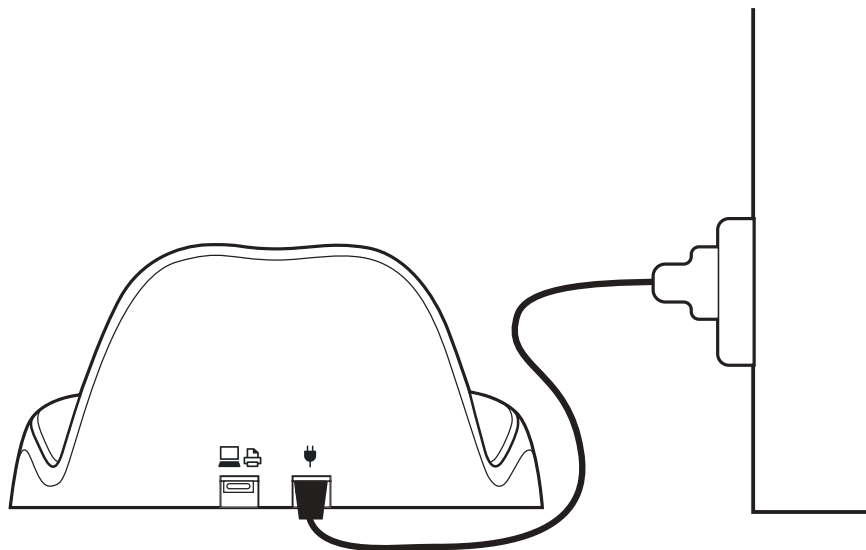
- 7** If you want to connect the cradle to a printer, do the following:
- a)** Connect the smaller plug of the *USB cable micro to type B* to the left USB port of the cradle (marked with the printer/PC icon).
 - b)** Connect the larger plug of the *USB cable micro to type B* to the corresponding USB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



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



- 9 For charging *EasyOne Air*, always connect the *ndd* power supply:
- Plug the *ndd* power supply into a power outlet.
 - Connect the cable of the *ndd* power supply to the right USB port of the cradle (marked with the plug icon).



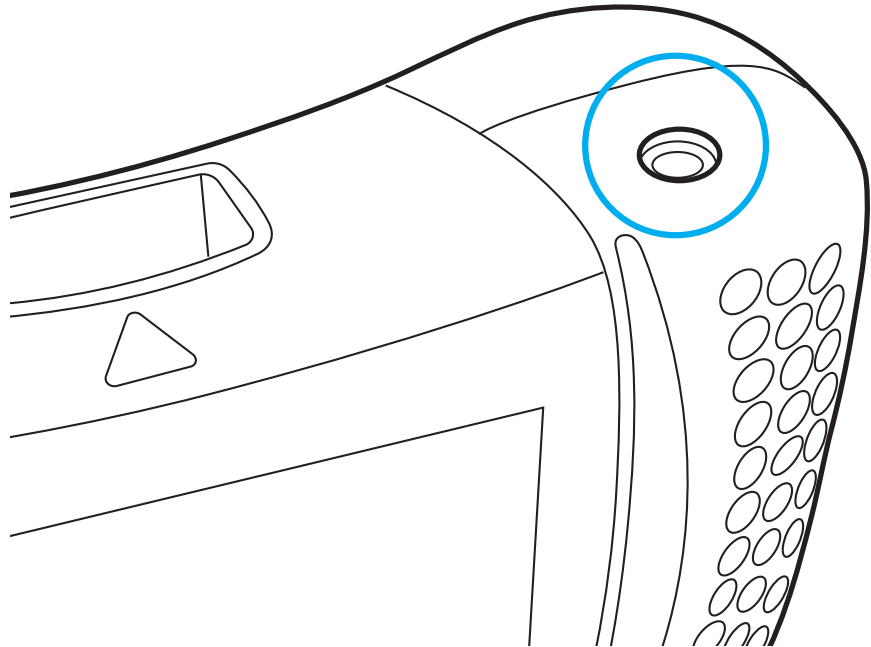
⇒ [Setting up the EasyOne Air spirometer, 24](#)

3.4 Setting up the *EasyOne Air* spirometer

Prerequisite

- You have set up the physical components
[Setting up the physical components, 20](#)

- 1 Turn on *EasyOne Air*.



- ✓ The region selection screen is displayed.
 - 2 Select your region from the world map.
 - ✓ The language selection screen is displayed.
 - 3 Select your language from the language selection list.
 - 4 Select the date and time format.
 - 5 Enter the date and time and choose **Next**.
 - 📖 If the battery is removed for more than 8 hours, you need to reenter date and time.
- ⇒ [Configuration of EasyOne Air, 93](#)
[Description of print settings of EasyOne Air, 100](#)

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

The procedure for installing *EasyOne Connect* is the same as for updating *EasyOne Connect*. If *EasyOne Connect* is already installed on your PC, the *ndd SmartInstaller* performs an update.

Prerequisite

- ☐ Your PC meets the system requirements for *EasyOne Connect*.

[List of system requirements for EasyOne Connect, 132](#) ↗

⚠ CAUTION

FAILED UPDATE

An update may fail unnoticed.

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

[Calibration check, 118](#) ↗

[Checking for correct operation of EasyOne Air, 122](#) ↗

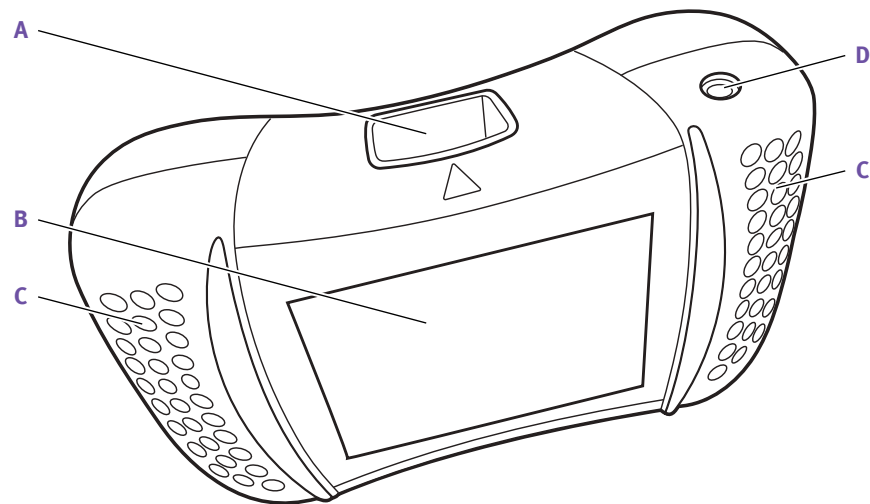
- 1 Connect the USB flash drive from the box contents to your PC.
- 2 Choose the file *SmartInstaller.exe*.
 - ✓ The User Account Control of Microsoft Windows is displayed and asks for confirmation.
- 3 In the User Account Control window, choose **Yes**.
 - ✓ The *ndd SmartInstaller* is displayed.
- 4 Choose **Install Software**.
 - ✓ The required software packages are automatically determined.
- 5 When required, choose **Next** repeatedly.
- 6 When the license agreement is displayed, read the license agreement, select **I Agree**, and choose **Next**.
 - ✓ *EasyOne Connect* and all required software packages are installed.
- 7 After the installation has finished, choose **Close** and/or **OK**.
 - ✓ The installation is complete.
- 8 In the *ndd SmartInstaller*, choose **Exit**.

4 Introduction

4.1 Introduction to the *EasyOne Air* spirometer

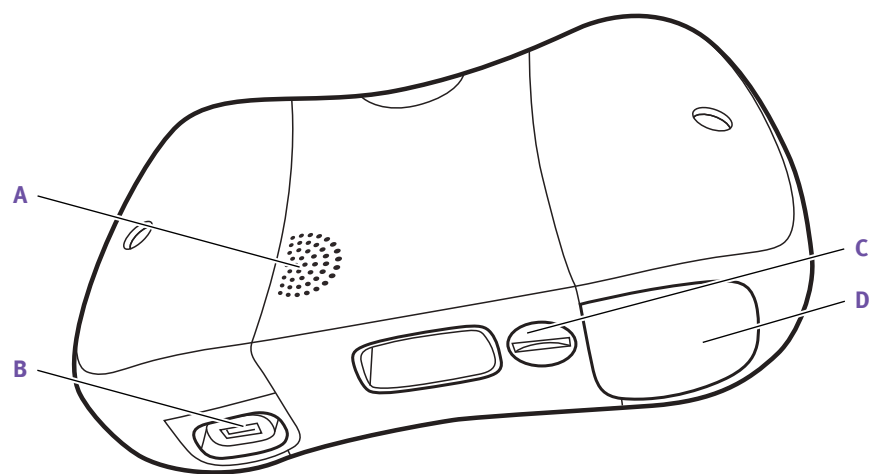
4.1.1 Overview of *EasyOne Air*

The *EasyOne Air* spirometer



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

☐ Top-view of *EasyOne Air*



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

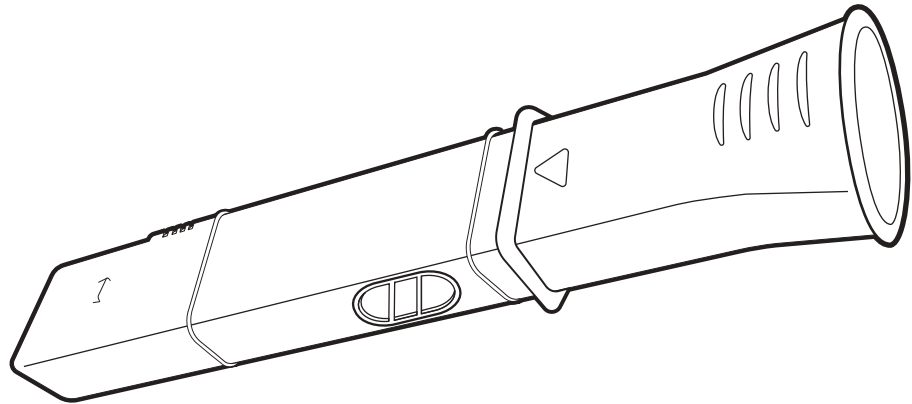
☐ Bottom-view of *EasyOne Air*

When *EasyOne Air* is turned on and not in use, the screensaver and automatic power-off function are activated to save battery power. You can change the default configuration in the following menu:

 >  >  > **Screensaver after** and **Power-off after**

A low battery message will alert you when battery power falls below 10%. Data saved in non-volatile memory is not lost when battery power is low or when batteries are removed.

The *EasyOne Flow Tube* respiratory tube for single-patient use



☐ The *EasyOne Flow Tube* respiratory tube

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

CAUTION

FALSE DIAGNOSIS

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

4.1.2 About using the touchscreen

There are some controls and gestures for the touchscreen, which you can use throughout the system.

Controls and gestures for navigating on the touchscreen

To choose a button or to select a list item, tap on the button or list item on the touchscreen. For every tap, you hear a clicking sound as audible feedback if this function is enabled. Also for every tap, the area or the key that you have tapped is highlighted as visible feedback.

To scroll through lists, a scroll bar is displayed on the right side of lists.

To move a slider on the touchscreen, drag your finger across the touchscreen.

Using the touchscreen with gloves

You can use the touchscreen wearing disposable gloves made of any material. Standard disposable gloves used in hospitals and general practitioners' offices work fine with the touchscreen.

4.1.3 Overview of the user interface of *EasyOne Air*

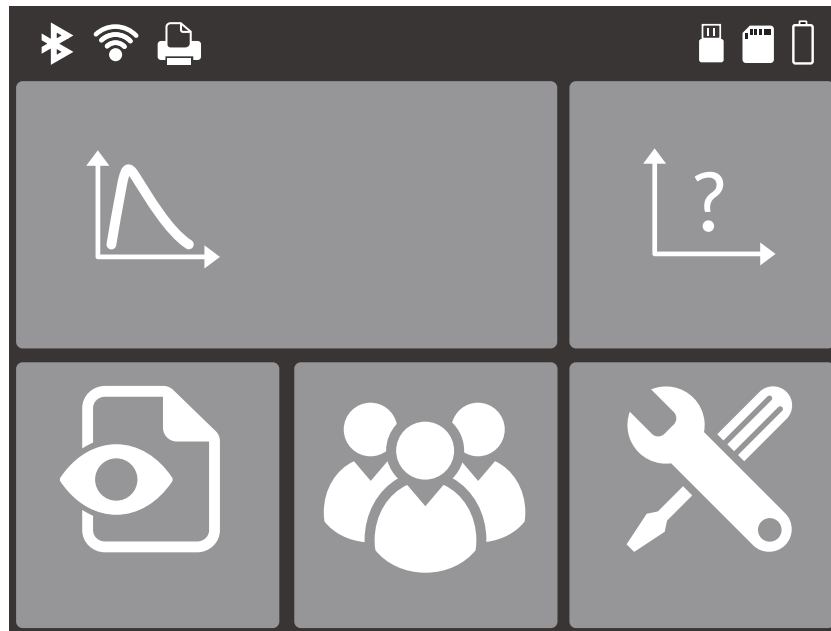
Basic interface elements are used throughout *EasyOne Air* for status information and for navigation in the menus.

HIPAA compliance

EasyOne Air is compliant to the *Health Insurance Portability and Accountability Act*. Access to *EasyOne Air* is password-protected. The internal database of *EasyOne Air* is encrypted.

The home screen

The home screen is the starting point when working with *EasyOne Air*.

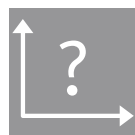


☐ The home screen of *EasyOne Air*

The home screen displays the following icons:



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



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



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



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



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



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

The patients menu displays the following icons:



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



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



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



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



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

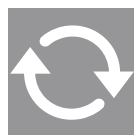
The tools menu displays the following icons:



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



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



In the update menu, you can perform firmware updates.



In the backup menu, you can backup the patient database, results 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 display settings menu, you have access to settings like language, date and time format, or settings for how results are displayed.



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

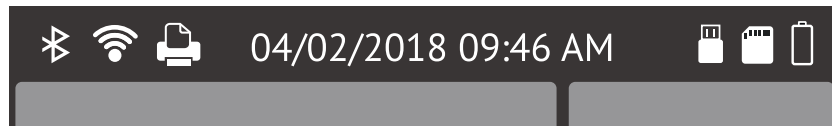


In the factory reset menu, you can reset the configuration of *EasyOne Air* to its delivery status. However, the patient data will not be deleted.

[Configuration of EasyOne Air, 93](#)

The status bar

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



- ☐ The status bar on the top

The status bar displays the following icons:



Indicates that Bluetooth is enabled. This icon is not applicable to the *EasyOne Air TL* variant.



Indicates that Wi-Fi is enabled. This icon is not applicable to the *EasyOne Air TL* variant.



Indicates a connection to a printer.



Indicates a connection to a PC.



Indicates that an SD memory card is inserted.



Indicates that charging level of the battery is very low.



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



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



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



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

The < Back button and the home button



☐ The < Back button is at the bottom left-hand side, and the home button is at the bottom in the middle.

In any menu, the < Back button is displayed at the bottom left and the home button at the bottom middle of the touchscreen. To go back to the home screen, choose the home button. To navigate back in menus, choose the < Back button.

4.2 Introduction to the *EasyOne Connect* software

4.2.1 Overview of features of *EasyOne Connect*

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.

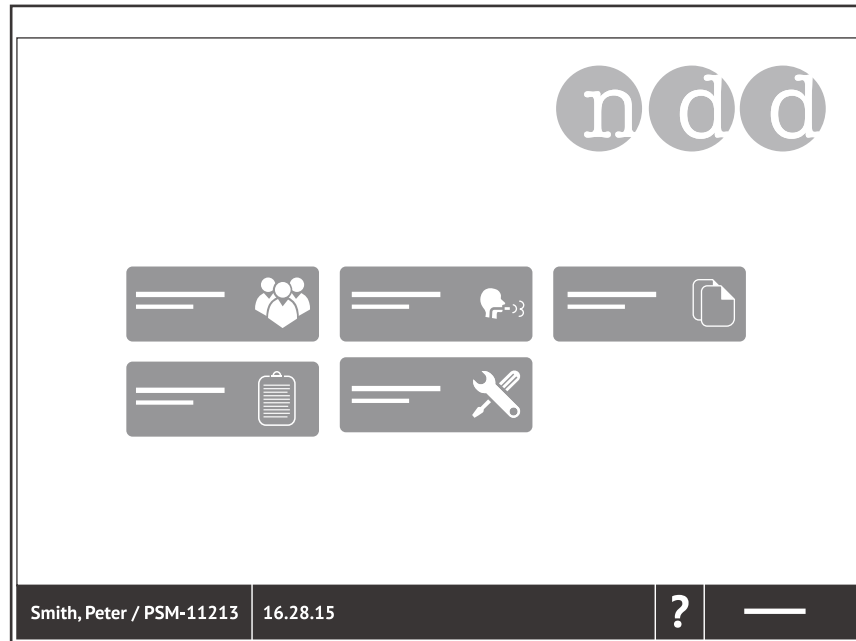
⇒ [Connectivity and data exchange, 44](#) ↗

4.2.2 Overview of the user interface of *EasyOne Connect*

Basic interface elements are used throughout *EasyOne Connect* for status information and for navigation in the menus.

The main menu

The main menu is the starting point when working with *EasyOne Connect*.



☐ The main menu of *EasyOne Connect*

The main menu displays the following icons:



In the patients menu, you have access to patient data and also to the reports.



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



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



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

This icon is only displayed if you have configured a connection to your EMR system.



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

The menu bar

The menu bar at the bottom of the screen is visible at all times. In the menu bar, you can navigate back to the main menu and quickly access the active patient data or this Operator’s Manual.



- ☐ The menu bar at the bottom of the screen

The menu bar displays the following areas:

This area displays the name and patient ID of the patient that you have selected last. To view a summary of the patient’s demographic data, choose this area.

To open the PDF file of this Operator’s Manual, choose [?](#).

With the menu area, you can navigate back to the main menu. The label and function of this area varies between menus.

4.3 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.
	For each test, a report exists.
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

4.4 List of tests and parameters

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

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

Tests

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

Parameters

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

☐ Parameters

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

☐ Parameters

4.5 List of abbreviations

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

 Abbreviations

4.6 About sources for predicted normal values

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

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

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

Application Notes for further information, 3 

Installing or updating the EasyOne Connect software on your PC, 25 

5 Cybersecurity

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

5.1 About cybersecurity

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

EasyOne Air itself is not directly connected to the network.

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

5.2 About password policies and password expiration

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

EasyOne Connect does not include functionality for password strength and password expiration requirements. In case user handling is deactivated a default password is used to restrict access to certain functionalities.

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 lowercase and uppercase alphabetic characters, numbers and symbols.
- Generate passwords randomly where feasible.

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

- Passwords should be renewed after 90 days.

⇒ [About user handling and the default password of EasyOne Connect, 105](#) ↗

5.3 About periodical software updates and patches

For secure use, perform software updates regularly.

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

⇒ [Installing or updating the EasyOne Connect software on your PC, 25](#) 
[Performing a firmware update with EasyOne Air, 101](#) 
[Contact information, 4](#) 

5.4 About backups

Whether or not *EasyOne Connect* performs backups automatically depends on whether a file-based database or an SQL-server-based database is used.

When using a file-based database

EasyOne Connect includes a separate backup storage that automatically stores the current database. The backup is performed each time *EasyOne Connect* is shut down.

In addition, the manufacturer recommends that you regularly backup the database manually to a different storage device and that you store this additional backup in a separate location.

When using an SQL-server-based database

In this case, no automatic backup is performed. It is the operating institution's responsibility to perform backups of the SQL server regularly.

⇒ [Utilities > Configuration > General > Storage, 106](#) 

5.5 Escalating in case of a security breach

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

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

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

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

Prerequisite

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

[About the user menu of *EasyOne Air*, 104](#)

[About user handling and the default password of *EasyOne Connect*, 105](#)

- 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 your installation of *EasyOne Connect* is not unlocked unintentionally by *ndd* staff for anyone else but you.

⇒ [Contact information, 4](#)

5.7 Using *EasyOne Air* securely – general guidelines

The manufacturer strongly recommends that you follow these guidelines at all times.

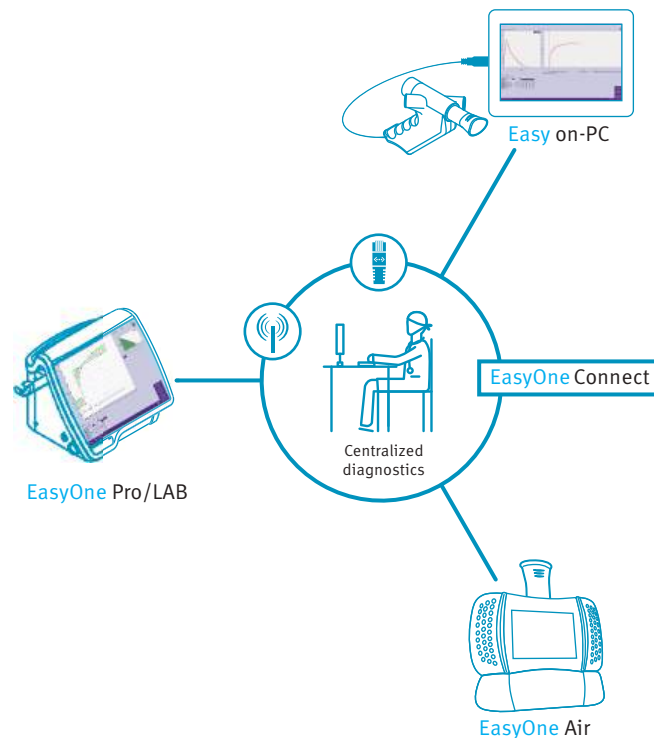
- 1 Activate user handling if unauthorized persons might have physical access to *EasyOne Air*. To activate user handling, do the following:
 - a) Choose **Utilities > Configuration > General > User Handling**.
 - b) Enter the default password **8005** and choose **Login**.
 - c) To add a user, choose **Add**.
 - d) Fill out the **User ID** field, the **Password** field, and the **Repeat Password** field.
 - e) Optionally, fill out the other fields.
 - f) Choose **OK**.
 - g) Select the **User Handling** check box.
 - h) Choose **Save**.
- ✓ User handling is activated. Now, users must log in to use *EasyOne Air*.

- 2 To prevent unauthorized access when *EasyOne Air* is unattended, activate automatic log off. To activate automatic log off, do the following:
 - a) Choose **Utilities > Configuration > General > User Handling**.
 - b) Select the **Screen times out after** check box.
 - c) In the **min** field, enter the desired period of inactivity after which automatic log off is to be activated.
 - d) Choose **Save**.
 - ✓ After the period that you have set, *EasyOne Air* is locked and users must log in again.
 - 3 Only use network file transfer (pdf, HL7, XML, etc.) in trusted and secured network environments.
 - 4 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*.
- ⇒ [About user handling and the default password of EasyOne Connect, 105](#)

6 Connectivity and data exchange

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

6.1 About connectivity between *EasyOne* products



☐ Connectivity between *EasyOne* products

All *EasyOne* products can connect to a shared comprehensive database through the *EasyOne Connect* PC software. The *EasyOne Pro* Respiratory Analysis System can connect to this shared database independently.

To enable connectivity between *EasyOne* products, the manufacturer recommends to set up an SQL-server-based database.

After you have configured an SQL-server-based database, you can review patient data and reports of all connected *EasyOne* products on any connected PC with *EasyOne Connect* or on any *EasyOne Pro/LAB*. Access to the server-based database is password-protected and requires a Microsoft Active Directory user account.

For support with the configuration of an SQL-server-based database, contact the *ndd* Servicing Department.

⇒ Application Note *EasyConnect – Database Connection*
Application Notes for further information, 3 [↗](#)
Utilities > Configuration > General > Storage, 106 [↗](#)
Contact information, 4 [↗](#)

6.2 About integration of EMR systems

6.2.1 About supported EMR standards

EasyOne Connect and *EasyOne Pro/LAB* can be interfaced with your EMR system.

EMR systems are, for example, hospital information system (HIS) and other information systems in the health sector that use the electronic medical record to exchange patient data in a standardized format. *EasyOne Connect* and *EasyOne Pro/LAB* have EMR plug-ins preinstalled:

- HL7 – *Health Level 7* is an international EMR standard.
- GDT – *Gerätedatentransfer* is a German EMR standard.
- XML file exchange – With this plug-in, you can connect your EMR system using a simple and configurable XML file exchange.

⇒ Operator's Manual of your EMR system

6.2.2 About possible workflows with your EMR system

There are two general possibilities for working with your EMR system: the order workflow and the direct-start workflow.

The order workflow

For the order workflow, *EasyOne Connect* or *EasyOne Pro/LAB* and your EMR system are connected over the network and exchange so-called orders.

In an additional menu on the main menu, *EasyOne Connect* and *EasyOne Pro/LAB* display the orders from your EMR system. With the order workflow, you initiate a spirometry test in *EasyOne Connect* or on *EasyOne Pro/LAB*.

You can also send test results to your EMR system manually even if these test results have not been ordered from your EMR system.

The direct-start workflow

Your EMR system is either connected to *EasyOne Connect* or *EasyOne Pro/LAB* over the network, or your EMR system is installed on the same PC as *EasyOne Connect*.

Either way, your EMR system can interact and launch *EasyOne Connect* or *EasyOne Pro/LAB* directly. *EasyOne Connect* or *EasyOne Pro/LAB* act as an external device to your EMR system.

This workflow is called direct-start workflow because you initiate a spirometry test from your EMR system.

⇒ [Sending individual test results to your EMR system, 50](#) ↗

6.2.3 About using *EasyOne Air* to process orders

When you synchronize *EasyOne Air* with *EasyOne Connect*, orders from your EMR system are also synchronized with *EasyOne Air*.

On *EasyOne Air*, you can select orders from your EMR system in the orders menu.

6.2.4 Overview of the integration process

Please contact the *ndd* Servicing Department to start an integration project. The integration process consists of the following steps:

- 1 Defining an interface based on clinical requirements, IT requirements, and security requirements
- 2 Implementing a configuration in close cooperation with your staff
- 3 Verifying the implemented configuration

NOTICE

CONNECTION FAILURE

Updates to the EMR system can potentially influence the connection.

When you update the EMR system, you must check the correctness of the transferred data to connected systems.

⇒ [Operator's Manual of your EMR system](#)
[SDK – ndd EMR plug-in Software Developer Guide](#)
[Contact information, 4](#) ↗

6.2.5 Overview of the plug-ins for EMR systems

Utilities > Configuration > EMR

6.2.5.1 About the HL7 plug-in

The HL7 plug-in allows you to work with orders, which you can process as you choose. This workflow is the order workflow.

Alternatively, you can use the direct-start workflow and initiate spirometry from your EMR system.

Supported Features

EasyOne Connect and *EasyOne Pro/LAB* support the following features of HL7:

- Receiving patient demographics from your EMR system
- Sending test results to your EMR system
- Working with orders
- File-based message exchange
- Message acknowledgments
- Sending discrete data
- Sending reports

⇒ Application Note *EasyConnect: HL7 Connector*
Application Notes for further information, 3 [↗](#)
Operator's Manual of your EMR system
Processing orders from your EMR system, 48 [↗](#)
Sending individual test results to your EMR system, 50 [↗](#)

6.2.5.2 About the GDT plug-in

With the GDT plug-in, you can only use the direct-start workflow and initiate spirometry from your EMR system. The order workflow is not supported.

Supported Features

EasyOne Connect and *EasyOne Pro/LAB* support the following features of GDT:

- Receiving patient demographics from your EMR system
- Sending test results to your EMR system
- File-based message exchange
- Sending discrete data
- Sending reports

⇒ Operator's Manual of your EMR system
Initiating a spirometry test with the direct-start workflow, 49 [↗](#)
Sending individual test results to your EMR system, 50 [↗](#)
Type, 113 [↗](#)

6.2.5.3 About the XML file exchange plug-in

The XML file exchange plug-in is a simple interfacing tool that allows you to connect to your EMR system with a simple custom configuration.

The XML plug-in supports the order workflow and the direct-start workflow.

Supported Features

EasyOne Connect and *EasyOne Pro/LAB* support the following features:

- Receiving patient demographics from your EMR system
- Sending test results to your EMR system
- Working with orders
- File-based message exchange
- Sending discrete data
- Sending reports

⇒ [Software Developer Guide SDK – ndd EMR plug-in](#)

6.2.5.4 About custom plug-ins

ndd offers a software development kit that enables third parties and customers to develop customized EMR plug-ins to interface with any EMR system.

⇒ [Software Developer Guide SDK – ndd EMR plug-in](#)

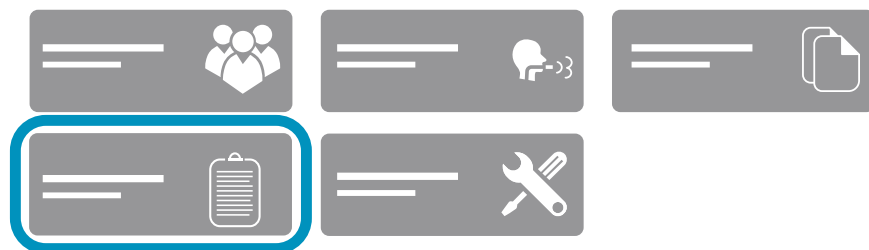
6.2.6 Working with your EMR system

6.2.6.1 Processing orders from your EMR system

If you have interfaced your EMR system with *EasyOne Connect* or *EasyOne Pro/LAB* through the HL7 plug-in or a custom EMR plug-in, you can access the patient data of your EMR system in the orders menu in *EasyOne Connect* or on *EasyOne Pro/LAB*. On the main menu, the additional **Orders** button is displayed. This procedure represents the order workflow.

Prerequisite

- ☐ You have configured the HL7 plug-in, the XML plug-in, or a custom EMR plug-in.



- ☐ Additional orders button in the main menu

In the orders menu, you process the orders. The orders menu is similar to the patients menu. However, you cannot edit patient data in the orders menu.

- 1 Choose **Orders**.
- 2 Select an order with the status *Pending*.
- 3 Choose **Test**.
- 4 Perform spirometry with the patient.
- 5 To view a completed order, choose **View**.
- 6 To delete an order, choose **Delete**.
- 7 Repeat steps 2 to 5 until you have completed all pending orders.
- 8 Choose **Close**.
 - ✓ All results are transmitted to your EMR system.

⇒ [Overview of the user interface of EasyOne Connect, 34](#) ↗

6.2.6.2 Initiating a spirometry test with the direct-start workflow

With the direct-start workflow, you initiate spirometry from your EMR system. All plug-ins support this workflow.

Prerequisite

- ☐ You have configured any one of the available plug-ins.

[About the HL7 plug-in, 47](#) ↗

[About the GDT plug-in, 47](#) ↗

[About the XML file exchange plug-in, 48](#) ↗

[About custom plug-ins, 48](#) ↗

- 1 Launch your EMR system.
- 2 Choose the external devices menu.
- 3 Select either *EasyOne Connect* or *EasyOne Pro/LAB* and confirm.
 - ✓ *EasyOne Connect* is launched automatically.
 - ✓ In *EasyOne Connect* or on *EasyOne Pro/LAB*, the screen for entering patient data is displayed.
- 4 **CAUTION!** False diagnosis: The predicted values and the system interpretation are based on the patient demographic data. Therefore, wrong patient data can cause false results. Enter patient data meticulously. Double-check that you have entered the patient data correctly.

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

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

- 5 In all other fields, enter additional patient data if necessary.
- 6 Choose **OK**.
- 7 Choose the desired test and confirm.
- 8 Perform spirometry with the patient.

- 9 If required, print an additional report from the test result screen.
 - 10 Choose **Finish**.
 - ✓ The test results are sent to your EMR system, and *EasyOne Connect* is closed automatically.
 - ✓ Your EMR system receives the test results.
 - 11 In your EMR system, confirm the received test results and proceed as required.
- ⇒ [Performing spirometry, 51](#) ↗

6.2.6.3 Sending individual test results to your EMR system

It is possible to send individual test results to your EMR system even if that test is not part of an order from the EMR system. This enables you to work without orders from your EMR system and to only send test results to your EMR system.

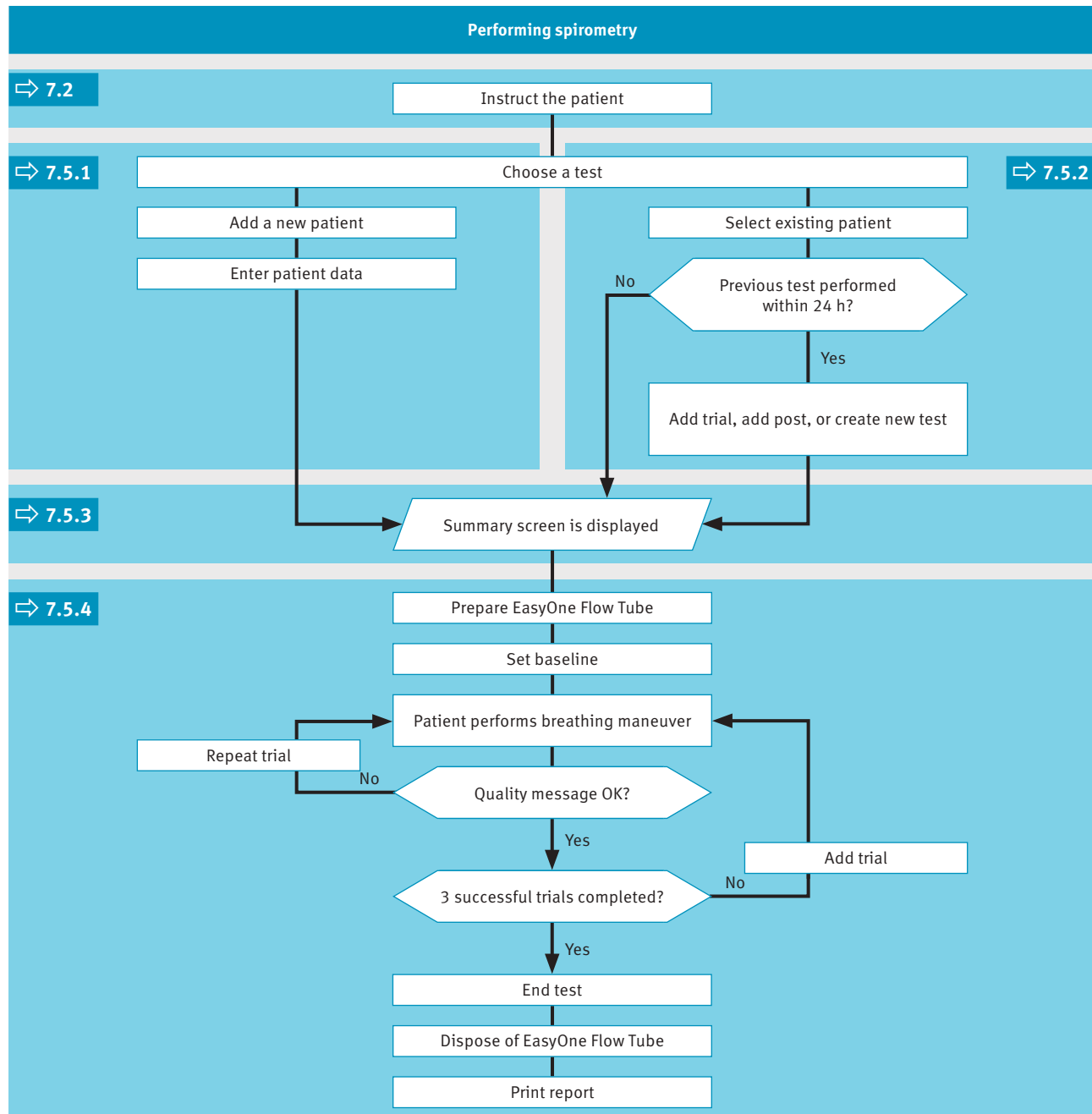
Prerequisite

- ☐ You have configured any one of the available plug-ins.

- 1 Choose **Patients**.
- 2 Select a patient.
- 3 Choose **History**.
- 4 Choose the  button.
 - ✓ Hidden buttons are revealed.
- 5 Choose **Send to EMR**.

7 Performing spirometry

7.1 Overview of the spirometry workflow



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

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

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

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

7.2 About preparation of spirometry and instructions for the patient

Preparing the patient

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

Explaining spirometry

Explain that the purpose of the test is to determine how much air a person's lungs can hold and how quickly that air can be expelled with a forceful, maximum effort. Since the spirometry test requires active participation on the part of the patient, it is very important to demonstrate the breathing maneuver to the patient.

The most commonly used spirometry test is the FVC test. Emphasize the essential elements of the breathing maneuver, for example, for the FVC test:

- Filling lungs completely
- Sealing lips around the *EasyOne Flow Tube* so that there are no leaks, taking care not to block its opening with the teeth or tongue and not to bite down excessively
- Blasting out as hard and fast as possible
- Blowing out continuously until the lungs are completely empty

Different breathing maneuvers for different tests

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

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

Carefully watch the patient

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

Animation program for children

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

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

- ⇒ [Breathing maneuvers for all available tests, 75](#)
- [Avoiding contamination while performing spirometry, 80](#)
- [Test Procedure, 108](#)

7.3 About quality messages for trials and quality grades for tests

Quality messages

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

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

Quality grades

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

- ⇒ [List of quality messages and quality grades, 73](#)

7.4 About posts and bronchodilation

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

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

7.5 Performing spirometry using *EasyOne Air* stand-alone

7.5.1 Choosing a test and adding a new patient

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

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

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

- 5 In the last step, choose **Finish**.
 - ✓ The summary screen is displayed.

⇒ About the summary screen, 56 

Performing a complete test using EasyOne Air stand-alone, 57 

7.5.2 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, 82](#)

[Copying patient data between EasyOne Air and EasyOne Connect, 88](#)

- 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, the summary screen is displayed. 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**.
 - ✓ The summary screen is displayed.
- ⇒ [About the summary screen, 56](#)
- [Performing a complete test using EasyOne Air stand-alone, 57](#)

7.5.3 About the summary screen

The summary screen displays common data about the patient, that you have entered before.

You can edit the data and for example, add the following medical data about the patient:

- Asthma status
- Dyspnea status
- Smoker status
- Cigarettes per day
- Smoke years
- Profession
- Occupation exposure
- Diagnosis

In addition, you can access reports of previous tests of the patient.

⇒ [Performing a complete test using EasyOne Air stand-alone, 57](#) ↗

7.5.4 Performing a complete test using *EasyOne Air* stand-alone

Required materials

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

Prerequisites

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

[Choosing a test and adding a new patient, 54](#) ↗

[Choosing a test and selecting an existing patient, 55](#) ↗

[About preparation of spirometry and instructions for the patient, 52](#) ↗

WARNING

PATIENT CROSS-CONTAMINATION

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

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

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

Only use an original *EasyOne Flow Tube* by the manufacturer.

PATIENT HEALTH HAZARD

Performing spirometry can cause an asthma attack or bronchospasm.

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

CAUTION

PATIENT HEALTH HAZARD

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

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

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

Do not leave the patient unattended during a test.

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

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

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

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

■ To prepare the test

1 Partly unwrap the *EasyOne Flow Tube*.

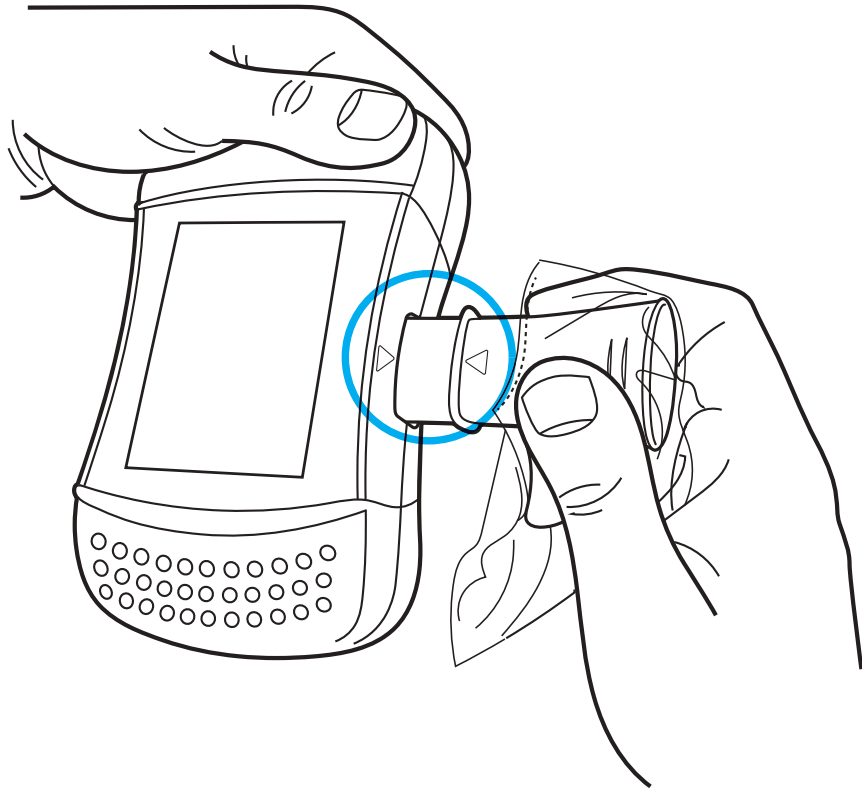
- For hygiene reasons, grip the partly unwrapped *EasyOne Flow Tube* only with the wrapper at the mouthpiece. Do not touch the *EasyOne Flow Tube*.



- 2 Fully insert the *EasyOne Flow Tube* into the *EasyOne Flow Tube* holder as depicted below, but keep the partly unwrapped wrapper on the mouthpiece of the *EasyOne Flow Tube*.

■ The shape of the *EasyOne Flow Tube* and the *EasyOne Flow Tube* holder guide the orientation of the *EasyOne Flow Tube*. You can only insert the *EasyOne Flow Tube* fully if it is positioned correctly.

■ When you insert the *EasyOne Flow Tube*, avoid direct sunlight as it can interfere with the automatic recognition of the *EasyOne Flow Tube*.



- 3 Choose **Start test**.
 - ✓ The sensor starts buzzing and the user action required window is displayed for setting the baseline.
- 4 To set the baseline, seal off one end of the *EasyOne Flow Tube* with the wrapper to avoid air flow.



- 5 Choose **OK**.
 - ✓ The **Please wait...** message is displayed while the baseline is set.
 - ✓ After the baseline has been set, a signal sounds, and the **BLAST OUT...** message is displayed.
 - 6 Remove the wrapper from the *EasyOne Flow Tube*.
 - 7 If you want to perform an FVL test, an MVV test, or an SVC test, attach the nose clip to the patient's nose.
 - 8 Hand *EasyOne Air* to the patient.
 - 9 Tell the patient to breathe at rest.
 - The following procedure **To perform the FVC breathing maneuver** represents the breathing maneuver for the FVC test as an example. If you want to perform any other test, replace the procedure **To perform the FVC breathing maneuver** with the breathing maneuver for the required test.
- [Breathing maneuvers for all available tests, 75](#)

■ To perform the FVC breathing maneuver

- 1 Tell the patient to fill the lungs completely.
- 2 Tell the patient to take the *EasyOne Flow Tube* into the mouth and to seal the lips around the *EasyOne Flow Tube*.
 - The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne Flow Tube*.

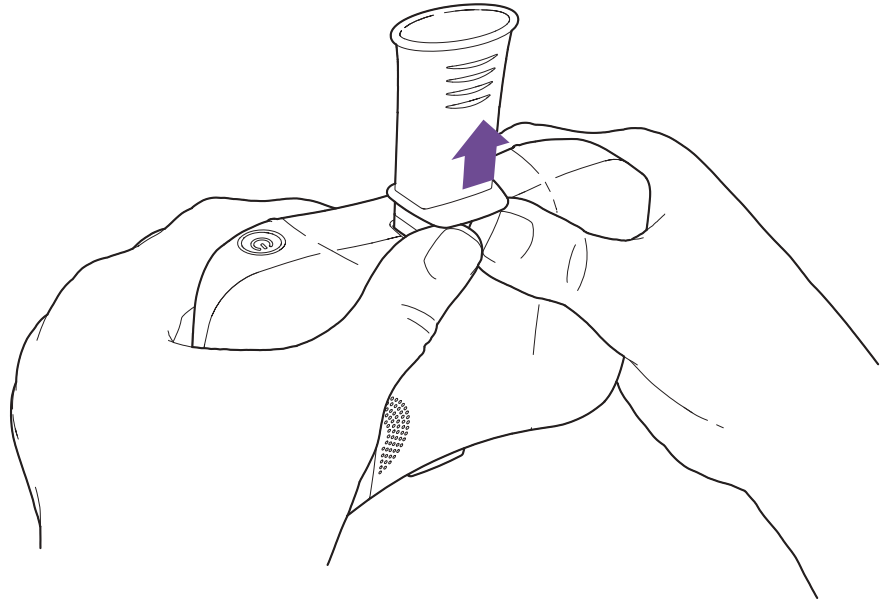
- 3 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
 - 📖 While the patient performs the breathing maneuver, a feedback sound indicates the effort of the patient. The harder the patient exhales, the faster the feedback sound is repeated. When the patient exhales more slowly towards the end, the feedback sound also gets slower.
 - ✓ At the end of the trial, another feedback sound indicates whether the trial is acceptable or not.
- 4 Tell the patient to take the *EasyOne Flow Tube* out of the mouth and to breathe normally again.
 - ✓ If the trial is acceptable, the green quality message is displayed.
 - ✓ If the trial is not acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

■ To add trials

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

■ To end the test

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



- 2 **WARNING!** Patient cross-contamination and infection of the technician: Always wear disposable gloves. Between patients, always exchange disposable gloves, clean *EasyOne Air*, and disinfect hands. / Electric shock, failure of *EasyOne Air*, and false diagnosis: Make sure that no fluid penetrates the *EasyOne Flow Tube* holder or the inside of *EasyOne Air* while cleaning. To clean *EasyOne Air*, do not fully dip *EasyOne Air* into any fluid. To clean *EasyOne Air* and to disinfect your hands after each patient, do the following:
 - a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions under [Hygiene and cleaning, 80](#) and wipe the handles and the display of *EasyOne Air*.
 - b) Put down *EasyOne Air*.
 - c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.
- 3 If you want to print the report immediately, choose **Print**.
 - ✓ A progress bar is displayed that indicates the progress of the print-out.

- 4 Choose **End**.
 - ✓ The home screen is displayed.
- ⇒ [List of cleaning solutions for EasyOne Air, 81](#) ↗
[About interpreting results, 72](#) ↗
[About compatible printers, 19](#) ↗

7.6 Performing spirometry using *EasyOne Connect* in combination with *EasyOne Air*

7.6.1 Connecting *EasyOne Air* to *EasyOne Connect*

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

Prerequisite

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

[List of box contents, 17](#) ↗

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

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

7.6.2 Performing a complete test using *EasyOne Connect* together with *EasyOne Air*

Required materials

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

Prerequisites

- ☐ You have connected *EasyOne Air* to *EasyOne Connect*.
- ☐ You have added the patient data to the database of *EasyOne Connect*.
- ☐ Or the patient data is already in the database of *EasyOne Connect*.
- ☐ You are wearing disposable gloves.
- ☐ You have instructed the patient on how to perform the test before you start with the test.

[Connecting EasyOne Air to EasyOne Connect, 63](#) ↗

[Adding patient data to the database of EasyOne Connect, 86](#) ↗

[About preparation of spirometry and instructions for the patient, 52](#) ↗

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Performing spirometry can cause an asthma attack or bronchospasm.

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

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

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

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

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

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

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

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

■ To prepare the test

- 1 Partly unwrap the *EasyOne Flow Tube*.

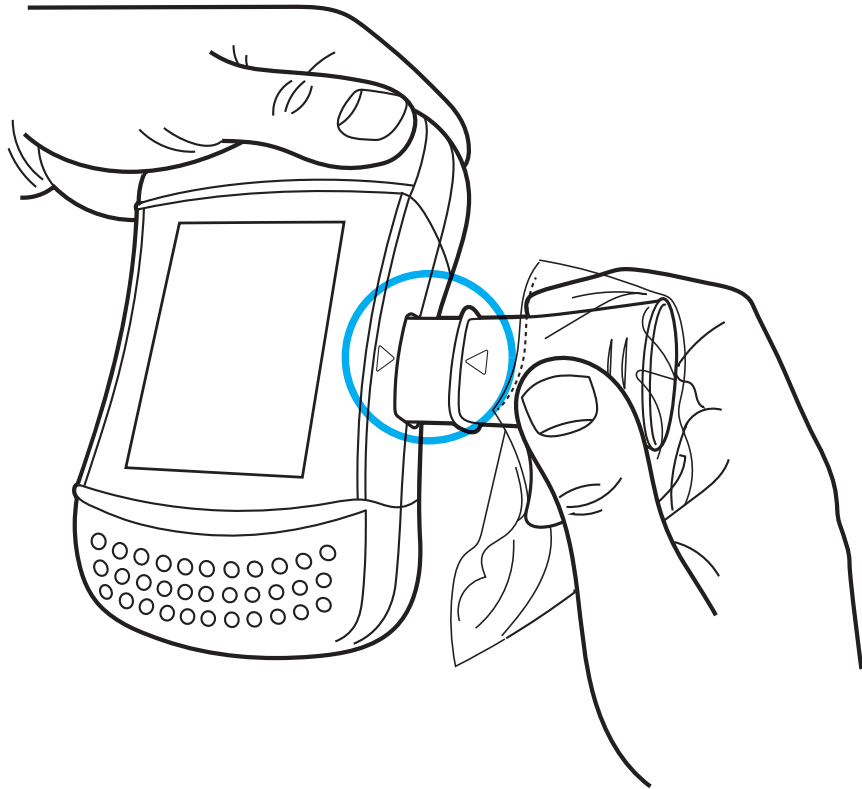
📄 For hygiene reasons, grip the partly unwrapped *EasyOne Flow Tube* only with the wrapper at the mouthpiece. Do not touch the *EasyOne Flow Tube*.



- 2 Fully insert the *EasyOne Flow Tube* into the *EasyOne Flow Tube* holder as depicted below, but keep the partly unwrapped wrapper on the mouthpiece of the *EasyOne Flow Tube*.

■ The shape of the *EasyOne Flow Tube* and the *EasyOne Flow Tube* holder guide the orientation of the *EasyOne Flow Tube*. You can only insert the *EasyOne Flow Tube* fully if it is positioned correctly.

■ When you insert the *EasyOne Flow Tube*, avoid direct sunlight as it can interfere with the automatic recognition of the *EasyOne Flow Tube*.



- 3 On the main menu of *EasyOne Connect*, choose **Patients**.
- 4 Select the patient that you want to test.
- 5 At the bottom of the screen, choose **Test**.
- 6 Choose the test that you want to perform.
- 7 If the environment conditions screen is displayed, enter the current values and choose **Confirm >>**.
 - For the FVL test, the MVV test, and the SVC test, you must enter the environment temperature within 1°C or 1.8°F accuracy.
 - ✓ If the patient has already performed a test on the same day, a selection window is displayed. Proceed with step 8.
 - ✓ If the patient has not performed a test on the same day, the screen of the selected test is displayed with a pop-up window that asks you to block the *EasyOne Flow Tube*. Proceed with step 9.

- 8 If the selection 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 **Test**.
 - ✓ The screen of the selected test is displayed with a pop-up window that asks you to block the *EasyOne Flow Tube*.
- 9 To set the baseline, seal off one end of the *EasyOne Flow Tube* with the wrapper to avoid air flow.



- 10 Choose **OK**.
 - ✓ In the colored status bar, *Setting baseline: Avoid flow!* is displayed.
 - ✓ After the baseline has been set, *Start test ...* is displayed.
- 11 Remove the wrapper from the *EasyOne Flow Tube*.
- 12 If you want to perform an FVL test, an MVV test, or an SVC test, attach the nose clip to the patient's nose.
- 13 Hand *EasyOne Air* to the patient.
- 14 Tell the patient to breathe at rest.
 - 📖 The following procedure **To perform the FVC breathing maneuver** represents the breathing maneuver for the FVC test as an example. If you want to perform any other test, replace the procedure **To perform the FVC breathing maneuver** with the breathing maneuver for the required test.

[Breathing maneuvers for all available tests, 75](#)

■ To perform the FVC breathing maneuver

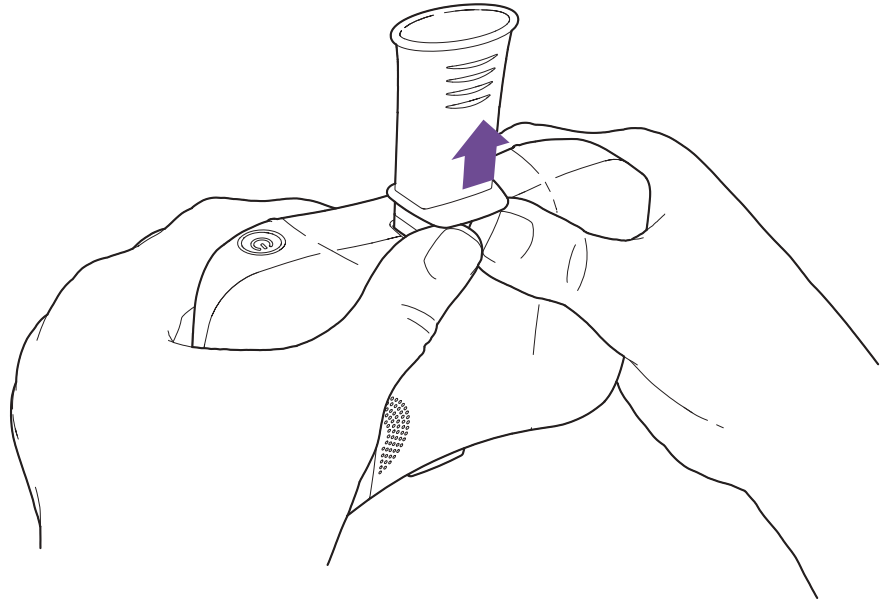
- 1 Tell the patient to fill the lungs completely.
- 2 Tell the patient to take the *EasyOne Flow Tube* into the mouth and to seal the lips around the *EasyOne Flow Tube*.
 - 📖 The patient must not block the opening with the tongue or teeth or bite down excessively on the *EasyOne Flow Tube*.
- 3 Tell the patient to exhale as hard and as fast as possible and to continue blowing out until the lungs are completely empty.
- 4 When the message *Manually End Test* is displayed, you can choose the Button **End Test** at your discretion.
 - 📖 You can configure manual test stop or automatic test stop under **Utilities > Configuration > Test > General > Test Procedure**.
 - ✓ The test result is displayed.
- 5 Tell the patient to take the *EasyOne Flow Tube* out of the mouth and to breathe normally again.
 - ✓ If the trial is acceptable, the green quality message is displayed.
 - ✓ If the trial is not acceptable, a yellow or red quality message is displayed suggesting how to improve the breathing maneuver.

■ To add trials

- 1 Choose **Add Trial**.
- 2 Repeat the previous procedure **To perform the FVC breathing maneuver** and this procedure **To add trials** until the green *Session Complete!* message is displayed.
 - 📖 In the **Test Information** area the quality grade for the test is displayed.
- 3 Do the following:
 - a) Review the test quality that is displayed in the **Test Information** area.
 - b) Decide whether the test quality is sufficient or not.
 - c) If necessary, add a trial and repeat the previous procedure **To perform the FVC breathing maneuver**.

■ To end the test

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



- 2 **WARNING!** Patient cross-contamination and infection of the technician: Always wear disposable gloves. Between patients, always exchange disposable gloves, clean *EasyOne Air*, and disinfect hands. / Electric shock, failure of *EasyOne Air*, and false diagnosis: Make sure that no fluid penetrates the *EasyOne Flow Tube* holder or the inside of *EasyOne Air* while cleaning. To clean *EasyOne Air*, do not fully dip *EasyOne Air* into any fluid. To clean *EasyOne Air* and to disinfect your hands after each patient, do the following:
 - a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions under [Hygiene and cleaning, 80](#) and wipe the handles and the display of *EasyOne Air*.
 - b) Put down *EasyOne Air*.
 - c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.
- 3 To print the report immediately, choose **Print** from the bottom right of the screen.
 - ✓ The report is generated and sent to the configured printer.

- 4 To preview the report, do the following:
 - a) Choose **Report** from the bottom right of the screen.
 - b) To print the report on the printer that you have configured, choose **Print** from the top of the screen.
 - c) To export the report as a PDF file or to select a different printer, choose **Print Menu** from the top of the screen.
 - d) To return to the test result screen, choose **Return** from the menu bar.
 - 5 To return to the main menu, choose **Main Menu** from the menu bar.
- ⇒ [List of cleaning solutions for EasyOne Air, 81](#) ↗
[About interpreting results, 72](#) ↗
[Description of printer configurations of EasyOne Connect, 116](#) ↗

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

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

Required materials

- ☐ A new *EasyOne Flow Tube* for each patient
- ☐ A nose clip

Prerequisites

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

[Utilities > Configuration > Test > Provocation, 115](#)

[About preparation of spirometry and instructions for the patient, 52](#)

[Performing the breathing maneuver for the FVL test, 76](#)

WARNING

PATIENT HEALTH HAZARD

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

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

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

Do not leave the patient unattended during a provocation test.

CAUTION

PATIENT HEALTH HAZARD

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

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

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

Do not leave the patient unattended during a test.

⚠ CAUTION

PATIENT CROSS-CONTAMINATION

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

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

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

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

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

[Breathing maneuvers for all available tests, 75 ↗](#)

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

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

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

⇒ [About interpreting results, 72 ↗](#)

7.7 About interpreting results

The quality grades *A* to *C* indicate a reliable result. The quality grades *D* and *F* indicate insufficient test quality. The result must then be interpreted with caution.

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

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

⇒ [List of tests and parameters, 36 ↗](#)

[List of quality messages and quality grades, 73 ↗](#)

[Configuration, 93 ↗](#)

7.8 List of quality messages and quality grades

7.8.1 About quality messages and quality grades

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

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

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, 132](#)

7.8.2 Quality messages for trials

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

Displaying quality messages for trials

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

7.8.3 List of quality grades for tests

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

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

Rating	Criteria
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)
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)
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)
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'C'. Quality message: <i>Result not reproducible</i>
D (2)	Only one acceptable trial Quality message: <i>Only one acceptable trial</i>
F	No acceptable trial available

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

Quality grades for the SSA test

Rating	Criteria
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
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.
F	No acceptable trial available

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

Quality grades for the SVC test

Rating	Criteria
A	At least 3 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.
B	At least 2 acceptable trials AND the difference between the best VC values is equal to or less than 150 mL.
D (1)	At least 2 acceptable trials but the results are not reproducible according to 'B'.
D (2)	Only one acceptable trial
F	No acceptable trial available

☐ Quality grades for the SVC test

8 Breathing maneuvers for all available tests

8.1 About breathing maneuvers for all available tests

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

⇒ [Performing spirometry, 51](#)

8.2 Performing the breathing maneuver for the FVC test

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

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

⇒ [Performing spirometry, 51](#)

8.3 Performing the breathing maneuver for the FVL test

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

Required material

- ☐ A nose clip

Prerequisite

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

⇒ [Performing spirometry, 51](#) ↗

8.4 About the OSHA test

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

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

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

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

Reports meet the requirements of the following institutions and standards:

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

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

 >  >  > **Predicted set 1**

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

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

⇒ [Performing spirometry, 51](#)

[Performing the breathing maneuver for the FVC test, 75](#)

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

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

8.5 About the SSA test

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

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

⇒ [Performing spirometry, 51](#)

[Performing the breathing maneuver for the FVC test, 75](#)

[Quality grades for the SSA test, 74](#)

8.6 Performing the breathing maneuver for the MVV test

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

Required material

- ☐ A nose clip

Prerequisite

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

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

⇒ [Performing spirometry, 51](#) ↗

8.7 Performing the breathing maneuver for the SVC test

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

Required material

- ☐ A nose clip

Prerequisite

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

⇒ [Performing spirometry, 51](#)

9 Hygiene and cleaning

9.1 Avoiding contamination while performing spirometry

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

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

WARNING

PATIENT CROSS-CONTAMINATION

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

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

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

Only use an original *EasyOne Flow Tube* by the manufacturer.

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

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

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

- a) Use a soft cloth with a cleaning solution according to the list of cleaning solutions under [Hygiene and cleaning, 80](#) and wipe the handles and the display of *EasyOne Air*.
- b) Put down *EasyOne Air*.
- c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.

⇒ [Calibration check, 118](#)

9.2 List of cleaning solutions for *EasyOne Air*

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

CAUTION

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

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

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

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

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

The cradle may be cleansed with the same cleaning solution.

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

10 Working with patient data and reports

CAUTION

FALSE DIAGNOSIS

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

Enter patient data meticulously.

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

10.1 Working with patient data and reports on *EasyOne Air*

10.1.1 Adding a patient to the database on *EasyOne Air*



1 Choose .

2 Choose .

✓ The add patient dialog is displayed.

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

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

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

✓ The summary screen is displayed.

10.1.2 Editing patient data on *EasyOne Air*



1 Choose .

2 Choose .

✓ The patient selection list is displayed.

3 Select a patient.

✓ The summary screen is displayed.

4 Choose a list item.

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

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

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

6 Choose **OK**.

7 Choose the home button.

10.1.3 Deleting a patient from the database on *EasyOne Air*



1 Choose .

2 Choose .

✓ The patient selection list is displayed.

3 Select a patient and confirm the message that is displayed.

✓ The selected patient data is deleted.

10.1.4 Exporting data from *EasyOne Air*

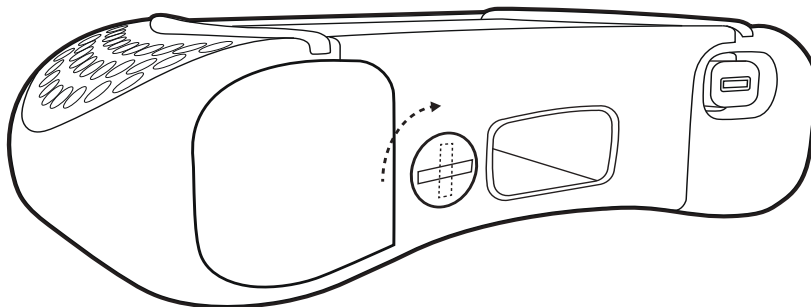


You can export data including reports to the SD memory card.

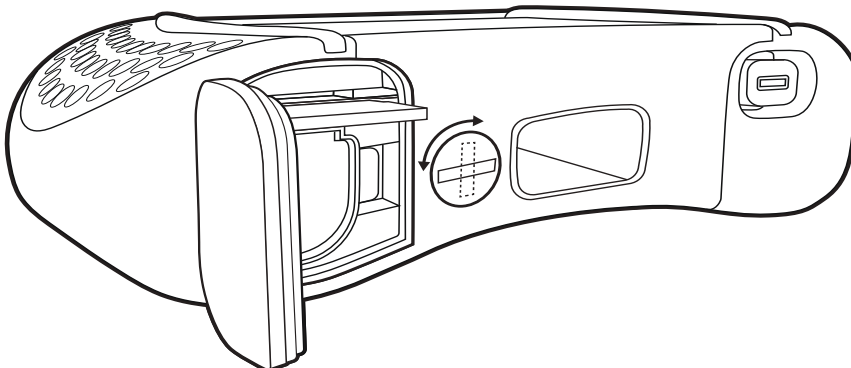
Required material

- ☐ An SD card

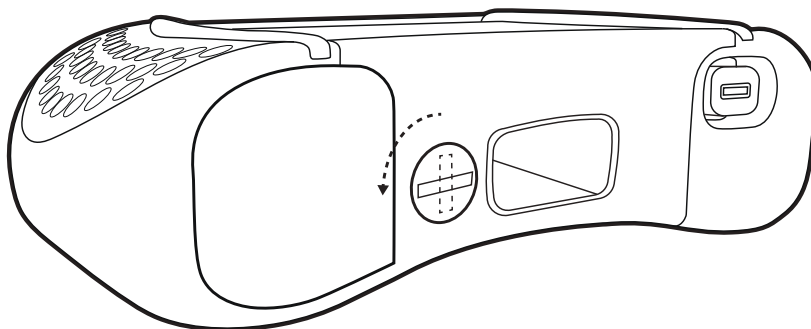
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



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



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



- 4 Choose  > .

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

10.1.5 Viewing and printing reports on *EasyOne Air*

- 1 Choose .
✓ The test selection list is displayed.
- 2 Select a test.
✓ The report screen is displayed.
- 3 To skip through the trials, choose **>>** or **<<**.
- 4 To enlarge, tap on the combined volume-time curve and flow-volume curve or on the parameter table.
- 5 To reduce, tap again on the combined volume-time curve and flow-volume curve or on the parameter table.
- 6 If you want to print the report, choose **Print**.
✓ A progress bar is displayed, which indicates the progress of the print-out.
- 7 To view another test, do the following:
 - a) Choose **< Back**.
 - b) From the test selection list, select another test.
✓ The report screen is displayed.
- 8 Choose the home button.
✓ The home screen is displayed.

10.1.6 About the reports menu and the history menu

To view the reports sorted by date, choose  from the home screen.

To view the reports sorted by patient, choose  **>** .

⇒ [Viewing and printing reports on EasyOne Air, 85](#)

10.2 Working with patient data and reports in *EasyOne Connect*

10.2.1 Adding patient data to the database of *EasyOne Connect*

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

Fill out those fields that are marked with an asterisk (*).
 You cannot complete adding patient data without filling out these fields.
- 4 In all other fields, enter additional patient data if necessary.
- 5 Choose **OK**.

10.2.2 Editing patient data with *EasyOne Connect*

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

Edit the fields that you want to change.
 You must fill out those fields that are marked with an asterisk (*).
- 5 In all other fields, enter additional patient data if necessary.
- 6 Choose **OK**.

10.2.3 Merging two patient data records with *EasyOne Connect*

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

Prerequisite

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

- 1 Choose **Patients**.
- 2 Select one of the two data records.
- 3 Drag and drop that data record onto the second data record by doing the following:
 - a) Right-click the first data record and keep the mouse button pressed.
 - b) Move the data record across the screen onto the second data record.
 - c) While the first data record is above the second, release the mouse button.
 - ✓ If the dates of birth of the two data records match, a confirmation window is displayed.
 - ✓ If the dates of birth of the two data records do not match, a warning is displayed. In this case, you cannot merge these two data records.
- 4 To finish, confirm the message.

10.2.4 Deleting patient data from the database of *EasyOne Connect*

- 1 Choose **Patients**.
 - 2 Select a patient.
 - 3 Choose **Delete**.
 - ✓ If user handling is not active, that is if you did not have to login to *EasyOne Connect*, you are prompted for the default password. Proceed with step 4.
 - ✓ If user handling is active, that is if you did have to login to *EasyOne Connect*, you are not prompted for a password. A confirmation window is displayed immediately. Proceed with step 5.
 - 4 Enter the default user name / password.
 -  The default user name / password is: *admin / 8005*
 - ✓ A confirmation window is displayed.
 - 5 Choose **Yes**.
 - ✓ The patient and all corresponding tests are deleted from the database.
- ⇒ [About user handling and the default password of EasyOne Connect, 105](#)

10.2.5 Copying patient data between *EasyOne Air* and *EasyOne Connect*

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

⚠ CAUTION

DATA LOSS

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

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

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

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

Use *EasyOne Connect* only

to create new patient records without results yet for sending to *EasyOne Air* to evaluate results,
to print reports,
to archive patient data and results,
or to send patient data and results from *EasyOne Connect* to your EMR system.

EASYONE AIR MAY FREEZE

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

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

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

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

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

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

Fill out those fields that are marked with an asterisk (*).
 You cannot complete adding patient data without filling out these fields.
 - 4 In all other fields, enter additional patient data if necessary.
 - 5 Choose **OK**.
 - 6 Select the patient record that you just have created.
 - 7 Choose  **> EasyOne**.
 - ✓ The selected patient record is send to *EasyOne Air*.
 - ✓ *EasyOne Connect* displays a message whether the sending has been successful.
 -  You can remove *EasyOne Air* from the cradle, or you can repeat steps 2 to 7 to create and send additional patient records.
- ⇒ [Viewing and printing reports with EasyOne Connect, 89](#) ↗
[Connectivity and data exchange, 44](#) ↗

10.2.6 Viewing and printing reports with *EasyOne Connect*

- 1 From the main menu, choose **Patients**.
- 2 Select a patient.
- 3 Choose **History**.
 - ✓ The history screen with a list of tests is displayed.
- 4 Select a test.
- 5 To view the results for the selected test, do the following:
 - a) Choose **View**.
 - b) If the test type is provocation, choose **Menu**.
 - c) To preview the report, choose **Report**.
 - d) To print the report, choose **Print**.
 - e) To go back to the history screen, choose **Return** and then **History**.
- 6 To view the results of another test, repeat steps 4 and 5.
- 7 To view the results of another patient, choose **Patients** and repeat steps 2 to 6.

10.2.7 About the trend view with *EasyOne Connect*

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

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

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

10.2.8 Assessing tests retrospectively and entering comments with *EasyOne Connect*

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

■ To assess tests retrospectively

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

■ To enter comments

- 1 In any result screen, select the comment area.
 - ✓ 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 3.
- 2 If the login window is displayed, enter your user ID.
 - ✓ The test comment window is displayed.
- 3 Enter your comment and choose **Save**.
 - ✓ Your comment is displayed on the result screen.

⇒ [About user handling and the default password of EasyOne Connect, 105](#)

10.2.9 About exporting comprehensive data from *EasyOne Connect*

Utilities > Export Data

This export is the most comprehensive export function in *EasyOne Connect*. You can select which data to include in the export.

Each check box produces one file with the corresponding data.

To access data on an SQL-server based database, the SQL server must accept the Microsoft Active Directory user account that the current Windows user is logged in with.

10.2.10 About exporting XML from *EasyOne Connect*

Utilities > Export XML

The XML export enables you to process patient data with your own software tools.

In the report configurations, you can configure which data to include in the XML export.

To access data on an SQL-server based database, the SQL server must accept the Microsoft Active Directory user account that the current Windows user is logged in with.

⇒ [Description of report configurations of EasyOne Connect, 115](#)
[Software Developer Guide SDK – ndd EMR plug-in](#)

10.2.11 About exporting from *EasyOne Connect* to *EasyWare*

Utilities > Export EasyWare

EasyWare is the PC software for *EasyOne World*, the predecessor model of *EasyOne Air*. *EasyWare* uses a different database format.

This export is compatible with the database format of *EasyWare*.

To access data on an SQL-server based database, the SQL server must accept the Microsoft Active Directory user account that the current Windows user is logged in with.

⇒ [EasyWare Operator's Manual](#)

11 Configuration

⚠ CAUTION

FALSE DIAGNOSIS

Wrong configuration settings can cause incorrect diagnostic calculations.

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

Verify the configuration settings.

11.1 Configuration of *EasyOne Air*



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

11.1.1 Configurations in the settings menu of *EasyOne Air*



11.1.1.1 Description of device settings of *EasyOne Air*



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

Setting	Purpose	Options	Default setting
Speaker volume	To set the speaker volume	0% – 100%	50%
Key click	To enable sound for audible click feedback	Selected, deselected	Selected
Beep during maneuver	To enable a beeping signal during breathing maneuvers as feedback about air flow	Selected, deselected	Selected
User Logon required	To enable password protection	Selected, deselected	Selected
System Time	To set the time	Numeric entry	(Not applicable)
System Date	To set the date	Numeric entry	(Not applicable)
Date format	To set the format of the date	YYY-MM-DD, MM/DD/YYYY, DD.MM.YYYY	(Determined by regional setting at first-time setup)
Time format	To set the format of the time	24h (00:00 – 23:59), 12h (AM/PM)	(Determined by regional setting at first-time setup)
Patient ID format	To set the format of the patient ID for compliance with national standards	Numbers only, Alphanumeric	(Determined by regional setting at first-time setup)

☐ Description of device settings

11.1.1.2 Description of spirometry settings of *EasyOne Air*



Predicted normal values setting

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

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

[Application Note Reference Predicted Normal Values](#)

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

[List of bibliographic references, 132](#)

Best trial/best value selection

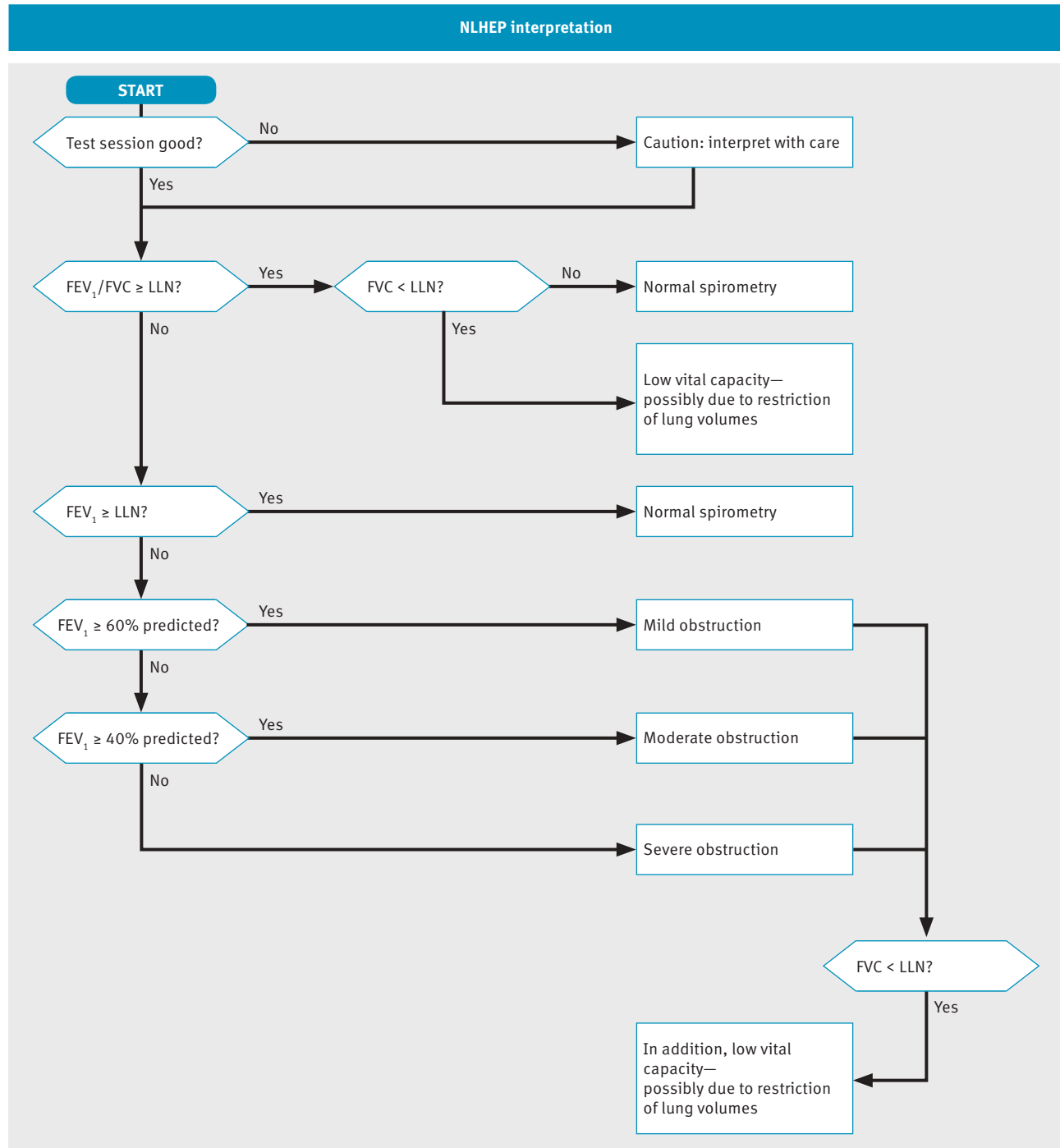
If you choose the **Best Trial** option, the complete best trial is selected for assessing the quality of the test and for assessing the interpretation. The trial with the largest sum of FVC and FEV₁ is selected, as suggested by ATS and ERS.

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

System Interpretation

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

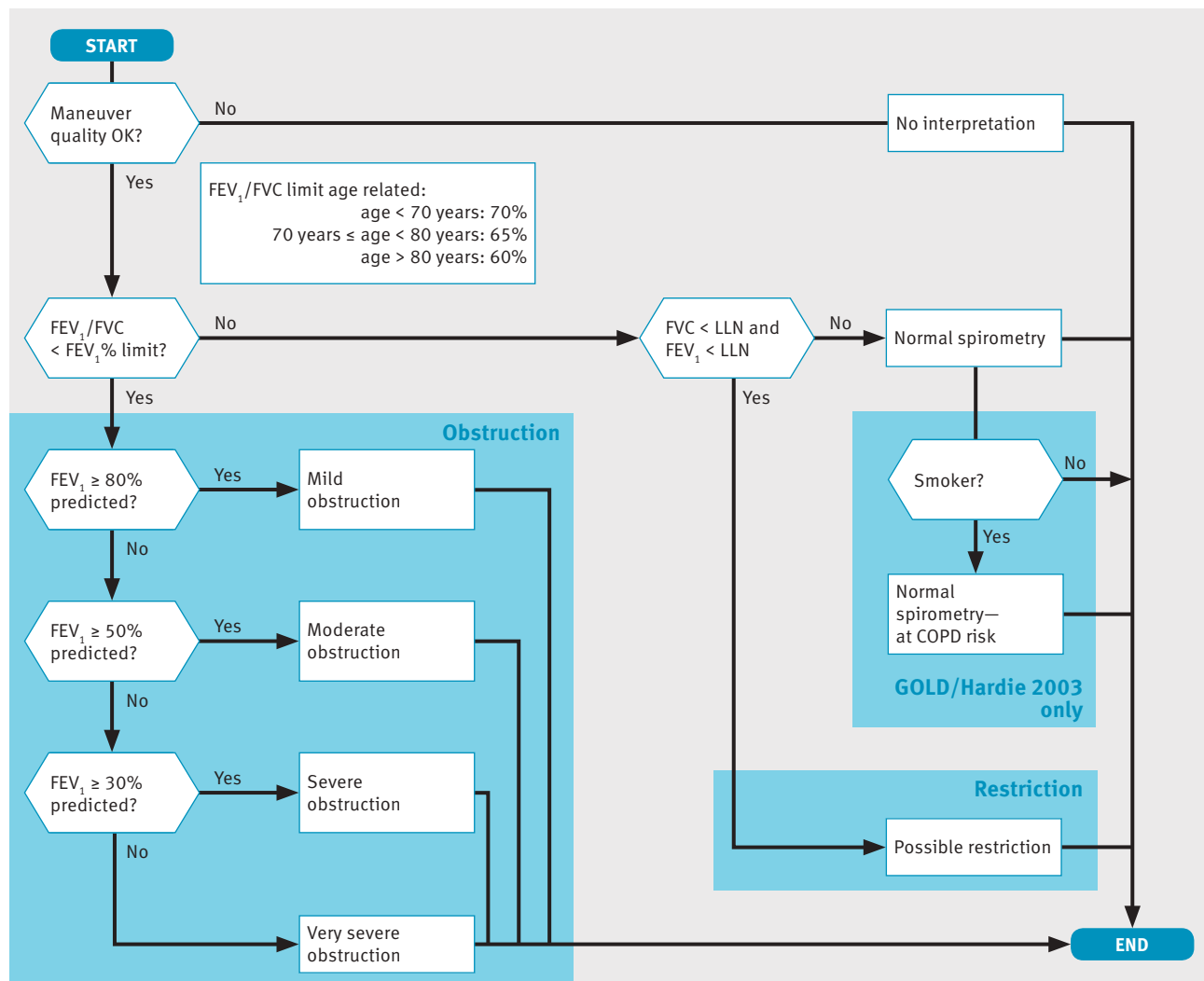
The default setting is GOLD/Hardie.



☐ NLHEP interpretation algorithm

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

GOLD/Hardie Interpretation 2003 & 2008

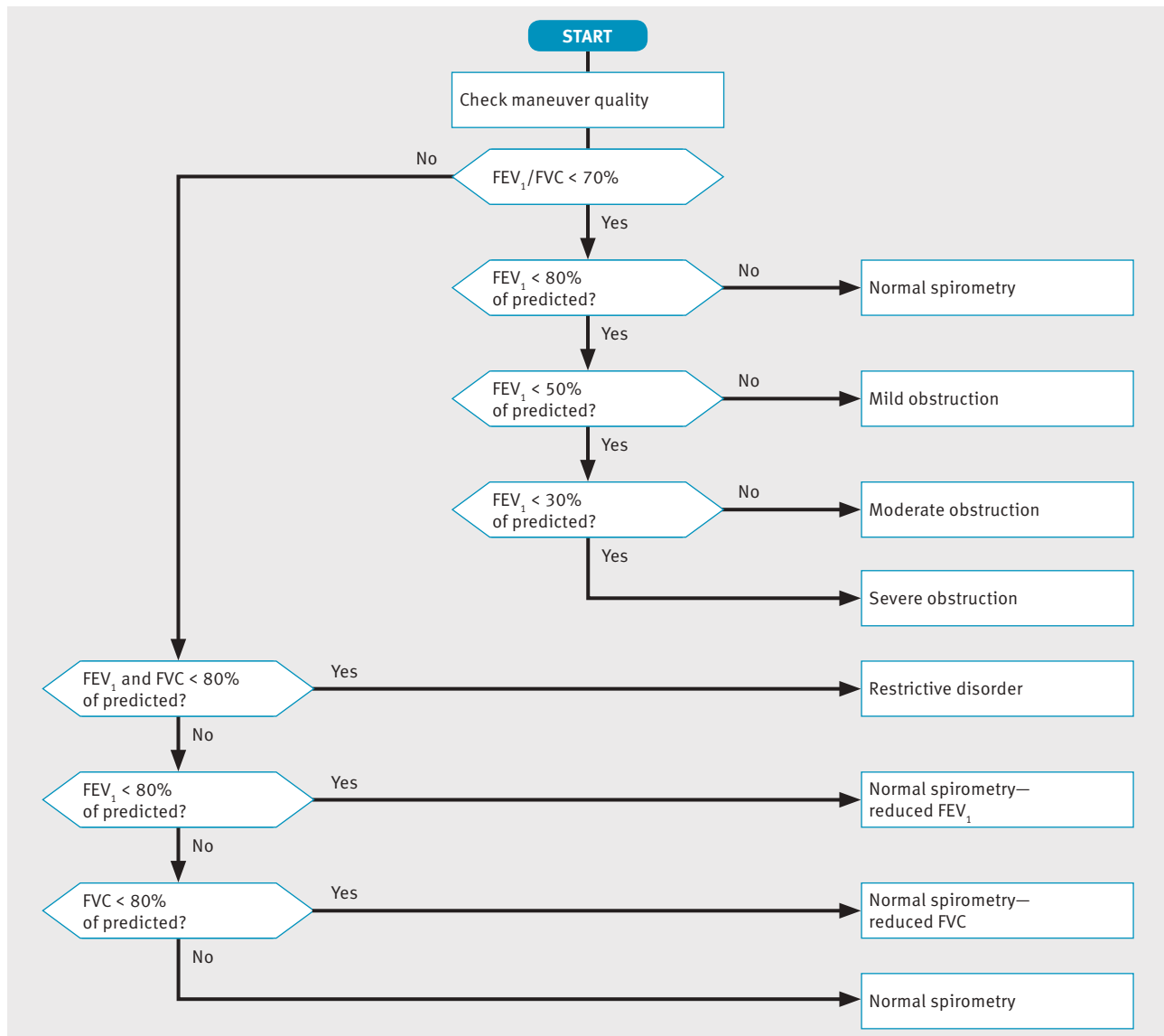


☐ GOLD/Hardie interpretation algorithm

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

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

NICE interpretation



☐ NICE interpretation algorithm

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

Lung age calculation

If the **Lung Age calculation** check box is selected, the lung age is displayed on the result screen and printed on the report. The lung age is only displayed if the patient is a smoker. You can set the smoker status on the summary screen.

When the calculated lung age is lower than the patient's actual age, the patient's actual age is displayed.

In the default setting, the **Lung Age calculation** check box is deselected.

[About the summary screen, 56](#)

Automatic QC grading

If the **Automatic QC grading** check box is selected, quality messages for trial and quality grades for tests are displayed.

In the default setting, the **Automatic QC grading** check box is selected.

[List of quality messages and quality grades, 73](#)

End-of-maneuver criteria selection

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.

The FVC test determines the forced expiratory vital capacity. The forced expiratory vital capacity is the maximum volume that the patient can exhale during the FVC breathing maneuver and is indicated by the FVC value in the report.

The FEV_6 value indicates the forced expiratory volume that the patient has exhaled after six seconds.

For diagnostic purposes, the FVC value is comparable with the FEV_6 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, 132](#)

PEF unit

The peak expiratory flow can be specified in liters per minute (L/min) or in liters per second (L/s).

Ethnic correction

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

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

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

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

[List of bibliographic references, 132](#)

11.1.1.3 Description of display settings of *EasyOne Air*



On this screen, you can choose settings that are related to the displayed software and to the touchscreen.

Setting	Purpose	Options	Default setting
Language	To set the language	English, French, German, Spanish	(Determined by regional setting at first-time setup)
Brightness	To set the brightness of the touchscreen	1% – 100%	50%
Screensaver after	To set the time, after which the screensaver is enabled	5 s – 600 s	120 s
Power-off after	To set the time, after which <i>EasyOne Air</i> is powered off to save battery	20 s – 1200 s	600 s
Volume/Time curve	To enable the display of the volume-time curve in addition to the flow-volume curve in the reports	Selected, deselected	Selected
Show predicted range	To enable visualization of the maximum curve and minimum curve in the volume-time curve and flow-volume curve in the reports	Selected, deselected	Selected

☐ Description of display settings

11.1.1.4 Description of print settings of *EasyOne Air*



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

Setting	Purpose	Options	Default setting
Printer	To select a physical printer or a virtual PDF printer (saves a PDF file)	PDF printer, External printer	External printer
Printer page format	To select the page format in imperial or metric dimensions	US, A4	A4
Number of pages	To select between a full-size or compact report format	one page (compact report), two pages (full-size report)	two pages
Data	To set whether one or three trials are included on the printout, corresponding to the best trial/best value selection in the spirometry settings	Best trial (one trial), best value (three trials)	Best value (three trials)
Curve	To set which curves are included on the printout, corresponding to the <i>Data</i> setting above	One curve, three curves	Three curves
Custom header	To specify four lines of text on the printout, for customizing the printout for your institution	Text entry	(Not applicable)

Description of print settings

- ⇒ [Best trial/best value selection, 94](#)
- [About compatible printers, 19](#)
- [Setting up the physical components, 20](#)
- [Description of report configurations of EasyOne Connect, 115](#)

11.1.2 Performing a firmware update with *EasyOne Air*



Required material

- ☐ An SD memory card from the manufacturer

In this menu, you can update the firmware of *EasyOne Air*.

⚠ CAUTION

FAILED UPDATE

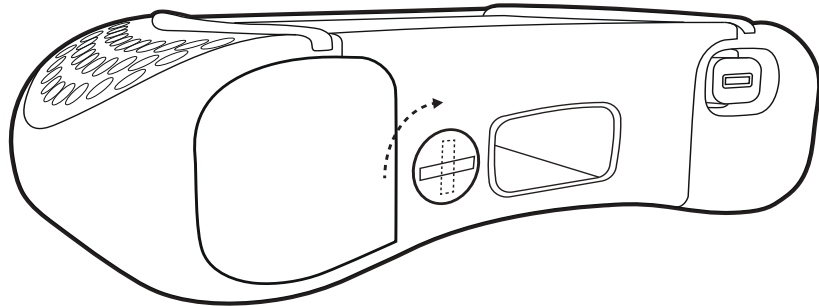
An update may fail unnoticed.

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

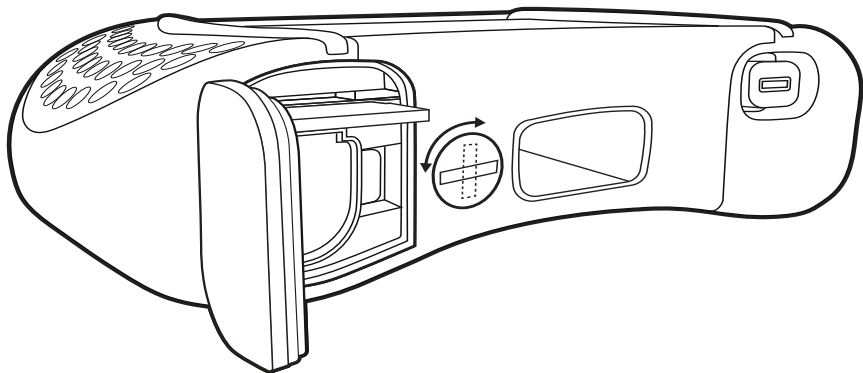
[Calibration check, 118](#)

[Checking for correct operation of EasyOne Air, 122](#)

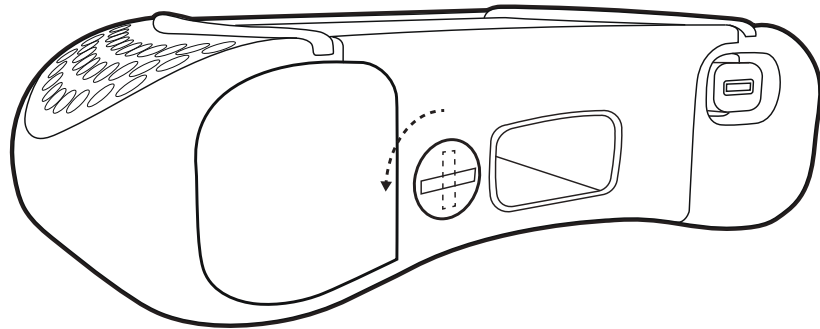
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



- 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  > .

 - ✓ The firmware update that is on the SD memory card is displayed.

- 5 Select the firmware update from the SD memory card.

 - ✓ The firmware update is performed.
 - ✓ After the firmware update, a message is displayed whether the update was successful, and *EasyOne Air* restarts.

- 6 Remove the SD memory card.

11.1.3 Performing a backup of *EasyOne Air*



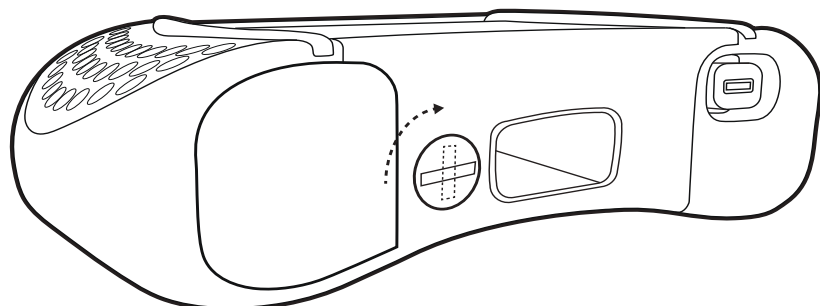
Required material

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

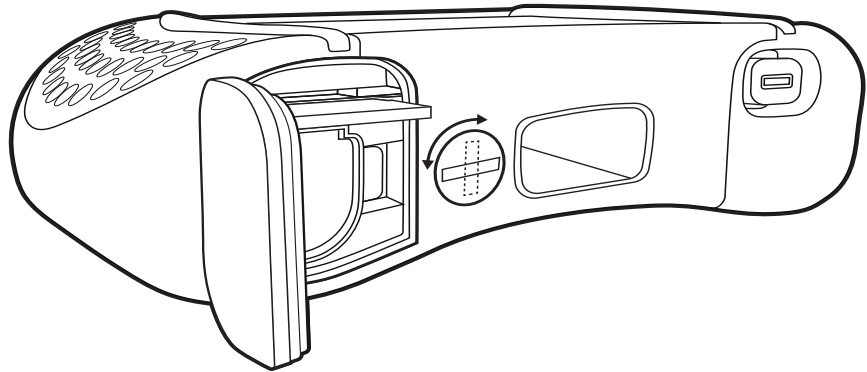
To archive a copy of the complete database (including patient data and results) and of the configuration settings, perform backups regularly. You can also use the backup to set up another *EasyOne Air* with the same database and configuration settings.

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

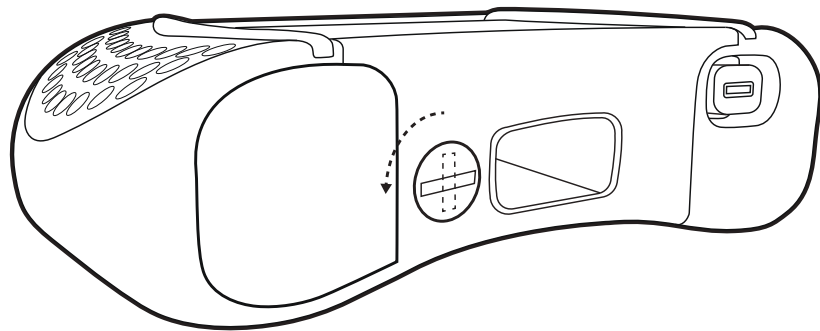
- 1 Unlock and open the battery compartment by turning the lock screw clockwise.



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



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



- 4 Choose  >  > **Backup**.
 - ✓ 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**.
 - ✓ The SD memory card is checked for sufficient free space.
 - ✓ The complete database and all configuration settings are backed up to the SD memory card.
 - ✓ After successful completion of the backup, a message is displayed.
- 6 Choose the home button.
- 7 Remove the SD memory card.

11.1.4 About the information menu of *EasyOne Air*



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

11.1.5 About the user menu of *EasyOne Air*



Inactive user handling

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

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

Active user handling

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

Security policies, like password strength and password expiration, must be handled by the operating institution, for example the hospital or practice.

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

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

User groups

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

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

11.2 Configuration of *EasyOne Connect*

Utilities > Configuration

11.2.1 About saving or discarding configuration changes of *EasyOne Connect*

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.

11.2.2 About user handling and the default password of *EasyOne Connect*

Utilities > Configuration > General > User Handling

Inactive user handling

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

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

Active user handling

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

Security policies, like password strength and password expiration, must be handled by the operating institution, for example the hospital or practice.

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

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

User groups

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

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

⇒ [About user handling and the default password of EasyOne Connect, 105](#) 
[Connectivity and data exchange, 44](#) 

11.2.3 Description of general configurations of *EasyOne Connect*

11.2.3.1 Utilities > Configuration > General > 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**.

11.2.3.2 Utilities > Configuration > General > 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 <i>EasyOne Connect</i> 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!

☐ Storage configuration

⇒ [Connectivity and data exchange, 44](#) ↗
 Application Note *EasyConnect – Database Connection*
 Application Notes for further information, 3 ↗

11.2.3.3 Utilities > Configuration > General > 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 <i>EasyOne Pro/LAB</i> .
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*.

11.2.3.4 Activating user handling and administering user accounts

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

⇒ About user handling and the default password of EasyOne Connect, 105 ↗

11.2.4 Description of test configurations of *EasyOne Connect*

11.2.4.1 Utilities > Configuration > Test > General

Best trial/best value selection

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

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

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 and the predicted values as percentage values also for the post, choose **Show % predicted column for post tests**.

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 **Max Number of Trials Forced/Slow**. 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.

11.2.4.2 Utilities > Configuration > Test > 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](#)

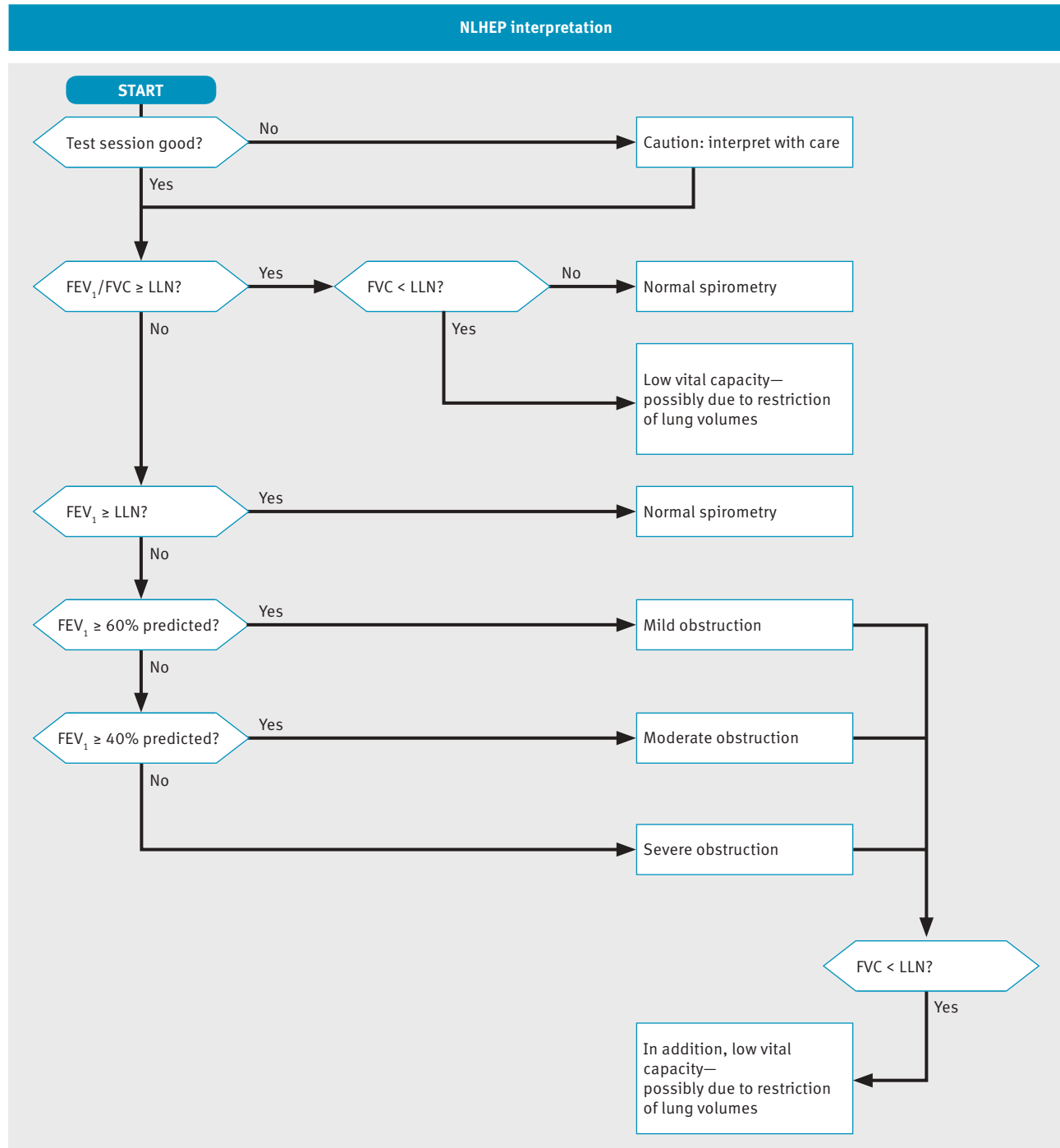
[Application Notes for further information, 3](#)

[List of bibliographic references, 132](#)

System Interpretation

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

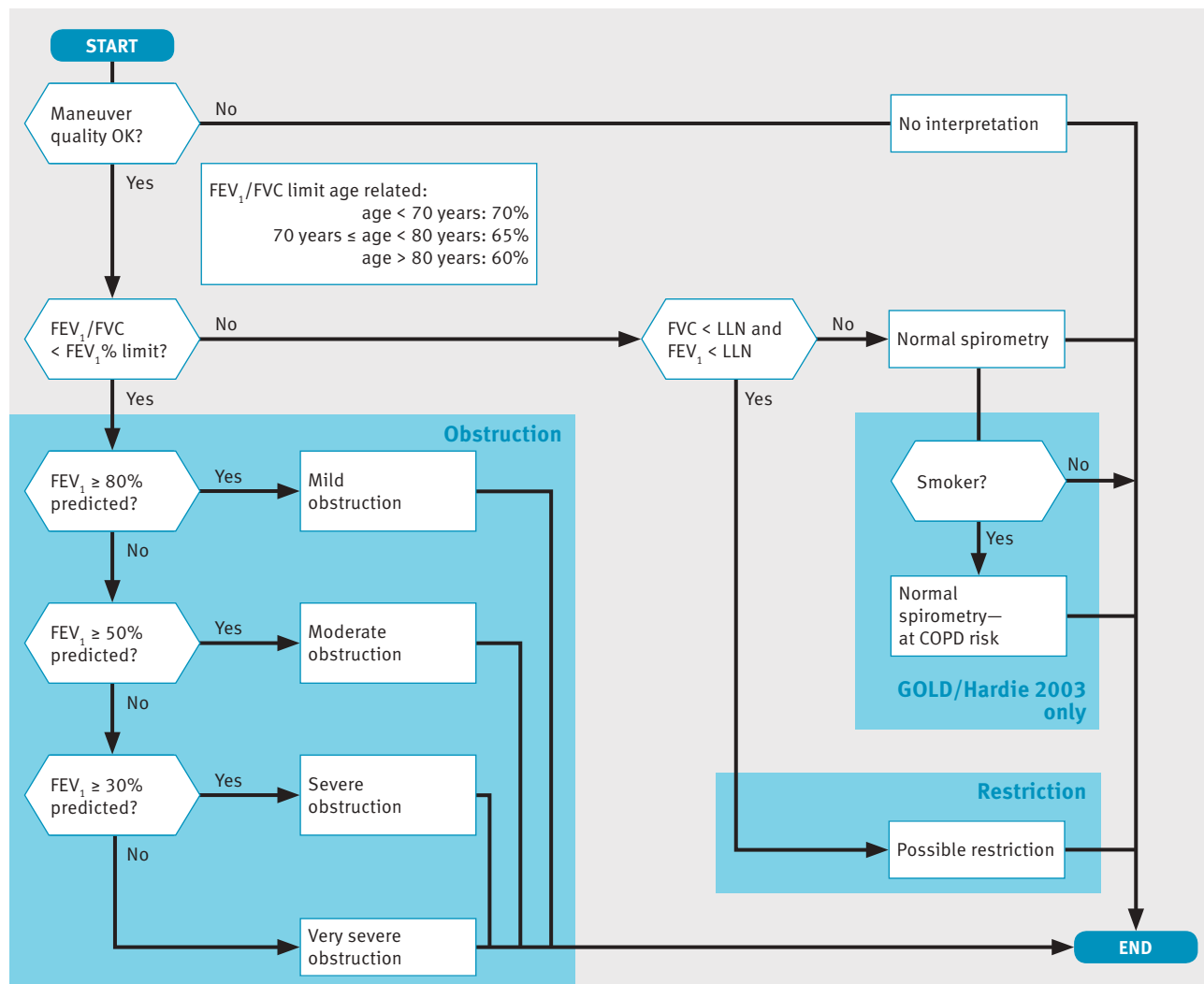
The default setting is GOLD/Hardie.



☐ NLHEP interpretation algorithm

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

GOLD/Hardie Interpretation 2003 & 2008

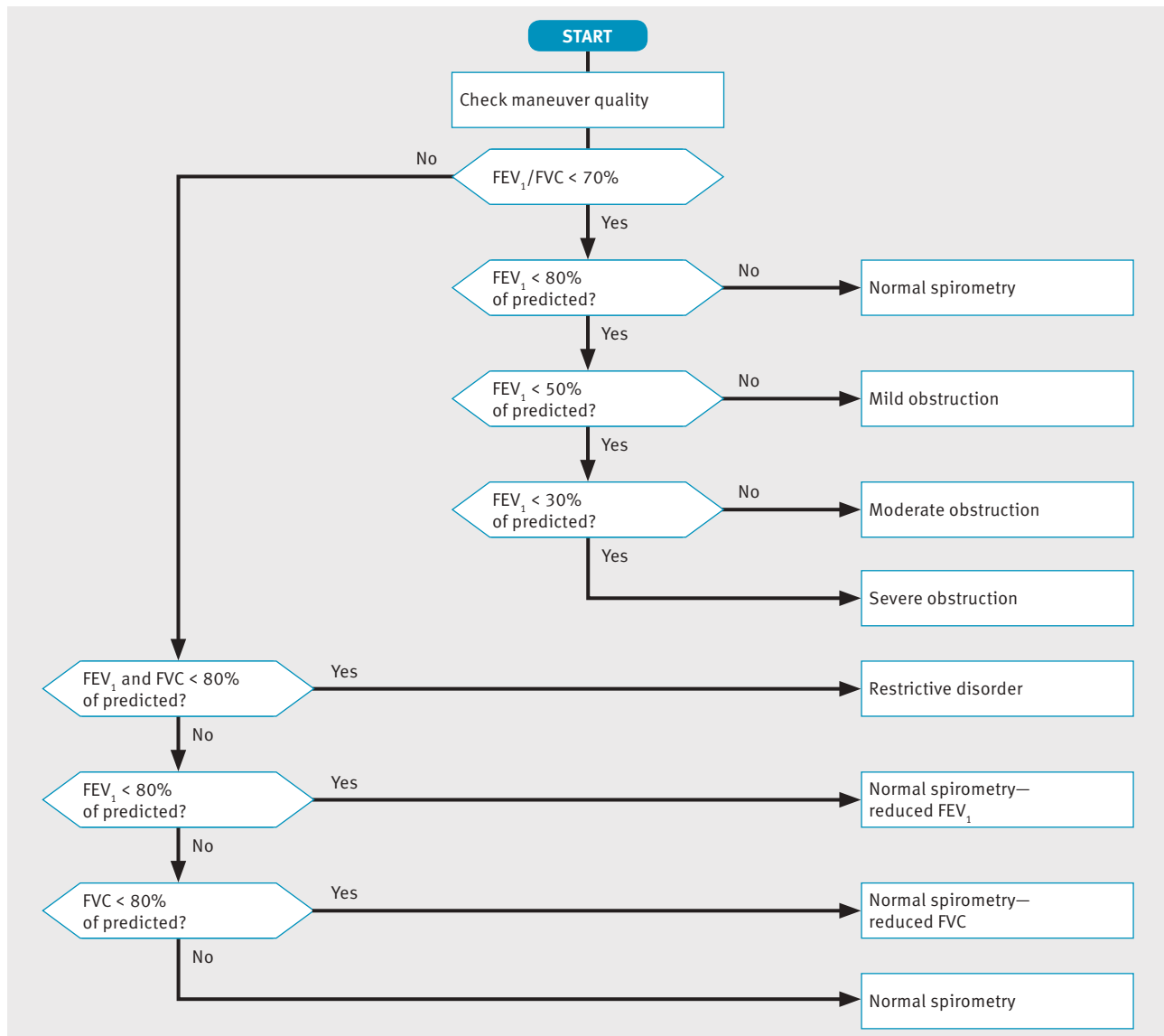


☐ GOLD/Hardie interpretation algorithm

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

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

NICE interpretation



☐ NICE interpretation algorithm

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

Ethnic correction

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

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

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

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

[List of bibliographic references, 132](#)

11.2.4.3 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.

11.2.4.4 Utilities > Configuration > Test > FVC / FVL

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 Flow Tube* 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, 108](#)

End-of-maneuver criteria selection

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.

The FVC test determines the forced expiratory vital capacity. The forced expiratory vital capacity is the maximum volume that the patient can exhale during the FVC breathing maneuver and is indicated by the FVC value in the report.

The FEV_6 value indicates the forced expiratory volume that the patient has exhaled after six seconds.

For diagnostic purposes, the FVC value is comparable with the FEV_6 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, 132](#)

Parameter

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

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**.

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 the lung age, choose **Off**.

The default configuration is **Smoker only**.

11.2.4.5 Utilities > Configuration > Test > SVC

Parameter

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

Type

To make regular breathing mandatory before the breathing maneuver, choose **Tidal Breathing Required**.

11.2.4.6 Utilities > Configuration > Test > MVV

Parameter

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

11.2.4.7 Utilities > Configuration > Test > 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.

11.2.4.8 Utilities > Configuration > Test > 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.

11.2.5 Description of device configurations of *EasyOne Connect*

Utilities > Configuration > Device

You can use *EasyOne Connect* in combination with any *EasyOne* product.

Easy on-PC

This tab displays hardware information about the connected *Easy on-PC* sensor.

If the *Easy on-PC* sensor cannot connect, the serial COM port might be used by another device. To switch to a free serial COM port, you can manually select one from the drop-down list or choose the **Auto Detect** button.

[Easy on-PC Operator's Manual](#)

EasyOne Air

Utilities > Configuration > Device > Selection

From this tab, select the device that you want to use for performing spirometry with *EasyOne Connect*.

11.2.6 Description of report configurations of *EasyOne Connect*

Utilities > Configuration > Report

Layout

CAUTION

MISINTERPRETATION OF RESULTS

Reports that are labeled as *Custom Report* are not validated.

Use customized reports at your own risk.

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

For details, contact your *EasyOne* dealer or the *ndd* Servicing Department.

[Contact information](#), 4 ↗

XML Export

If you do not require curve data or trial values in exported XML, you can exclude this data by deselecting the check boxes.

By default, these check boxes are selected.

11.2.7 Loading and selecting a custom report layout of *EasyOne Connect*

You can load custom report layouts according to your requirements. For easy identification you can rename the report layouts. Your *EasyOne Air* dealer or the *ndd* Servicing Department can assist you in creating a custom report layout.

Prerequisite

- ☐ You have created or received a report layout file with an *.repx file extension.
- ☐ You have connected the drive with the report layout file, or you have copied the report layout file to PC that runs *EasyOne Connect*.

If you want to rename the report layout, you only need to rename the REPX file. The name of the report layout file is printed on every report.

■ To load the report layout file

- 1 Choose **Utilities > Configuration > Report**.
- 2 Choose **Load**.
- 3 Navigate to the report layout file, select the file, and choose **Open**.
- 4 Read and confirm the warning message about custom report layouts.

■ To select your custom report layout

- 1 From any result screen, choose **Report**.
- 2 From the **Layout Selection** drop-down list on the top left, choose your custom report layout.

11.2.8 Description of printer configurations of *EasyOne Connect*

Utilities > Configuration > Printer

From the drop-down list, choose a printer. To be displayed in the drop-down list, the printer must be installed in *Microsoft Windows*.

With the **Refresh** button, you can refresh the drop-down list after you have installed a new printer in *Microsoft Windows*.

With the **System Default** button, you choose the printer that is set as the default printer in *Microsoft Windows*.

⇒ [About compatible printers, 19](#)

11.2.9 Description of environment configurations of *EasyOne Connect*

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)

12 Calibration check

CAUTION

FALSE DIAGNOSIS

A number of reasons can lead to malfunction of *EasyOne Air*, and malfunction of *EasyOne Air* can lead to false results and false diagnosis.

Perform calibration checks periodically, according to ATS/ERS.

[Calibration check, 118](#)

[Checking for correct operation of EasyOne Air, 122](#)

MALFUNCTION

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

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

Do not open or remove the casing.

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

[Contact information, 4](#)

12.1 About calibration check with *EasyOne Air*

There are three types of calibration checks: *single cal check*, *multi-flow cal check*, and *linearity cal check*.

Single cal check

Single cal check is not standard-compliant. The manufacturer recommends *multi-flow cal check* and *linearity cal check*.

With single cal check, you simulate one inspiration and one expiration in a single trial. The measured volume must be within $\pm 3.5\%$ accuracy. You can perform multiple trials.

EasyOne Air displays exclusively the best trial. But all trials are stored. The printout shows the best three trials.

Multi-flow cal check

With *multi-flow cal check*, you simulate one inspiration and one expiration for three different flow levels each:

- 3 L in approximately 0.5 s (flow rate of 6 L/s)
The trial is accepted if the parameter FEF_{25-75} or FIF_{25-75} is between 5.50 L/s and 6.50 L/s.
- 3 L in approximately 3 s (flow rate of 1 L/s)
The trial is accepted if the parameter FEF_{25-75} or FIF_{25-75} is between 0.75 L/s and 1.25 L/s.
- 3 L in approximately 6 s (flow rate of 0.5 L/s)
The trial is accepted if the parameter FEF_{25-75} or FIF_{25-75} is between 0.40 L/s and 0.75 L/s.

To pass the complete calibration check, there must be one acceptable trial for each flow level.

The printout shows at least three trials, one for each flow level.

Linearity cal check

The procedure for *linearity cal check* is the same as for *multi-flow cal check*, except that three acceptable trials for each flow level are required.

The printout shows at least nine trials, three for each flow level.

⇒ [List of tests and parameters, 36](#)

12.2 Performing a calibration check with *EasyOne Air*



Required materials

- ☐ A calibration syringe (separately available)
- ☐ An *EasyOne Flow Tube* cal check adapter (separately available)
- ☐ An *EasyOne Flow Tube*

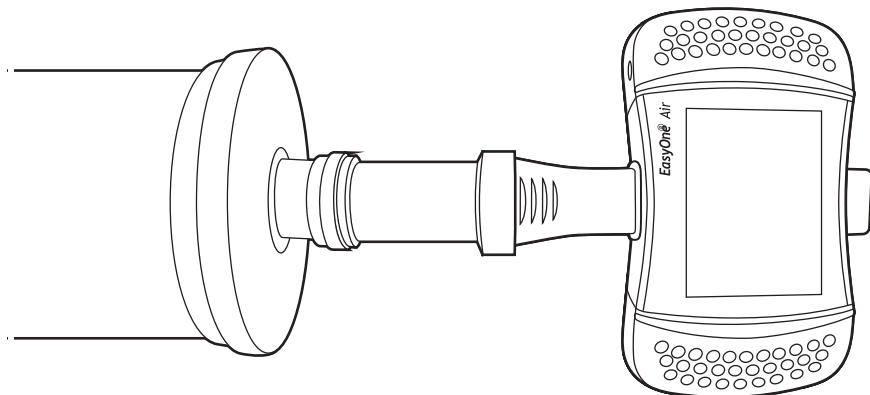
The ultrasonic sensor of *EasyOne Air* does not require calibration. Only unforeseeable reasons can lead to a malfunction that affects results. In these cases, you can determine whether *EasyOne Air* operates normally with a simple calibration check. Therefore, a regular calibration check is recommended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

For criteria for acceptable trials, refer to the previous chapter.

About calibration check with *EasyOne Air*, 118 [↗](#)

- 1 To assure that the temperature inside the syringe and the room temperature are the same, push and draw the piston five times.
 -  A temperature difference may lead to a failed calibration check.
 -  Do not warm the body of the calibration syringe with your hands.
- 2 Push the piston of the calibration syringe all the way in.
- 3 Unwrap the *EasyOne Flow Tube*.
- 4 Insert the *EasyOne Flow Tube* into *EasyOne Air*.
 -  The shape of the *EasyOne Flow Tube* and the *EasyOne Flow Tube* holder guide the orientation of the *EasyOne Flow Tube*. You can only insert the *EasyOne Flow Tube* fully if it is positioned correctly.
- 5 Attach the *EasyOne Flow Tube* cal check adapter to the calibration syringe.
 -  To avoid any temperature differences, fixate the syringe with two fingers at the one end of the syringe only.
- 6 Attach the nozzle of the *EasyOne Flow Tube* cal check adapter to the *EasyOne Flow Tube* and make sure that the piston is fully inserted.

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



- 7 Choose  >  > **Single flow**, **Multi flow**, or **Linearity** and confirm the message that is displayed.
 - 8 Wait for the baseline to be set.
 - 9 Pull the piston all the way out as slow or as fast as required by the flow level that is displayed.
 - 10 Push the piston all the way in again with the same speed.
 - 11 To end the maneuver, pull the piston briefly again.
 - ✓ If the maneuver was not acceptable, you need to repeat steps **9** to **11**.
 - ✓ If you have chosen **Single flow** before and the maneuver was acceptable, the calibration check is completed.
 - ✓ If you have chosen **Multi flow** or **Linearity** before and the maneuver was acceptable, proceed with step **12**.
 - 12 If you have chosen **Multi flow** or **Linearity** before and the previous maneuver was acceptable, perform the next maneuvers according to the messages that are displayed.
 - ✓ If a maneuver was not acceptable, you need to repeat steps **9** to **11**.
 - ✓ If all maneuvers were acceptable, the calibration check is completed.
- ⇒ [List of troubleshooting solutions, 122](#) ↗
[Contact information, 4](#) ↗

13 Servicing and troubleshooting

13.1 About charging the battery of *EasyOne Air*

The rechargeable battery of *EasyOne Air* lasts for an entire working day. To fully charge the battery after a day of work, the manufacturer recommends to charge *EasyOne Air* over night. In addition, you can also charge *EasyOne Air* multiple times during the day between spirometry tests.

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

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

13.2 Checking for correct operation of *EasyOne Air*

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

⇒ [Calibration check, 118](#)

[Performing spirometry, 51](#)

[List of troubleshooting solutions, 122](#)

[Contact information, 4](#)

13.3 List of troubleshooting solutions

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

Problem	Possible cause	Solution
<i>EasyOne Air</i> cannot be switched on.	Battery is dead. You did not press and hold the ON/OFF key for at least 2 seconds.	Replace the battery. Press and hold the ON/OFF key for at least 2 seconds.
When the <i>EasyOne Air</i> is switched on, you hear three consecutive tones as a warning signal.	The spirometer is defective.	Consult your <i>EasyOne</i> dealer or the <i>ndd</i> Servicing Department.

☐ Troubleshooting solutions

Problem	Possible cause	Solution
When <i>EasyOne Air</i> is switched on, you see the following message on the display: “Self-test failed”	The spirometer is possibly defective.	Turn the spirometer off and on. Try again. If you receive the same message again, contact your <i>EasyOne</i> dealer or the <i>ndd</i> Servicing Department.
When <i>EasyOne Air</i> is switched on, the message “device self test error #20” appears on the touchscreen.	An <i>EasyOne Flow Tube</i> was inserted while <i>EasyOne Air</i> was switched on. The <i>EasyOne Flow Tube</i> was not inserted correctly.	Wait for <i>EasyOne Air</i> to finish starting up before you insert an <i>EasyOne Flow Tube</i> . Insert the <i>EasyOne Flow Tube</i> as displayed in To prepare the test, 58 .
Every time you switch <i>EasyOne Air</i> on, you are prompted to enter Date etc.	The internal battery of <i>EasyOne Air</i> is defective.	Consult your <i>EasyOne</i> dealer or the <i>ndd</i> Servicing Department.
When you start a test, you see the following message: “Please insert <i>EasyOne Flow Tube</i> correctly”	The <i>EasyOne Flow Tube</i> is not correctly positioned.	Ensure the <i>EasyOne Flow Tube</i> is inserted correctly and fully pushed in.
<i>EasyOne Air</i> is outside of $\pm 3.5\%$ when conducting the calibration check.	The <i>EasyOne Flow Tube</i> is not correctly positioned.	Insert the <i>EasyOne Flow Tube</i> correctly.
	You have not used an <i>ndd</i> adapter.	Use the <i>EasyOne Flow Tube</i> cal check adapter.
	There are leaks in the syringe connection.	Check the connections.
	The specified syringe volume does not correspond to the actual syringe volume.	Choose the correct syringe volume under “Configuration”.
The curve is missing on the printout.	The ink cartridge of your printer is empty.	Replace the cartridge.
	In the configuration of your <i>EasyOne Air</i> , a black and white printer is selected, but you actually use a color printer.	Go to “Configuration”, then “Report Settings” and select the right printer.
When printing a report, the printer prints meaningless characters, or the printer does not respond.	A wrong printer type has been selected in the settings.	Set the correct printer.
	The printer cable is not correctly connected or is defective.	Switch off the spirometer and printer. Check all plug connections.
	The printer is not switched on or is not ready.	Ensure that the printer is switched on and also has paper. Switch the printer off and back on again.
	<i>EasyOne Air</i> is not correctly positioned on the base unit.	Insert <i>EasyOne Air</i> correctly into the base unit.
If <i>EasyOne Flow Tube</i> is not inserted correctly or if the <i>EasyOne Flow Tube</i> detection is not working correctly.	An <i>EasyOne Flow Tube</i> was inserted while <i>EasyOne Air</i> was switched on the instrument, or the <i>EasyOne Flow Tube</i> was not inserted correctly.	Try again with the <i>EasyOne Flow Tube</i> inserted correctly. If you receive the same message again, contact your <i>EasyOne</i> dealer or the <i>ndd</i> Servicing Department.
Wireless connection to external device is not working correctly.	Bluetooth is not enabled, or distance is too far, or Bluetooth is already connected to another device.	Enable Bluetooth (configuration), make sure device is close enough (within 5 meters or 16.4 feet), check setup.

Troubleshooting solutions

⇒ [List of quality messages and quality grades, 73](#)
[Contact information, 4](#)

13.4 About reactivating *EasyOne Air* after storage

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

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

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

- ⇒ [List of specifications for EasyOne Air, 125](#) ↗
- [About charging the battery of EasyOne Air, 122](#) ↗
- [Setting up the EasyOne Air spirometer, 24](#) ↗
- [Checking for correct operation of EasyOne Air, 122](#) ↗
- [Contact information, 4](#) ↗

13.5 Exporting logging information

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

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

- ⇒ [Contact information, 4](#) ↗

14 Specifications and bibliography

14.1 List of specifications for *EasyOne Air*

Size		87 x 155 x 36 millimeters (3.4 x 6.1 x 1.4 inches)
Weight	without battery	302 grams (11 ounces)
	with battery	356 grams (13 ounces)
Measuring accuracy	Volume	±2% or 0.050 L
	Flow, except PEF	±2% or 0.020 L/s
	PEF	±5% or 0.200 L/s
	MVV	±5% or 5 L/min
Measuring resolution	Volume	1 mL
	Flow	4 mL/s
Measuring range	Volume	±12 L
	Flow	±16 L/s
Resistance		0.3 cm H ₂ O/L/s at 16 L/s
Measurement principle		Ultrasonic transit-time measurement
Display		320 x 240 LCD display
Input method		Touchscreen
Test storage capacity		Up to 10,000 tests
Languages		English, French, German, Spanish
Data Management		<i>EasyOne Connect</i> PC software
Printing option		Direct to printer or with <i>EasyOne Connect</i> PC software
Export/EMR		HL7, XML, GDT (with <i>EasyOne Connect</i> PC software)
Hardware interface		USB, Bluetooth
Age range for patients		Spirometry >4 years
Respiratory tube		Disposable <i>EasyOne Flow Tube</i> respiratory tube
Power supply		Rechargeable lithium-ion battery, USB power supply
Voltage (<i>EasyOne Air</i>)	Input	4.5 V to 5.5 V
	Output	3.6 V
Power consumption (<i>EasyOne Air</i>)		Up to 7.5 W
Voltage (<i>ndd</i> power supply)		5 V DC
	Standby	0.3 W
	Nominal input voltage	100 to 240 V AC, 50 to 60 Hz
Appliance class		Class II

☐ Specifications for *EasyOne Air*

Instrument classification		Type BF applied part Powered internally with a lithium-ion battery Short time operation, less than 10 minutes Instrument not suitable for use in areas with flammable anesthetic gases and in areas with mixtures containing O ₂ or NO	
			
Wireless connection	This specification is not applicable to the <i>EasyOne Air TL</i> variant.		
	Type	Bluetooth: v2.1 + EDR, v3.0 + HS, v4.0	WiFi : IEEE 802.11a/b/g/j, 802.11n, 802.11d/e/i/w, 802.11X, 802.11k/r/v, 802.11h
	Modulation	Bluetooth: GFSK, DQPSK, 8DPSK	WiFi: OFDM with BPSK, QPSK, 16-QAM, 64-QAM 802.11b with CCK and DSSS
	QoS	WMM and WMM Power Save Support	
	Frequency band	Bluetooth: 2.402 GHz to 2.480 GHz	WiFi: 2412 MHz – 2484 MHz and 4910 MHz – 5825 MHz
	Transmit power	Bluetooth: 15 dBm (class-1)	WiFi: 18dBm
	Receive sensitivity	Bluetooth: -94dBm	WiFi: -97dBm
	Contains transmitter module	FCC ID: XF6-RS9113SB	
		IC ID: 8407A-RS9113SB	
Storage 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)	
	Relative humidity	5% to 90%	
	Atmospheric pressure	700 hPa to 1060 hPa	

☐ Specifications for *EasyOne Air*

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	ATS/ERS 2005, NIOSH, OSHA
Life time		7 years

☐ Specifications for *EasyOne Air*

- ⇒ [List of tests and parameters, 36](#)
- [Application Note *Reference Predicted Normal Values*](#)
- [Application Notes for further information, 3](#)
- [Contact information, 4](#)

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

CAUTION

RISK OF PERSONAL INJURY

Do not expose the battery to fire or dispose of the battery in fire.

Do not put the battery in a charger or equipment with wrong terminals connected.

Do not short circuit.

Avoid excessive physical shock or vibration.

Do not disassemble or deform the battery.

Do not immerse in water.

Do not use the battery in combination with any other batteries.

Keep out of the reach of children.

Only charge the battery when inside of *EasyOne Air* and in conjunction with the cradle and the power supply provided by the manufacturer.

Never use a modified or damaged *EasyOne Air*, cradle, or power supply.

Store the battery in a cool, dry and well-ventilated area.

Dispose of the battery in accordance with local regulations. Regulations vary for different countries.

RISK OF FIRE AND BURNS

Do not open, crush, heat above 50°C/122°F, or incinerate.

Follow the instructions in this Operator's Manual.

The following table contains additional information about the battery of *EasyOne Air* that might be required by a third party testing and certification organization.

Manufacturer	CTU Ltd. Second Floor Zhongxing Industrial Zone Chuang Ye Rd. Nanshan Shenzhen 518054 China
Model	Lithium-ion Battery Pack 1ICR1865
Size	20 millimeters x 71 millimeters (0.79 x 2.80 inches), cylindrical
Weight	54 grams (1.9 ounces)
Nominal capacity	3400 mAh, 12.06 Wh
Nominal voltage	3.6 V DC
Charge current (C-rate)	0.5C
Standard charging method	1) 0.5C constant current up to 4.2 V 2) Constant voltage of 4.2 V until charge current declines to ≤0.01C
Charging time with standard charging method	Approximately 5 h

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

Maximum charging method		1) 0.7C constant current up to 4.2 V
		2) Constant voltage of 4.2 V until charge current declines to $\leq 0.01C$
Charge cut-off voltage		4.2 V to 4.25 V
Standard discharge current (C-rate)		0.2C constant current down to end voltage of 3.0 V
Maximum discharge current (C-rate)		0.7C constant current down to end voltage of 3.0 V
Discharge cut off- voltage		2.8 V to 3.0 V
Initial impedance		$\leq 200 \text{ m}\Omega$
The following standard conditions are identical to the conditions of <i>EasyOne Air</i> . Storage and operation under these conditions is safe.		
Standard storage 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*

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.

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

14.3 List of order numbers and accessories for *EasyOne Air*

Item	Description	Intended region	Order number
<i>EasyOne Air</i> US type A package	<i>EasyOne Air</i> complete package with device, power plug and adapter, cradle, USB cables, battery pack, etc.	United States of America	2500-2A
<i>EasyOne Air</i> EU type C package	<i>EasyOne Air</i> complete package with device, power plug and adapter, cradle, USB cables, battery pack, etc.	European Union (excluding United Kingdom)	2500-3C
<i>EasyOne Air</i> AUS type I	<i>EasyOne Air</i> complete package with device, power plug and adapter, cradle, USB cables, battery pack, etc.	Australia	2500-4I
<i>EasyOne Air</i> UK type G package	<i>EasyOne Air</i> complete package with device, power plug and adapter, cradle, USB cables, battery pack, etc.	United Kingdom	2500-5G
<i>EasyOne Air</i> IND type M package	<i>EasyOne Air</i> complete package with device, power plug and adapter, cradle, USB cables, battery pack, etc.	India	2500-6MJKM
<i>EasyOne Flow Tube</i> box of 50 pcs.	<i>EasyOne Flow Tube</i> , individually wrapped, box of 50 pieces	Worldwide	5050-50
<i>EasyOne Flow Tube</i> box of 200 pcs.	<i>EasyOne Flow Tube</i> , individually wrapped, box of 200 pieces	Worldwide	5050-200
<i>EasyOne Flow Tube</i> box of 500 pcs.	<i>EasyOne Flow Tube</i> , individually wrapped, box of 500 pieces	Worldwide	5050-500
<i>ndd</i> calibration syringe 3 L with <i>EasyOne Flow Tube</i> cal check adapter	<i>ndd</i> calibration syringe 3 liters, for optional calibration check procedures, includes an <i>EasyOne Flow Tube</i> cal check adapter	Worldwide	2030-2
<i>EasyOne Flow Tube</i> cal check adapter	Individual cal check adapter for use with <i>ndd</i> calibration syringe and <i>EasyOne Flow Tube</i>	Worldwide	5030-2
<i>EasyOne Air</i> USB cable B–micro (cradle to printer)	USB cable from cradle to printer (replacement)	Worldwide	2500-50.1
<i>EasyOne Air</i> battery pack	Battery pack for <i>EasyOne Air</i> (replacement)	Worldwide	2500-50.4
<i>EasyOne Air</i> power supply with adapter type A	Power supply for <i>EasyOne Air</i> with adapter for the United States (replacement)	United States of America	2500-50.5A
<i>EasyOne Air</i> power supply with adapter type C	Power supply for <i>EasyOne Air</i> with adapter for the European Union (replacement)	European Union (excluding United Kingdom)	2500-50.5C
<i>EasyOne Air</i> power supply with adapter type I	Power supply for <i>EasyOne Air</i> with adapter for Australia (replacement)	Australia	2500-50.5I
<i>EasyOne Air</i> power supply with adapter type G	Power supply for <i>EasyOne Air</i> with adapter for The United Kingdom (replacement)	United Kingdom	2500-50.5G
<i>EasyOne Air</i> power supply with adapter type M	Power supply for <i>EasyOne Air</i> with adapter for India (replacement)	India	2500-50.5MJKM

☐ Order numbers and accessories for *EasyOne Air*

14.4 List of system requirements for *EasyOne Connect*

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

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

☐ System requirements for *EasyOne Connect*

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- ⇒ [Application Note *Reference Predicted Normal Values*](#)
[Application Notes for further information, 3](#) ↗

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A Appendix

A.1 Electromagnetic Compatibility (EMC)

A.1.1 General

A.1.1.1 Environment

See:

⇒ [Intended use of the EasyOne Air spirometer, 2](#)

A.1.1.2 EMC conformance

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

A.1.2 Safety information

See:

⇒ [Safety information regarding electromagnetic compatibility, 14](#)

A.1.3 Compliant cables and accessories

WARNING

INCREASED EMISSIONS OR DECREASED IMMUNITY

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

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

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

USB cable micro to type A, shielded, 1.8 m

USB cable micro to type B, shielded, 1.8 m

ndd power supply 5.0 V DC

☐ Accessories with which the manufacturer claims EMC compliance

⇒ [List of box contents, 17](#)

A.1.4 Wireless module

EasyOne Air contains a wireless module for Bluetooth communication.

See *Wireless connection* in:

⇒ [List of specifications for EasyOne Air, 125](#) ↗

A.1.5 Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	<i>EasyOne Air</i> uses RF energy for its internal function. Additionally, the EUT contains a Radio Bluetooth, BLE and WLAN module, which complies with the national regulations. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. However, a separation distance of 30 cm shall be maintained.
RF emissions CISPR 11	Class B	<i>EasyOne Air</i> is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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

A.1.6 Electromagnetic immunity

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

Guidance and manufacturer's declaration – electromagnetic Immunity

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

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

☐ Electromagnetic immunity

Immunity test standard	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the <i>EasyOne Air</i> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 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 may 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 may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *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 may 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 may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Note: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.			

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