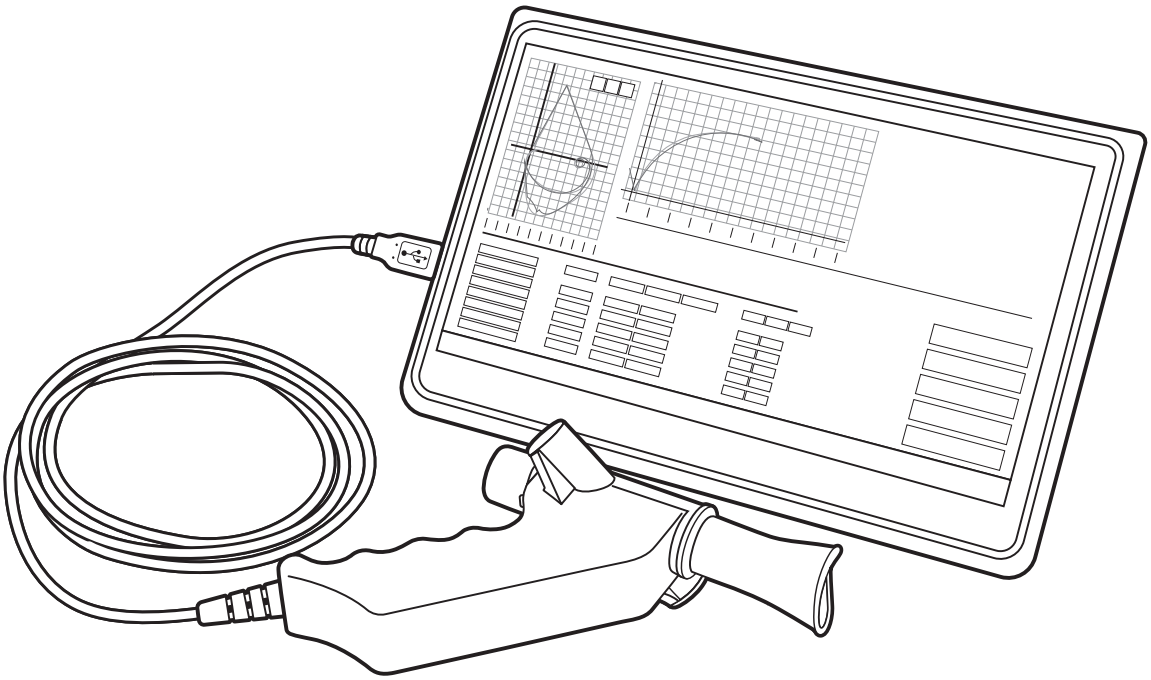
Medical Technologies



Easy on-PC

Operator's Manual V09

9000008/09

1. Preface

1.1. Using this Operator's Manual

Read this Operator's Manual prior to operating *Easy on-PC*.

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

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

1.2. Identification and revision of *Easy on-PC* spirometer

Easy on-PC comprises *Easy on-PC* sensor and the *Easy on-PC* software, which is called *EasyOne Connect*.

This revision V09 of the *Easy on-PC* Operator's Manual applies to the *EasyOne Connect* software V3.9.3.x or higher.

The functionality of *Easy on-PC* is determined by the latest version of the *EasyOne Connect* software and not by the hardware of *Easy on-PC* sensor. *Easy on-PC* sensors with a serial number smaller than 190,000 are merely not compatible with the latest version of *EasyOne Connect*.

If you are in doubt whether this revision of the Operator's Manual applies to your particular *Easy on-PC* sensor, please contact the *NDD* Servicing Department.

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

⇨ Contact information 4
www.nddmed.com

1.3. Intended use/Indications for Use of *Easy on-PC* spirometer

The software program *EasyOne Connect* in conjunction with the flow sensor is designed for spirometric measurements in adults and children over the age of 4. The *Easy on-PC* system is used by general practitioners, specialists, in occupational medicine, and in hospitals. It may also be used in frontline applications (pharmacies, screening places, first aid centers). *Easy on-PC* is used in combination with the *Spirette* respiratory tube to conduct slow and forced spirometric maneuvers and MVV tests. The *EasyOne Connect* PC software contains data management functions such as displaying, reporting, and exporting of test data.

1.4. 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.

1.5. Revision history of *Easy on-PC* Operator's Manual

Revision Date	Version	Description
29 November 2021	V09	Integration of *EasyOne* Filter and minor general changes
4 December 2020	V08	Revised to comply with European Medical Device Regulation 2017/745/EU (MDR)
12 November 2018	V07	Revised version due to the transition to a new notified body in the EU, includes exchanged CE mark and a number of small changes
13 April 2018	V5.1	Revised version
		Updated content, alignment with the Operator's Manuals of other *EasyOne* products

Revision history of the *Easy on-PC* Operator's Manual

1.6. Application Notes for further information

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

⇨ www.nddmed.com

1.7. Legal information

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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

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

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

⇨ www.nddmed.com/legal/patents

1.8. Contact information

NDD Medizintechnik AG
Technoparkstrasse 1
CH-8005 Zurich, Switzerland
Tel: +41 (0) 44 512 65 00
Fax: +41 (0) 44 512 65 01
www.nddmed.com

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

1.9. Product registration

Registering your *Easy on-PC* facilitates the handling of warranty claims.

To register *Easy on-PC*, go to the *NDD* website.

⇨ www.nddmed.com

1.10. Disposal

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

In any case, consider recycling the cardboard packaging material. Ensure that the plastic packaging material is treated in waste management facilities and not released into the environment.

Table of contents

2. Safety information

2.1. Classification

In this manual, safety information is classified as follows:

⚠ WARNING

WARNING . . .

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

⚠ CAUTION

CAUTION . . .

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

2.2. General safety information

Personnel instruction

Uninstructed personnel working with the device may lead to malfunction.

- Make sure that all personnel are familiar with this Operator's Manual and have understood its content.

Electric shock

Patients and technicians may be exposed to dangerous voltage.

- To ensure electric safety, connect only equipment, such as PCs, printers and network equipment, that complies with the IEC 62368-1 or IEC 60950-1 standard and/or the IEC 60601-1 standard for electrical safety.
- When connecting *Easy on-PC* sensor to another electrical equipment, the systems of both equipments are classified as medical electrical systems, that is, "ME SYSTEM" according to the IEC 60601-1 standard. The system operator is responsible for the fulfillment of all requirements according to IEC 60601-1 Clause 16.

False diagnosis

Setup with wrong environment data can cause false results and false diagnosis.

- Verify the set up environment data.

False diagnosis	For various reasons, malfunction of *Easy on-PC* can lead to false results and false diagnosis. *Easy on-PC* may be damaged when dropped or during transport. If *Easy on-PC* has been dropped, check for correct operation of *Easy on-PC*. • Perform an incoming inspection when you first receive *Easy on-PC*. If you detect any damage, contact your *Easy on-PC* distribution partner or the *NDD* Servicing Department. • Do not drop *Easy on-PC*. • Perform calibration checks periodically. Calibration check 60 Checking for correct operation of Easy on-PC 65
Malfunction	Viruses, malware, and other hazardous software on your PC may adversely affect the performance of *EasyOne Connect*. • Install anti-virus software.
Cross-contamination	Tuberculosis or other diseases spread by droplet nuclei and can cause aerosol infection. • Proper attention to environmental engineering controls, such as ventilation, air filtration, or ultraviolet decontamination of air, must be used.
Malfunction	Calibration and servicing must only be carried out by *NDD* staff or by qualified service personnel of official *NDD* distributors. • Do not open *Easy on-PC* sensor.
Malfunction	Non-original accessories and disposables, like the *Spirette* respiratory tube, can cause malfunction. • Only use original accessories and disposables by *NDD*.
False diagnosis	Non-original respiratory tubes can cause measurement error and false results. • You must only use *Spirette* respiratory tubes by the manufacturer *NDD* to assure accuracy, long-life, and full warranty coverage.
Data loss	Data can be deleted accidentally. The database can become corrupted. • Backup the database of *EasyOne Connect* frequently.
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).
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.

2.3. Safety information regarding electromagnetic compatibility

Influence by HF surgical equipment

Electrical devices with a high RF (Radio Frequency) power output (e.g. High frequency (HF) surgical equipment) can influence the operation of *Easy on-PC*.

- 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 *Easy on-PC*.

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 *Easy on-PC*.

- Keep a distance of at least 30 cm (12 in) to any part of *Easy on-PC*.

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 *Easy on-PC*.

- Do not use accessories, transducers, and cables other than those specified by the manufacturer.

Proximity to other equipment

Proximity to other equipment can influence the operation of *Easy on-PC*.

- Do not use *Easy on-PC* adjacent to or stacked with other equipment. Should close proximity or stacking be unavoidable:
- closely watch the configuration in which it is used to ensure that the equipment is functioning normally.

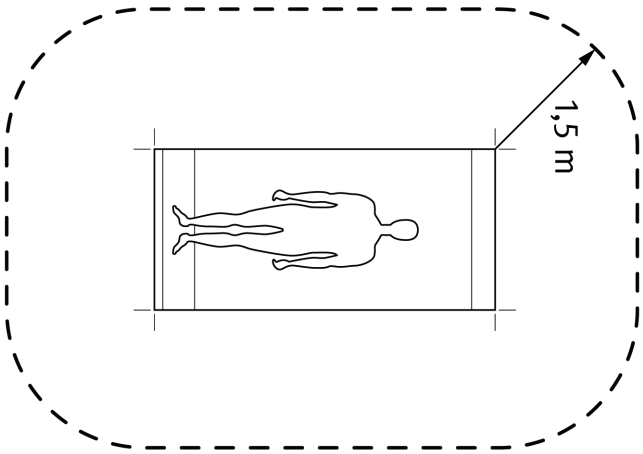
Appendix A - Electromagnetic compatibility (EMC) 75

2.4. About requirements for connections to external devices

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 62368).



☐ 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 µA
- with interruption of the (not permanently connected) protective earth conductor: 500 µA

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

IEC 60601-1 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

	Consult instructions for use
	Caution
	Follow instructions for use
	Do not reuse, i.e., single-patient use (applicable to the *Spirette*)
	CE mark including Notified Body Identification Number
	Compliance with additional US and Canadian safety requirements for medical electrical equipment
	Manufacturer
	Date of manufacture
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner
	The product you have purchased should not be disposed of as unsorted municipal waste. Please make use of your local Waste of Electrical and Electronic Equipment (WEEE) collection facilities to dispose of this product and otherwise observe all applicable requirements.
	Instrument classification: Type BF applied part
	Universal Serial Bus (USB 1.0/1.1, USB 2.0, max. 100 mA)—standard for connecting devices and data transfer, applies to cables and connectors
	Do not use if package is damaged
	Keep dry
	Temperature limit
	Humidity limitation

	Atmospheric pressure limitation
SN	Serial number
LOT	Batch code
REF	Catalogue number
MD	Medical Device
EC REP	Authorized representative in the European Community
UDI	Unique Device Identifier

2.6. List of used symbols in Operator's Manual

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

3. First-time setup

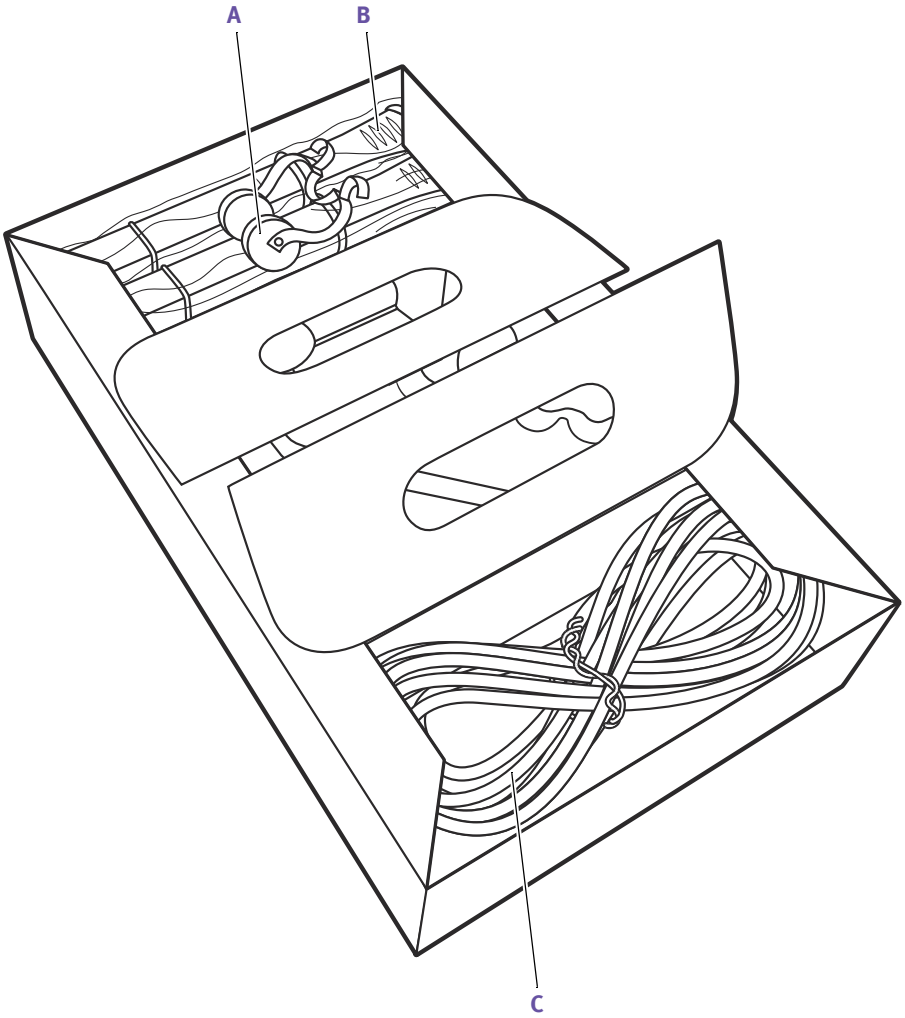
3.1. List of box contents

The box contains the following items:

A The *Easy on-PC* sensor

B USB flash drive with product documentation

☐ Box contents – after initial unpacking



A Nose clip

B *Spirette* respiratory tubes

C USB cable of *Easy on-PC* sensor (affixed)

☐ Box contents – with inlays opened

The box contains the following documents:

- The *Easy on-PC* Quick Guide
- The Certificate of Stability

The USB flash drive contains the following:

- The *Easy on-PC* Operator's Manual
- The *Easy on-PC* Quick Guide
- The *EasyOne Connect* PC software

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

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

Prerequisites

- ☐ Your PC meets the system requirements for *EasyOne Connect*.
  List of system requirements for EasyOne Connect 69
- ☐ Your Windows user has administrator privileges.

⚠CAUTION

FAILED UPDATE

An update may fail unnoticed.

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

Checking for correct operation of Easy on-PC 65

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

3.3. About compatible printers

EasyOne Connect can use any printer that is installed on your PC as a regular printer within Microsoft Windows.

⇨ Operator's Manual of your printer
For installing printers, online help of Microsoft Windows

3.4. About setting up *Easy on-PC*

⚠WARNING

ELECTRIC SHOCK

Dangerous voltage can be accessible to the patient or the technician.

- Connect only equipment, like printers and PCs, that comply with the IEC 62368-1 or 60950-1 standard for electrical safety.

After you have installed *EasyOne Connect*, and when you connect the *Easy on-PC* sensor via USB, the drivers are installed automatically.

The *Easy on-PC* sensor draws power from the USB port. No other power source is necessary.

When not in use, consider unplugging *Easy on-PC* sensor to minimize power consumption.

For correct measurement, you must enter accurate environment data. You can enter environment data under **Utilities > Configuration > Environment**.

⇨ About requirements for connections to external devices 11
About requirements for connections to external devices 11
Description of environment configurations of EasyOne Connect 59

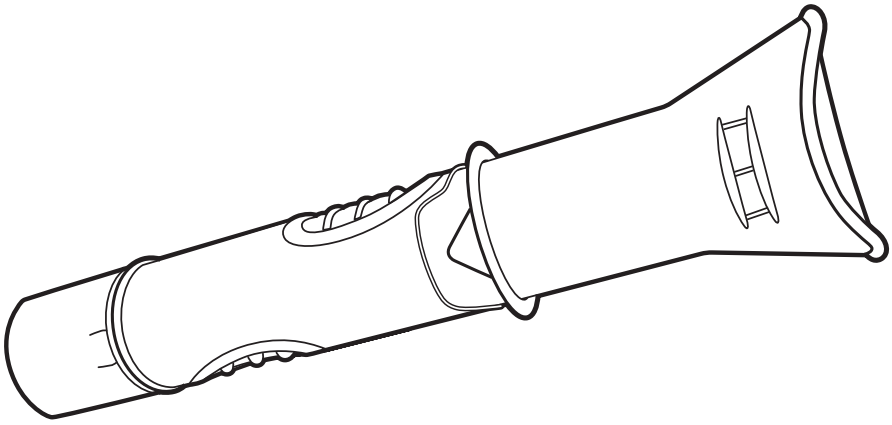
4. Introduction

4.1. Introduction to *Easy on-PC* spirometer

The *Easy on-PC* spirometer

Easy on-PC comprises the *Easy on-PC* sensor and the *EasyOne Connect* PC software. You connect the flow sensor to your PC via USB.

The *Spirette* respiratory tube for single-patient use



☐ The *Spirette* respiratory tube

To ensure hygienic testing, the *Spirette* respiratory tube is a disposable for single-patient use. The *Spirette* is designed to work accurately with the ultrasonic sensor of *Easy on-PC*. For reliable results, use only the original *NDD Spirette*.

⚠ CAUTION

FALSE DIAGNOSIS

Non-original respiratory tubes can cause measurement error and false results.

- You must only use *Spirette* respiratory tubes by the manufacturer *NDD* to assure accuracy, long-life, and full warranty coverage.

4.2. Overview of features of *EasyOne Connect*

EasyOne Connect serves to control the *Easy on-PC* sensor and to work with patient data and test results.

You can add patient data, edit patient data, perform spirometry, evaluate test results, and print reports. In addition to the functionality with the *Easy on-PC* sensor, you can connect to other *EasyOne* products or to your EMR system

through *EasyOne Connect*. This connectivity enables you to exchange patient data, test results, and reports according to your needs.

⇨ About connectivity and data exchange 25

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.
	A test comprises one or more trials. At least three trials are recommended, but not required.
	For each test, a report is generated.
trial	The performing of one breathing maneuver.
	A trial is part of a test.
parameter	For each trial, parameters are calculated from its curve.
post	Short for post bronchodilator.
	A post is performed after the patient is treated with a bronchodilator. Prior to the medication, the same test has been performed to be compared with the post.

Terms and definitions

4.4. 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	ATI, BEV, EOTV, FEF_{10}, FEF_{25}, FEF_{25-75}, FEF_{25-75_6}, FEF_{40}, FEF_{50}, FEF_{50}/FVC, FEF_{50}/VC_{max}, FEF_{60}, FEF_{75}, FEF_{75-85}, FEF_{80}, FET, FET_{25-75}, $FEV_{.25}$, $FEV_{.5}$, $FEV_{.5}/FVC$, $FEV_{.75}$, $FEV_{.75}/FEV_6$, $FEV_{.75}/FVC$, $FEV_{.75}/VC_{max}$, FEV_1, FEV_1/FEV_6, FEV_1/FVC, FEV_1/FVC_6,FEV1/VC, FEV_1/VC_{max}, FEV_3/FVC, FEV_3/VC_{max}, FEV_3, FEV_6, FVC, MEF_{20}, MEF_{25}, MEF_{40}, MEF_{50}, MEF_{60}, MEF_{75}, MEF_{90}, MMEF, MTC_1, MTC_2, MTC_3, MTCR, PEF, PEFT, t_0, VC, VC_{max}
FVL	Flow volume loop test	ATI, BEV, CVI, E_{50}/I_{50}, EOTV, FEF_{10}, FEF_{25}, FEF_{25-75}, FEF_{25-75_6}, FEF_{40}, FEF_{50}, FEF_{50}/FVC, FEF_{50}/VC_{max}, FEF_{60}, FEF_{75}, FEF_{75-85}, FEF_{80}, FET, FET_{25-75}, $FEV_{.25}$, $FEV_{.5}$, $FEV_{.5}/FVC$, $FEV_{.75}$, $FEV_{.75}/FEV_6$, $FEV_{.75}/FVC$, $FEV_{.75}/VC_{max}$, FEV_1, FEV_1/FEV_6, FEV_1/FIV_1,FEV1/FIVC, FEV_1/FVC,FEV1/VC, FEV_1/VC_{max}, FEV_3/FVC,FEV_3/VC_{max}, FEV_3, FEV_6, FIF_{25}, FIF_{25-75}, FIF_{50}, FIF_{50}/FEF_{50}, FIF_{75}, $FIV_{.25}$, $FIV_{.5}$, FIV_1, FIVC, FVC, MEF_{20}, MEF_{25}, MEF_{40}, MEF_{50}, MEF_{60}, MEF_{75}, MEF_{90}, MIF_{25}, MIF_{50}, MIF_{75}, MMEF, MMIF, MTC_1, MTC_2, MTC_3, MTCR, PEF, PEFT, PIF, t_0, VC, VC_{max}
MVV	Maximum voluntary ventilation test	MVV, MVV_6, MVV_{time}, Rf, VC_{ext}, VT
SVC	Slow vital capacity test	ERV, IC, IRV, Rf, VC, VC_{ex}, VC_{in}, VC_{max}, VT

Tests

Parameter	Parameter description	Unit
ATI	VC_{max}-FVC/ VC_{max}	%
BEV	Back extrapolated volume	L
$BTPS_{ex}$	BTPS factor used for expiration	–
$BTPS_{in}$	BTPS factor used for inspiration	–
CVI	Ratio of $FEV_{.5}$ to $FIV_{.5}$	–
E_{50}/I_{50}	Ratio of FEF_{50} to FIF_{50}	–
EOTV	End of test volume	L
ERV	Expiratory reserve volume	L
FEF_{10}	Forced expiratory flow at 10% of vital capacity—synonymous with MEF_{90}	L/s
FEF_{25}	Forced expiratory flow at 25% of vital capacity—synonymous with MEF_{75}	L/s
FEF_{25-75}	Forced expiratory flow from 25% to 75% of vital capacity—synonymous with MMEF	L/s
FEF_{25-75_6}	FEF_{25-75} based on FEV_6 instead of FVC	L/s
FEF_{40}	Forced expiratory flow at 40% of vital capacity—synonymous with MEF_{60}	L/s
FEF_{50}	Forced expiratory flow at 50% of vital capacity—synonymous with MEF_{50}	L/s

Parameters

Parameter	Parameter description	Unit
FEF_{50}/FVC	Ratio of FEF_{50} to FVC	1/s
FEF_{50}/VC_{max}	Ratio of FEF_{50} to VC_{max}	1/s
FEF_{60}	Forced expiratory flow at 60% of vital capacity—synonymous with MEF_{40}	L/s
FEF_{75}	Forced expiratory flow at 75% of vital capacity—synonymous with MEF_{25}	L/s
FEF_{75-85}	Forced expiratory flow from 75% to 85% of vital capacity	L/s
FEF_{80}	Forced expiratory flow at 80% of vital capacity—synonymous with MEF_{20}	L/s
FET	Forced expiratory time	s
FET_{25-75}	Forced expiratory time between FEF_{25} and FEF_{75}	s
$FEV_{.25}$	Forced expiratory volume after 0.25 seconds	L
$FEV_{.5}$	Forced expiratory volume after 0.5 seconds	L
$FEV_{.75}$	Forced expiratory volume after 0.75 seconds	L
$FEV_{.75}/FEV_6$	Ratio of $FEV_{.75}$ to FEV_6	–
$FEV_{.75}/FVC$	Ratio of $FEV_{.75}$ to FVC	–
$FEV_{.75}/VC_{max}$	Ratio of $FEV_{.75}/VC_{max}$	–
FEV_1	Forced expiratory volume after 1 second	L
FEV_1/FEV_6	Ratio of FEV_1 to FEV_6	–
FEV_1/FIV_1	Ratio of FEV_1 to FIV_1	–
FEV_1/FVC	Ratio of FEV_1 to FVC	–
FEV_1/FVC_6	Ratio of FEV_1 to FEV_6	–
FEV_1/VC	Ratio of FEV_1 to VC	–
FEV_1/VC_{max}	Ratio of FEV_1 to VC_{max}	–
FEV_1/VC_{ext}	Ratio of FEV_1 to VC_{ext}	–
FEV_3	Forced expiratory volume after 3 seconds	L
FEV_3/FVC	Ratio of FEV_3 to FVC	–
FEV_3/VC_{max}	Ratio of FEV_3 to VC_{max}	–
FEV_6	Forced expiratory volume after 6 seconds	L
FIF_{25}	Forced inspiratory flow at 25% of vital capacity—synonymous with MIF_{75}	L/s
FIF_{50}	Forced inspiratory flow at 50% of vital capacity—synonymous with MIF_{50}	L/s
FIF_{25-75}	Forced inspiratory flow at 25% to 75% vital capacity	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
IC	Inspiratory capacity from end of tidal breathing	L
IRV	Inspiratory reserve volume	L

Parameters

Parameter	Parameter description	Unit
MEF_{20}	Mean expiratory flow at 80% of vital capacity—synonymous with FEF_{80}	L/s
MEF_{25}	Mean expiratory flow at 75% of vital capacity—synonymous with FEF_{75}	L/s
MEF_{40}	Mean expiratory flow at 60% of vital capacity—synonymous with FEF_{60}	L/s
MEF_{50}	Mean expiratory flow at 50% of vital capacity—synonymous with FEF_{50}	L/s
MEF_{60}	Mean expiratory flow at 40% of vital capacity—synonymous with FEF_{40}	L/s
MEF_{75}	Mean expiratory flow at 25% of vital capacity—synonymous with FEF_{25}	L/s
MEF_{90}	Mean expiratory flow at 10% of vital capacity—synonymous with FEF_{10}	L/s
MIF_{25}	Mean inspiratory flow at 75% of vital capacity—synonymous with FIF_{75}	L/s
MIF_{50}	Mean inspiratory flow at 50% of vital capacity—synonymous with FIF_{50}	L/s
MIF_{75}	Mean inspiratory flow at 25% of vital capacity—synonymous with FIF_{25}	L/s
MMEF	Mean mid-expiratory flow—synonymous with FEF_{25-75}	L/s
MMIF	Mean mid-inspiratory flow	L/s
MTC_1	$(FEF_{75} - FEF_{50}) * 4 / FVC$	1/s
MTC_2	$(FEF_{50} - FEF_{25}) * 4 / FVC$	1/s
MTC_3	$FEF_{25} * 4 / FVC$	1/s
MTCR	Ratio of MTC_1 to MTC_3	–
MVV	Maximum voluntary ventilation	L/min
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_{ext}	Vital capacity from another test	L
VC_{in}	Inspiratory vital capacity, from slow inspiration	L
VC_{max}	Highest VC value from all trials of one test	L
VT	Tidal volume	L

Parameters

4.5. 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
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
SD	Standard deviation
SEE	Standard error of the estimate
SSL	Secure Sockets Layer
SQL	Structured Query Language
USB	Universal Serial Bus (USB)—standard for connecting devices and data transfer, applies to cables and connectors
XML	Extensible Markup Language

Abbreviations

4.6. About sources for predicted normal values

The available predicted normal values for *Easy on-PC* are updated as required through software updates.

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

⇨ Reference Predicted Normal Values:
Application Notes for further information 3
Installing or updating EasyOne Connect software on your PC 17

4.7. About connectivity and data exchange

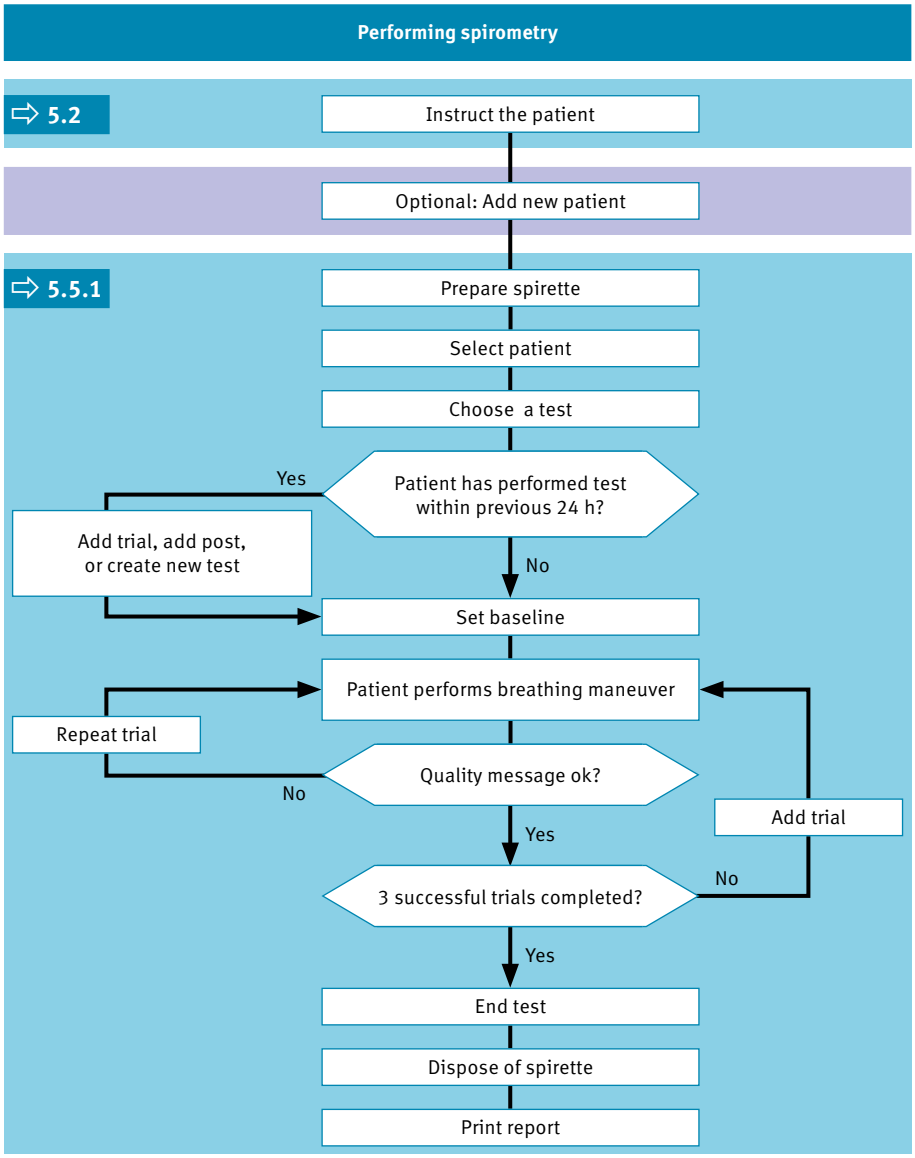
For data exchange, you can connect *EasyOne* products with the *EasyOne Connect* PC software. In addition, you can interface *EasyOne Connect* with the information system in your hospital or practice.

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

⇨ www.nddmed.com

5. Performing spirometry

5.1. Overview of the spirometry workflow



General spirometry workflow

⚠ CAUTION

ELECTRIC SHOCK, PATIENT HEALTH HAZARD, AND FALSE DIAGNOSIS

Casing damage or broken components and/or disposables may cause dangerous voltage accessible to the patient or technician. Small parts can be ingested or inhaled by the patient. Measurement errors can cause false diagnosis.

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

5.2. About preparation of spirometry and instructions for the patient

Preparing the patient

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

Instructing the correct usage of *Spirette*

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

Different breathing maneuvers for different tests

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

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

Carefully watch the patient

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

Animation program for patient

An animation program is available for the FVC test, the FVL test and the SVC test. You can choose between two animations: cake and elephant.

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

Recommended number of trials per test

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

⇨ Breathing maneuvers for all available tests 40
Avoiding contamination while performing spirometry 43

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

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

Quality grades according to the 2005 standard

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

⇨ List of quality messages and quality grades 37

5.4. 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.

5.5. Performing spirometry

5.5.1. Performing a complete test

Required materials

- ☐ A new *Spirette* for each patient
- ☐ For an FVL test, an MVV test, or an SVC test, a nose clip is recommended.

Prerequisites

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

About preparation of spirometry and instructions for the patient 27

⚠WARNING

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.

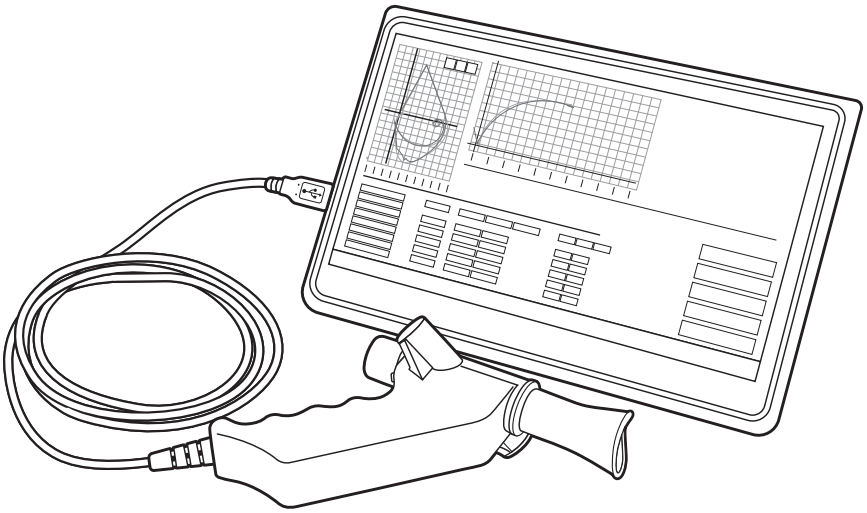
- Make sure the patient cannot be injured by objects in the vicinity if the patient falls.
- Watch the patient for signs of dizziness and support the patient if necessary.
- Do not leave the patient unattended during a test.

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

If the *Spirette* or its wrapper have a defect, discard the *Spirette*, take another *Spirette*, and visually recheck.

To connect *Easy on-PC* sensor and to launch *EasyOne Connect*

1 Connect *Easy on-PC* sensor to a USB port on your PC.



- The *Easy on-PC* sensor draws power from the USB port. No other power source is necessary.

2 On your PC, launch the *EasyOne Connect* software.

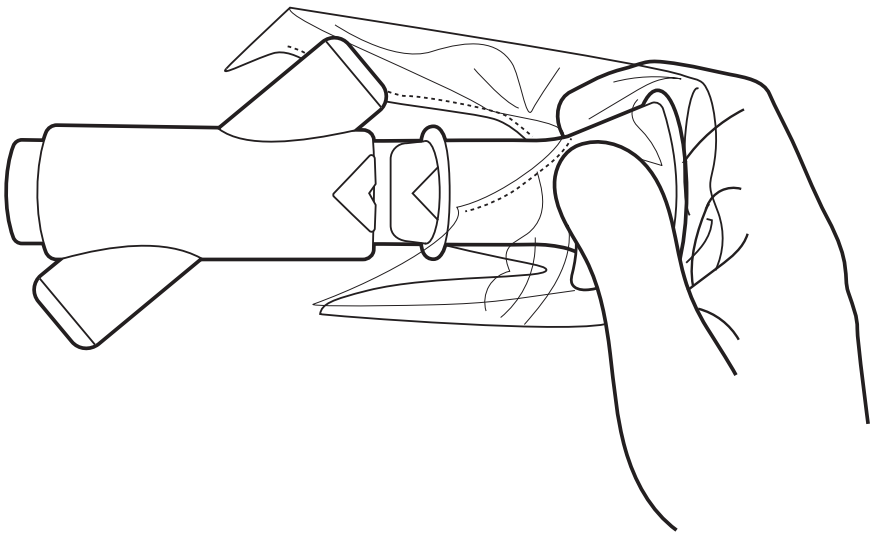
To prepare the test

1 Partly unwrap the *Spirette*.

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

2 Caution! An incorrectly inserted *Spirette* can lead to inaccurate measurement, false results, and false diagnosis.
Fully insert the *Spirette* into the *Spirette* holder as depicted below, but keep the partly unwrapped wrapper on the mouthpiece of the *Spirette*.

- The shape of the *Spirette* and the *Spirette* holder guide the orientation of the *Spirette*. You can only insert the *Spirette* fully if it is positioned correctly.



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 *Spirette*. Proceed with step **9**.

8 If the selection window is displayed, do one of the following:

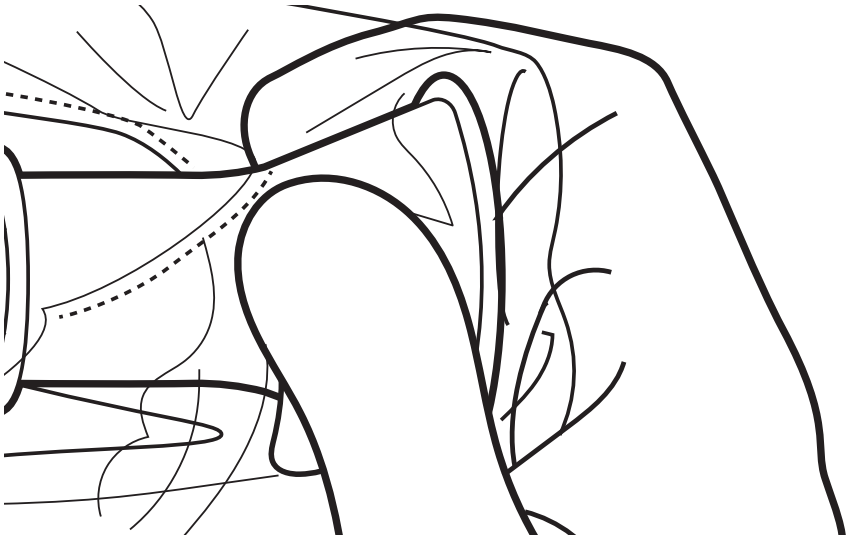
   a) To add a trial to the existing test, choose **Add Trial**.

   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 *Spirette*.

9 To set the baseline, seal off one end of the *Spirette* 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 *Spirette*, but keep the wrapper.

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 the *Easy on-PC* sensor 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 40

To perform the FVC breathing maneuver

1 Tell the patient to fill the lungs completely.

2 Tell the patient to take the *Spirette* into the mouth and to seal the lips around the *Spirette*.

The patient must not block the opening with the tongue or teeth or bite down excessively on the *Spirette*.

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 *Spirette* 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:

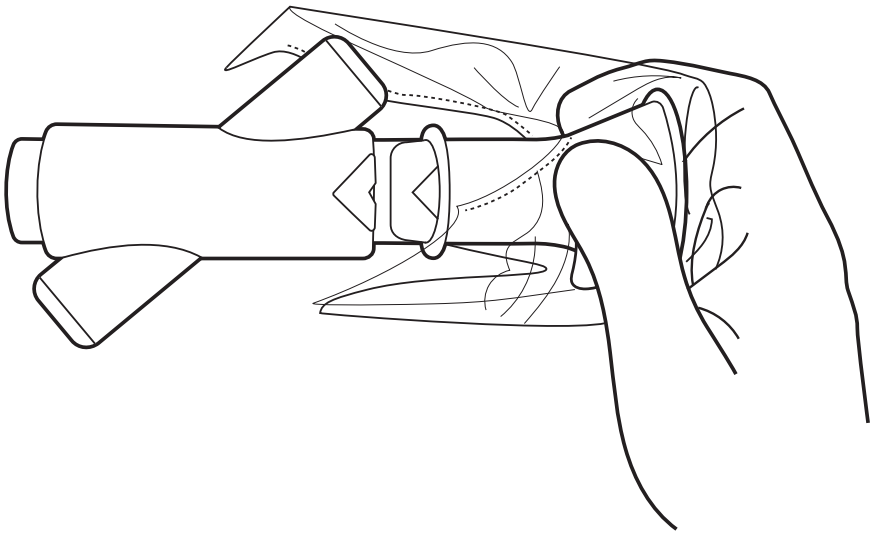
a) Review the test quality that is displayed in the **Test Information** area.

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 Grip the *Spirette* with the wrapper again and pull the *Spirette* out of the *Spirette* holder. Do not touch the *Spirette*.



2 Dispose of the *Spirette* together with the wrapper.

3 Caution! Always wear disposable gloves. Between patients, always exchange disposable gloves, clean the *Easy on-PC* sensor, and disinfect hands. Make sure that no fluid penetrates the *Easy on-PC* sensor while cleaning. To clean the *Easy on-PC* sensor, do not immerse the *Easy on-PC* sensor in any fluid.
To clean the *Easy on-PC* sensor 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 and wipe the *Easy on-PC* sensor.
   Maintenance 43

   b) Put down the *Easy on-PC* sensor.

   c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.

4 To print the report immediately, choose **Print** from the bottom right of the screen.

   ✓ The report is generated and sent to the configured printer.

5 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.

6 To return to the main menu, choose **Main Menu** from the menu bar.

⇨ List of cleaning solutions for Easy on-PC sensor 44
About interpreting results 37

5.5.2. Performing a bronchial provocation test

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 *Spirette* 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 57
About preparation of spirometry and instructions for the patient 27
Performing the breathing maneuver for the FVL test 41

⚠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 *Spirette*, contamination from an infected patient can be deposited on the *Spirette*. The contamination from an infected patient can later be passed on to the next patient who is tested.

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

- Always replace the *Spirette* with a new one between patients or when performing lung function test on yourself.
- Only use an original *Spirette* 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 40

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

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

If the *Spirette* or its wrapper have a defect, discard the *Spirette*, take another *Spirette*, and visually recheck.

⇨ About interpreting results 37

5.6. About interpreting results

Quality grades are included in all results and indicate a result's reliability. The quality grades range from *A* to *F*. Their interpretation differs depending on the test. List of quality grades for tests 38.

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

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

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

⇨ List of tests and parameters 21
List of quality messages and quality grades 37
Configuration 48

5.7. List of quality messages and quality grades

5.7.1. 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], [15], and [17].

Quality grading is based on the sources [4], [13], [14], [15], and [17].

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

⇨ List of bibliographic references 69

5.7.2. 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 from the parameter table on the result screen (**Patients > select patient > History > select test**).

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

⇨ Application Notes for further information 3

5.7.3. 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 and the FEV1 parameter according to the 2019 standard

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

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

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

Rating	Criteria	Result reliability
A	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV_1 and FVC values is equal to or less than 100 mL (80 mL if FVC <1.0 L) (for age 6 and under: 80 mL or 8% of FVC or FEV_1 whichever is greater)	Reliable result
B	At least 3 acceptable trials (for age 6 and under: 2 acceptable) AND the difference between the best two FEV_1 and FVC values is equal to or less than 150 mL (100 mL if FVC <1.0 L) (for age 6 and under: 100 mL or 10% of FVC or FEV_1 whichever is greater)	Reliable result
C	At least 2 acceptable trials AND the difference between the best two FEV_1 and FVC values is equal to or less than 200 mL (150 mL if FVC <1.0 L) (for age 6 and under: 150 mL or 15% of FVC or FEV_1 whichever is greater)	Reliable result
D (1)	At least 2 acceptable trials but the results are not reproducible according to Quality message: *Result not reproducible*	Result might have clinical utility. Interpret with caution.
D (2)	Only one acceptable trial Quality message: *Only one acceptable trial*	Result might have clinical utility. Interpret with caution.
F	No acceptable trial available	Result should not be used.

Quality grades for the SVC test

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

6. Breathing maneuvers for all available tests

6.1. 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 26

6.2. 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 *Spirette* into the mouth and to seal the lips around the *Spirette*.
   - The patient must not block the opening with the tongue or teeth or bite down excessively on the *Spirette*.
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 *Spirette* 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 26

6.3. Performing the breathing maneuver for the FVL test

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

Recommended material

☐ A nose clip

Prerequisite

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

1 Tell the patient to breathe at rest.

2 Tell the patient to fill the lungs completely.

3 Tell the patient to take the *Spirette* into the mouth and to seal the lips around the *Spirette*.

   The patient must not block the opening with the tongue or teeth or bite down excessively on the *Spirette*.

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 *Spirette* in the mouth, to breathe in, and to continue inhaling until the lungs are completely filled again.

6 Tell the patient to take the *Spirette* 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 26

6.4. Performing the breathing maneuver for the MVV test

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

Recommended material

☐ A nose clip

Prerequisite

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

1 Tell the patient to breathe at rest.

2 Tell the patient to fully exhale.

3 Tell the patient to take the *Spirette* into the mouth and to seal the lips around the *Spirette*.
   - The patient must not block the opening with the tongue or teeth or bite down excessively on the *Spirette*.
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 *Spirette* out of the mouth and to breathe normally again.

⇨ Performing spirometry 26

6.5. Performing the breathing maneuver for the SVC test

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

Recommended material

☐ A nose clip

Prerequisite

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

1 Tell the patient to breathe at rest.
2 Tell the patient to take the *Spirette* into the mouth and to seal the lips around the *Spirette*.
   - The patient must not block the opening with the tongue or teeth or bite down excessively on the *Spirette*.
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 *Spirette* out of the mouth and to breathe normally again.

⇨ Performing spirometry 26

7. Maintenance

7.1. Hygiene and cleaning

7.1.1. Avoiding contamination while performing spirometry

When handling the *Spirette*, you must be careful not to contaminate the next *Spirette* or *Easy on-PC*.

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

1 To protect yourself and to avoid infection of patients, wear disposable gloves.

2 Never touch the *Spirette* directly, but partly unwrap the wrapper and grip the *Spirette* 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 *Spirette* with the wrapper again and dispose of the *Spirette* together with the wrapper.

5 Clean the device after performing spirometry.

6 Caution! Always wear disposable gloves. Between patients, always exchange disposable gloves, clean the *Easy on-PC* sensor, and disinfect hands. Make sure that no fluid penetrates the *Easy on-PC* sensor while cleaning. To clean the *Easy on-PC* sensor, do not immerse the *Easy on-PC* sensor in any fluid.
To clean the *Easy on-PC* sensor 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 and wipe the *Easy on-PC* sensor.

   b) Put down the *Easy on-PC* sensor.

   c) Take off or change the disposable gloves and disinfect your hands before you put on new disposable gloves.

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Calibration check 60

7.1.2. List of cleaning solutions for *Easy on-PC* sensor

Do not use just any cleaning solution for *Easy on-PC* sensor. Only use the listed cleaning solutions.

⚠ CAUTION

ELECTRIC SHOCK, FAILURE OF *EASY ON-PC*, AND FALSE DIAGNOSIS

- Follow the disinfectants' instructions for use.
- Make sure that no fluid penetrates the *Spirette* holder or the inside of *Easy on-PC* sensor while cleaning.
- To clean *Easy on-PC* sensor, do not immerse *Easy on-PC* sensor in any fluid.
- After cleaning and disinfection, make sure that there is no obvious or wet residue deposited on the device.

To clean *Easy on-PC* sensor from environmental dirt, you can use a damp cloth.

After each patient, clean *Easy on-PC* sensor. You can use a soft cloth with a cleaning solution according to the following list:

- Alcohol-based disinfectants (e.g., ethanol, isopropanol)
- Hydrogen-peroxide-/H_2O_2-based disinfectants (e.g., Oxivir® Tb Wipes)
- Quaternary-ammonium-based disinfectants (e.g., Sani-Cloth®)
- Chlorine-based solutions (e.g., Tristel™)

7.2. Cybersecurity

To maintain safety regarding cybersecurity, you must follow the guidelines that are laid out in this chapter.

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

7.2.2. About password policies and password expiration

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

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

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

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

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

- Passwords should be renewed after 90 days.

⇨ About user handling and the default password 48

7.2.3. About periodical software updates and patches

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

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

⇨ Installing or updating EasyOne Connect software on your PC 17
Contact information 4

7.2.4. About backups

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.

To back up the database, perform the following steps:

1) Choose **Utilities > Configuration > General > Storage**
2) Choose **Backup**
3) Choose the desired location of the backup database.

To restore a database, you can choose either **Select**, to replace the current database with the backup database, or **Import**, to merge the current database with the backup database.

⇨ Utilities > Configuration > General > Storage 49

7.2.5. 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 *Easy on-PC* has been compromised, contact the *NDD* Servicing Department.

7.2.6. Using *Easy on-PC* 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 Connect*. To activate user handling, do the following:

a) Choose **Utilties > 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 Connect*.

2 To prevent unauthorized access when *EasyOne Connect* 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 time period of inactivity after which automatic log off is to be activated.

d) Choose **Save**.

✓ After the time period that you have set, *EasyOne Connect* 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 Connect*.

⇨ About user handling and the default password 48

8. 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.

8.1. 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.

8.2. About user handling and the default password

Utilities > Configuration > General > User Handling

Inactive user handling

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

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

Active user handling

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

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

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

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

User groups

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

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

⇨ About connectivity and data exchange 25

8.3. Description of general configurations for *EasyOne Connect*

8.3.1. 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**.

8.3.2. 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 *EasyOne Connect* as a database client to a database server. SQL database servers are supported.
Import button	To import a second database file into the currently active database—both databases are merged. Entries that exist in both databases are not duplicated.
Backup button	To save a copy of the currently active database file.
Load Configuration button	To load a configuration file—a configuration file can contain settings, for example for predicted normal values, report headers, or user handling.
	Be aware that loading a configuration overrides the current configuration settings!
Change database password	The password of the database can be changed. Once the password is changed, the manufacturer can not recover the password.
	Make sure, to remember the password. Otherwise the data cannot be accessed anymore.

🗔 Storage configuration

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EasyConnect – Database Connection:
Application Notes for further information 3

8.3.3. 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 *EasyOne Connect*.
Patient Entry options	To choose between different entry formats for the patient's age.

System Settings

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

8.4. Description of test configurations for *EasyOne Connect*

8.4.1. Utilities > Configuration > Test > General

Best Value selection

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 FEV_6) and the largest FEV_1 from all acceptable tests (unless all tests are unacceptable). Other parameters are taken from the best trial (also defined by the largest sum of FEV_1 and FVC).

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

Best Trial selection

If you choose the **Best Trial** option, the complete best trial is selected for assessing the quality of the test and for assessing the interpretation. The trial with the largest sum of FVC and FEV_1 is selected, as suggested by ATS and ERS.

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

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

Curve Overlay

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

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

Test Procedure

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

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

General

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

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

To display ratio parameters (for example FEV_1/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.

“Limit number of trials...”

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

8.4.2. 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.

Reference Predicted Normal Values:
Application Notes for further information 3
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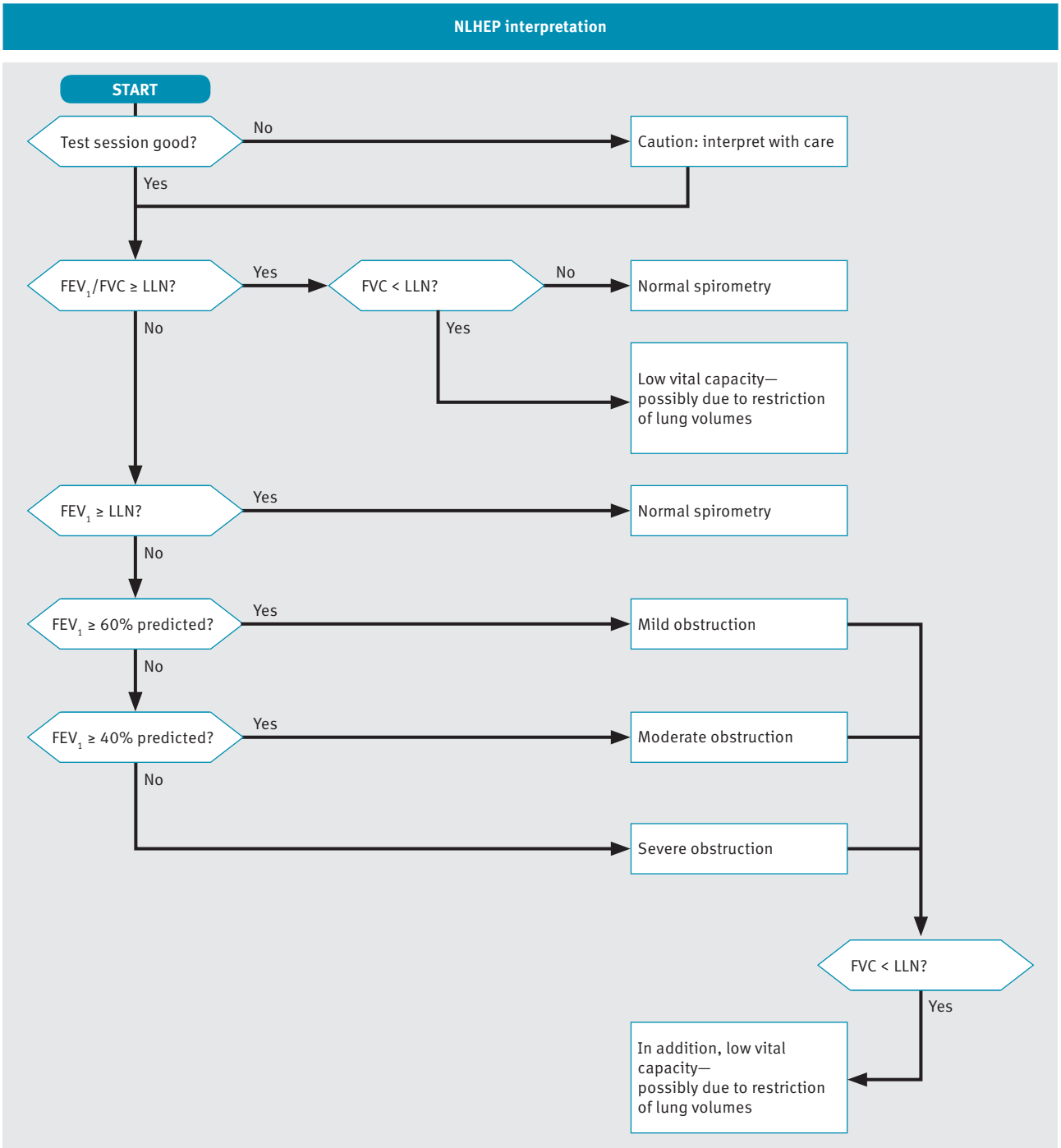
System Interpretation

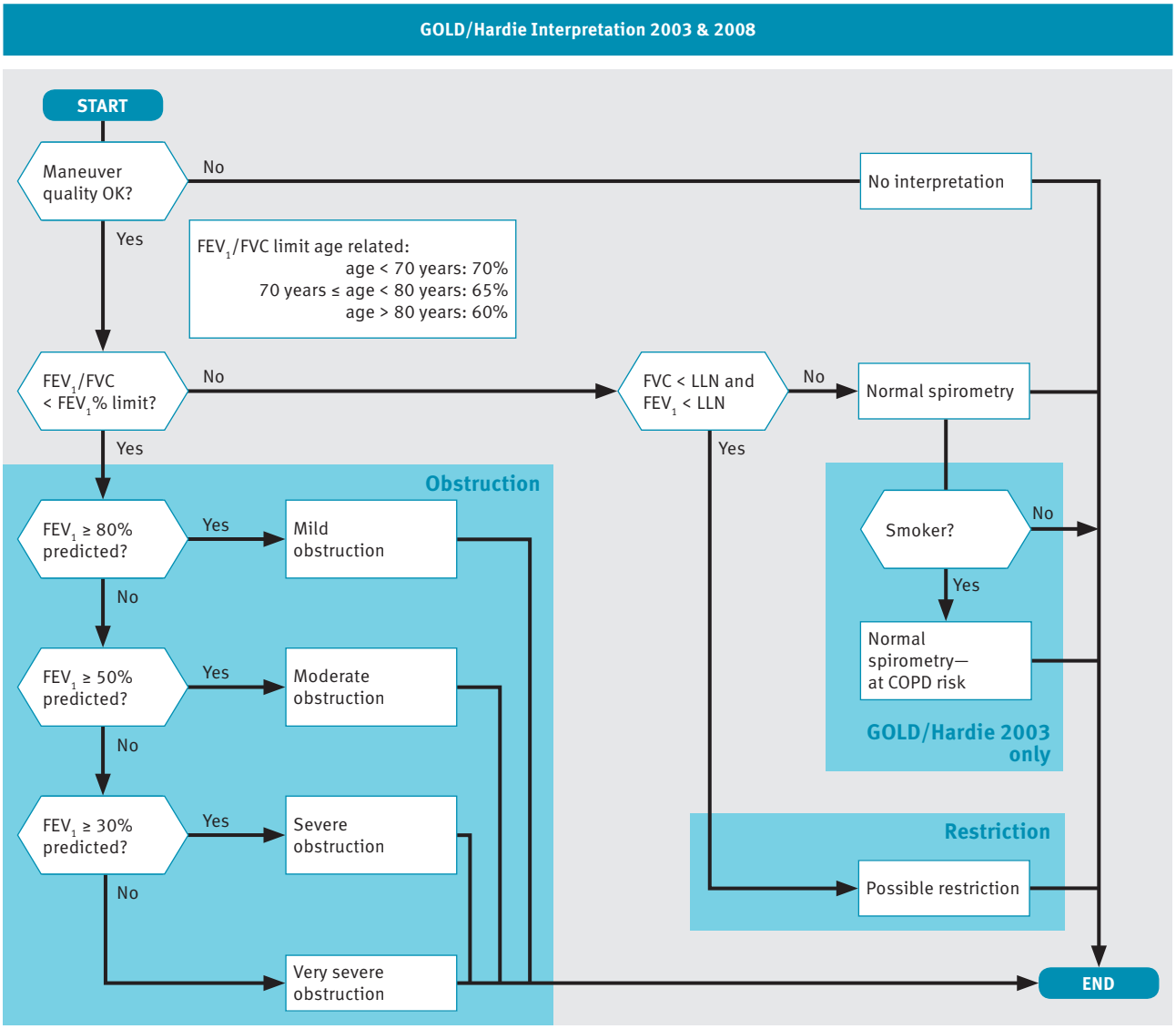
Choose from the interpretation standards NLHEP, GOLD/Hardie, and NICE, or disable automatic interpretation.

The default setting is GOLD/Hardie.



☐ NLHEP interpretation algorithm

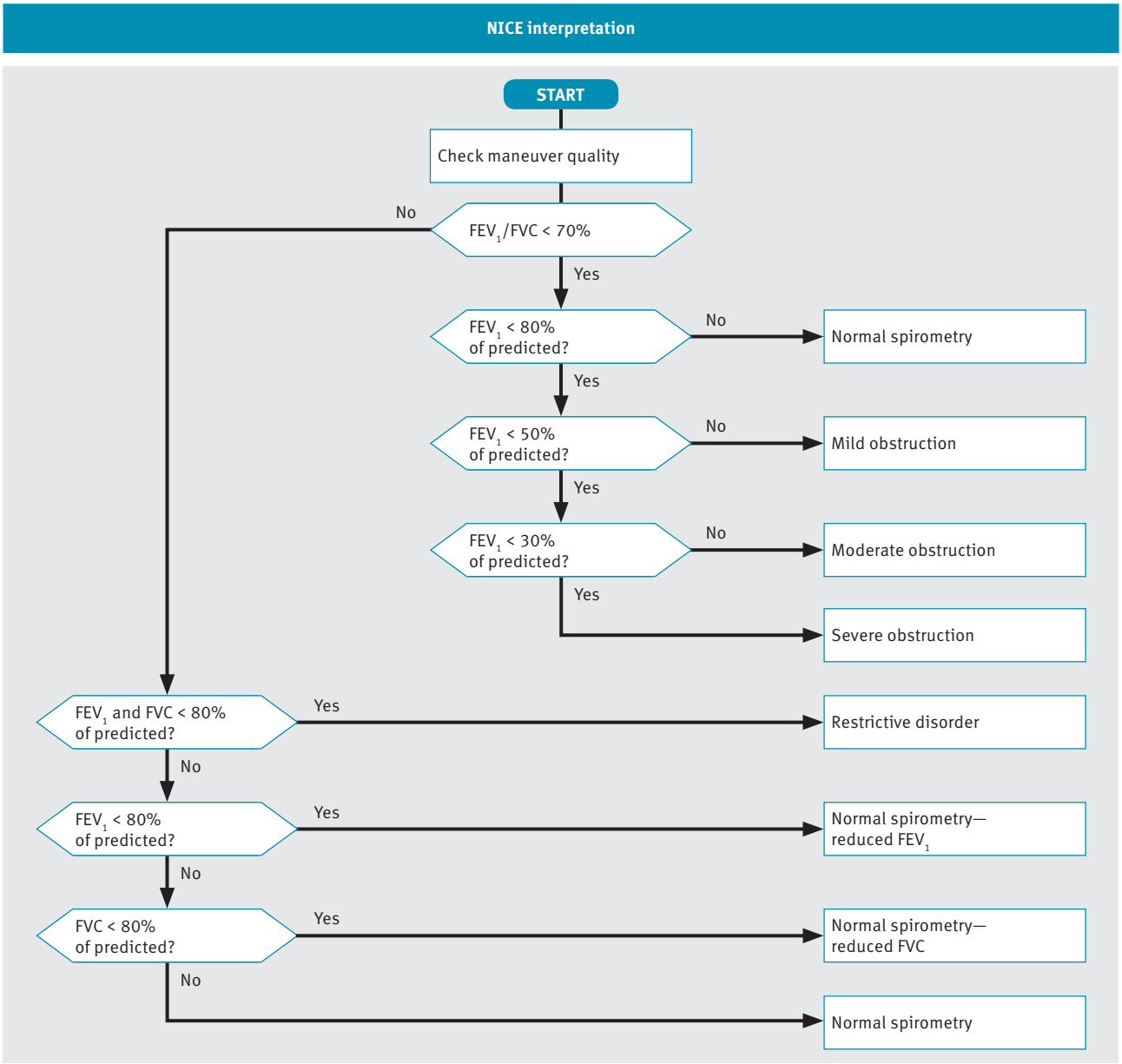
The diagram above shows how the interpretation for NLHEP is determined, according to Ferguson (2000/NLHEP) [4].



GOLD/Hardie interpretation algorithm

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

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



NICE interpretation algorithm

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

Adjusting result values based on ethnicity

Some studies for predicted values take into account the physiological 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 a factor in percent for adjusting a patient's result values based on their ethnicity. You can then compare the adjusted result values with the predicted values for Caucasian patients.

There is an exception to this function. If specific values are available for the chosen group of predicted values and for the chosen ethnic group, they will be used instead of the factor in percent that you enter here.

The American Thoracic Society's publication *Lung Function Testing: Selection of Reference Values and Interpretative Strategies* [8] provides guidance on the subject of adjusting result values based on ethnicity. This paper recommends using 88% as a factor when comparing the result values of African patients with the predicted values for Caucasian patients. For other ethnic groups, the paper provides general guidance on selecting adjustments.

⇨ List of bibliographic references 69

8.4.3. 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.

8.4.4. Utilities > Configuration > Test > FVC / FVL

Applied Spirometry Standard

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

Note that switching from one standard to another does not affect the evaluation of existing tests. Older versions of EasyOne Connect software behave consistently with the later versions where the 2005 spirometry standard is applied.

Preferred Test Type

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

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

To allow the patient to breathe regularly through the *Spirette* 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 51

FVC Selection

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

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

If you choose the **FEV_6** option, the measurement stops after six seconds. With this setting, none of the intermediate flow values, e.g. MEF_{25}, FEF_{25-75}, are reported.

For diagnostic purposes, the FVC value is comparable with the FEV_6 value. The advantage of choosing the **FEV_6** 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 69

Parameter

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

8.4.5. Utilities > Configuration > Test > SVC

Parameter

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

Type

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

8.4.6. Utilities > Configuration > Test > MVV

Parameter

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

8.4.7. 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.

8.4.8. 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.

8.4.9. 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* distribution partner or the *NDD* Servicing Department.

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 lung age, choose **Off**.

The default configuration is **Smoker only**.

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8.5. 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.

EasyOne World/EasyOne Plus

For *EasyOne World/EasyOne Plus*, consult the corresponding Operator's Manual.

EasyOne World/EasyOne Plus Operator's Manual

8.6. 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)

9. Calibration check

Calibration check is a preventive inspection to ensure that *Easy on-PC* sensor calibration has not been adversely affected. Calibration check is different from calibration and is the procedure used to validate that *Easy on-PC* sensor is within calibration limits. According to the ATS/ERS standard 2019 [17, List of bibliographic references 69], the user must perform calibration checks daily. The user must always perform a calibration check with the same configuration as during the spirometry. If tests have been performed using a filter, calibration checks have to be performed using a filter.

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

⚠ CAUTION

FALSE DIAGNOSIS

For unforeseen reasons, malfunction of *Easy on-PC* can lead to false results and false diagnosis.

- Perform calibration checks periodically.
  Calibration check 60
  Checking for correct operation of Easy on-PC 65

MALFUNCTION

Calibration of *Easy on-PC* is not possible. You can merely check *Easy on-PC* for correct calibration.

- Do not attempt to repair *Easy on-PC* yourself. A third-party service must not attempt to repair *Easy on-PC* either.
- Do not open or remove the casing.
- If a calibration check fails, contact only your *EasyOne* distribution partner or the *NDD* Servicing Department for repairs.
  Contact information 4

9.1. Performing a calibration check

Required materials

- ☐ A calibration syringe within ±0.015 L or ±0.5% accuracy of its full scale (separately available)
- ☐ A *Spirette* cal check adapter (separately available)
- ☐ A *Spirette*

Prerequisites

- ☐ You have configured the correct syringe volume.

☐ You have connected the *Easy on-PC* sensor to your PC and launched *EasyOne Connect*.
Utilities > Configuration > Test > CalCheck 57

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

If you do not reach ±3.0% accuracy, troubleshoot. If you are not able to remedy the defect, contact your *EasyOne* distribution partner or the *NDD* Servicing Department.

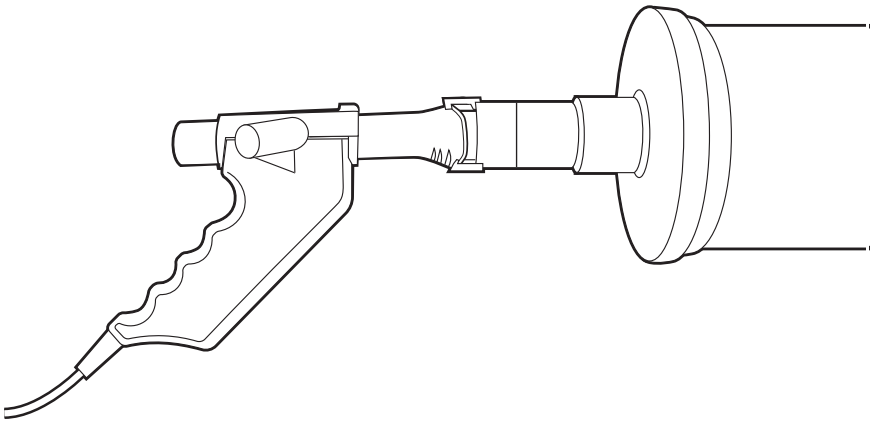
1 Push and draw the piston five times.
- This step is necessary to assure that the temperature inside the syringe and the room temperature are the same. A temperature difference may lead to a failed calibration check.
- Therefore also be careful not to warm the body of the calibration syringe with your hands.

2 Unwrap the *Spirette*.

3 Insert the *Spirette* into the *Easy on-PC* sensor.
- The shape of the *Spirette* and the *Spirette* holder guide the orientation of the *Spirette*. You can only insert the *Spirette* if it is in the correct orientation.

4 Attach the *Spirette* cal check adapter to the calibration syringe.
- To avoid any temperature differences, fixate the syringe with two fingers at the one end of the syringe only.

5 Attach the nozzle of the *Spirette* cal check adapter to the *Spirette* and make sure that the piston is fully inserted.
The *Spirette* snaps into the nozzle of the *Spirette* cal check adapter.



6 Choose **Utilities > Check Calibration > Linearity Cal Check** and confirm the message that is displayed.

7 Wait for the baseline to be set.

8 Push the piston of the calibration syringe all the way in.

9 Continuously push and pull the syringe repeatedly until a green quality message is displayed.

- Try to reproduce the same flow-volume curve with each repetition.

10 Repeat step **7** until the green *Accuracy confirmed* message is displayed.

- 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.
- Calibration checks are filed in the history menu as patients with the last name *Calibration Check*.

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Contact information 4

9.2. Performing biological quality control

9.2.1. About biological quality control

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

Overview

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

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

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

Detailed description

FEV_1, FVC, and FEV_6 are the spirometry parameters used for biological quality control. The software will establish a baseline mean value (precision range) for each known subject and sensor from trials repeated daily for 20 days.

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

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

⇨ Performing spirometry 26

9.2.2. Performing and assessing biological quality control

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

Prerequisite

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

■ To perform biological quality control

1 Choose **Utilities > Calibration Check > Biological Quality Control**.

2 If you test the subject for the first time, do the following:

a) Choose **Add New BioCal Subject**.

b) Choose **New**.

c) Enter the required data and choose **OK**.

d) From the patient selection list, select the subject that you have just added.

e) Choose **Add Selected Subject**.

3 If you test a known subject that you have tested before, select the known subject from the BioCal subject selection list.

4 Choose **Add New Test**.

5 Choose a test.

6 Perform the test like a regular spirometry test.

■ To assess the biological quality control

1 From the BioCal subject selection list, select the known subject.

2 To view a visualization of the parameters over time, choose **Graph**.

3 Evaluate the quality criteria for biological quality control.

4 To print a report, choose the reports button.

⇨ Performing spirometry 26

9.2.3. List of quality criteria for biological quality control

For each parameter (FEV_1, FVC, FEV_6) an individual quality criterion is calculated. Additionally the lowest grade of all parameters is reported.

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

Specifications of quality criteria for biological quality control

10. Servicing and troubleshooting

10.1. Checking for correct operation of *Easy on-PC*

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, *Easy on-PC* is operating correctly.

b) If the results of steps **1** and **2** are not plausible, troubleshoot.

c) If you are not able to remedy the defect, contact your *EasyOne* distribution partner or the *NDD* Servicing Department.

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10.2. List of troubleshooting solutions

If you encounter problems operating *Easy on-PC*, consult the table below.

Problem	Possible cause	Solution
When *EasyOne Connect* is launched, you see the error message from the next column.	Self-test failed	Quit the program and restart. If you receive the same message again, contact your *EasyOne* dealer or the *NDD* Servicing Department.
When you start a test, you see the message “Check *Spirette* insertion”.	The *Spirette* is not correctly positioned.	Ensure that the triangle on the spirometer is lined up with the triangle on the *Spirette*.
Calibration check outside of ±3.5%.	The *Spirette* is not correctly positioned.	Ensure that the triangle on the spirometer is lined up with the triangle on the *Spirette*.
	You have not used an *NDD* adapter.	Use the *Spirette* cal check adapter.
	There are leaks in the syringe connection.	Check the connections.
	The specified syringe volume differs from the actual syringe volume.	Choose the correct syringe volume under **Configuration > Test > CalCheck**.

Troubleshooting solutions

⇨ List of quality messages and quality grades 37
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10.3. About reactivating *Easy on-PC* after storage

If you have stored *Easy on-PC* sensor for a longer period of time, follow this procedure to ensure correct operation.

1 Verify that *Easy on-PC* sensor has been stored under the specified storage conditions.

2 Perform a software update of *EasyOne Connect*.

3 Check for correct operation of *Easy on-PC* sensor

4 If you encounter difficulties, contact your *EasyOne* dealer or the *NDD* Servicing Department.

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10.4. 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.

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11. Specifications and bibliography

11.1. List of specifications for *Easy on-PC*

Measuring accuracy	Volume Flow MVV	±2% or 0.050 L ±2% or 0.020 L/s, (except PEF) PEF: ±5% or 0.2 L/s ±5% or 5 L/min
Measuring range		±16 L/s
Resolution		4 mL/s
Resistance		Approximately 0.3 cm H_2O/L/s at 16 L/s
Measurement principle		Ultrasonic transit-time measurement
Sample rate		400 Hz
Mode of operation		Continuous operation
Languages		Chinese, Croatian, Danish, Dutch, English, Finnish, French, French (Canada), German, Italian, Japanese, Norwegian, Portuguese, Portuguese (Brazil), Russian, Spanish, Swedish, Turkish, Vietnamese
Printing option		Direct to printer or over network
Data Management		*EasyOne Connect* PC software
Export/EMR		HL7, XML, GDT
Hardware interface		USB 2.0 (compatible with USB 1.1, 2.0, 3.0 and 3.1 ports)
Age range for patients		>4 years
Respiratory tube		Disposable *Spirette* respiratory tube
Appliance class		not applicable
IP Code		IP20
Voltage		5 V DC
Power consumption		0.5 W
Instrument classification		Type BF applied part (the surface of the *Easy on-PC* enclosure) Additional comment: The *Easy on-PC* cable can get in contact with the patient, but it is not defined as an applied part. Furthermore, *Easy on-PC* is not intended to be used in the presence of oxygen rich environments.
Transport and storage conditions	Temperature	-20°C to +50°C (-4°F to +122°F)
	Humidity	5% to 95% non-condensing
	Atmospheric pressure	500 hPa to 1060 hPa
Operating conditions	Temperature	0°C to 40°C (32°F to 104°F)
	Humidity	5% to 95%
	Atmospheric pressure	620 hPa to 1060 hPa

Specifications for *Easy on-PC*

Certifications and 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 9001 Quality management systems — Requirements
		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 *NDD* website under “Certificates”
	US	FDA 510(k) market clearance
	Associations and institutes	ATS/ERS 2019 and 2005, SSA Disability, NIOSH, OSHA
Life time		7 years

Specifications for *Easy on-PC*

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Reference Predicted Normal Values:
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11.2. List of order numbers and accessories for *Easy on-PC*

Easy on-PC	International	2700-3
Spirette Standard box of 50 pcs.	International	2050-1
Spirette Standard box of 200 pcs.	International	2050-5
Spirette Standard box of 500pcs.	International	2050-10
Nose Clip box of 25 pcs.	International	3000-50.21
NDD Calibration Syringe 3 L with Spirette Cal Check Adapter	International	2030-2
Spirette Cal Check Adapter	International	2030-3
EasyOne Filter SP	International	2091-412

List of order numbers and accessories for *Easy on-PC*

11.3. 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*

11.4. List of bibliographic references

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[16] American Thoracic Society *Recommendations for a Standardized Pulmonary Function Report*. American Journal of Respiratory and Critical Care Medicine, Vol 196, 2017, pp 1463-1472

[17] Graham, Steenbruggen, Miller, et al. *Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement*. American Journal of Respiratory and Critical Care Medicine, Vol 200, Iss 8, 2019, pp e70–e88.

⇨ *Reference Predicted Normal Values*:
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12. Appendix A - Electromagnetic compatibility (EMC)

12.1. General

Environment

Intended use/Indications for Use of Easy on-PC spirometer 2

EMC conformance

Easy on-PC 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). *Easy on-PC* is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the information given in tables below.

Safety information

Safety information regarding electromagnetic compatibility 11

Compliant cables and accessories

Easy on-PC has no accessories that affect EMC compliance.

Wireless module

No wireless module is included.

12.2. Electromagnetic emission

Guidance and manufacturer's declaration – electromagnetic emissions

Easy on-PC is intended for use in the electromagnetic environment specified below. The user of *Easy on-PC* should assure that it is used in such an environment

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	*Easy on-PC* uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

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

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class B	*Easy on-PC* 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 Harmonic emissions 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

12.3. Electromagnetic immunity

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

Guidance and manufacturer's declaration – electromagnetic Immunity

Easy on-PC is intended for use in the electromagnetic environment specified below. The user of *Easy on-PC* 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	None
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% UT (0.5 cycles) 40% UT (5 cycles) 70% UT (25 cycles) <5% UT for 5 s	<5% UT (0.5 cycles) 40% UT (5 cycles) 70% UT (25 cycles) <5% UT for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
	Note: UT 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 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz		30 A/m
	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 *Easy on-PC* is used exceeds the applicable RF compliance level above, the *Easy on-PC* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the *Easy on-PC*.		
	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 *Easy on-PC*

Easy on-PC is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of *Easy on-PC* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *Easy on-PC* 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
	$d = 0{,}35\sqrt{P}$	$d = 0{,}35\sqrt{P}$	$d = 0{,}7\sqrt{P}$
0.01 W	0.035 m	0.035 m	0.07 m
0.1 W	0.11 m	0.11 m	0.22 m
1 W	0.35 m	0.35 m	0.70 m
10 W	1.1 m	1.1 m	2.2 m
100 W	3.5 m	3.5 m	7.0 m
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
Note: An additional factor of 10/3 is used in calculating the recommended separation distance to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.			

Recommended separation distances between portable and mobile RF communications equipment and *Easy on-PC*

13. Appendix B - Optional usage with *EasyOne Filter SP*

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

13.1. Intended use/ Indications for Use

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

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

13.2. Compatible software

Required software of the associated device:

- *EasyOne Connect* software V3.9.3.x or higher.

13.3. Safety information

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Malfunction

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

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

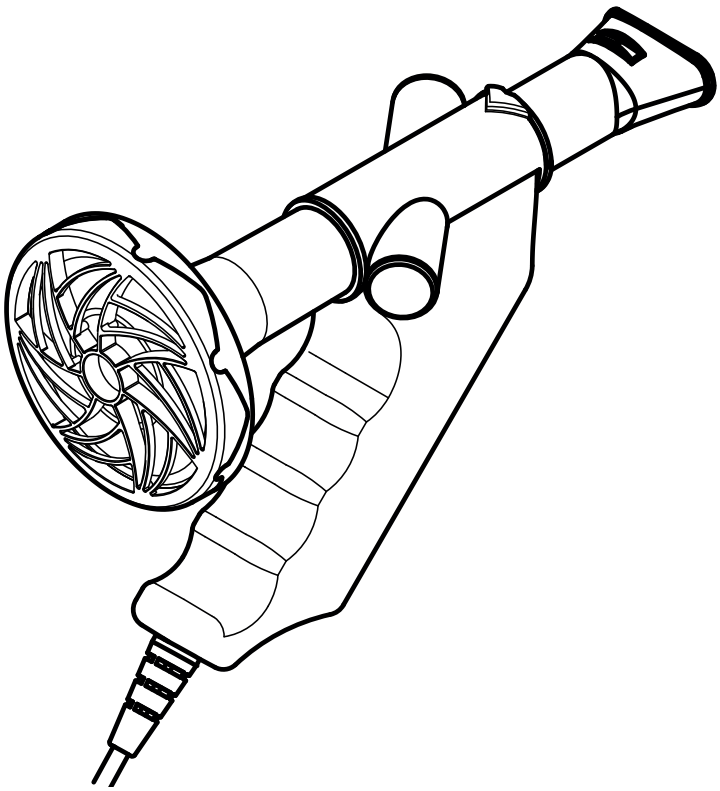
Environmental conditions

Environmental conditions outside the range can cause measurement errors.

- Use, store, and transport the *EasyOne Filter* only within the specified environmental conditions.
  List of Specifications 84

Cross-contamination	If operators do not follow hygienic procedures, operators and patients may be infected with pathogens from other patients. • Follow all applicable hygienic procedures. Avoiding contamination while performing spirometry 43 • Exchange the filter between patients. • Dispose of the filter after use.
False diagnosis	For unforeseen reasons, malfunction of the spirometry device can lead to false results and false diagnosis. To make sure the configuration is set properly • Perform calibration checks periodically.

13.4. Overview of *EasyOne Filter*



The filter can optionally be attached at the distal end of the *Spirette* to filter pathogens from the exhaled air. Cross contamination is prevented by using the devices and breathing tubes as intended.
Intended use/Indications for Use of Easy on-PC spirometer 2

The filter is designed to work accurately with the *Spirette* respiratory tube. If the correct configuration is selected, the measurements of relevant spirometry parameters are not influenced.

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

13.5. Performing tests using *EasyOne Filter*

To perform a test using a filter, follow the instructions below while attaching the filter. For performing the test, refer to
Performing a complete test 29↗.

Prerequisites

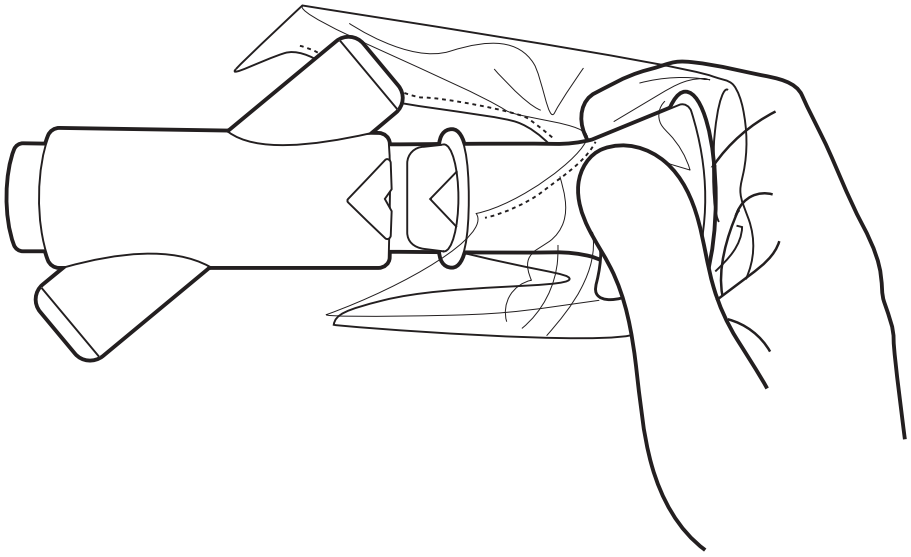
- ☐ You have configured the use with filters.
  Configuring the use with EasyOne Filter 82↗
- ☐ You have checked for further prerequisites.
  Overview of the spirometry workflow 26↗

■ To attach *EasyOne Filter*

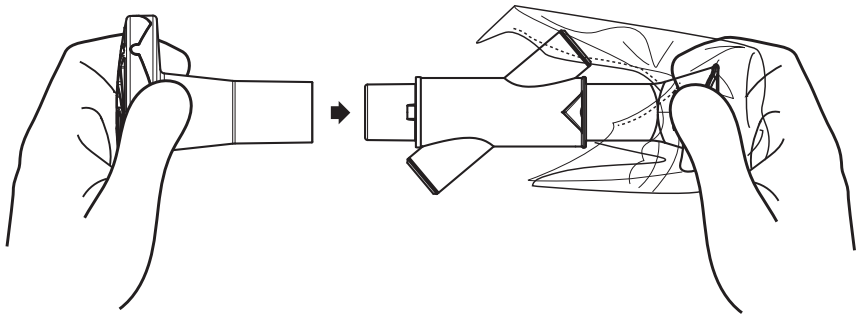
1 Unpack the filter.

2 Partly unwrap the *Spirette*.

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

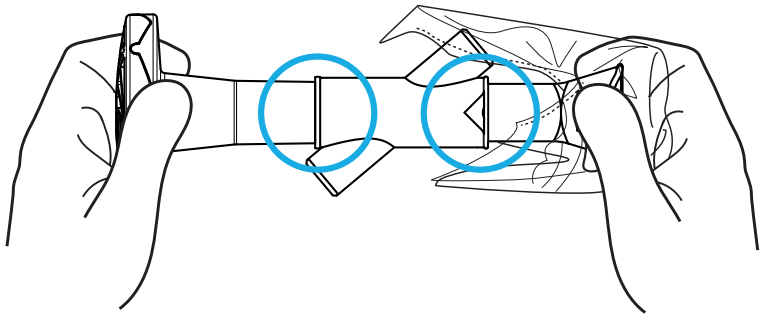


3 Keeping the partly unwrapped wrapper on the mouthpiece of the *Spirette*, fully insert the *Spirette* into the *Spirette* holder.



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

4 Hold the *Spirette* holder and the wrapped *Spirette* with one hand, and attach the filter at the end of the *Spirette*.



5 Caution! An incorrectly inserted *Spirette* can lead to inaccurate measurement, false results, and false diagnosis.
Ensure that the *Spirette* and the filter are fully inserted.

a) If the *Spirette* is not fully inserted, gently press against the filter and the *Spirette proximal end (mouthpiece)* until the filter and the *Spirette* are fully inserted.

b) Check again if the *Spirette* and the filter are fully inserted.

6 Make sure that the wrapper protects the mouthpiece of the *Spirette* until you hand the *Spirette* holder to the patient.

To perform a test using *EasyOne Filter*

1 Check for further prerequisites.
Performing spirometry 26

2 Ensure whether filter use is enabled.
Configuring the use with EasyOne Filter 82

3 When choosing a test on the user interface, the **Inline Filter Confirmation** window is displayed. Confirm the use of a filter.
   - If the first trial or test of one session was performed with a filter, all consecutive trials or tests of the same session must be performed with a filter.
   - If the first trial or test of one session was performed without a filter, all consecutive trials or tests of the same session must be performed without a filter.

4 Perform the test.
Performing a complete test 29

To end the test

1 Caution! Cross-contamination.
Always use disposable gloves and disinfect hands between patients.

2 Remove the filter.

3 Directly dispose of the filter after use. The filter is a disposable for single-patient use. It is not intended to be cleaned.

13.6. Configuring the use with *EasyOne Filter*

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

To configure the use with *EasyOne Filter*

1 Choose **Utilities > Configuration > Device > Inline Filters**.

2 Choose your spirometry device which is to be used with a filter.

3 Select the **Use Inline Filter** check box.

4 From the **Select inline filter configuration** drop-down list, choose the *EasyOne Filter*.

5 Choose **Save**.
   - The **Import inline filter configuration** function is only for *NDD* maintenance purposes.

13.7. Performing a calibration check using *EasyOne Filter*

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

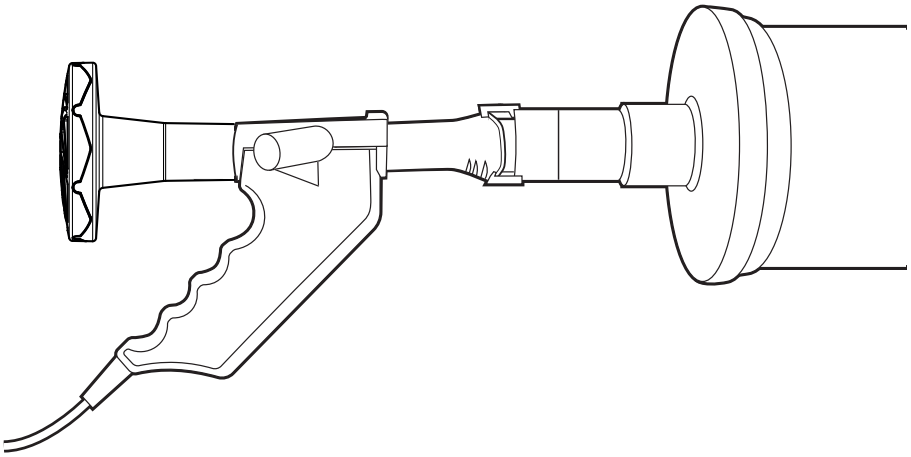
Prerequisites

- ☐ You have configured the use with filters.
  Configuring the use with EasyOne Filter 82
- ☐ You have checked for further prerequisites.
  Performing a calibration check 60

■ To perform a calibration check using *EasyOne Filter*

1 Follow the instructions to the point where the device is connected to the calibration syringe.
Performing a calibration check 60

2 Attach the filter at the end of the *Spirette*.



3 Ensure that the *Spirette* and the filter are fully inserted.

a) Align the arrow on the *Spirette* with the arrow on the *Spirette* holder.

b) If the *Spirette* and/or the filter are not fully inserted, gently press against both until the *Spirette* and the filter are fully inserted.

c) Check again if *Spirette* and filter are fully inserted.

4 Continue following the calibration instructions.
Performing a calibration check 60

13.8. List of Specifications

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

List of Specifications

13.9. List of equipment icons


Manufacturer

Batch code

Catalogue number


Temperature limit


Atmospheric pressure limitation


Do not reuse, single-patient use

Authorized representative in the European Community


Consult instructions for use


Minimal compatible software


Compliance with requirements of the European Medical Devices Regulation (EU) 2017/745

Medical Device

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


Humidity limitation


Keep dry


Do not use if package is damaged


Expiration date


Date of manufacture

Unique Device Identifier