EasyGuide

English

EasyOne™ Spirometer

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Contents

1 Introduction

Thank you for choosing the EasyOne Spirometer.

With EasyOne you have chosen a high quality spirometer that minimizes the need for maintenance due to its unique ultrasound technology. EasyOne does not need calibration and remains consistently accurate over years. The spirette breathing tube assures perfectly hygienic conditions for every patient at low cost even if the spirometer is frequently used.

The EasyOne Diagnostic Spirometer has two operating modes for you to choose from:

In the **Diagnostic mode**, EasyOne offers you extensive and diverse options for spirometric tests in accordance with the standards of the European Respiratory Society (ERS) and the American Thoracic Society (ATS).

In the **Frontline mode**, EasyOne offers you the option of greatly simplified spirometric measurement. In the **NLHEP mode**, the EasyOne fulfills all requirements of the National Lung Health Education Program (NLHEP [4]). This mode is a little more restrictive than the Frontline Mode (only FEV6 maneuvers).

The EasyOne Frontline Spirometer only offers the Frontline and NLHEP mode. The differences between the two operating modes are described in the table that follows.

	Diagnostic mode	**Frontline and NLHEP mode**
Test modes	FVC (expiratory), F/V Loop (inspiratory and expiratory), slow VC, MVV, Pre-Post measurement US: Unit can be configured to meet NIOSH/OSHA and Disability reporting requirements.	FVC (expiratory), Pre-Post measurement
Parameters	FEV1, FVC, FEV1/FVC, FEV6, FEV1/FEV6, MEF25-75, MEF25, MEF50, MEF75, PEF, FET, FIVC, PIF, IVC, IRV, ERV, FEV1/VC, MVV, pre-post % variation, QC rating	FEV1, FEV6, FEV1/FEV6, FVC, FEV1/FVC, PEF, pre-post % variation, QC rating NLHEP mode: only FEV6, no PEF display
Quality control	Requires 3 acceptable, reproducible maneuvers. Details in Chapter 10.1.	Requires 2 acceptable, reproducible maneuvers. Details in Chapter 10
Automatic quality control	Quality control can also be overridden manually.	Automatic control is always active
Trial storage and display	Can store and display the best, or the best 3 trials, including curves.	Stores and displays only the best trial and curve
Report Configuration	Report can be customized for curve type and size.	Report is fixed, showing the smaller sized FV and VT curves

The default setting of the EasyOne Spirometer is the Diagnostic Mode. To switch the EasyOne into the Frontline Mode, see Chapter 8 under “General Settings”.

The EasyOne-line Spirometer does not contain the EasyOne cradle. Instead it contains the EasyOne Screen Connector in conjunction with the EasyWare software for the PC. The screen connector can be used to display real time curves on the PC Screen, it can however not be used for direct connection of EasyOne to a printer. The EasyWare manual describes installation and use of the PC software.

2 Warning Information

The following terms are used as follows in this document:

Caution: Possibility of injury or serious damage

Please note: Important information for avoiding damage to the instrument or facilitating operation of the instrument

Please note the following information on safe operation of the EasyOne spirometer:

 means: Read the User Manual.

Caution:	The instrument is not suitable for use in the presence of explosive or flammable gases.

Caution:	Connect only printers and computers that comply with IEC/EN 60950-1 Standards, or that bear the UL or CSA mark.

Caution:	For AA batteries, do not attempt to charge, connect improperly, or dispose of in fire as there is possibility of leakage or explosion. Follow manufacturer's recommendation for proper disposal.

Caution:	Calibration and servicing may be carried out only by ndd staff. Do not open the instrument.

Caution:	Pulmonary function tests require maximum effort on the part of the patient and may lead to sensations of dizziness or giddiness.

Please note:	Use only alkaline batteries, and remove the batteries from the battery compartment if you intend not to use the instrument for a long period.

Please note:	The direct printing option from EasyOne supports only a limited set of printers. Please visit the ndd web site www.ndd.ch in order to get the most recent list of supported printers.

Please note: 	The product you have purchased should not be disposed of as unsorted municipal waste. Please utilize your local WEEE collection facilities in the disposition of this product and otherwise all applicable requirements.

Please note:	Use only authentic ndd disposables to assure accuracy, long-life and full warranty coverage.

3 Intended Use

The ndd EasyOne is designed for conducting simple spirometric measurements on adults and children over the age of 4 by general practitioners, specialists, in occupational medicine and in hospitals. The EasyOne spirometer is used together with the spirette respiratory tube in order to conduct slow and forced spirometric maneuvers and MVV tests.

4 Instrument Installation

In case of the EasyOne Screen Spirometer please refer to the EasyWare manual for installation and use of the PC software.

4.1 Setting Up the Instrument

The EasyOne spirometer is delivered with USB cradle, 2 AA batteries, a USB cable, 4 spirette breathing tubes and a Quickstart CD. The following picture shows the spirometer in combination with a printer.

The following picture shows the parts supplied with the EasyOne-line. It additionally includes the Easy-Ware PC software and the screen connector instead of the USB cradle.

Install the two AA alkaline batteries (included) in the compartment on the rear of the spirometer, taking care to match the polarity marking on the batteries with the markings inside the battery compartment.

Caution:	Do not attempt to charge or burn the AA batteries used in the instrument. Please follow the manufacturer's instructions on battery disposal.

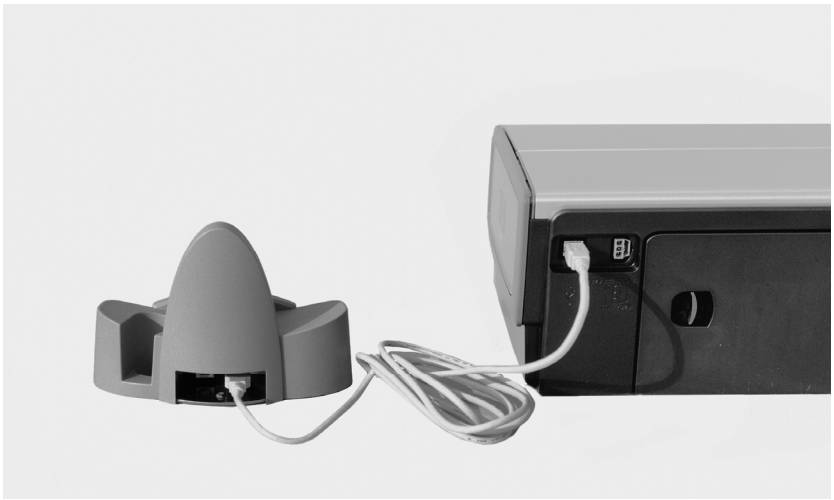
Please note:	Use only alkaline batteries, and remove the batteries from the battery compartment if you intend not to use the instrument for a long period.

Please note:	A low battery message will alert you when battery power falls below 10%. Data saved in memory is not lost when battery power is low, or when batteries are removed.

Install the spirette as shown. Be sure to orient the spirette so that the arrow on the spirette lines up with the arrow on the spirometer. Push the spirette all the way in to the stop. For maximum hygiene, consider tearing the spirette bag from the bottom, leaving spirette partially wrapped during insertion and until the spirometer is handed to the patient. The spirette is easily removed by pushing it up from the bottom.

Please note:	Use only authentic ndd disposables to assure accuracy, long-life, and full warranty coverage.

If you wish to print reports or export data to a PC, connect the EasyOne base unit to the printer or to the PC using the corresponding cable.



The following picture shows how the EasyOne Screen Connector is used:

Caution: Connect only printers and computers that comply with IEC 60950-1 Standards.

4.2 Setting Language, Date, Time, Altitude (above sea level) and Printer Type

Press the (ON/OFF) key for at least 2 seconds in order to switch on the instrument. The instrument switches off automatically if no key is pressed for 15 minutes.

If you are switching on the instrument for the first time, you will be prompted to choose a region, the language and to enter the date, time, altitude above sea level and approximate relative humidity at the instrument's location. This data is not pre-set. If you intend to print reports, you can also select the right printer type on the instrument.

The spirometer is delivered with the pre-set default settings. Please refer to Chapter 8 of this User Manual for the procedure for changing the settings. Adapting the settings to your needs allows you to get the most out of your EasyOne instrument.

After you have made the above settings when switching on the instrument for the first time, you can then change any settings at any time using the CONFIGURATION menu item from the main menu.

4.3 Operating the Keys

(ON/OFF)	This switches EasyOne on or off. Press and hold the key (for at least 2 sec.) until you hear an audible signal.
(ENTER)	This confirms data entry or the selection and moves you to the next entry field.
(‹)	Deletes last character, scrolls to the left or up.
(›)	Scrolls to the right or down
(0,ESC)	Press the key briefly in order to enter (0), keep the key pressed longer (at least 1 sec.) in order to return to the previous field with (ESC) or abort the operation, press the key briefly twice in order to enter a blank (the key function operates only if letters can be entered).
(2,abc), etc.	Press the key briefly in order to enter the digit "2", press the key briefly in order to enter "A" (the key function operates only if letters can be entered), press the key briefly twice in order to enter "B" (the key function operates only if letters can be entered), if you press the same key quickly several times consecutively, you will scroll first to the upper-case letters, then to the number and then to the lower-case letters, umlauts and special characters can be found on key (1).

Please note:	The escape key (Esc-0) is particularly helpful and important in unit navigation. The escape function requires the key to be pressed and held momentarily. Escape is useful for moving to previous menus, items, or fields, and escaping a spirometry test. Pressing this key rapidly in fields where letters are possible, such as patient name and report header, allows the entry of a blank space or a zero.

5 Performing Spirometry

5.1 Preparing the Patient

Prepare for testing by having the patient loosen tight clothing, remove dentures, and relax. The patient may sit or stand. If standing you may want to perform testing in an area free of sharp table or counter edges, or have a chair handy as there is a slight possibility that the patient could faint during the strenuous spirometry maneuver.

Explain that the purpose of the test is to determine how much air a person's lungs can hold and how quickly that air can be expelled with a forceful, maximal effort. Since the spirometry test requires active participation by the patient it is very important to demonstrate the maneuver for the patient. Emphasize the essential elements of the test:

- filling lungs completely
- sealing lips around the spirette so that there are no leaks, taking care not to block its opening with teeth or tongue or bite down excessively
- blasting out as hard and fast as possible
- continue blowing out until the lungs are completely empty

If you are new to spirometry, you should practice testing yourself and others prior to testing patients. You will learn to recognize a poor effort by observing the patient and/or interpreting the Quality Messages displayed by the spirometer after each effort. After a poor effort you must explain what went wrong. Develop enthusiastic coaching techniques to use during the maneuver to maximize your chances of getting quality results with a minimum number of efforts.

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

5.2 Measuring the Forced Vital Capacity (FVC)

- Choose “Perform Test” in the main menu and then NEW. Confirm with ENTER. The instrument will now allow you to enter the patient data.
- Enter the corresponding patient data line by line. Use the keys as described in Chapter 4.3. Confirm with ENTER each time.
- After entering the patient data, you then move on to the "Test selection" menu. Choose the FVC test and confirm with ENTER.
- Insert a spirette into the instrument. Ensure that the arrow on the spirette is lined up with the arrow on the instrument.
- Once again briefly prepare the patient for the test. When the patient is ready, press ENTER. You will now hear the sensor buzzing.
- The instrument now prompts you to avoid air flow in the spirette since it is setting the baseline. It is advisable to block off the spirette on one end in order to ensure that the baseline is set precisely even if the room is draughty. An audible signal will sound when the baseline has been set. You will see prompt "Blast out" on the screen.
- Hand the instrument to the patient. Ask the patient to breathe in deeply, insert the spirette correctly into his or her mouth. Now ask the patient to exhale as firmly and as quickly as possible, and continue exhaling until all air has been exhaled.
- At the end of the maneuver, you will see a message on the display indicating whether the maneuver was acceptable. At least three acceptable maneuvers must have been performed before you see message "Session complete".
- Using keys (›) and (‹), you can view the result on the screen. In order to print the result, choose the PRINT field and press ENTER. Then place the instrument into the base unit. The report is then printed.

If you want to get back to the main menu at any time, press and hold the escape key (esc-0)for 1 second. Repeat this until you reach the main menu.

You can conduct the following tests with EasyOne: FVC (expiratory), FVL (inspiratory and expiratory), Tidal FVL, pre/post tests, slow spirometry and MVV. Please also see Chapter 9. There are also protocols that ensure that testing complies with the guidelines for NIOSH/OSHA/Cotton Dust and Social Security Administration Disability evaluations.

5.3 Checking the Test Quality

In order to assess the pulmonary function of the patient, it is necessary to obtain acceptable test quality. The test quality depends on co-operation of the patient and this, in turn, depends on the quality of the physician's instructions. Consequently, EasyOne incorporates an automatic quality control function with prompts to facilitate the physician's job of providing the patient with good instructions. After each maneuver, a message on the screen will inform you as to whether the maneuver was acceptable or not. If not, the message will guide you on how to coach the patient to do better.

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. Please refer to Chapter 10.2. for further information on the quality grades. The table below gives you the possible prompts that EasyOne provides you with after a maneuver:

Prompt	The prompts relates to	How to improve
Don't hesitate	...the quality of the last test	The patient should exhale in one breath and should not stop in-between.
Blast out faster	...the quality of the last test	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer	...the quality of the last test	The patient has discontinued exhalation too early. The patient must exhale even more and press as much air as possible out of his or her lungs.
Good effort, do next	...the quality of the last test	Good test. Just one to two more good tests and the test is complete.
Blast out harder (only in Frontline mode)	...the reproducibility of the maneuvers: PEF is non-reproducible	The test differs greatly from the previous tests. The patient can blow still more firmly and achieve a higher peak flow.
Deeper breath	...the reproducibility of the maneuvers. FVC or FEV1 are non-reproducible	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
Session complete		The test is complete. An adequate number of good maneuvers have been conducted.

Only one of the above prompts is shown after a maneuver. As soon as you see message "Session complete", you need not conduct further maneuvers. If, even after repeated attempts, it is not possible to obtain an adequate number of good maneuvers, you should take a break, depending on how the patient feels or stop measurement. Even after a break, the measurement is stored and can be printed out under "Print results" in the main menu. You also have the option of adding tests subsequently. Read more on this in Chapter 9.6.

5.4 Interpreting Results

When interpreting the results, it is important to allow for the quality rating of the test. The quality ratings A to C indicate a reliable result. A quality rating between D and F indicates insufficient test quality. The result must then be interpreted with caution.

As soon as you obtain the message "Test complete" after conducting a test, you can either print out the report immediately with ENTER or select the DATA field and view the result on the display.

On the printed report, parameters that are below the lower limit of normal (LLN) are printed in red and marked with an asterisk (*). EasyOne also offers an automatic interpretation aid. Please refer to Chapter 11 for further information on this interpretation.

It is possible to deactivate both the QC-Grade function and the Interpretation function.

5.5 Printing a Report

You will require a base unit and a compatible printer in order to print a report.

Immediately after completion of the test, you have the option of printing by selecting the PRINT field and confirming this with ENTER. You will see message "Please connect device to cradle". Insert the instrument into the cradle and wait until the print job has been printed. EasyOne issues an audible signal indicating when the instrument can be removed.

You can also print old tests. To do this, select option ”Print Results”, “Single Test” in the main menu, choose the required test with key (›) or (‹) and press ENTER. You can also print a number of tests at once by choosing “Print Results”, “Range of Tests” and entering a start and end date. You will once again see message "Please connect device to cradle ".

Depending on the type of printer, it will take between 30 and 90 seconds to print out the report. Should you have problems printing out, please refer to the information in Chapter 15.

5.6 Saving and Retrieving Measurements

EasyOne saves all test results automatically. No data is lost even if the batteries are removed. The oldest test is overwritten when the memory is full (up to 700 measurements).

You can recall saved measurements for the purpose of conducting a new test with the same patient, adding maneuvers, adding a post-test, viewing results, or printing results. You can add a maneuver or a post-test only on the same day that the original test was performed. See Chapters 9.5 and 9.6.

In order to add a test to an old measurement, choose “Perform Test” in the main menu and then choose RECALL. Follow the rest of the instructions.

In order to view an old test, choose “View Results” in the main menu and choose the desired test.

5.7 Quick Test

You have the option to perform a quick test without entering patient data. Select “Perform Test” in the main menu and then QUICK. Choose the desired test using the arrow keys and press ENTER.

Please note:	When Quick Test is selected, no comparison to predicted normals are displayed or printed. Predicted normals are only available when age, height and gender are entered.

It is possible to enter patient data after having performed a quick test. Proceed as described in Chapter 5.8. Once patient data is entered predicted normals will be displayed and printed.

5.8 Editing Patient Data

You have the option of editing or adding patient data after a test has been performed. To do this, choose “Edit Database” in the main menu and press ENTER. Choose the desired test with keys (‹) and (›) and make the changes.

Please note:	Editing patient data may influence predicted computation and interpretation of the test result. You should thus recheck the measured result when age, height or gender are changed.

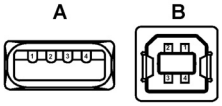
6 Specifications

6.1 EasyOne Model 2001 Spirometer

Size:	83 x 158 x 43 millimetres (3.3 x 6.2 x 1.7 inches)
Weight:	255 grams (9 ounces)
Measuring accuracy	Volume: ±2% or 0.050 l Flow: ±2% or 0.020 l/s, (except PEF) PEF: ±5% or 0.200 l/s MVV: ±5% or 5 l/min.
Measuring range:	Volume: ±12 l Flow: ±16 l/s
Resistance:	approx. 0.3 cm H_2O/L/s
Display:	64 x 160 graphic display
Data entry:	14-key keyboard
Data memory:	for up to 700 tests
Test modes 'Diagnostic':	FVC, FVL, Tidal FVL, Slow VC, MVV, Pre/Post (US devices: OSHA, SSA)
Test modes 'Frontline':	FVC, Pre/Post
Parameters 'Diagnostic':	FVC, MVV, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, FEF75 (MEF25), FEF50 (MEF50), FEF25 (MEF75), MEF25%-75%, PEF, FET, FIVC, PIF, IVC, VC, FEV1/VC, ERV, IRV, pre-post % variation, Lung Age
Parameters 'Frontline':	FVC, FEV6, FEV1, FEV1/FVC, FEV1/FEV6, PEF, pre-post % variation, Lung Age
Respiratory tube:	Disposable spirette respiratory tube
Measurement principle:	Ultrasound transit-time measurement
Predicted:	ERS (ECCS), Roca, Austria, NHANES III, Knudson 1976, Knudson 1983, Crapo, Morris, Cherniak. Optional: Berglund, Gulsvik, Hedenstroem, Asia 1-4, JRS2001, Gore, Pereira, Finnish. Paediatrics: Zapletal, Dockery, Hsu, Polgar. Optional: Hibbert
Power supply:	2 alkaline batteries, type AA, 1.5V
Power consumption:	0.6 W
Battery service life:	approx. 400 tests
Report:	A4 or 8.5” x 11”, in conjunction with selected printers from HP, Canon or Epson
Storage:	Temperature: -40 to 70 °C, Relative humidity: 0% to95% Ambient pressure: 500 to 1060 hPa
Operating conditions:	Temperature: 0 to 40 °C, Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
Certifications and standards:	CE Declaration of Comformity, see attachment. C CSA US approval, CAN/CSA-C22. 2 NO. 601.1-M90, S1-94, CSA 601.1 Amendment 2: 1998, UL Std No. 2601.1, FDA 510 (k) approval, K993921 EasyOne meets or exceeds the published targets of the European Respiratory Society (ERS), the American Thoracic Society (ATS) and the National Lung Health Education Program (NLHEP).
Instrument classification:	 Type BF applied part Powered internally with (2) AA alkaline batteries Short time operation, less than 10 minutes Instrument not suitable for use in flammable anaesthetic gases in mixtures with O_2 or NO.
Life time:	7 years

6.2 EasyOne Model 2010 Cradle (optional)

Size:	119 x 173 x 83 millimetres (4.7 x 6.8 x 3.3 inches)
Weight:	284 grams (10 ounces)
Power supply:	From the batteries of the EasyOne spirometer or from USB power
Power consumption:	Type 0.15W
Function:	Connects the EasyOne spirometer to a printer or PC
Interface:	Standard USB type A and B connectors (alternatively DB25 connector for serial or parallel interface), for connection to PC or printer.

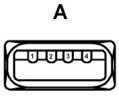


Pins: 1 = V_{Bus}, 2 = D–, 3 = D+, 4 = GND

Storage:	Temperature: -40 to 70 °C, Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
Operating conditions:	Temperature: 0 to 40 °C, Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
PC:	The PC must comply with corresponding IEC standard (ex. IEC 60950-1. The user is responsible that requirements of IEC 60601-1-1 for safety of medical electrical systems are met.

6.3 EasyOne Model 2010 Screen Connector (optional)

Size:	64 x 44 x 25 millimetres (2.5 x 1.7 x 1.0 inches)
Weight:	82 grams (3 ounces)
Power supply:	From USB port
Power consumption:	Type 0.15W
Function:	Connects the EasyOne spirometer to a PC
Interface:	Standard USB type A connector for connection to PC



Pins: 1 = V_{Bus}, 2 = D–, 3 = D+, 4 = GND

Storage:	Temperature: -40 to 70 °C, Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
Operating conditions:	Temperature: 0 to 40 °C, Relative humidity: 0% to 95% Ambient pressure: 500 to 1060 hPa
PC:	The PC must comply with corresponding IEC standard (ex. IEC 60950-1. The user is responsible that requirements of IEC 60601-1-1 for safety of medical electrical systems are met.

6.4 Accessories

2050-1	Case of 50 spirettes
2050-5	Case of 200 spirettes
2050-6	Case of 75 spirettes no wrapping
2040-2	EasyWare USB
2030-2	Calibration Syringe

Please note:	Use only authentic ndd disposables to assure accuracy, long-life, and full warranty coverage.

7 Definition of Parameters

FVC	Forced Vital Capacity (expiratory)
FIVC	Forced Vital Capacity (inspiratory)
FEV1	Forced Expiratory Volume (1 sec).
FEV6	Forced Expiratory Volume (6 sec).
FEV1/FVC	Ratio of FEV1 to FVC
FEV1/VC	Ratio of FEV1 to VC taken from SVC test
FEV1/FEV6	Ratio of FEV1 to FEV6
MEF 25	Mid Expir. Flow at 75% of Vital capacity
MEF 50	Mid Expir. Flow at 50% of Vital capacity
MEF 75	Mid Expir. Flow at 25% of Vital capacity
MEF 25-75	Mid Expir. Flow at 25%-75% of Vital capacity
PEF	Peak Expiratory Flow (in l/min or l/sec)
PIF	Peak Inspiratory Flow
FET	Forced Expiratory Time
PRE/POST% variation	Percentage variation of measured values before and after bronchial spasmolysis
LLN	Lower Limit of Normal
BEV	Back Extrapolated Volume
VT	Tidal Volume
ERV	Expiratory Reserve Volume
IRV	Inspiratory Reserve Volume
VC or VCmax	Maximum Vital Capacity
VCex	Expiratory Vital Capacity
VCin	Inspiratory Vital Capacity
IC	Inspiratory Capacity
MVV	Maximum Voluntary Ventilation (per min.)
Lung Age	Lung Age, see Chapter 17, [8] for reference

8 System Configuration

If you wish to change the instrument setting, please choose the “Configuration” option in the main menu. You will now be in the Configuration menu. The tables below provide an overview of the setting options offered to you by EasyOne. Choose the option you require.

8.1 Test Settings

Test settings are not available in NLHEP mode (all options are fixed in this mode).

Relates to	Option	Default setting	Description
Predicted	See Specifications	EU: ERS/Zapletal US: NHANES-III	You can select your desired predicted values from the predicted publications listed. US: Frontline only supports NHANES-III
Additional paediatrics	Dockery, Hsu, Polgar, none	None	You have the option of selecting different predicted values for children than those for adults. US: Frontline only supports NHANES-III
Best value selection "ValueSel" (*)	BEST VALUE, BEST TRIAL	EU: BEST TRIAL US: BEST VALUE	In BEST VALUE setting, the relevant, best value from different tests is selected. BEST TRIAL selects the test which has provided the best results (see Chapter 10.3).
Interpretation (*)	NLHEP, GOLD/ Hardie, none	GOLD/Hardie	Automatic interpretation (see Chapter 11) is activated or deactivated here.

Relates to	Option	Default setting	Description
Lung Age (**)	yes, no	No	If set to “yes”, the lung age is displayed on the result screen and printed on the report. Lung Age is only shown if the patient is a smoker. When the calculated lung age is lower than the patient’s actual age, the patient’s actual age is shown..
Automated Test QC (*)	Yes, no	Yes	The automated test QC (see also Chapter 10) is activated and deactivated here.
FVC selection	FVC, FEV6	FVC	FEV6 indicates the exhaled volume after 6 seconds. When set to FEV6, EasyOne stops the measurement after 6 seconds. MEF25, MEF50, MEF75 and MEF25-75 are not reported in that setting. When set to FVC, EasyOne continues the measurement until end of test criteria are met.
PEF unit	l/s, l/min, OFF	l/s	Peak flow can be specified in litres per minute or in litres per second. OFF: PEF is not shown.
African ethnic corr. (***)	75%-110%	88%	The predicted value is corrected by this additional factor if the selected predicted publication does not specify a separate calculation for this ethnic group.
Asian ethnic corr.	75%-110%	100%	The predicted value is corrected by this additional factor if the selected predicted publication does not specify a separate calculation for this ethnic group.
Latin American ethnic corr. (***)	75%-110%	100%	The predicted value is corrected by this additional factor if the selected predicted publication does not specify a separate calculation for this ethnic group.
Other ethnic corr.	75%-110%	100%	The predicted value is corrected by this additional factor if the selected predicted publication does not specify a separate calculation for this ethnic group.
Curve storage (*)	all curves, best curve	best curve	When set to ALL EasyOne can save up to 8 curves of a test. This is necessary if you want to print the 3 best curves or if you want to export the curve data of each trial. Please note that saving all 8 curves uses substantially more memory.

* Only available in Diagnostic Mode
** Only available in Frontline mode.
*** In Frontline US devices not available because NHANES III supports African & Hispanic ethnic groups

8.2 General Settings

Relates to	Option	Default Setting	Description
Time format	24 hours, am/pm	EU:24 hours US:AM/PM	Sets the time format for 12 or 24 hour.
Date format	DD.MM.YY, DD/MM/YY, MM/DD/YY	EU:DD.MM.YY US:MM/DD/YY	Sets the data format.
Current date			Please enter the correct date at this point and confirm with ENTER.
Current time			Please enter the correct time at this point and confirm with ENTER.
Alphanumeric ID	Yes, no	No	If the ID you use also consists of letters, please set to “Yes”.
Technician ID	Yes, no	No	If you want the technician ID to be saved as well and listed on the report, please choose “Yes”.
Syringe volume	1.0l, 1.5l, ...7.0l	3.0l	Choose the volume of your syringe if you wish to use it to conduct a calibration check.
Height unit	m/cm, ft/inch	EU: m/cm US: ft/in	Choose how the unit will indicate height and altitude.
Weight unit	kg, lbs	EU: kg US: lbs	Choose how the unit will indicate weight.
Age, date of birth	Age, birth	EU: Birth US: Age	If you use a database, consider entering the date of birth so that the age can be calculated correctly at a later point.
Lang.	German, English, others	English	Choose the desired language.
Contrast			Changes the display contrast.
Op. mode	Diagnostic, Frontline, NLHEP	Diagnostic	see Chapter 1
Temp. unit	°C, °F	EU: °C US: °F	Determines how temperature is reported.
Altitude above sea level	0m, ...4000 m	0 m or ft	Set the altitude above sea level of your location.
Rel. humidity	0...100%	40%	Enter the average relative humidity at your location.

8.3 Printer Settings

Relates to	Option	Default setting	Description
Printer type	HP b&w, HP color, Canon b&w, Canon color, Epson b&w, Epson color, via PC	HP b&w	Choose the right option to match your available printer. See Chapter 15 if you have problems. Via PC should be entered if you want to print using EasyWare.
Result data	3 best values, best values	best values	You have the choice of printing out only the best test or the 3 best tests on the report.
Number of Curves	3 best curves, best curve	best curve	Choose if you want to print the 3 best curves of the tests or only the best curve. It is only possible to print the 3 best curves if the 3 best curves were saved (see test settings ”Save curve data”).
Graph Types	FV&VT small, FV large, VT large, FV&VT large	FV&VT small	Choose what curves you wish to have on the report.
Header 1-4	Optional entry	Blank	You can enter the name and address of the institution or other information in 4 lines of 40 characters each.

9 Test Types

When you enter the patient data or select an existing patient, you will see the Test menu with the following selection options:

- FVC (expiration)
- FVL (inspiration and expiration)
- Tidal FVL
- MVV
- Slow VC

It is also possible to add a “Post” test to a FVC or FVL Test.

The various measurement methods are outlined below. Good co-operation on the part of the patient is essential with all methods. Consequently, you should explain to the patient clearly beforehand what he or she has to do and motivate the patient to co-operate. Choose the required measurement method with keys (›) or (‹) and confirm with ENTER.

9.1 FVC (expiration)

This is the most commonly used spirometric measurement. Prepare the patient as described in Chapter 5.1.before you start the test. Then proceed as follows.

- Insert a spirette into the instrument. When doing this, please ensure that the arrow on the spirette is lined up with the arrow on the instrument.
- Press ENTER when the patient is ready. You will now hear the sensor buzz.
- The instrument prompts you to avoid flow in the spirette while it is setting the baseline. It is necessary to block off the spirette at one end in order to ensure that the baseline is set precisely. An audible signal sounds when the baseline is set. You will see the prompt "Blast out" on the screen.
- Hand the instrument to the patient and ask the patient to breath in deeply first, then to insert the spirette correctly into his or her mouth, to exhale as firmly and quickly as possible and to continue exhaling until all the air has been exhaled.
- At the end of the maneuver, you will see a message on the screen indicating whether the maneuver was acceptable. At least three acceptable, reproducible maneuvers must be performed before you see message "Session complete". In Frontline mode, only two acceptable, reproducible maneuvers need to be performed.

9.2 FVL (inspiration and expiration)

With this test mode, a deep inhalation follows the exhalation maneuver directly. Proceed in the same way as with the above-described FVC test. However, instruct the patient not to remove the spirette from his or her mouth after exhaling, but to follow up with a deep, maximum inhalation. Three acceptable tests should be conducted with this test as well.

9.3 Tidal FVL

In this test mode the patient can do tidal breathing before the full FVL maneuver, as described in Chapter 9.2.. When the maneuver is finished press enter to manually stop the trial. This test mode is mainly used with the EasyOne –line setup.

9.4 Slow VC

Slow spirometry serves to determine the vital capacity and the lung volumes (see Chapter 7). You can repeat the maneuver several times. The best test is saved. Proceed as follows:

- Insert a spirette into the instrument. Ensure that the arrow on the spirette lines up with the arrow on the instrument.
- Press ENTER when the patient is ready. You will now hear the sensor buzz.
- The instrument now prompts you to avoid flow in the spirette while it is setting the baseline. It is advisable to block off the spirette at one end to ensure the baseline is set precisely. An audible signal sounds when the zero point is set.
- The patient must now insert the spirette into his or her mouth and breathe at rest (about 3-5 breaths) until you hear an audible signal.
- The patient must then take a deep inspiration followed by a maximum exhalation.
- The instrument stops automatically at the end of the maneuver.

If you are only interested in the vital capacity without determination of the other volumes (ERV, IRV, VT, IC) the VC maneuver can also be performed without waiting for the acoustic signal.

At the end of the SVC test you can decide to immediately add an FVC test. If you do so the parameter FEV1/VC (Tiffeneau) is also shown on the printed report of the FVC test.

9.5 MVV

- Insert a spirette into the instrument. Ensure that the arrow on the spirette is lined up with the arrow on the instrument.
- Press ENTER when the patient is ready. You will now hear the sensor buzz.
- The instrument now prompts you to avoid flow in the spirette while it is setting the baseline. It is advisable to block off the spirette at one end to ensure precise setting of the baseline. An audible signal sounds when the baseline is set.
- The patient must then insert the spirette into his or her mouth and must fully inhale and exhale for an uninterrupted period of at least 12 seconds.

9.6 OSHA Cotton Dust Protocol (US units only)

This is a specialized routine for users who want to ensure that occupational testing and reports meet the requirements of NIOSH/OSHA. The unit will automatically perform as described here, regardless of how the configuration is set. When this protocol is chosen testing and reports are affected as follows:

- Only FVC tests are performed
- Test quality criteria meets the requirements defined by the Cotton Dust Standard
- The Knudson 1976 predicted normals are used
- The best three tests and Volume-Time curves will be saved and printed
- The curves will be printed in large, validation size
- There will be no clinical interpretation displayed or printed

9.7 Disability Protocol (US units only)

This is a specialized routine for users who want to ensure that testing associated with disability determinations meets the requirements of the Social Security Administration. The unit will automatically perform as described here, regardless of how the configuration is set. When this protocol is chosen testing and reports are affected as follows:

- A multi-flow calibration is required prior to testing
- Unit will be accurate to within 1%
- Only FVC tests are performed
- The best three tests and Volume-Time curves will be saved and printed
- The curves will be printed in large, validation size
- Report will include the calibration results
- There will be no clinical interpretation displayed or printed

9.8 Post-Test

The Post-Test is usually performed to determine the response on bronchodilating asthma medication. This is done by treating the patient with a bronchodilator after having performed a FVC or FVL test. Approximately 10 to 20 minutes after the medication (when bronchodilator shows effect) a second FVC or FVL test (“post-Test”) is performed. The results of the pre-test and the post test are then compared on the result screen and on the test protocol. Post-Tests can only be added to previous tests on the same day.

To add the “Post”-test immediately after the FVC or the FVL test select the field POST on the result screen.

When coming from the main menu you can add a post test to a previous test as follows:

- Select “Perform Test” in the main menu
- Choose the field RECALL and press ENTER
- Scroll through the list of tests until you get to the desired pre-med test and press ENTER
- Select the field POST
- Proceed as described in Chapter 9.1 and 9.2

9.9 Adding a Trial

If you would like to add trials to a previous test, e.g. if the patient needed a break, please proceed as follows:

- Select “Perform Test” in the main menu
- Choose the field RECALL and press ENTER
- Scroll through the list of tests until you get to the desired test and press ENTER
- Select the field ADD
- Proceed as described in Chapter 9.1 and 9.2

Please mind that it is only possible to add a trial to a previous test that was performed on the same day.

10 Quality Messages and Quality Grades

10.1 Quality Messages

The quality messages assist you in conducting the measurement. After each test, they provide information as to whether the test is acceptable or what to do to improve the result.

Message	Criterion	Recommended action
Don't hesitate	Back-extrapolated volume greater than 150 ml or 5% of FVC whichever is greater (for age <= 6: 80ml or 12.5% of FVC whichever is greater)	The patient must exhale all air at once and not exhale in short bursts.
Blast out faster	Time until peak flow greater than 120 ms	The patient must exhale more explosively and as firmly and quickly as possible.
Blow out longer	Expiration time less than 2 seconds OR volume during last 0.5 seconds >40 ml when expiration time is <6 seconds OR volume during last second >25 ml when end-of-test was initiated by an inspiration**	The patient stopped exhaling too early. The patient must exhale still further and force as much air as possible out of his or her lungs.
Good effort, do next	Test meets above criteria	Good test. Only one to two more good tests and the test is complete.
Blast out harder (only in Frontline mode)	Peak flow not reproducible. Difference with respect to best test greater than 1.0 l/s	The test differs greatly from previous best test. The patient can blow even more firmly and achieve a higher peak flow.
Wait until buzz before blowing out	The time to peak flow (PEFT) is less than 25ms	Instruct the patient to wait until the baseline setting is finished and the device signals that the trial can start
Cough detected. Try again...	A cough has been detected	Instruct the patient to avoid coughing during the first second.
Deeper breath	FEV1 or FVC* not reproducible. Difference with respect to best test greater than 150 ml or 100ml if FVC is < 1.0L. (for age <= 6: 100ml or 10% of FEV1 or FVC* whichever is greater)	The test differs greatly from previous tests. The patient can inhale even more deeply and exhale even more air.
Test complete	QC grade A or B reached. After 5 trials loosened to include QC grade C. See QC grade documentation.	The test is complete. An adequate number of good tests is available.

* when using FEV6 instead of FVC, FEV6 is also used for the determination of the quality message

** This last criteria has been introduced in V5.0 of the EasyOne firmware

10.2 Quality Grades

The quality grades allow you to assess the reliability of the measurement result. Quality grades A to C indicate a reliable result. A quality grade between D and F indicates inadequate test quality. The result must then be interpreted with caution.

The quality ratings can be activated or deactivated under "Configuration". See also Chapter 8.

The table below defines the criteria for the classification of quality grades:

Rating	Criteria in Diagnostic mode	Criteria in Frontline and NLHEP mode
A	At least 3 acceptable tests (for age <= 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 100ml (80ml if FVC < 1.0 L) (for age <= 6: 80ml or 8% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 100ml
B	At least 3 acceptable tests (for age <= 6: 2 acceptable) AND the difference between the best two FEV1 and FVC values is equal to or less than 150ml (100ml if FVC < 1.0 L) (for age <= 6: 100ml or 10% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 150 ml
C	At least 2 acceptable tests AND the difference between the best two FEV1 and FVC values is equal to or less than 200ml (150ml if FVC < 1.0 L) (for age <= 6: 150ml or 15% of FVC whichever is greater)	At least 2 acceptable tests AND the difference between the two FEV1 and FEV6 values is equal to or less than 200 ml
D	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable trial. Quality message: "Only one acceptable trial"	At least 2 acceptable trials but the results are not reproducible. Quality message "Result not reproducible" OR only one acceptable test. Quality message "Only one acceptable trial"
F	No acceptable test available	No acceptable test available

If the Automated Test QC function is activated the instrument determines automatically which trial is acceptable. For the evaluation of the best trial, the interpretation and the Pre/Post comparison acceptable trials are used first.

In the Diagnostic mode the Automated Test QC function can be deactivated (see Chapter 8). In this case each trial can be accepted manually. To do so simply select ACCEPT after the maneuver and the trial will be considered acceptable.

10.3 Best Test Selection

In the system configuration the best value selection can be set to "Best Trial" or "Best Value". The two settings are defined as follows:

Best trial: EasyOne selects the trial with the largest sum of FVC and FEV1 (this is suggested by ATS and ERS).

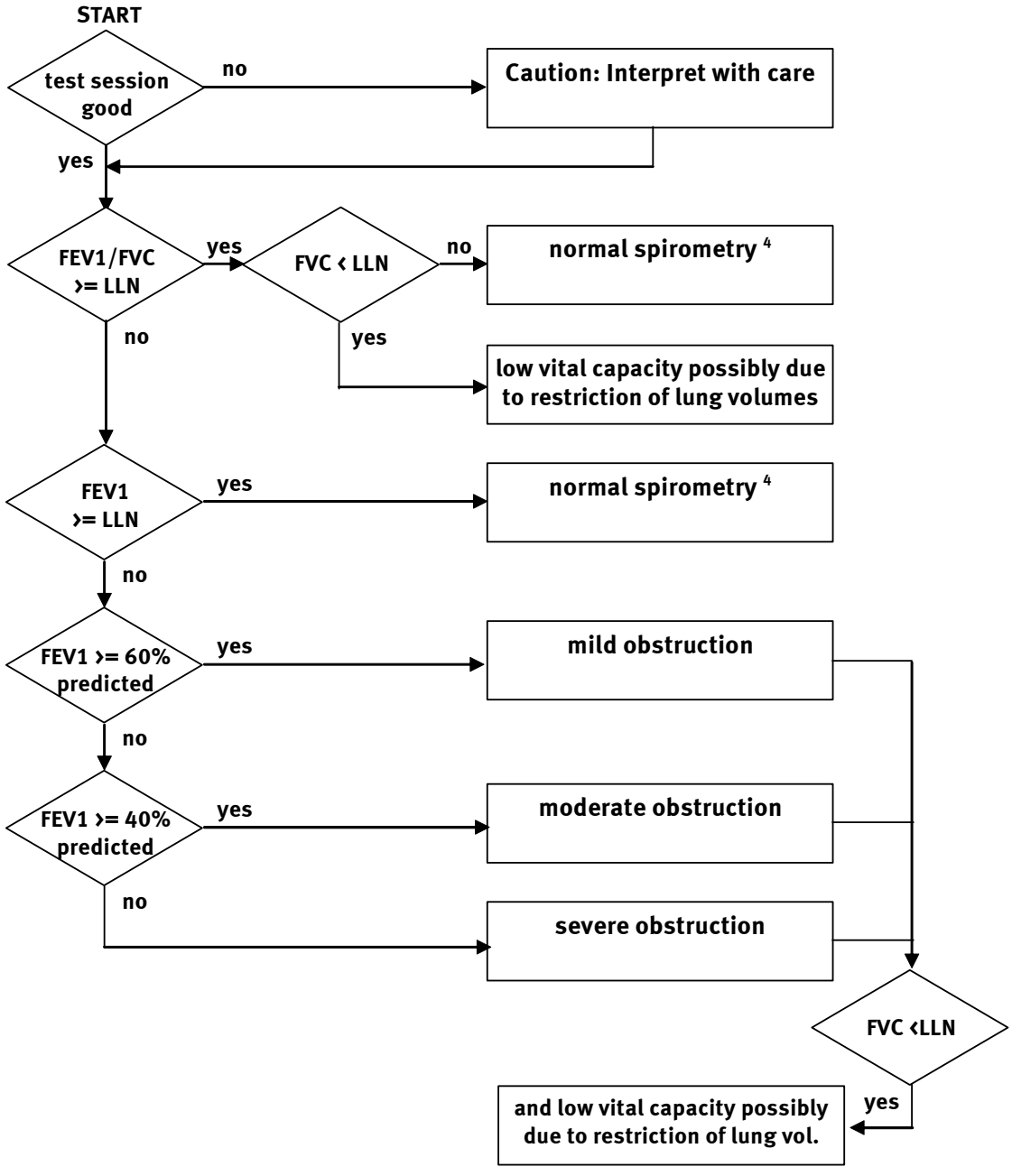
Best value: The "Best" column shows the largest FVC (or FEV6) and the largest FEV1 from all acceptable tests (unless all tests are unacceptable). All other parameters are taken from the best trial (again defined by the largest sum of FEV1 and FVC).

11 Interpretation

Automatic interpretation can be activated (Setting: NLHEP or GOLD/HARDIE) or deactivated under "Configuration" (see Chapter 8)

11.1 NLHEP Interpretation

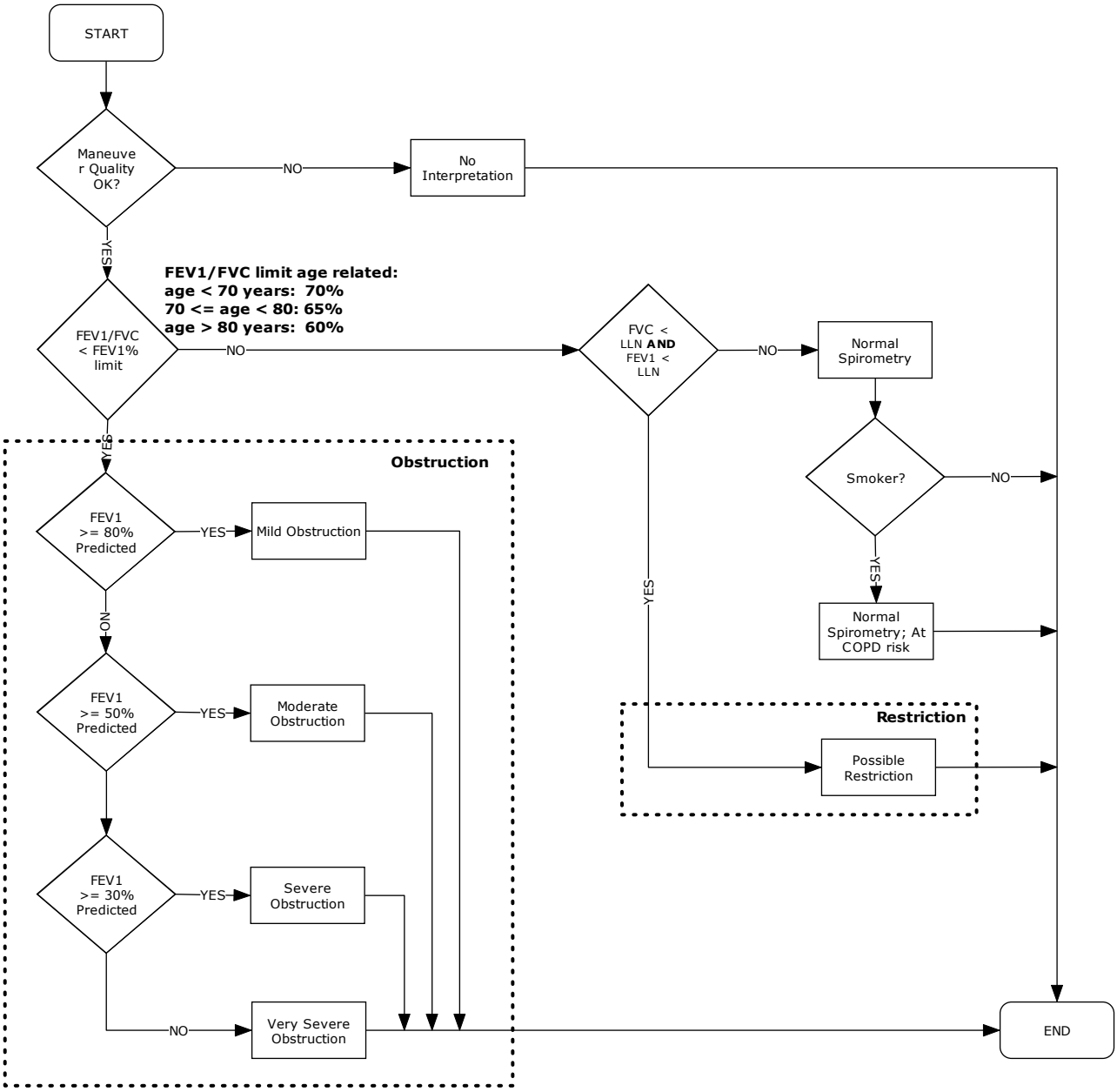
The diagram below describes how the interpretation is determined (see reference [6])..



Notes:
1. LLN = Lower Limit of Normal
2. Where FVC is indicated in chart FEV6 may be substituted, if used.
3. Where there is no lower limit of normal (LLN) defined within the selected predicted normal, the value used for LLN is calculated as Predicted Value – 1.645 x SEE (standard error of the estimate). If SEE is not defined LLN of FEV1/FVC is set to 90% of Predicted Value, LLN of FEV1 is set to 80% of Predicted Value; LLN of FVC is set to 80% of Predicted Value.
4. If the quality grade is D and the results are within normal limits, the interpretation states "normal, but the reported values should not be used for comparisons with previous or subsequent tests."

11.2 GOLD/Hardie Interpretation

The diagram below describes how the interpretation is determined (see reference [11] , [12])



12 Predicted Values

EasyOne offers a number of published predicted value tables allowing comparison of the measurement results. In order to compute the predicted values, it is necessary to enter the sex, age and height and, in many cases, the ethnic group and the weight of the patient. See also Chapter 8 on selection of the predicted values.

Where there is no lower limit of normal (LLN) defined within the selected predicted normal, the value used for LLN is calculated as Predicted Value – 1.645 x SEE (standard error of the estimate). If SEE is not defined LLN of relational parameters, e.g. FEV1/FVC are set to 90% of Predicted Value, LLN of all other parameters are set to 80% of Predicted Value.

If the patient data lies outside of the range defined in the publication (Age, Height) EasyOne uses extrapolated values. The report explicitly points out that the predicted values are extrapolated values and that, consequently, particular caution must be taken when interpreting the results.

12.1 Predicted Values for Adults

[1] Morris, James F., Koski, Arthur, Lavon Johnson, "Spirometric Standards for Healthy Non-Smoking Adults", *American Review of Respiratory Disease,* Volume 10-3, 1971. p.57-67

[2] Morris, James F., Koski, Arthur, Breese, John,'Normal Values and Evaluation of Forced Expiratory Flow', *Am Rev Respir Dis,* Vol. 111, 1975, p.755-761

[3] Cherniak, R.M. and Raber M.B. "Normal Standards for Ventilatory Function using an Automated Wedge Spirometer" *Am Rev Respir Dis,* Vol. 106, 1972, p.38-46

[4] Knudson, Ronald J., Ronald Slatin, Michael Lebowitz, Benjamin Burrows, "The Maximal Expiratory flow-Volume Curve", *American Review of Respiratory Disease,* Volume 113, 1976, p. 587-600.

[5] Knudson, Ronald J., Michael Lebowitz, Holberg Catherine J., Benjamin Burrows, "Changes in the Normal Maximal Expiratory Flow-Volume Curve with Aging", *American Review of Respiratory Disease,* Volume 127, 1983, p. 725-734

[6] Crapo, Robert O., Gardner Reed M., Morris Alan H., "Reference Spirometric Values Using Techniques and Equipment that Meets ATS Recommendations", *American Review of Respiratory Disease*. Volume 123, 1981, p. 659-674

[7] Forche G., Harnoncourt K., Stadlober E.. "Neue spirometrische Bezugswerte für Kinder, Jugendliche und Erwachsene", Öst. Ärzteztg. 43/15/16 (1988) 40

[8] P.H. Quanjer. Lung Volumes and Forced Ventilatory Flows. Eur Respir J, Vol 6, Suppl 16, p.5-40, 1993

[9] NHANES III: Hankinson, Odencrantz, Fedan, 'Spirometric Reference Values from a Sample of the General U.S. Population' *Am J Respir Crit Care Med*, Vol. 159, 1999, p 179-187.

12.2 Predicted Values for Children

[1] Zapletal, T. Paul, M. Samanek. "Die Bedeutung heutiger Methoden der Lungenfunktionsdiagnostik zur Feststellung einer Obstruktion der Atemwege bei Kindern und Jugendlichen." Z. Erkrank. Atm.-Org., Volume 149, 343-371, 1977

[2] Hsu KHK, Bartholomew PH, Thompson V, Hseih GSJ, "Ventilatory Functions of Normal Children and Young Adults – Mexican-American, White, Black. I. Spirometry", *J. Pediatrics* 1979, 95: p.14-23

[3] NHANES III: Hankinson, Odencrantz, and Fedan, 'Spirometric Reference Values from a Sample of the General U.S. Population', *Am J Respir Crit Care Med*, Vol. 159, 1999, p. 179-187.

[4] Dockery, D.W. et al., Distribution of Forced Vital Capacity and Forced Expiratory Volume in One Second in Children 6 to 11 Years of Age, American Review of Respiratory Disease. Volume 128, p. 405-412, 1983

[5] Polgar, Promadhat, Pulmonary Function Testing in Children: Techniques and Standards. W.B. Saunders Co., Philadelphia, 1971

12.3 Ethnic Correction

While some predicted normal studies take into account the differences between certain ethnic groups, most studies 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 ethnic options. In the system configuration there are four Ethnic Correction settings that allow you to customize the amount of adjustment that is made when African-American, Hispanic, Asian, or other is chosen during patient data entry. The adjustment is made to the Caucasian values.

There is an exception to this function. When specific values are available for the chosen normal and ethnic group they will be used rather than the correction entered in the configuration. Refer to Section 6 for instructions on setting the Ethnic Correction Configuration.

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

13 Hygiene and Servicing of the Instrument

EasyOne has been designed to minimize maintenance and servicing effort if the instrument is used correctly.

When you use the spirette respiratory tube, you do not need to clean the instrument. Instead of cleaning, you simply exchange the respiratory tube. In order to ensure absolute hygiene, we recommend that the spirette be used only once.

Caution:	Always exchange the spirette if you suspect the risk of infection. This is the only way of absolutely preventing transmission of diseases.

Use a damp cloth to clean the spirometer housing and the base unit. Use a soft cloth and alcohol (e.g. isopropyl alcohol) for particularly thorough cleaning.

Caution:	Avoid fluid penetrating the spirette holder or the inside of the instrument when cleaning the spirometer.

Please follow the instructions for changing batteries: Open the battery cover on the backside of the instrument. Remove the empty batteries. Please insert two new Alkaline batteries (Type AA, 1,5V) into the battery case and close the battery cover.

Please consult your EasyOne dealer or call the ndd Servicing Dept., number +41 (44) 445 29 70 in the event of defects or malfunctions.

Proceed as follows to check correct operation of your instrument:

1. Check calibration. Please read Chapter 14.
2. Conduct a spirometry test on yourself.
3. Ensure that the results are plausible and that you can print out the report as required.

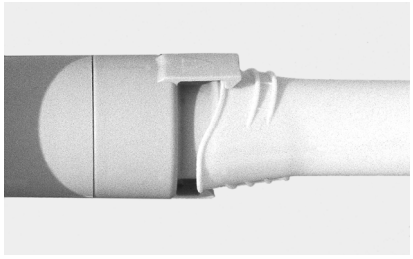
Consult your EasyOne dealer if you encounter problems with one of these points.

14 Checking Calibration

Calibration of the instrument can be checked with a syringe using the calibration check function. The American Thoracic Society (ATS) recommends that calibration be checked every day. The EasyOne spirometer requires no calibration, even if used frequently.

To perform a calibration check, you need the optional ndd calibration adapter and an optional calibration syringe (order number 2030-2), in addition to the spirometer and a spirette. Ensure that the correct syringe volume is entered in the instrument's configuration setting (see also Chapter 8). Proceed as follows:

- Choose item "Check calibration" in the main menu.
- Connect the spirometer as shown below using the calibration adapter and the syringe. Ensure that the piston is fully inserted and at the stop position.



- Now press ENTER
- Wait until the baseline has been set and you hear an audible signal.
- Now execute one full inspiratory pump stroke followed by one full expiratory pump stroke at moderate speed.
- After you perform the maneuver, you will see the text "Accuracy confirmed" at the top of the display and, beneath it, the percentage deviation and the average flow velocity of the pump stroke.
- You can repeat the test, print the result or quit the program. The calibration test remains stored and can also be viewed or printed out later.

If you do not reach ±3% accuracy, please follow the troubleshooting instructions in Chapter 15. Should you not be able to remedy the defect by following these instructions either, please consult your EasyOne dealer.

Please note:	Field service or internal calibration of this unit is not recommended. Cover should not be removed except by qualified service personnel.

15 Troubleshooting Tips

Should you encounter problems operating your spirometer, please consult the table below.

Problem	Possible cause	Solution
EasyOne cannot be switched on	Batteries are dead	Insert new batteries.
	Batteries are inserted wrong	Insert the batteries correctly (see Chapter 4.1.)
	Did not press and hold the ON/OFF key for at least 2 seconds	Press and hold the ON/OFF key for at least 2 seconds.
When the EasyOne is switched on, you hear three consecutive tones as a warning signal	The spirometer is defective	Consult your EasyOne dealer.
When the EasyOne is switched on, you see the following message on the display: "Self-test failed"	The spirometer is possibly defective	Turn off and on the spirometer. Try again. If you receive the same message again, contact your EasyOne dealer.
Every time you switch the instrument on you are prompted to enter Date etc.	The internal battery of EasyOne is defective	Consult your EasyOne dealer.
When you start a test, you see the following message: "Please insert spirette correctly"	The spirette is not correctly positioned	Ensure that the triangle on the spirometer is lined up with the triangle on the spirette.
EasyOne is outside of ±3% when conducting the calibration check	The spirette is not correctly positioned	Insert the spirette as described in Chapter 4.1.
	You have not used an ndd adapter	Use the ndd calibration adapter.
	There are leaks in the syringe connection	Check the connections.
	The specified syringe volume does not correspond to the actual syringe volume	Choose the correct syringe volume under “Configuration”.
The curve is missing on the printout	The color cartridge of your printer is empty	Replace the cartridge.
	In the configuration of your EasyOne a black and white printer is selected, but you actually use a color printer	Go to “Configuration”, then “Report Settings” and select the right printer.
When printing a report the printer prints meaningless characters.	A wrong printer type has been selected in the settings	Set the correct printer. Read Chapter 8.2.
	The printer cable is not correctly connected or is defective	Switch off the spirometer and printer. Check all plug connections.
The printer does not respond.	The printer is not switched on or is not ready	Ensure that the printer is switched on and also has paper. Switch the printer off and back on again.
	The printer cable is not correctly connected or is defective	Switch off the spirometer and printer. Check all plug connections.
	EasyOne is not correctly positioned on the base unit	Insert EasyOne correctly into the base unit.
When switching on the instrument, the message “device self test error #20” appears on the screen	A spirette was inserted while turning on the instrument OR was not inserted correctly	Try again with the spirette inserted correctly. If you receive the same message again, contact your EasyOne dealer.

Problem	Possible cause	Solution
When starting a new test, the message “device selftest error #14 or #15” appears in the screen	The spirette is not positioned correctly	Insert the spirette as described in Chapter 4.1.
When switching on the instrument, the message “device self test error #25” appears on the screen	The internal battery of the EasyOne may be defect	Switch the EasyOne off and on again. If the same message appears again please contact your EasyOne dealer.

16 Bibliography

[1] American Thoracic Society. Standardization of Spirometry: 1994 Update, Nov. 11, 1994. Am J Resp Crit Care Med 1995; 152:1107-1136.

[2] Occupational Health and Safety Administration (OSHA), Pulmonary Function Standards for Cotton Dust, 29 CFR: 1910.1043 Appendix D.

[3] Social Security Administration Disability (SSD) Guidelines, CFR404: Appendix 1 to Subpart P.

[4] Ferguson GT, Enright PL, Buist AS, et al. Office spirometry for lung health assessment in adults: a consensus statement from the National Lung Health Education Program. Chest 2000; 117:1146-1161.

[5] ATS Pulmonary Function Laboratory Management and Procedure Manual, American Thoracic Society, New York, NY 10019.

[6] Enright PL, Hyatt RE. Office Spirometry. Lea & Febiger, Philadelphia, 1987.

[7] Hyatt, RE, Scanlon PD, Nakamura M. Interpretation of Pulmonary Function Tests – A Practical Guide. Lippincott – Raven, Philadelphia, 1997.

[8] American Thoracic Society. Lung Function Testing: Selection of Reference Values and Interpretative Strategies, Am Rev Respir Dis 1991; 144:1202-1218.

[9] Morris JF, Temple W. Short Report: Spirometric “Lung Age” Estimation for Motivating Smoking Cessation, Preventive Medicine 14. 655-662 (1985).

[10] Polgar, Promadhat, Pulmonary Function Testing in Children: Techniques and Standards. W.B. Saunders Co., Philadelphia, 1971

[11] Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease, Executive Summary, Updated 2003 (GOLD)

[12] Hardie et. al., “Risk of over-diagnosis of COPD in asymptomatic elderly never-smokers” Eur Respir J2002;20: 1117-1122

17 Electromagnetic Compatibility (EMC)

Changes or modification to the EasyOne system not expressly approved by ndd could cause EMC issues with this or other equipment. The EasyOne system is designed and tested to comply with applicable regulation regarding EMC and needs to be installed and put into service according to the EMC information stated as follows.

WARNING
Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

WARNING
The equipment or system should not be used adjacent to, or stacked with, other equipment. If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in the configuration in which it is being used.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The EasyOne is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the EasyOne is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions EN 55011	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011	Class B	The equipment is suitable for use in all establishments inclusively in domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2	Not applicable	
Voltage fluctuations/Flicker emissions EN 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The EasyOne is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that the EasyOne is used in such an environment.

Immunity Test	**EN 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	The product has no power supply lines. The product has no input or output lines that require testing.	
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	The product has no power supply lines.	
Voltage dips, short interruptions and voltage variations on power supply input lines EN 61000-4-11	<5% U_t (>95% dip in U_t) for 0.5 cycles 40% U_t (60% dip in U_t) for 5 cycles 70% U_t (30% dip in U_t) for 25 cycles <5% U_t (>95% dip in U_t) for 5 s	The product has no power supply lines	
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE: U_t is the AC mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The EasyOne is intended for use in the electromagnetic environment specified below. It is the responsibility of the customer or user to assure that the EasyOne is used in such an environment.

Immunity Test	EN 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF EN 61000-4-6 Radiated RF EN 61000-4-3	3 Vrms 150 KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V rms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

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

Recommended Separation Distances

The table below provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the EasyOne. The EasyOne is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The cust-omer or the user of the EasyOne can help prevent electromagnetic interference by maintaining a minimum distance between portable and mo-bile RF communications equipment (transmitters) and the EasyOne as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Output Power of Transmitter in Watts	Separation Distance in Meters (m) According to Frequency of Transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters (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 instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Compliant Cables and Accessories

The product has no accessories which affect EMC compliance.

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EC Declaration of Conformity

Manufacturer: ndd Medizintechnik AG

Address: Technoparkstrasse 1
CH-8005 Zürich, Switzerland

declares under its sole responsibility, that the product

Product designation: **Spirometer**

Product name: **EasyOne™**

EasyOne has been classified as Class IIa and is in conformity with the essential requirements and provisions of Council Directive 93/42 EEC,

is in conformity with the following standards transposing harmonized standards:

EN 1041:1998
EN ISO 14971:2000 and A1 : 2003
EN 60601-1: 1990 and A1 :1993 and A2 : 1995
EN 60601-1-1: 2001
EN 60601-1-2: 2001
EN 60601-1-4: 1996 and A1: 1999

is subject to the procedure set out in ISO 9001:2000, ISO 13485:2003, and in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd Systems & Services Certification 202B Worl Parkway, Weston-super-Mare, BS22 6WA UK

Zurich, October 30th, 2006

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