

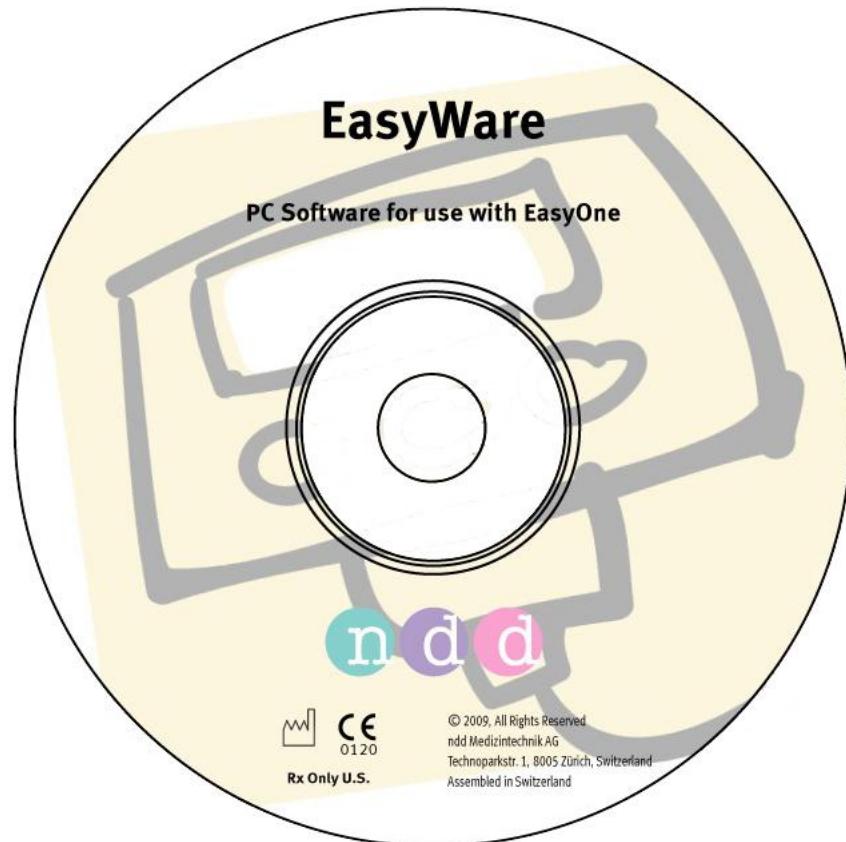


EasyWare

PC Software for use with *EasyOne Spirometer*

Operator's Manual

English



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1 Introduction

With the *EasyWare* PC software, the *EasyOne* spirometer can be used in conjunction with a PC. The main features of *EasyWare* are:

- direct printing via PC,
- searching for patients or IDs,
- quickly previewing test results,
- entering patient data on the PC,
- saving measurement data (including curves) in a Microsoft Access compatible database,
- print and print preview protocols directly from the PC database,
- export of data from the database into text files,
- configuration of the *EasyOne* device,
- displaying real-time curves using the *EasyOne ScreenConnector*.

2 Installing the PC software

2.1 PC/Laptop Requirements

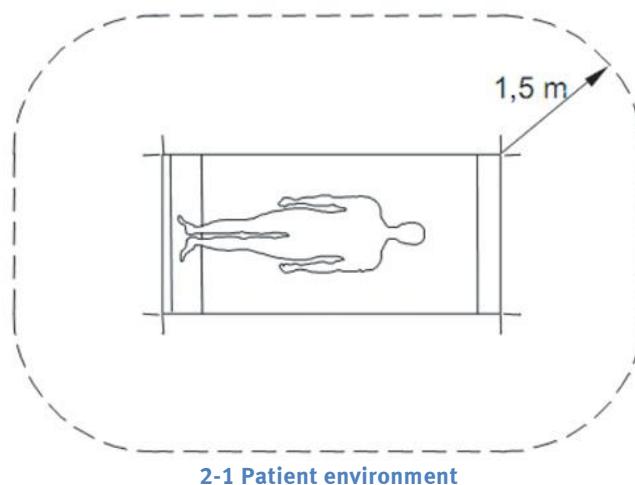
The minimum requirements for installing the PC software are as follows:

Operating system: 32 + 64 Bit	Microsoft Windows XP Home and Professional (min. SP2), Microsoft Windows Vista (all versions), Microsoft Windows 7 (all versions)
Processor:	Pentium \geq 1.0 GHz
Screen resolution:	SVGA 1024 x 768
Hard disk memory:	100 MByte free
RAM:	256 MByte
Internet Explorer:	Microsoft Internet Explorer 6.0 or higher

The *EasyWare* software is installed on a PC or laptop computer to which the *EasyOne* is connected by means of a USB cable (USB cradle or *ScreenConnector*). The PC or laptop computer which is not part of the equipment supplied by ndd Medizintechnik AG is thus considered a requisite accessory necessary for the intended use of the device.

In your capacity as the operator of the medical electrical device you are obliged to ensure that the specific, applicable requirements of the standard EN 60601-1:2006 are complied with. The following conditions must be met:

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



If IEC XXXXX devices (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.

These are the applicable limits:

- 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.

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

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

In altitudes above 2000 meters above sea level the air clearance of the applicable IEC safety standards (e.g. IEC 60950-1) for the requisite accessories is no longer sufficient, because IEC 60601-1 adds an additional factor which increases with altitude.

Suggestions:

- Use of isolating transformer which is in conformance to IEC 60601-1 for the PC or
- Use of isolating transformer which is in conformance to IEC 60601-1 with built-in multiple socket-outlets for the PC and the devices connected to it.

2.2 Installation of the *EasyWare* PC software

You will require Administrator privileges to install the software. Proceed as follows:

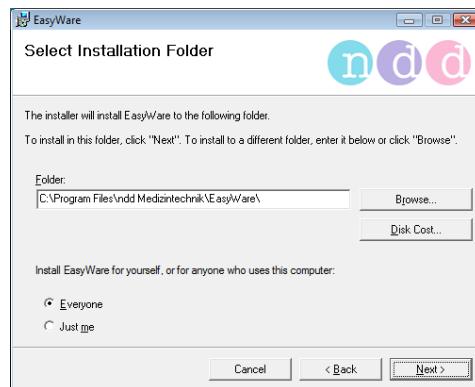
- **Do not yet** connect the *ScreenConnector* nor the USB-Cradle to the PC.
- You will require Administrator privileges on the PC in order to install the software.
- Quit all programs and insert the *EasyWare* CD into your CD ROM drive. The installation routine should start automatically within 30 seconds of inserting the CD. If the installation routine does not start automatically, switch to directory 'Setup' on the CD-ROM and run the SmartInstaller.exe program. You will then see the following window:



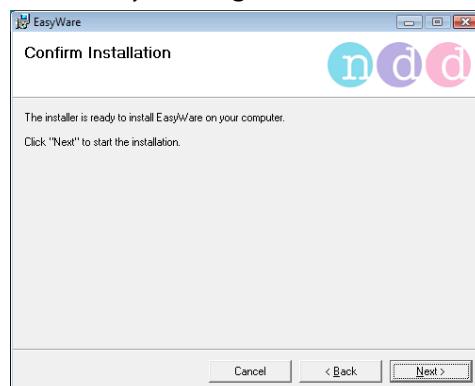
- SmartInstaller facilitates the reading and printing of manuals and also the installation of the software.
- Click on "Install EasyWare".



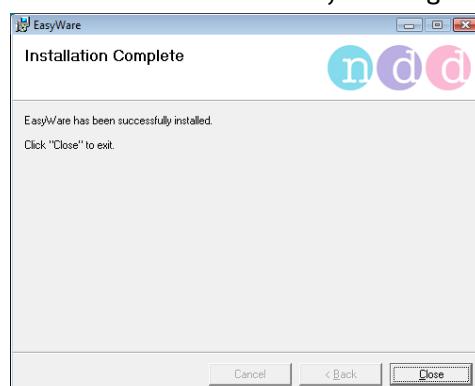
- Click on "Next >".



- In the bottom part of the window, you can still select whether this application is to be installed for all users ("Everyone") or for you only ("Just me").
- Click on "Next >" to confirm the displayed installation path. If you wish to change the displayed installation path, you can do this by clicking on "Browse...".



- Confirm the summarized installation information by clicking on "Next >".

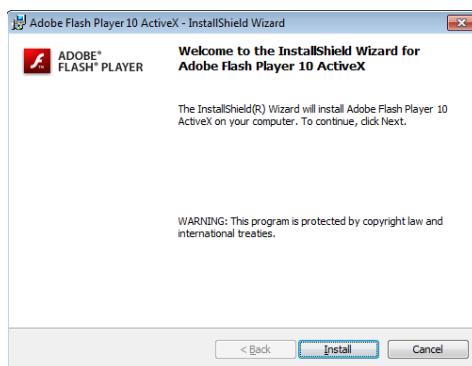


- Confirm completion of installation by clicking on "Close".

- Optional for Flash Player: Click on "Yes" if dialog is shown (Adobe Flash Player must be installed on your system in order to display the pediatric animation).



- Confirm installation by clicking on "Install".



- Confirm completion of installation by clicking on "Finish".



- Your computer may need to be restarted during this installation procedure under certain circumstances.
- The SmartInstaller can be terminated by clicking on "Exit". Remove the CD from the drive.
- An *EasyWare* icon will have been installed on your desktop after installation.
- Launch *EasyWare*. When *EasyWare* is launched for the first time, you are prompted to choose the language.

2.3 Installing *EasyWare* in a network

- Install *EasyWare* on each PC on which you wish to use *EasyWare* and set the following configuration.
- You will require Administrator privileges to install the software. During installation, choose the option for allowing all users to use the software. After installation, you will need to start the software once with Administrator privileges. Now enter the software serial number and define the location of the database using Properties in the File menu, see chapter 4.18 Preferences.
- Enter the complete path and name of the database under 'Database path and name'. You can also search for an existing database with the '...' button.
- If you do not yet have a database, enter "EasyWare.mdb" for instance as the name of the database.
- After *EasyWare* has been installed correctly, you can access an *EasyWare* database from different PCs at the same time. If you have several *EasyOne* devices, you can also synchronize several *EasyOne* devices with the same database at the same time.
- Please note that the test list may be empty after the first start of *EasyWare*. In that case please select the device that should be displayed, see chapter 4.15 Select device in DB.

3 Performing a spirometry test using *EasyWare*

3.1 Performing an off-line spirometry test

The following step-by-step procedure describes how to use *EasyOne* in conjunction with the *EasyWare* PC software. The procedure assures the use of a USB cradle, it can however also be performed using the *ScreenConnector*.

- Connect the cradle to a USB port using standard USB cable.
- Start *EasyWare* on your PC by double-clicking on the *EasyWare* icon on the desktop.
- Turn the power of *EasyOne* on and put it in the cradle. *EasyWare* now connects to the spirometer and the status bar should display ‘Device connected’ on the right-most indicator field at the bottom of the *EasyWare* window.
- In order to perform a new test with a patient select Edit / New Patient or select the appropriate icon. In the patient dialog enter patient name, patient ID, birth date, height and additional information. Confirm with OK.
- Take the *EasyOne* out of the cradle and press ESC. The *EasyOne* restarts and enters the main menu.
- Select ‘Perform Test’ and then ‘Recall’. The patient entered previously using *EasyWare* is automatically selected. Press enter to confirm and select the appropriate test type. Now perform now the test with the patient.
- After the test has been performed exit by pressing ESC to go back to the main menu. Put the *EasyOne* in the cradle. *EasyWare* now re-connects to *EasyOne* and synchronizes the database.
- The new test is now also available in the PC database.
- In order to print the test report select the top-most test, select the File / Print menu or press the appropriate toolbar icon.
- In order to view a test double-click on it or use the appropriate toolbar icon.

3.2 Performing an on-line spirometry test (for *ScreenConnector*)

This chapter describes the procedure for conducting a spirometry test using *EasyWare* and *EasyOne*. For this purpose, *EasyOne* must be operated in so-called On-line mode. *EasyOne* must be connected to a USB port of the PC via the *ScreenConnector*. Make sure to connect the *EasyOne* first to the *ScreenConnector* before plugging in the USB cable.

Please proceed as follows in order to conduct a test:

- Connect the *EasyOne* to the *ScreenConnector* -> the *EasyOne* can not yet be operated, only the data is synchronized
- Create a new patient record by choosing New Patient in the Edit menu. This step is optional. A new patient record can also be entered subsequently with the *EasyOne* keyboard (see below).
- Use the menu or the toolbar of the *EasyWare* to switch to On-line mode. A window similar to the Test Preview window is displayed on the PC screen.
- The *EasyOne* can now be operated normally with the instrument’s keyboard. Choose “Perform Test / Search” to retrieve the previously entered patient data or choose “Perform Test / New” to enter new patient data. Now conduct a spirometry test as normal.
- When you conduct the test on the patient, flow/volume and volume/time diagrams are shown in real time. The most recent curve is always shown in dark red, and the messages for the current test are shown beneath the numeric data. Alternatively, a pediatric animation can be used for FVC tests.

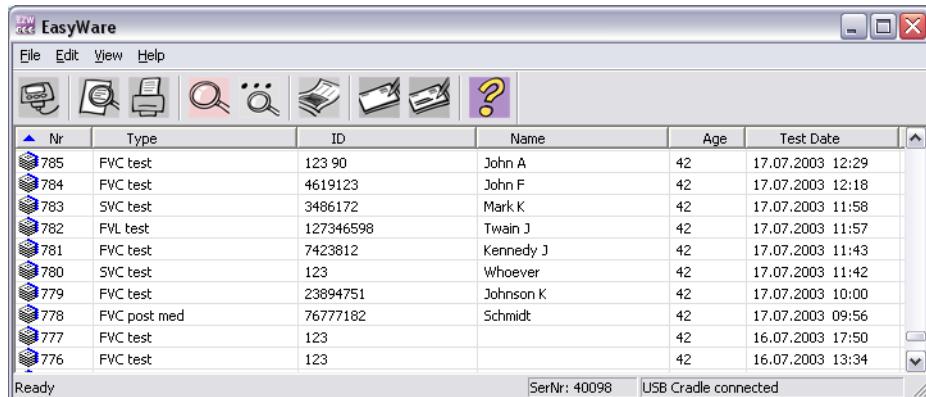
Remarks:

- On-line mode can be quit at any time with the OK button
- On-line mode can be used with all test types and also with Post test
- *EasyOne* synchronizes again automatically with *EasyWare* when you quit or finish the test

4 Details of *EasyWare*

4.1 The *EasyWare* main window

The illustration below shows *EasyWare*'s main window.



From top to bottom, you can see menus, toolbar, list of all records from the PC database and status bar.

The list can be sorted in ascending or descending sequence by record number, type, ID, name, age or test date by clicking on the corresponding column header.

The following information is available for each record, i.e. for each test conducted:

Symbol	Identification of the status of the record (see below)
No.	Internal record number. This is also displayed in <i>EasyOne</i> when selecting the test.
Type	Type of test conducted
ID	Patient identification number (if entered)
Name	Name of the patient (if entered)
Age	Age of the patient
Test date	Date and time of the test

The symbols below serve to identify the record status.

- ! A red exclamation mark indicates a record that has not yet been synchronized with the *EasyWare* PC database, i.e. this record is currently saved only in *EasyOne*.
- ! A blue database symbol identifies a record that is available in the *EasyWare* PC database.
- ! A red database symbol indicates a record that exists in the PC database but that has been updated or supplemented in *EasyOne*. One example is adding a Post test. This record is synchronized during the next synchronization operation.
- ! An amber sheet indicates a patient record that was generated in *EasyWare*. This record contains only patient data and no measurement data. This record can be used in *EasyOne* for future measurements.

The status bar, i.e. the lower area of the *EasyWare* main window, shows the serial number of the connected instrument and the current connection status (for example 'Not connected' or 'Device connected' etc.).

4.2 The PC database and synchronization with *EasyOne*

A Microsoft Access compatible PC database is used to store the data of an *EasyOne* record (measurement). The database file is preset to "EasyWare.mdb". The path of the database directory can be specified in the Preferences dialog (menu File / Preferences). The detailed structure of the database is described in Attachment A: Database Structure..

The program normally synchronizes the *EasyOne* database automatically with the PC database. All records that are marked with a red exclamation mark or a red database icon will be stored (or updated) in the database. Synchronization requires approx. 0.2 seconds per record.

When synchronization is complete the list in the EasyWare window is redrawn and all records are now shown as 'blue database icons' and 'yellow patient data sheets'.

Synchronization range

Records are within the synchronization range if their date is more recent or the same as the date of the most recent record in the database. Due to this the time & date of *EasyOne* and *EasyWare* should not differ much. Therefore a warning is displayed if the difference is more than 15 minutes.

New Patient Records

New patient records can only be created if *EasyOne* is connected to the PC.

Modified Records

In the synchronization process, *EasyOne* has always priority. If *EasyOne* is connected with *EasyWare* and the patient data is edited, it is done on both sides. If they are not connected, two cases have to be considered: a) within or b) outside of synchronization range. Within the synchronization range only records modified in *EasyOne* will be synchronized. Outside of the synchronization range modified records will generally not be synchronized. This means that if you edit a record in *EasyWare* and the *EasyOne* is connected again, the data from the *EasyOne* overwrites the edited *EasyWare* data.

Deleted Records

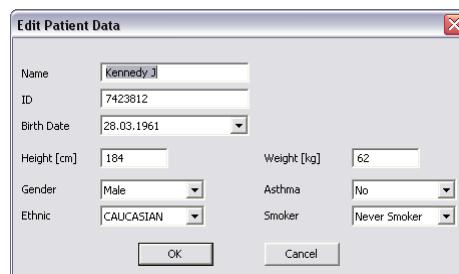
Records cannot be deleted in *EasyWare* as long as they are in the synchronization range. The delete command can be executed. The next synchronization however, will undo this effort because the records will be re-synchronized from *EasyOne*.

Note

Note that the first synchronization operation for an *EasyOne* may take a relatively long time since, under certain circumstances; many records may have already been saved in *EasyOne*.

4.3 Viewing patient data

Patient data can be viewed and edited if a record is selected and the Edit / Patient Data menu or the toolbar icon is used. The following dialog window is displayed:



If *EasyOne* is connected to the PC the patient data can also be manipulated. The data in *EasyOne* is then automatically updated.

4.4 Entering a new patient data

To create a new patient record, select Edit / New Patient or the appropriate toolbar icon. Enter the patient data and confirm. A new patient data record will be generated. The new patient data record will also appear on top of the list. If 'Technician ID' is activated (see *EasyOne* manual, 'General Settings'), the Technician ID can also be entered.

This function is only available if *EasyOne* is connected to the PC.

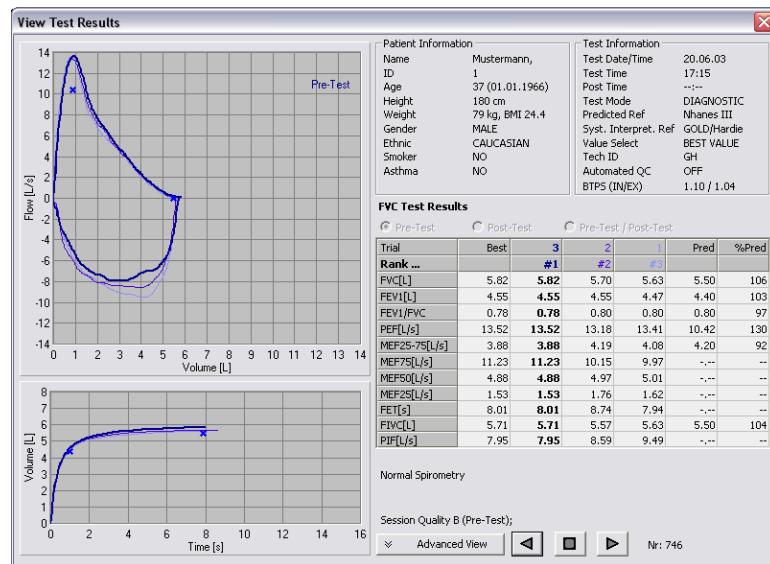
4.5 Deleting records

Records in the PC database can be deleted by selecting the appropriate records and using the Edit / Delete menu. Several records can be selected by using the shift or the Ctrl keys.

Records cannot be deleted as long as they are in the synchronization range (see above). In this case the records will be re-synchronized from *EasyOne*.

4.6 Viewing test results in 'Normal View'

By selecting and double clicking a record the test results can be displayed. Alternatively the menu View / Test Result or the appropriate icon can be used. The following window is displayed:



The example above uses 'Best Value' display (see chapter 4.17 Device configuration). If 'Best Trial' is selected the trial rank will additionally be displayed in the header of the table. Please note that in 'Normal View' only the three best trials (rank #1 to #3) are displayed. If additional trials have been performed, and if the curve data of all data is stored, then data and curves of these additional trials are displayed in 'Advanced View' (see chapter below).

The test result window contains the following information:

- Curves depending on the measurement type. Pre and/or post curve with predicted values.
- Patient and test information.
- Numerical test results of pre and/or post test.
- Warnings and interpretation.

By clicking on the trial number or on the trial rank individual curves can be highlighted

By using the arrow buttons the next or the previous record can be displayed. Instead of the buttons the PgUp or PgDown keys can also be used.

EasyWare Test Previews can easily be copied into other applications (e.g. Microsoft Word). Please execute the following operations:

1. Start the application where you want to copy the *EasyWare* report (e.g. Microsoft Word).
2. Start *EasyWare*.
3. Select the test you would like to copy and double click in the test list or select View / Test Result in the menu. This opens the View Test Result window.
4. Select what detail is shown (Baseline, Post or Baseline combined with Post)
5. Press and hold the Alt-key on the keyboard. Press the PrtScr-key. This copies the content of the current active window into the clipboard.
6. Change to the other application (Microsoft Word)
7. Press Ctrl-V or select Edit / Paste in the menu. This copies the content of the clipboard into the application.

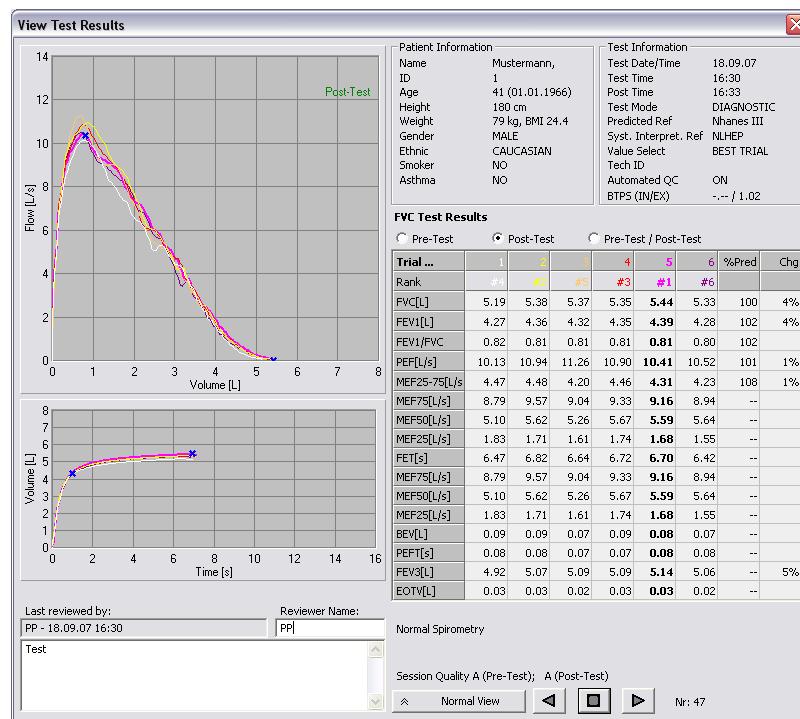
4.7 Viewing test results in 'Advanced View'

The selection field 'Advanced View' enables additional features.

4.7.1 Displaying of up to 8 trials

In 'Advanced View' the trials are always displayed sequentially, i.e. the tests are ordered according to their test time. The rank is now displayed in a second line of the header. Again, trials can be highlighted by clicking on the trial header in the list. The picture below shows an example of a post test with 6 trials; in this example the best trial is the fifth trial, marked with rank #1.

Please note that *EasyOne* firmware only supports storage of up to 8 trials starting from firmware V5.0.



4.7.2 Reviewing tests

In 'Advanced View' tests can also be reviewed. In order to review tests please enter a reviewer name in the appropriate field. A comment can now be added to the test. This comment will be stored in the database.

4.7.3 Changing Trial Ranking and Trial Acceptability

After entering a reviewer name trial ranking and trial acceptability can be edited manually: By clicking on a trial rank indicator the trial ranking can be changed. Please note that this can only be done if 'all curve storage' is used in the *EasyOne* (please consult the *EasyGuide* manual for further information).

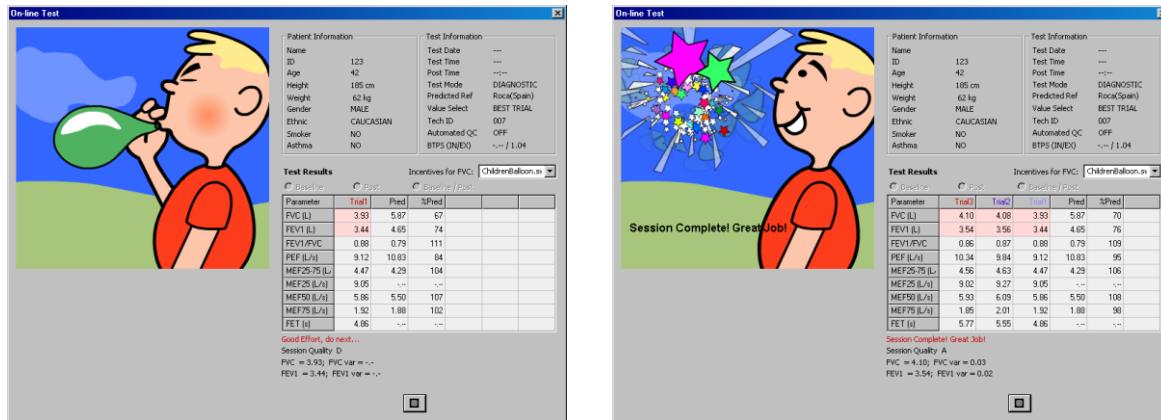


The following changes can be selected:

- Make it highest ranked: The selected trial is ranked #1.
- Make it accepted: An unaccepted trial can be made acceptable.
- Make it accepted and highest ranked: An unaccepted trial is made acceptable and its rank is set to #1.
- Make it not accepted: An accepted trial can be set to 'not accepted'.
- Restore original *EasyOne* trial ranking: The automatic trial ranking defined by *EasyOne* is restored.

4.8 Children Incentive

If the *EasyOne ScreenConnector* is available and tests are performed in the on-line mode a children incentive display can be selected for the FVC tests. Select the appropriate incentive display by using the drop-down list. The following picture shows the incentive display during the blow and at the end of a successful trial:



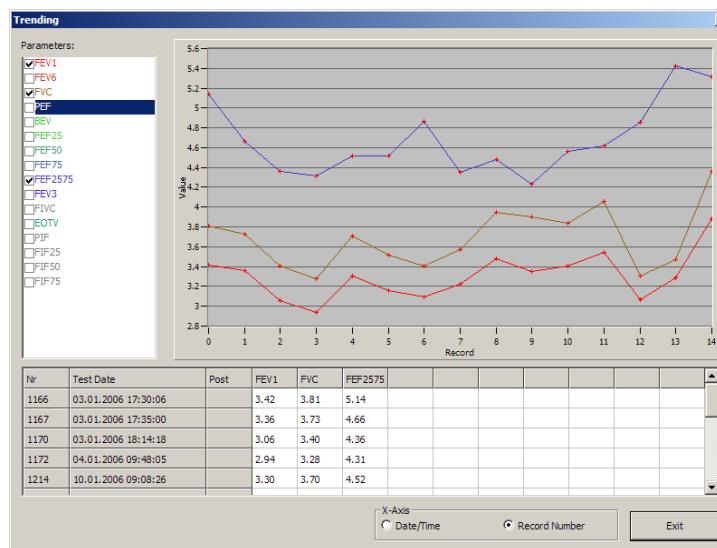
The incentive display is not available for FVL, SVC and MVV tests.

4.9 Trending

The View / Trending menu activates a simple trending tool. The tool can be used in the following way:

- Sort the main list view by patient ID or patient name (click on the name or ID header).
- Manually select those tests that should be used for a trend analysis; use the shift or the control key in order to select multiple tests.
- Select the menu 'View /Trending'.

The window shows the trend report. Number and type of parameters can be selected on the left side. The trend report can be displayed ordered by date/time or ordered by record number.



4.10 Finding Records

By using the menu View / Find or the appropriate icon in the toolbar records can be searched for name or ID. Partial name entry is also supported (e.g. entering "Thom" will also find "Thomas"). The record is searched starting at the currently selected position. The menu View / Find Next or the appropriate toolbar icon will find the next occurrence.

4.11 Printing a test and creating PDF reports

- Select File / Print Preview (or the appropriate toolbar icon) to preview the printout.
- Select File / Print to print the test.

- Select File / Print PDF in order to generate a PDF report. For details of the PDF report settings please see chapter 4.18 Preferences.

The report format depends on the current *EasyOne* device settings (see chapter 4.17 Device configuration).

4.12 Direct printing via PC

EasyOne supports direct printing via the PC. In order to print a test using the ‘direct printing’ feature please perform as follows:

- Start the *EasyWare* application on the PC.
- *EasyOne*: Select the printer type ‘via PC’ in Configuration / Report Settings.
- *EasyOne*: Select Print Results in the Main menu and select a test. The device now displays “Please connect device to cradle”.
- Put the *EasyOne* into the cradle.
- The *EasyOne* is automatically detected by *EasyWare* and the report is printed to the currently selected printer (please consult the Windows manual on how to select the default printer).

4.13 Exporting data

EasyWare supports the following data exports:

Text Export (CSV): All Records	All records from the currently selected device are exported to a csv File. See Attachment B: Text File Export Data Format. The file names are created from the device serial number and the record numbers.
Text Export (CSV): New Records	New records from the currently selected device are exported to a csv File. See Attachment B: Text File Export Data Format. The file names are created from the device serial number and the record numbers.
Text Export (CSV): All Devices	All records from all devices in the database are exported to a CSV file. In this format a test is exported to a single line that contains the patient data and the test values. This export format is compact and can be used to quickly evaluate a study.
GDT Export	A GDT file from the selected record is created. The GDT format is used to exchange data with selected patient information systems.
XML Export (XML)	The selected records are exported to XML files. The file names are created from the device serial number and the record numbers.
ATS/ERS Export (CSV)	The selected records are exported to a csv file according to the ATS/ERS data export format (ATS/ERS Task Force: Standardization of Lung Function Testing. Eur Respir J 2005; 26:319-338).

By default the files are exported to the directory that is set in the File / Preferences menu.

4.14 Importing data

EasyWare can import the following data files: XML, p7m (encrypted EMail) or eml (not encrypted Email). The data import feature is mainly used in conjunction with *EasyOne* NET.

4.15 Select device in DB

The database can store data from multiple *EasyOne* units. The units are differentiated by serial number. When no unit is connected to the PC, the user can select the device from which the data will be listed. Go to “Select Device in DB...” in the View menu. The serial number of all *EasyOne* units that have been synchronized to that database is listed. Select the serial number of the unit you would like to look at.

4.16 Device status

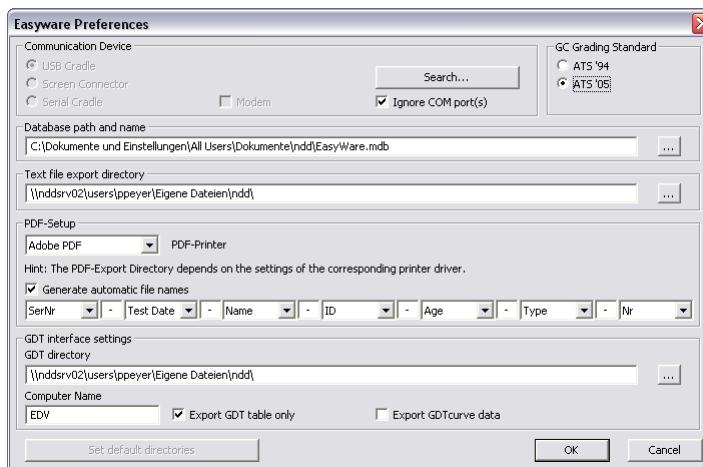
The device status (menu View / Device Status) reports serial number, firmware version, boot software version, hardware version and device type of *EasyOne*.

4.17 Device configuration

EasyOne device configuration can also be changed via PC. The settings here are identical to the settings in the Configuration menu of *EasyOne*. Please consult the *EasyGuide* manual for further information. On the 'General Configuration' tab the internal clock of *EasyOne* can be synchronized to the clock of the PC.

4.18 Preferences

By entering the File / Preferences menu the following dialog window is shown:



The following settings can be defined:

- Selection of the way *EasyOne* is connected to the PC: USB cradle, *ScreenConnector* or serial cradle.
- In the case of the serial cradle the number of the COM-Port must be specified (see installation instructions) and the use of a modem can be specified (this feature is only supported by special *EasyOne* devices).
- File name and directory of the *EasyWare* database. By default the database name is “*EasyWare.mdb*” in the directory where the *EasyWare* program is installed.
- Directory for text file exports.
- PDF-Setup: This option allows customization of the PDF export. In order to use this feature a PDF printer is required. If such a printer is not available please download and install an appropriate printer. Examples of such printer drivers are Adobe Acrobat (www.adobe.com), PDF Creator (freeware, sector7g.wurzel6.de/pdfcreator) or Bullzip (freeware, www.bullzip.com).
- Menu "Save as PDF" is enabled if one test is selected. The file name can optionally be generated by using Serial Number, Record Number, Type of Test, Patient ID, Patient Name, Patient Age and/or Test Date.
- Additional settings are used for a electronic medical record software interface mainly used in Germany. The GDT interface description is detailed in chapter Attachment C: Electronic Medical Record Interface
- Recalculation of quality grades based on ATS 94 or ATS 05.
- “Search...” scans for communication ports connected to PC.

4.19 Language Selection

The language of the application can be selected using the menu 'File / Switch Language'. Please note that the language of *EasyWare* can be selected independently of the language selected in *EasyOne*.

5 Attachment A: Database Structure

The following diagram shows the organization of the database.

Devices	TestDescr	PrePost	Trial	Info
Index 0	Index 1	Index2	Index3	
SerNr long	SerNr long	SerNr long	SerNr long	
RecNum long	RecNum long	RecNum long	RecNum long	
SyncDate date/time	Date date/time	PrePost bool	PrePost bool	
Status ByteArray	Export ⁽¹⁰⁾ byte	Date date/time	TrialNum ⁽¹¹⁾ byte	
DecrKey text	PatientID text	NoOfTrials byte	Date date/time	
DecrKeydesc text	BirthDate date/time	Boolean1 bool	Accept bool	
LogoName text	Height float	Boolean2 bool	TrialTyp byte	
	Weight float	Boolean3 bool	TrialNo ⁽¹¹⁾ byte	
	Gender bool	Boolean4 bool	FEV1 *§ float	
	Smoker bool	Boolean5 bool	FEV6 *§ float	
	Asthma byte	QCGrade byte	FVC *§ float	
	Ethnic byte	Word0 integer	PEF float	
	Name text	Word1 integer	BEV float	
	Spare byte	Word2 integer	FET *# float	
	TechnID text	BtpsExp float	PEFT *# float	
	TypeOfTest byte	BtpsIn float	FEF25 float	
	FEV6Selected bool		FEF50 float	
	AutoQCon bool		FEF75 float	
	StorageOption bool		FEF2575 § float	
	CRC long		FEV3 *# float	
	Memo memo		FIVC * float	
	Status OLE		IVC float	
	ReviewerName text		VC (EOTV) float	
	ReviewDate date/time		PIF *§ float	
	ExtendedData memo		FIF25 \$ float	
	TVersion byte		FIF50 float	
			FIF75 \$ float	
			Tzero float	
			CuFVLen integer	
			CuVTLen integer	
			CurveFV ⁽³⁾ ByteArray	
			CurveVT ⁽⁴⁾ ByteArray	
			OrigTrialNum text	

Notes:

1. Key fields are marked with a thicker frame.
2. The data type is indicated on the right hand side.
3. Format of CurveFV ByteArray: The ByteArray contains 2 byte integer values with low byte followed by high byte. The listed values are flow values with a resolution of 10 ml/s per bit. The volume spacing between samples is 30 ml. The first point of the curve at (0,0) has been omitted.
4. Format of CurveVT ByteArray: Organization identical to CurveFV. The listed values are volume values with a resolution of 10 ml per bit. The time spacing between samples is 60 ms. The first point of the curve at (0,0) has been omitted.
5. Trial fields marked with * have a different meaning if the test type is 'slow vital capacity'.
6. Trial fields marked with # have a different meaning if the test type is 'MVV'.
7. Trial fields marked with § have a different meaning if the test type is 'Calibration Check'.
8. Trial fields marked with \$ have a different meaning if the test type is 'FVC'.
9. Most of the field names are identical to the names used in the text file export. For an explanation please refer to the following Attachment.
10. The field labeled 'Export' in the TestDescr table is used to identify the export status of the test.
11. TrialNum is the rank of the trial, TrialNo is the sequence number of the trial.

6 Attachment B: Text File Export Data Format

The *EasyWare* program exports data files with the following file names: SNsssss-rrrrr.csv, where ssss stands for the *EasyOne* serial number (unique), and rrrrr stand for the internal test record number (also unique up to 32768 records on a single unit). The file name is therefore unique.

The following describes the format used for data export from *EasyOne*.

Nr	Parameter Name	Suf fix	Type	Description
0	SerNr		int	EasyOne device serial number
1	RecNum		int	record number
2	TypeOfTest		int	the following test types are defined: 2 = FVC 3 = FVC incl. post 5 = FVC NLHEP 6 = FVC NLHEP incl. post 8 = FVL 9 = FVL incl. post 11 = MVV 12 = Challenge 13 = Disability 14 = SVC 15 = Calibration 16 = Multiflow Calibration 20 = disability 21 = Disability incl. post 23 = OSHA 24 = OSHA incl. post
3	NoOfTrials	_p	int	number of trials in baseline measurement
4	FEV6Selected		bool	indicates if FEV6 or FVC mode is used
5	AutoQCOn		bool	indicates if automatic QC is used
6	Storage Option		bool	indicates if only best or three best curves are stored
7	Boolean1	_p	bool	boolean value for future use
8	Boolean2	_p	bool	boolean value for future use
9	Boolean3	_p	bool	boolean value for future use
10	Boolean4	_p	bool	boolean value for future use
11	Boolean5	_p	bool	boolean value for future use
12	QCGrade	_p	int	the following quality grades are defined: 0 = F 1 = D 2 = D not reproducible 3 = C 4 = B 5 = A
13	Date		date	date of test
14	Word0	_p	word	word value for future use
15	Word1	_p	word	word value for future use
16	Word2	_p	word	word value for future use
17	BtpsExp	_p	int	Expiratory BTPS factor: 0.90 + BtpsExp/100
18	Btpsln	_p	int	inspiratory BTPS factor: 0.95 + Btpsln/100
19	PatientID *		string	Patient identifier
20	BirthDate *		date	Patient birth date (if 'Age' is selected then actual date minus age)
21	Height *		int	Patient height in cm
22	Weight *		int	Patient Weight in kg*100
23	Gender *		int	Patient gender: 0 = male, 1 = female
24	Smoker *		int	Patient smoker status: 0 = yes, 1 = no, 2 = ex
25	Asthma *		int	Patient asthma status: 0 = no, 1 = possible, 2 = yes
26	Ethnic *		int	The following patient ethnic groups are defined: 0 = African 1 = Caucasian / European 2 = Mexican 3 = Asian 4 = Other
27	Name *		string	Patient name
28	TechnID		string	Technician identifier
29	Spare		int	Spare patient data for future use
30	Accept	_p	int[3]	trial acceptability: 0 = not acceptable, 1 = acceptable
31	TrialTyp	_p	int[3]	not used
32	TrialNo	_p	int[3]	number of this trial
33	Time	_p	date[3]	time

					SVC	MVV	Cal. Check
34	FEV1	_p	float[3]	Forced exp. vol. in 1 sec. [l]	VT, tidal vol [l]		insp. Vol. [l]
35	FEV6	_p	float[3]	Forced exp. vol. in 6 sec. [l]	ERV [l]		exp. Vol. [l]
36	FVC	_p	float[3]	Forced Vital capacity [l]	VCex [l]		syringe vol. [l]
37	PEF	_p	float[3]	Peak exp. flow [l/s]			
38	BEV	_p	float[3]	back extrapolated volume [l]			
39	FET	_p	float[3]	Forced Exp. Time [s]	SVC time [s]	MVV time [s]	
40	PEFT	_p	float[3]	Peak Exp. Flow Time [s]	Rf [1/min] / 2		
41	FEF25	_p	float[3]	forced exp. flow 25% [l/s]			
42	FEF50	_p	float[3]	forced exp. flow 50% [l/s]			
43	FEF75	_p	float[3]	forced exp. flow 75% [l/s]			
44	FEF2575	_p	float[3]	forced exp. flow 25-75% [l/s]			mean exp.flow
45	FEV3	_p	float[3]	forced exp. volume in 3 s [l]	IRV [l]	MVV [l/min]/160	
46	FIVC	_p	float[3]	forced insp. vital capacity [l]	VCin [l]		
47	VCmax	_p	float[3]	VCmax [l] (see 12)	VCmax [l]		
48	EOTV	_p	float[3]	end Of Test Volume [l]			
49	PIF	_p	float[3]	peak insp. flow [l/s]	IC, insp.cap. [l]		insp.peak [l/s]
						FVC	Cal. Check
50	FIF25	_p	float[3]	forced insp. flow 25% [l/s]		FEV0.5 [l]	FIF2575
51	FIF50	_p	float[3]	forced insp. flow 50% [l/s]			
52	FIF75	_p	float[3]	forced insp. flow 75% [l/s]		FEV0.75 [l]	
53	Tzero	_p	float[3]	time zero from back extrap. [s]			
54	CuFVLen	_p	int[3]	length of flow/volume curve			
55	CuVTLen	_p	int[3]	length of volume/time curve			
56	CurveFV	_np	int[3][x]	flow/volume curve			
57	CurveVT	_np	int[3][x]	volume/time curve			

Notes:

- In the case of SVC and MVV test some parameters contain different values; i.e. the parameter named FEV3 contains IRV if the test type is SVC, it contains MVV if the test type is MVV.
- In order to comply with limitations of Excel, curve data is exported in vertical format.
- Boolean values: zero stands for false, unequal zero for true.
- Suffix _p: This suffix is added to the parameter name if it is a post parameter. Example: FEV1Best_p is the parameter name for the best FEV1 of the post test. Parameters with _p are only present if a post test has been performed.
- Suffix _np: This suffix is only used for curve data. Depending on the test, up to three curves can be exported: CurveFV_1, CurveFV_2, CurveFV_3. The numbers indicate 1 = best, 2 = second best and 3 = third best. The additional suffix p again denotes the post curves.
- CurveFV contains exactly the number of values given in CuFVLen. The same applies CurveVT.
- Scaling of FV curve: The listed values are flow values with a resolution of 10 ml/s. The volume spacing between samples is 30 ml. The first point of the curve at (0,0) has been omitted.
- Scaling of VT curve: The listed values are volume values with a resolution of 10 ml. The time spacing between samples is 60 ms. The first point of the curve at (0,0) has been omitted.
- Scaling of MVV parameter: In the export the MVV parameter is scaled in the same way as the FEV3 parameter. In order to convert MVV in [l/min] the parameter must be multiplied by 160.
- The parameters PatientID to Name (19 to 27) are defined during patient data entry.
- Sign of parameters: Inspiration positive, expiration negative.
- The VCmax Parameter is set under the following circumstances: a) FVL test, b) combined SVC test with FVC or FVL, c) SVC test.

7 Attachment C: Electronic Medical Record Interface

Introduction

The following describes the interface set up to facilitate the data communication between *EasyWare* and an Electronic Medical Record System (EMR). As an example the integration of the German GDT standard is described.

Version history

EasyWare Version	Description	Date	Document Version
1.3.1	First implementation of the GDT interface	3.4.2002	1.1
2.4	Correction of the GDT file name, now without "_"	N/A	N/A
2.7	Curve data export, export of <i>EasyOne</i> serial number and record number. Implementation of Test Recall.	17.9.2004	1.2
2.8	Recall via record type 6311. Support of first name and last name with 3101, 3102. Export of interpretation and predicted values.	14.4.2005	1.3

Software Settings

The following settings need to be made in File/Preferences menu of *EasyWare*:

Parameter	Description
GDT Folder	The GDT folder of the EMR system. This may also be a folder in a network drive. For convenient path entry the button Browse may be used. The GDT file will be written to this folder and read in from this folder.
Computer Name	Name of the EMR computer.
Export only GDT table	If this is activated: Only formatted text of the result table (GDT field 6228) will be exported (see also example forced spirometry below).

Data accepted by *EasyWare* from EMR / GDT

The following data is read in by *EasyWare* from the GDT interface. The data that is actually transmitted depends on the EMR (GDT) system used. Excessive data is ignored by *EasyWare*.

GDT Field ID	Description	Comment
8000	Record ID	
8316	GDT-ID of EMR	When this information is sent, the GDT-ID is automatically accepted used by <i>EasyWare</i> (see chapter "Software Settings").
3000	Patient ID	The ID may include letters and numbers. Maximum length: 15 characters
3101	Name	First name, maximum number of characters: 47
3102	First Name	Last Name, maximum number of characters: 47
3103	Date of Birth	
3110	Gender (1 = male)	
3622	Height (in cm)	
3623	Weight (in kg)	

Here an example of a GDT file (nddPCS.gdt), received from an EMR with the name PCS:

```
014810000202
01380006302
0158315Extern
0128316PCS
014921802.00
01030001
0093100
0143101Meier
0163102Manfred
017310301011966
0093104
019310624106 Kiel
0203107Schulstr. 1
01031101
0123622185
011362363
```

In addition to some GDT specific information the file contains the following patient information: Name, date of birth, gender, height in cm, weight in kg. For correct interpretation of these data the EMR computer name must be entered as "PCS" in File / Preferences.

View of tests with *EasyWare*

EasyWare supports 3 ways to recall a test stored in the EMR system:

ViewTest using command line parameters

As of *EasyWare* V2.7 record number and *EasyOne* serial number are exported in the *EasyWare* export file. A record number in combination with a serial number do clearly identify a test. The data is transmitted in the following way:

0298410SN:RecNum 40098:1030

Serial number and record number are transmitted using GDT record type 8410 (comment) and are separated by colon ,:'. When *EasyWare* is started with the following parameters

EasyWare /r:40098:1030

The test view window of the selected record will automatically be shown.

View test via GDT record type 6311 using *EasyOne* serial number and record number

As of *EasyWare* V2.8 the GDT record type 6311 is supported. As described above *EasyOne* serial number and record number will be transmitted using GDT record type 8410 when the test results are transmitted using GDT record type 6310. That information allows clear identification of the test. If the same GDT record type 8410 is used again when a test is recalled via GDT record type 6311, the appropriate test is automatically displayed in *EasyWare*.

View test via GDT record type 6311 with patient name, ID and date and time of test

As of *EasyWare* V2.8 GDT record type 6311 is supported. In the transmission of test results using GDT record type 6310, record type 8432 (date) and 8439 (time) are always included:

8432ddmmYYYY	(Day, Month, Year)
8439hhmmss	(Hour, Minutes, Seconds)

In case of a recall via GDT record type 6311 the test can be identified by name, ID, date and time and will be shown.

Example EMR Application "TurboMed"

TurboMed software settings

The following settings have to be applied only when the EMR interface is used:

1. Start TurboMed software and select the record of a patient.

In the patient record select „Konsultationen / Geräteanbindung“.

Select „Gerät anbinden“.

Enter the following:

Field	Entry	Description
Name	EasyOne	Name of equipment
Programm	c:\nndmed\EasyWare.exe	Complete path of <i>EasyWare</i> software.
Export-File	c:\nndmed\nndturbomed.gdt	Name and path of the export file.
Import-File	c:\nndmed\turbomedndd.gdt	Name and path of the import file. The path (in the example c:\nndmed\) must be identical to the export file path.
Type	2	Version of the GDT / EMR interface

Confirm the entry with: „Speichern“.

Confirm the dialog „Geräte anbinden“ with „Ende“.

These adjustments are sufficient for the set up of the EMR software. Now proceed with the set up of *EasyWare*.

Set up *EasyWare* Software

When the EMR interface is used for the first time, the following settings have to be done:

1. Start *EasyWare*.
- Open menu „File / Preferences“.
- Enter the path of the EMR folder according to the export path set in EMR TurboMed (in the above example c:\nddmed\).
- Enter the EMR computer name to „TurboMed“.
- At „Only export GDT table“ the box must be checked.
- Confirm the dialogue with OK.
- Close *EasyWare*.

Performing a measurement

The following describes the test procedure.

1. Start TurboMed, select a patient and open that file.
2. Select „Konsultationen / Geräteanbindung“.
3. Select "EasyOne" and then „Start“.
4. *EasyWare* is automatically started. In case where a) *EasyOne* is not inserted in the cradle, or b) not connected to the PC via the *ScreenConnector*, or c) not switched on the software will prompt you to do so.
5. A message box shows the synchronization between *EasyOne* and software.
6. The patient data entry window appears automatically. Enter the required data.
7. Confirm with OK. The data will be sent to *EasyOne* automatically.
8. Take *EasyOne*.
9. Select „Perform Test“.
10. Select „ALT“ and confirm with „Enter“.
11. The data of the patient appears. Confirm with „Enter“.
12. Select the appropriate test type (FVC, FVL, SVC, MVV) and confirm with „Enter“.
13. Perform a complete test with the patient, but do not print the test.
14. Put *EasyOne* back into the cradle.
15. The data will be automatically synchronized and written into the *EasyWare* data base.
16. Print a report if required.
17. Close *EasyWare*.
18. TurboMed now receives the data. Confirm with OK
19. Close the program now with „Ende“.

Remarks

Pre / post tests are supported: In case you want to show pre / post tests directly in the EMR TurboMed proceed as follows: Perform the pre test as described above. Without putting *EasyOne* into cradle perform the post test. After completion of pre and post test you may put *EasyOne* into cradle and proceed as described above. TurboMed now shows the pre / post test.

Example “forced expiratory spirometry”

Here the example transmission GDT Export with a forced expiratory test. The data marked grey will be exported only when the „Export GDT table only“ is NOT checked. Due to the amount of data the curve data at the end of the example are not shown in its entirety.

```
01380006310
014810008153
0128315PCS
0128316NDD
014921802.00
0298410SN:RecNum 40098:1030
01030001
0143101Meier
017310301011966
01031101
0123622175
014362370.00
0158402LUFU02
017620017092004
0476228-----
0476228Parameter Einheit Ist Soll %Soll
0476228-----
0476228FEV1    l  3.79  4.13  92
0476228FVC    l  4.33  5.15  84
0476228FEV1/FVC   0.88  0.80  109
0476228MEF75   l  9.96  0.00  -
0476228MEF50   l  5.96  0.00  -
0476228MEF25   l  2.22  0.00  -
0476228MEF2575 l/s  5.04  3.97  127
0476228PEF    l/s  10.52 9.96  106
0476228FET    s  5.36  -  -
0138411FEV1
01484203.794
0108421l
01484604.128
0128411FVC
01484204.334
0108421l
01484605.151
0178411FEV1/FVC
01484200.875
0098421
01484600.802
0148411MEF75
01484209.961
0128421l/s
0098460
0148411MEF50
01484205.956
0128421l/s
0098460
0148411MEF25
01484202.224
0128421l/s
0098460
0178411MEF25-75
01484205.039
0128421l/s
01484603.971
0128411PEF
015842010.516
0128421l/s
01484609.961
0128411FET
01484205.360
0108421s
0098460
1458410CurveFV_1, CurveFV_2, CurveFV_3, CurveVT_1, CurveVT_2, CurveVT_3, ...
0398417280,400,240,0,0,0,,,
0398417300,420,390,0,0,0,,,
0418417290,590,520,10,10,0,,,
```