SPIROLA

Spirometry Longitudinal Data Analysis

Version 3.0.2
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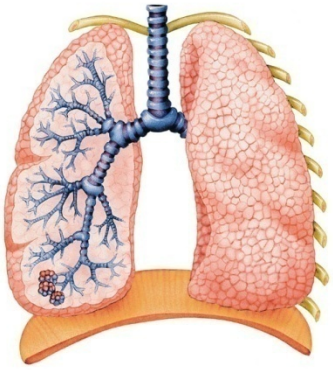

User Manual

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Disclaimer: This software is provided to assist health care practitioners in their management of occupational medical monitoring programs using spirometry. The software is only intended to assist the user in assembling the information required to make medical decisions, but cannot be substituted for competent and informed professional judgment. NIOSH does not warrant the reliability or accuracy of the software, graphics, or text. The users need to be aware of applicable federal, state and local laws and regulations that may impact utilization of this software.

Contents

Spirometry Longitudinal Data Analysis i
Contents i
1. Background 1
2. SPIROLA Installation 3
2.1 Start and close SPIROLA 4
3. SPIROLA Databases: Requirement and Management 5
3.1 Required Databases 5
3.2 Spirometry Database Format 5
3.3 Create an Empty SPIROLA Database 6
3.4 Open and Manage Spirometry Database 7
Types of databases SPIROLA can open 9
Select a subset from spirometry database 9
Change data input format 9
Select reference equation 10
Re-load database and obtain database information 11
Open or locate administrative database 11
4. Spirometry Data Evaluation and Screening 12
4.1 Group Selection Menu 12
4.2 Individual Evaluation Menu 12
Monitor FEV_1 in an individual 12
Monitor FVC in an individual 15
Monitor percent predicted values in an individual 15
Display summary report 16
Display multiple charts 17
Search for an individual by name or identity number 18
Display data values and remove outliers 19
4.3 Group Evaluation Menu 19
Monitor longitudinal data precision in a group 19
Monitor mean FEV_1 and FVC values in a group 21
Display multiple charts 22
4.4 Print Menu 23
4.5 Risk List Menu 24
Screen for individuals at risk of developing respiratory impairment 24
Interpretation and suggested actions 25
Suggested Risk List evaluation procedure 27
Suggested intervention measures 28
5. Intervention Menu 29
5.1 Tag Individuals for Spirometry Quality Control or Retesting 29
5.2 Setup and Evaluate Intervention Plan for Individuals 31
Setup intervention plan 31
Evaluate or modify interventions 31
5.3 Methods of Implementing Interventions 32
5.4 Electronic Safety or Lifestyle Assessment at Worksite 33
Creating safety or lifestyle assessment request 33
Sending safety or lifestyle assessment request to worksite 34

Completing safety or lifestyle assessment request at worksites 35
Loading completed safety or lifestyle assessment requests to SPIROLA 36
5.5 Design Intervention Plan Template 37
Create or modify choices of responses 38
5.6 Export Intervention Data..... 40
5.7 Manage Participants Menu 41
6. Questionnaire Menu 43
6.1 View or modify questionnaires..... 44
6.2 Design Questionnaire Template..... 44
Design questionnaire cover page 44
Design questionnaire questions..... 46
Save blank questionnaire to PDF file..... 46
6.3 Perform Questionnaire Survey..... 46
Check questionnaires for errors 48
Load questionnaires into SPIROLA 51
6.4 Export Questionnaire Survey Data 52
6.5 Manage Participants Menu 52
7. Spirometry Quality Control Menu..... 53
8. Options Menu..... 54
8.1 Display—Critical limit curves..... 54
8.1 Define longitudinal limits for FEV_1 or FVC..... 55
8.4 Cross-sectional evaluation—Customize reference equations..... 56
9. Administrative Database Management..... 59
10. Theoretical Background..... 61
10.1 Evaluation of FEV_1 precision in a group 61
10.2 Estimation of limits of longitudinal decline for an individual..... 62
11. References..... 64
Appendix A: Software requirements to run SPIROLA..... 65
Appendix B: Open different types of spirometry datasets..... 66
Appendix C: Installing new Spirola data provider..... 70
Appendix D: Note to .NET Developers on Programming Spirola Data Provider 71
Appendix E: Create ODBC data source for Excel 2007..... 75
Appendix F: Starting SPIROLA from Third Party Applications..... 78
Appendix G: Import an Excel spreadsheet into the newly created Access database using Microsoft Access 2003 79
Appendix H: Import an Excel spreadsheet into the newly created Access database using Microsoft Access 2007 80

1. Background

Monitoring of lung function in at-risk populations enables the identification of individuals with excessive decline of lung function. The spirometry test of forced expiratory volume in one second (FEV_1) is the measure best suited for monitoring changes in lung function over time. An excessive decline in FEV_1 over several years can indicate development of lung disease and has been shown to be associated with increased respiratory morbidity, loss of productivity at an earlier age, and increased mortality.[1-5]

The ***Spirometry Longitudinal Data Analysis*** (SPIROLA) software is an integrated visual and quantitative tool to aid in monitoring lung function in individuals participating in spirometry-based health monitoring programs. To ensure that individuals with excessive decline in lung function can be identified accurately and in timely manner, it is important to maintain acceptable quality of the spirometry tests[6] and precision of the longitudinal spirometry data.[7] For that purpose, SPIROLA enables the user to monitor spirometry tests' quality grades and longitudinal data precision for a monitoring program. This monitoring also provides a basis on which to determine an appropriate limit of longitudinal decline in individuals.[8-9] SPIROLA may help to preserve lung function through identification of individuals with excessive decline followed by appropriate intervention. The intervention function helps to obtain information on potential risk factors, and plan, record, and evaluate the effect of intervention strategies. The questionnaire function helps to conduct questionnaire surveys of workers.

SPIROLA provides the following functions:

<u>For an individual evaluation:</u>

- It monitors the level of FEV_1 and FVC in relation to criteria for assessment of cross-sectional data: the lower limit of normal (LLN) (i.e., the lower 5^{th} percentile) and the lower 0.1^{th} percentile (approximately comparable to 60% predicted).
- It monitors FEV_1 and FVC change over time in relation to criteria for assessment of longitudinal changes: the limit of longitudinal decline (LLD).
- It provides interpretation of the rate of FEV_1 and FVC decline and data variability in an individual's summary report and suggests actions to prevent further excessive loss.
- It enables to plan, record, and evaluate intervention measures.

<u>For a group evaluation:</u>

- It provides a screening function "Risk List" that helps to screen for individuals whose lung function level, decline, or variability may be abnormal, and provides statistics on the number of individuals screened and with various abnormalities.
- It monitors group means for FEV_1 and FVC (observed, predicted and z-score) to enable the user to identify time-related changes taking place at a group level. The

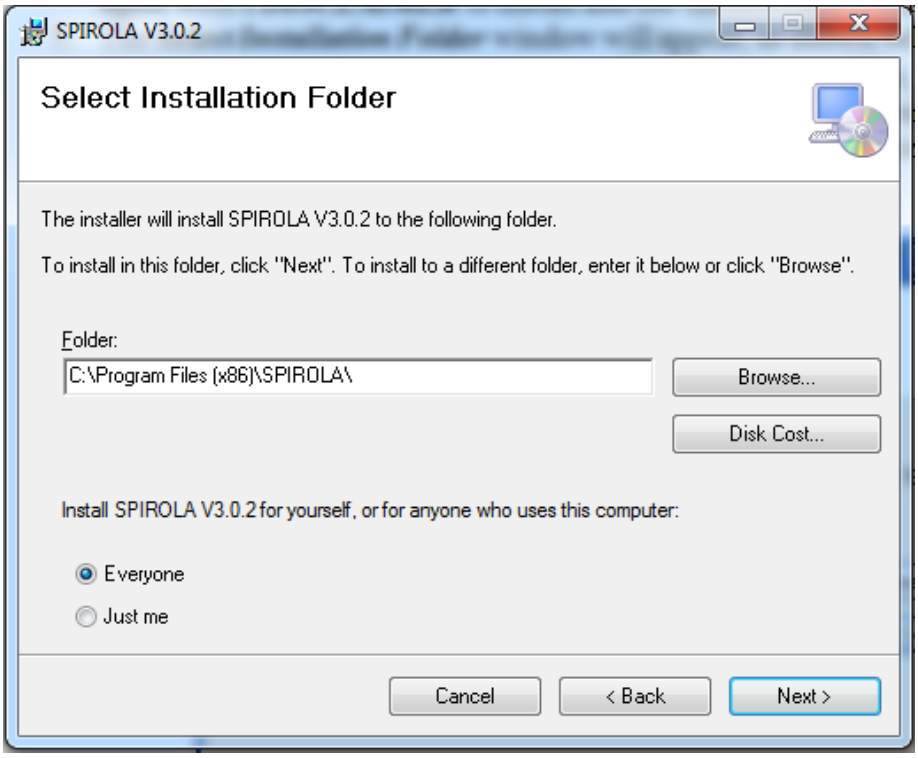
group means can be monitored for all participants, or for sub-groups selected by Risk List, i.e., those with certain abnormalities or participants undergoing intervention.

- It monitors longitudinal FEV_1 and FVC data precision using the pair-wise estimate of within-person variation s_p (absolute) or s_r (relative).[6-8] This function helps to identify changes in data variability that may be due to changes in testing procedures (e.g., a new spirometer, technician, or healthcare provider) or effects of exposure.
- It helps to monitor the percentage of spirometry testing sessions that do not meet the 2005 ATS/ERS criteria for acceptability and repeatability, overall and by a technician.
- It enables the user to conduct a computerized questionnaire survey.

2. SPIROLA Installation

SPIROLA runs on PC with Microsoft Windows system, see Appendix A for details.

1. Open NIOSH SPIROLA webpage http://www.cdc.gov/niosh/topics/spirometry/spirola-software.html.
2. Click on SPIROLA V 3.0.2 link to download SPIROLA.
3. Extract the contents of the Zip file to a temporary folder (e.g., C:\SpirolaSetup). Run the setup.exe file to start the installation.
4. Follow instructions specified by the installation procedure. User needs to read and agree with a ***DISCLAIMER*** to install and use the software. Click **Next>** to proceed.
5. The ***Select Installation Folder*** window will appear, as shown below. By default, SPIROLA is installed into **C:\Program Files\SPIROLA** folder. If a user does not have security permissions to install on the Program Files, an alternative location can be specified (e.g. c:\SPIROLA, My Documents or Desktop). Click **Next>** to proceed.

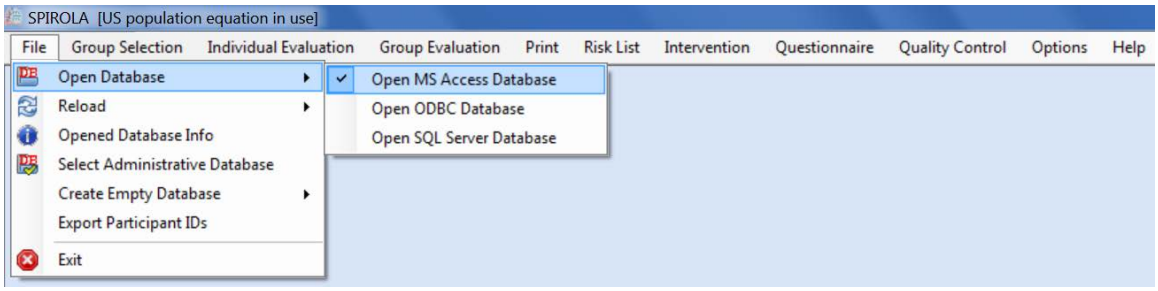


6. Follow the setup wizard instructions to complete the installation. On completion, an ***Installation Complete*** window will display message "SPIROLA has been successfully installed". Click **Close** to exit.
7. SPIROLA item will be added to the **All Programs** menu on the Windows Start menu, and a SPIROLA icon will be created on the Desktop.
8. If SPIROLA is being uninstalled by the user for an update, and if **Intervention** and **Questionnaire** menus have been used, the user should create a back-up copy of the administrative database, SPIROLA_Admin.mdb, in a safe location (see Section 9).

2.1 Start and close SPIROLA

To run SPIROLA using a demonstration database:

1. Double click the **SPIROLA** icon from the Desktop, or start the **SPIROLA** program via **Start** > **All Programs** > **SPIROLA** to open SPIROLA.
2. On the **File** menu click on **Open Database** and on **Open MS Access Database** (see below).
3. In the next window open **DemoDataSet.mdb** database located in the same folder as SPIROLA (see Section 3 for more details).
4. To test SPIROLA, view individual charts using the **Individual Evaluation** menu.
5. To close SPIROLA, on the **File** menu click **Exit**, or just click the **close** button in the right upper corner of the window.



3. SPIROLA Databases: Requirement and Management

3.1 Required Databases

SPIROLA requires a spirometry database of a specific format (see Section 3.2). Initially, the user can create an empty spirometry database of the required format (see Section 3.3) and type or import into it the required data. The user can also create an automatic link to an existing spirometry database created by a spirometer or medical record database that contains spirometry data (see Section 3.4). To see an example of SPIROLA database, the user can open and view the demonstration database "DemoDataSet.mdb" stored in the same folder as SPIROLA. For management purposes, SPIROLA automatically creates an administrative database, "SPIROLA_Admin.mdb", to store information it needs to remember, mainly intervention and questionnaire survey data (see Section 9).

The following types of databases can be used to store the spirometry data:

- Microsoft Access databases (See Appendix A)
- Microsoft Excel files
- Text files
- Microsoft SQL Server databases
- Any other type of database for which ODBC (i.e., Open Database Connectivity) driver is installed on the workstation on which SPIROLA is installed.

3.2 Spirometry Database Format

Each record in the spirometry database should contain unique identity information (ID) to identify a participant, demographics (sex, race, height, age or birth date), and information on a single spirometry test; see essential and optional fields (variables) listed below. The variables' names need to conform to the names specified below, but are not case sensitive. The variables can be in any order. Databases sorted by ID and date of test (TestDate) will be processed faster.

The default input format for dates, heights, lung function values (i.e., FEV1, FVC) and the values for gender and race as shown below can be changed (see Section 3.4, **Change data input format**) to reflect the original data format.

The following variables are <u>essential</u> (must be included):

- **ID –** A text field (alpha numerical) to uniquely identify an individual. To speed up the data processing, a numerical ID field is preferable, but it is not a requirement.
- **Sex –** A text field to store "M" for male or "F" for female gender.
- **Race –** A text field to store "M" or "I" for Mexican-Americans, "B" or "A" for African-Americans, or "W" or "C" for Caucasians and "S" for Asian-Americans. This variable is used for selecting the appropriate set of reference equations.

- **Age –** A numerical field for age in years at a test (optional if date of birth provided).
- **BirthDate –** A date field (format: mm/dd/yyyy) to store date of birth (optional if age is provided). This field allows more accurate calculation of age, (e.g., 45.5 vs. 45).
- **Height –** A numerical field to store height (cm) measurements of a tested individual
- **FEV1 –** A numerical field to store best FEV_1 (mL) value from a test.
- **FVC –** A numerical field to store best FVC (mL) value from a test.
- **TestDate –** A date field (format: mm/dd/yyyy) to store test dates.

The following variables are optional for spirometry quality analysis:

- **FEV12 –** A numerical field to store second best FEV_1 (mL) value.
- **FVC2 –** A numerical field to store second best FVC (mL) value.
- **QFEV1** – A character variable for FEV_1 quality grades (if available).
- **QFVC** – A character variable for FVC quality grades (if available).
- **QTest** – A character variable for session quality grades (if available).
- **Oper** – A character variable for operator (spirometer technician) code or name.
- **Provider –** A character variable for a provider (e.g., a van service).

The following name variables are optional and are needed for a search by name:

- **Last_Name** – A text field (Surname/family name).
- **Middle_Initial** – A text field (leave blank if not available).
- **First_Name** – A text field.

Inclusion of names in the database enables the user to identify an individual by name using **Search for a Participant** function in the **Individual Evaluation** menu. If both **Last_Name** and **First_Name** are provided, the reports will include the names.

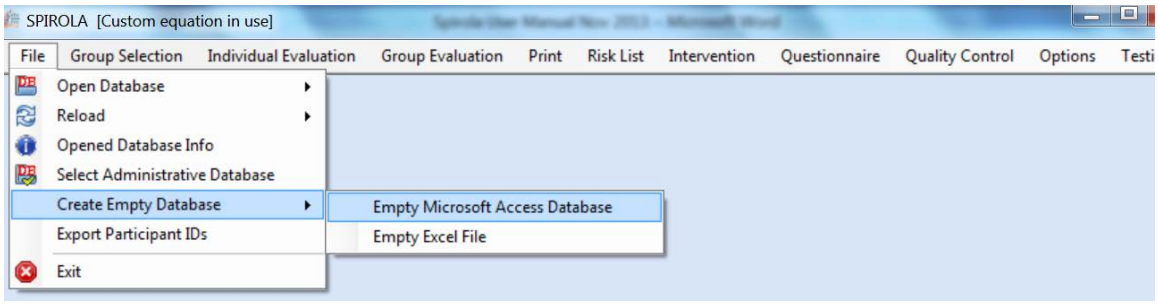
Additional fields containing, for example, weight, smoking status, cigarettes/day, asthma status, or respiratory symptoms data can be added. These data will be shown with the individual's FEV1 chart, but will not be used in the analysis.

TROUBLESHOOTING: If individual charts do not appear, the first step is to check that the format and units of the essential variables are correctly defined. If the format differs from the one provided above, for example height is in inches, use **Change data input format** (Section 3.4) to define the correct data input format.

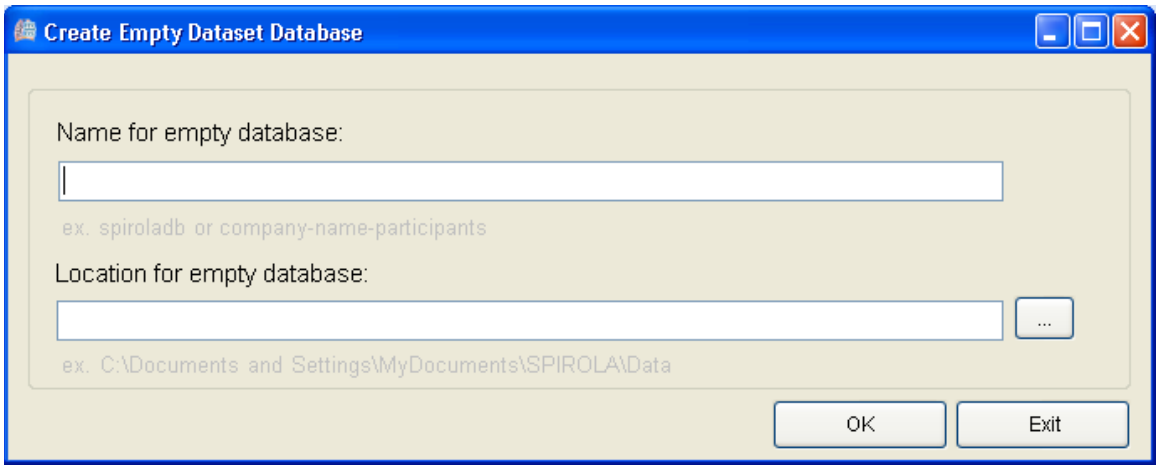
3.3 Create an Empty SPIROLA Database

An easy way to start learning how to use SPIROLA is to create an empty SPIROLA database, type or import sample data into the database, open it in SPIROLA (see Section 3.4 below) and try SPIROLA's various functions.

1. On the **File** menu click on **Create Empty Database**.
2. Click on the menu item with the preferable database, **Empty Microsoft Access Database** or **Empty Excel File** (see below).



3. In the window which appears next (see below), name the database and assign its location.
4. Click **OK** and follow the link to open the newly created file.

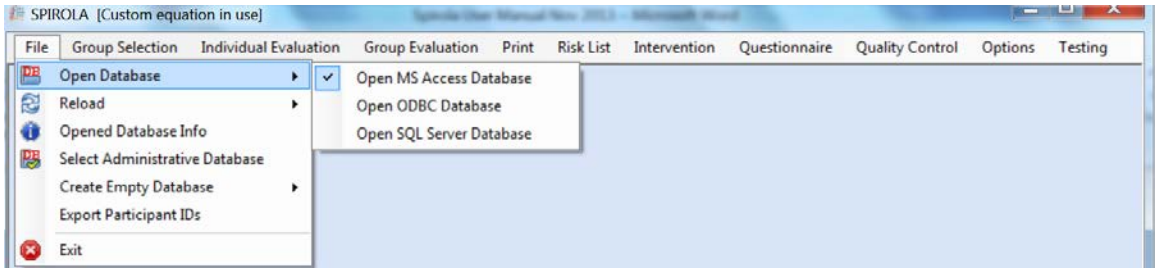


5. Right click to **Open** the database and right click to **Open** one of the two tables: Standard (contains essential variables) or Full (includes also optional variables).
6. To import data into the SPIROLA database see Appendix G.

Note: Because SPIROLA reads MS Access database directly (see Section 3.4 below), this database is preferable. Alternatively, the user can create an Excel database and import it into MS Access, or use the ODBC Menu (see below) to connect to the Excel file with SPIROLA application (see Appendix E: Create ODBC data source for Excel 2007).

3.4 Open and Manage Spirometry Database

To open SPIROLA dataset click on **File** menu and then on **Open Database**, see below. Once a database is specified, SPIROLA will remember the database address until the user specifies another database address.

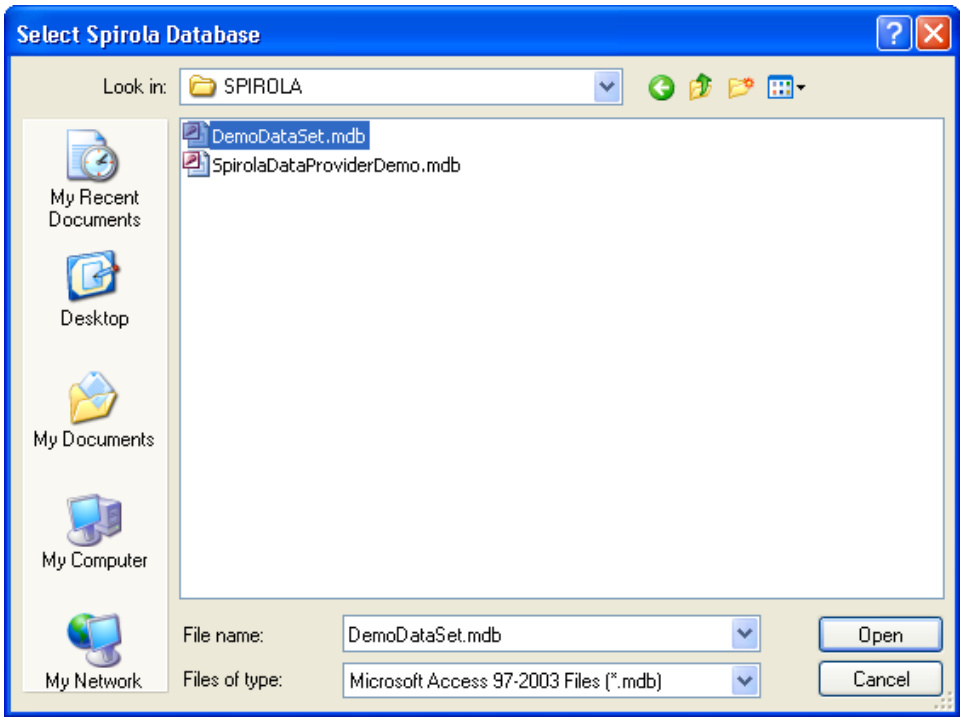


The **Open Database** menu allows the user to open the following types of databases:

a) **Open MS Access Database** menu opens Microsoft Access database. A file dialog window will appear (see the picture below), where the user should select the MS Access file (for example DemoDataSet.mdb, see below) and click **Open** to proceed. For demonstration purposes SPIROLA package includes MS Access database "DemoDataSet.mdb" installed in the same folder as SPIROLA (e.g., **C:\Program Files\SPIROLA\ DemoDataSet.mdb)**.

b) **Open ODBC Database** menu opens the following databases: Microsoft Excel files, text files, SAS files, Oracle databases, and other databases supported by the ODBC system. If the database is not a Microsoft Access database or Microsoft SQL Server database select **Open ODBC Database** menu (see Appendix B: Open different types of spirometry datasets).

c) **Open SQL Server Database** opens Microsoft SQL Server database (Appendix B).



Types of databases SPIROLA can open

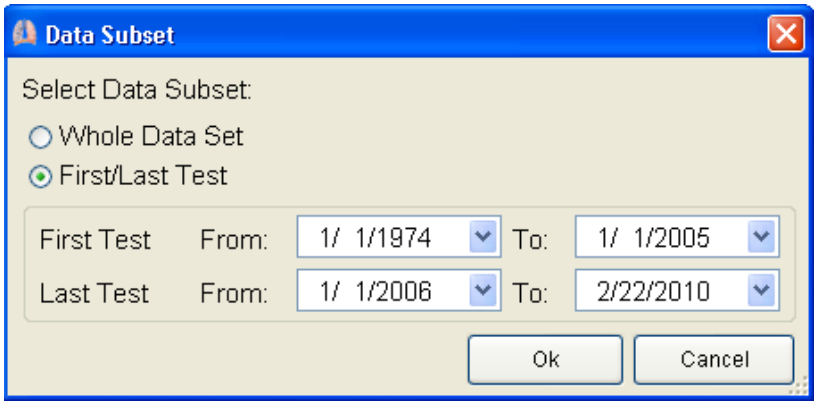
(i) Databases in a tabular format, where all records are stored in a single table (e.g., MS Excel or Access files), and all essential variables are included (see Section 3.2).

(ii) Databases for which converter software **Spirola data provider is installed**, which enables SPIROLA to read data from other types of databases (e.g., databases created by spirometers). Spirola data providers have the following characteristics:

   a. They are DLL or EXE extension files which convert data in a spirometry database to a database which has a SPIROLA required format (see above).
   b. They can be programmed using any .NET programming language, such as C#.NET or VB.NET.
   c. Their installation is easy, and usually involves copying the data provider file (i.e., DLL extension file) to a specific directory. See Appendix D for details.
   d. Spirola data providers already installed in SPIROLA include: **SpirolaDataProviderDemo.dll**, **EasyOneSpirolaDataProvider.dll**, **KeystoneSpirolaDataProvider.dll**, and **OMISpirolaDataProvider.dll**. **SpirolaDataProviderDemo.dll** data provider can be used to open the demo database **SpirolaDataProviderDemo.mdb**, which comes with SPIROLA. The other three providers can be used to open databases generated by EasyOne, Keystone, and OMI spirometers.

Select a subset from spirometry database

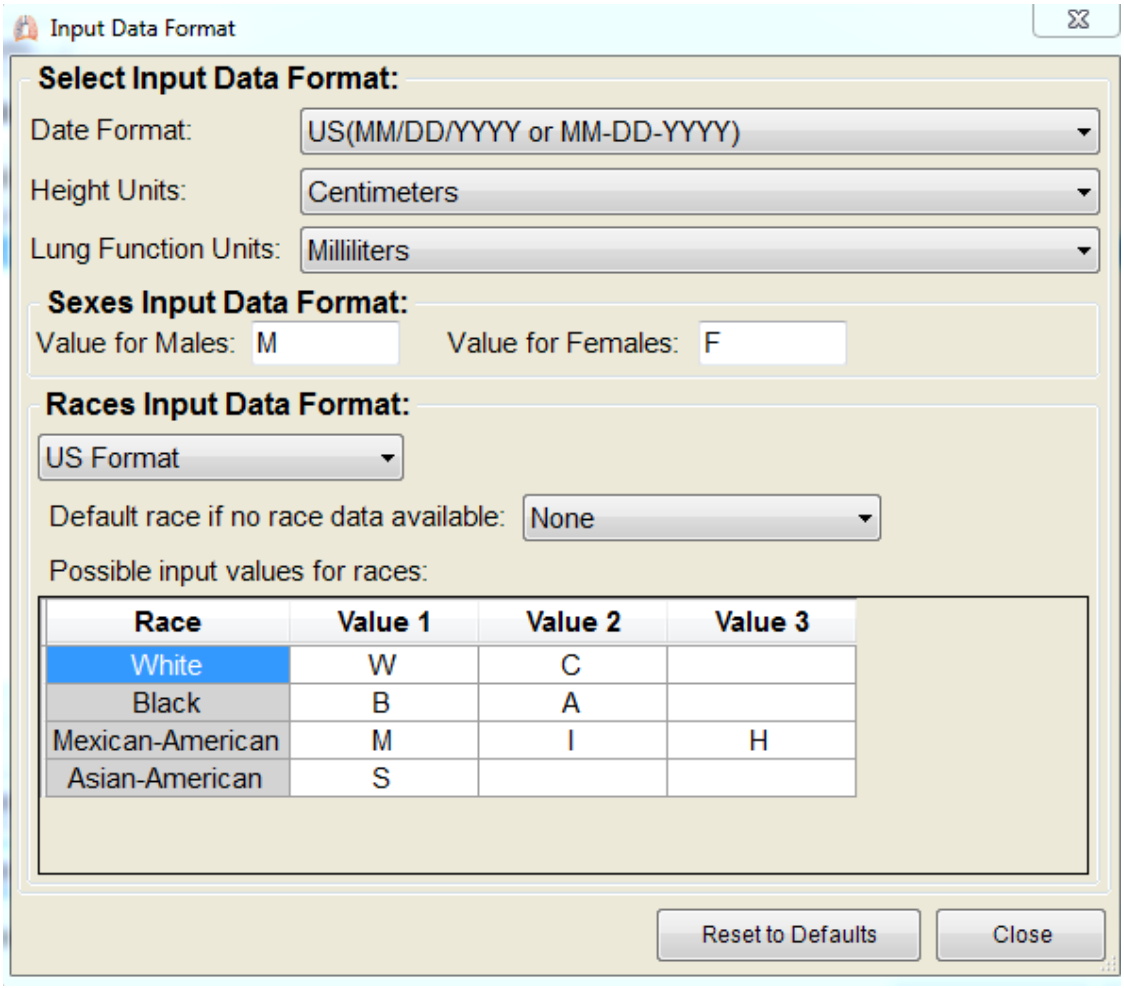
By default SPIROLA will load the whole dataset. To select a subset of individuals whose first test and/or last test are within a specified period, click on **Select Data Subset** and select the appropriate period for the first test or for the most recent test (see below). If the checkbox next to Select Data Subset button is not checked, it means that no subset is selected. This function is useful for selecting individuals tested within recent years.



Change data input format

To change the default input format (see above), click on the **Select Data Input Format.** The date input format can be change to the dd/mm/yyyy, dd-mm-yyyy or dd.mm.yyyy.

The format for height can be in inches or centimeters, and lung functions can be read in liters or milliliters. The race value is used to select an appropriate reference equation. In the example below, SPIROLA will apply **White** as a default race when race value is missing. The user can change Race input values under Race and Value 1 to Value 3 for White, Black, Mexican-American, and Asian-American race/ethnicity corresponding to US reference equations provided by default.

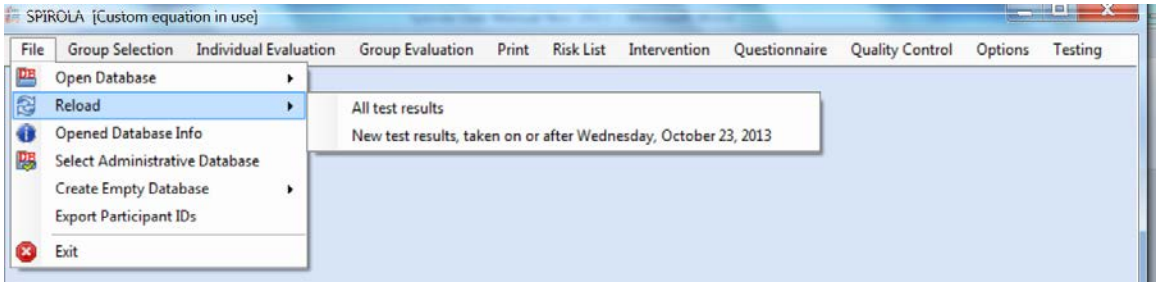


Select reference equation

At this stage, spirometry reference equations can be selected out of three sets of reference equations: US population reference equations, European population reference equations, and custom reference equations. Note, the custom reference equations can be changed later by clicking on the **Options** menu and **Reference Equation**s (Section 8.4 Cross-sectional evaluation—Customize reference equations).

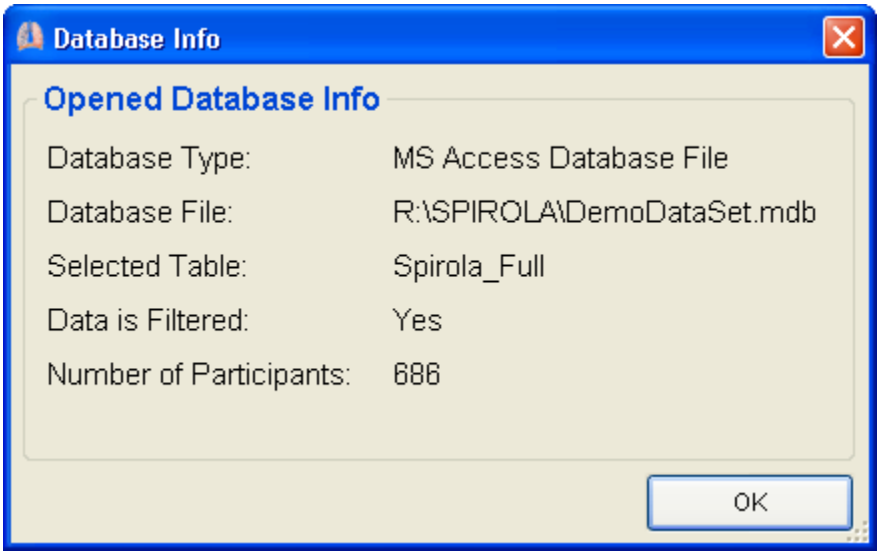
Re-load database and obtain database information

After the spirometry data is loaded into SPIROLA from the database, it is possible that new test results are added to the database, or existing test results are modified. The menu **File > Reload** can be used to quickly reload spirometry data into SPIROLA (see below).



1. Click on **All test results** to reload all test results into SPIROLA.
2. Click on **New test results, taken on or after "Date when SPIROLA was opened"** to quickly load test results taken on or after date when SPIROLA was opened. To include test results taken before SPIROLA was opened click on **All test results**.

To obtain database information, on the **File** menu, click on **Opened Database Info**, to display information about the currently opened database (see below).



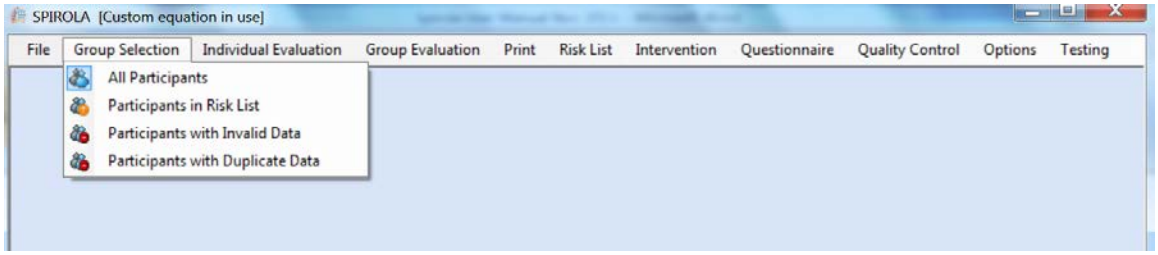
Open or locate administrative database

Administrative database **SPIROLA_Admin.mdb**, contains information that SPIROLA needs to remember while processing the spirometry data. Also, the administrative database stores permanently information created using the **Intervention** and **Questionnaire** menus. When **Intervention** or **Questionnaire** menus are used, then the administrative database should be kept in a secured location that is regularly backed-up (see Section 9). The same applies to the SPIROLA spirometry database.

4. Spirometry Data Evaluation and Screening

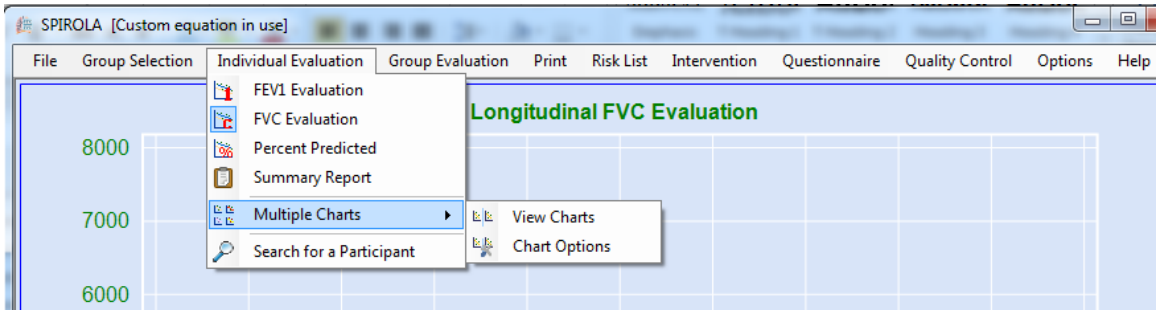
4.1 Group Selection Menu

By default all participants are evaluated. To view observations identified to have invalid data, click on **Group Selection** and **Participants with Invalid Data.** Values that are not valid are shown in red. To view individuals previously selected by the Risk List function, click on **Participants in Risk List.** To view participants with duplicate records, click on **Participants with Duplicate Data**. To restore to default, click on **All Participants**. . If needed, correct the values in the original database or in the SPIROLA MS Access database.



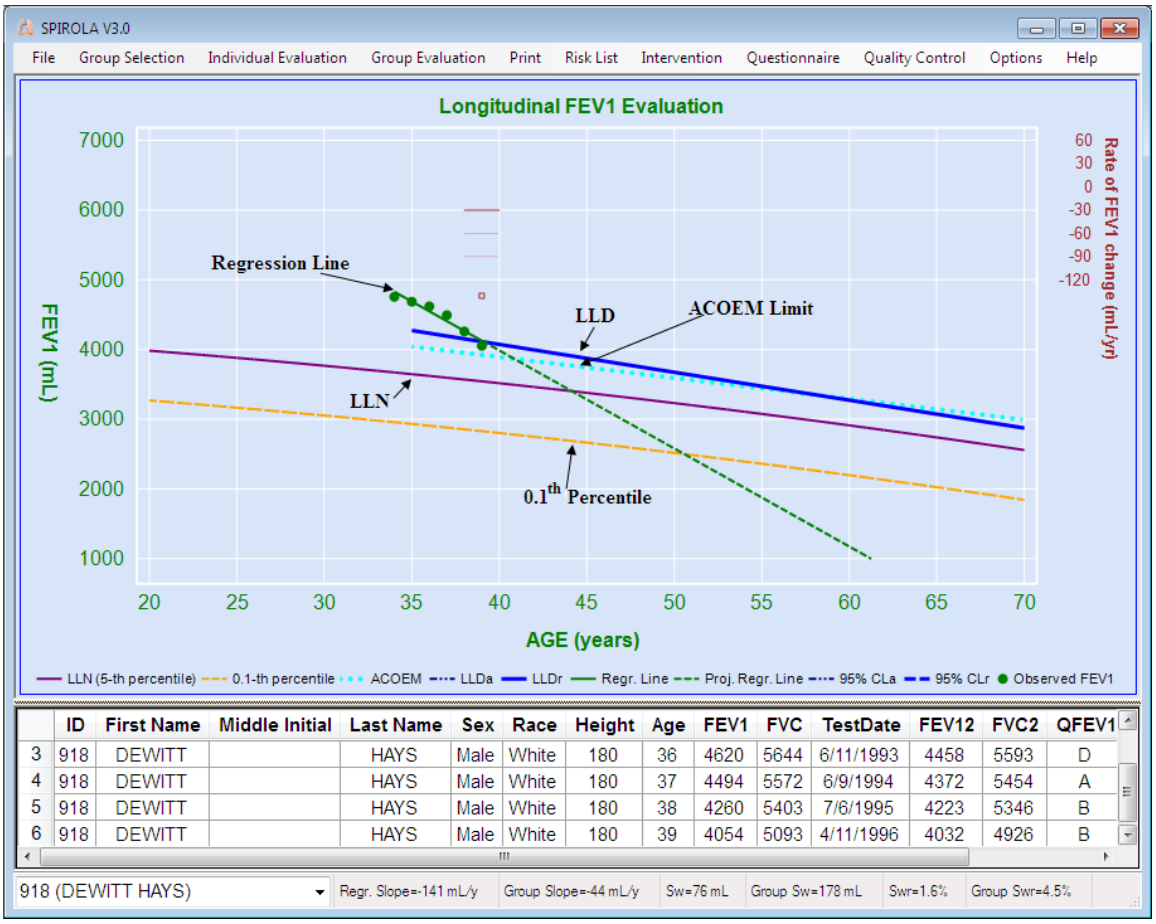
4.2 Individual Evaluation Menu

The **Individual Evaluation** menu lists evaluations that can be done on an individual.



Monitor FEV_1 in an individual

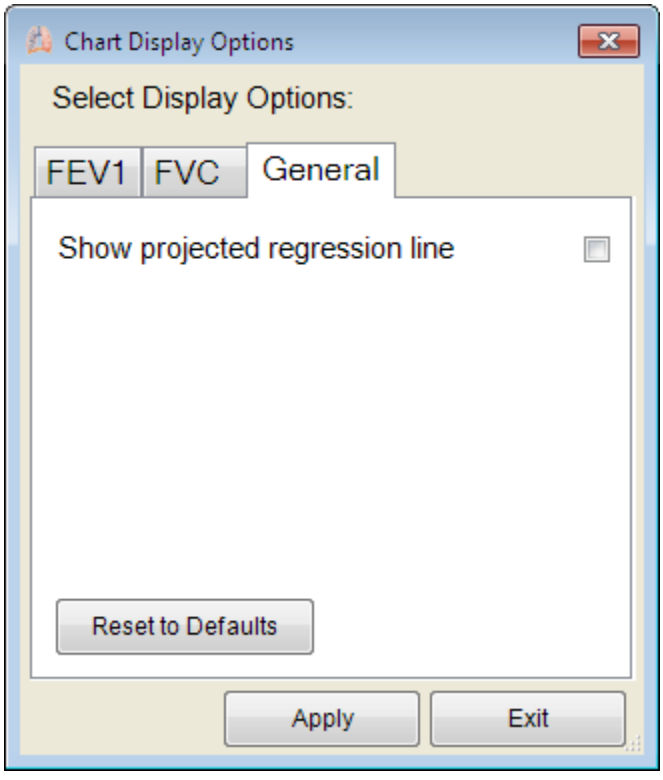
1. On the **Individual Evaluation** menu click **FEV1 Evaluation** to show a FEV_1 chart.
2. Click the arrow next to combo box (ID box) on the left bottom corner to select the ID. Alternatively, select a participant using the **Search for a Participant** menu (see above); see Section **Search for an individual by name or identity number** below.



The individual FEV_1 chart shows: the observed FEV_1 values (green dots) plotted against age; the linear regression line (green line) fitted to the observed FEV_1 data when at least 4 years of follow-up data are available; cross-sectional lower limit of normal (LLN), i.e., the lower 5th percentile (purple line) and the lower 0.1th percentile (comparable to 60% predicted) (orange line). The percentiles help to determine the probability with which an observed value is likely to occur in the reference population. U.S. population-based reference equations are used by default,[7] but user can specify own equations (see Section 8). The blue solid line represents the limit of longitudinal decline (LLD_r) calculated from the baseline observation(s). The default LLD_r is based on ≈10% annual decline, i.e., the default relative within-person variation of 4% and reference slope of 40 mL/yr (see Section 10 and Section 8). This LLD_r is used to identify excessive declines up to 8 years of follow-up. Observations that fall below LLD_r should be evaluated as to whether the decline represents data quality issue or true decline. The turquoise (greenish-blue) dashed line represents the American College of Occupational and Environmental Medicine (ACOEM) longitudinal limit of decline calculated as LLD=Baseline FEV_1×0.85-years×30 mL/yr, based on 15% annual decline.[10] The user can select the ACOEM limit for decision-making by selecting LLD_r of 15% and referential rate of decline of 30 mL/yr as default. See Section 8 on instructions how to change the default options.

Beginning with 4 years of follow-up, SPIROLA also tracks changes in the rate of FEV_1 decline and displays this against the scale on the right axis. The brown dots show the running rate of decline up to each data point and enable the user to discern the change in the rate due to the last data point. The yellow dots show the running change in the slope for the previous 8 years and enable the user to discern changes in the rate of decline in the last 8 years. The three parallel lines represent 30, 60, and 90 mL/yr rates of decline.[3] The bottom margin displays the linear *Regression Slope* and *Within-person variation* (s_w) for the individual who has 4 or more years of follow-up, and the mean *Group Slope* and mean within-person variation *Group* s_w, calculated as the averages of the individual linear regression statistics.

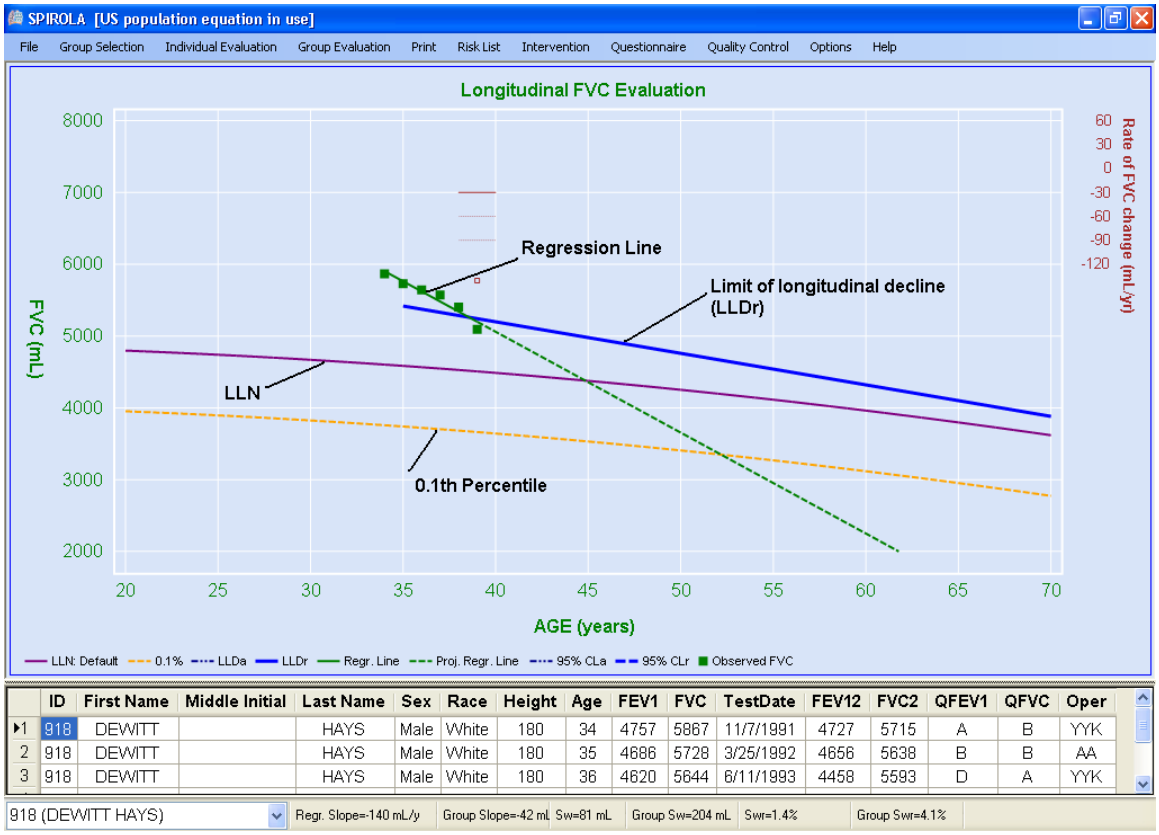
Beginning with 8 years of follow-up, SPIROLA's decision-making is based on the estimated regression slope and the projected age when the regression (dashed green) line crosses the 0.1^{th} percentile (dashed yellow line). The blue dashed line shows the longitudinal lower 95% confidence limit (CL) for the fitted regression line, estimated from 8 years of follow-up data. This limit can be used to test whether the last observation deviates significantly from the regression line predicted using all observations (Sections 9 and 10). To display the linear regression line extended beyond observed data, on the **Options** menu click **Display**, **Curves**, **General**, and **Show projected regression line** as shown below.



The table below the chart shows the individual's demographic and lung function data at each test date. Other data, for example name, weight, smoking status, cigarettes per day, quality control data, and a technician's code will be shown also if included in the SPIROLA database (see Section 3.2).

Monitor FVC in an individual

1. On the **Individual Evaluation** menu click **FVC Evaluation** to show a FVC chart.
2. Click the arrow next to combo box (ID box) on the left bottom corner to select an ID. Alternatively, type the ID into the **Search for a Participant** box on the **Individual Evaluation** menu.

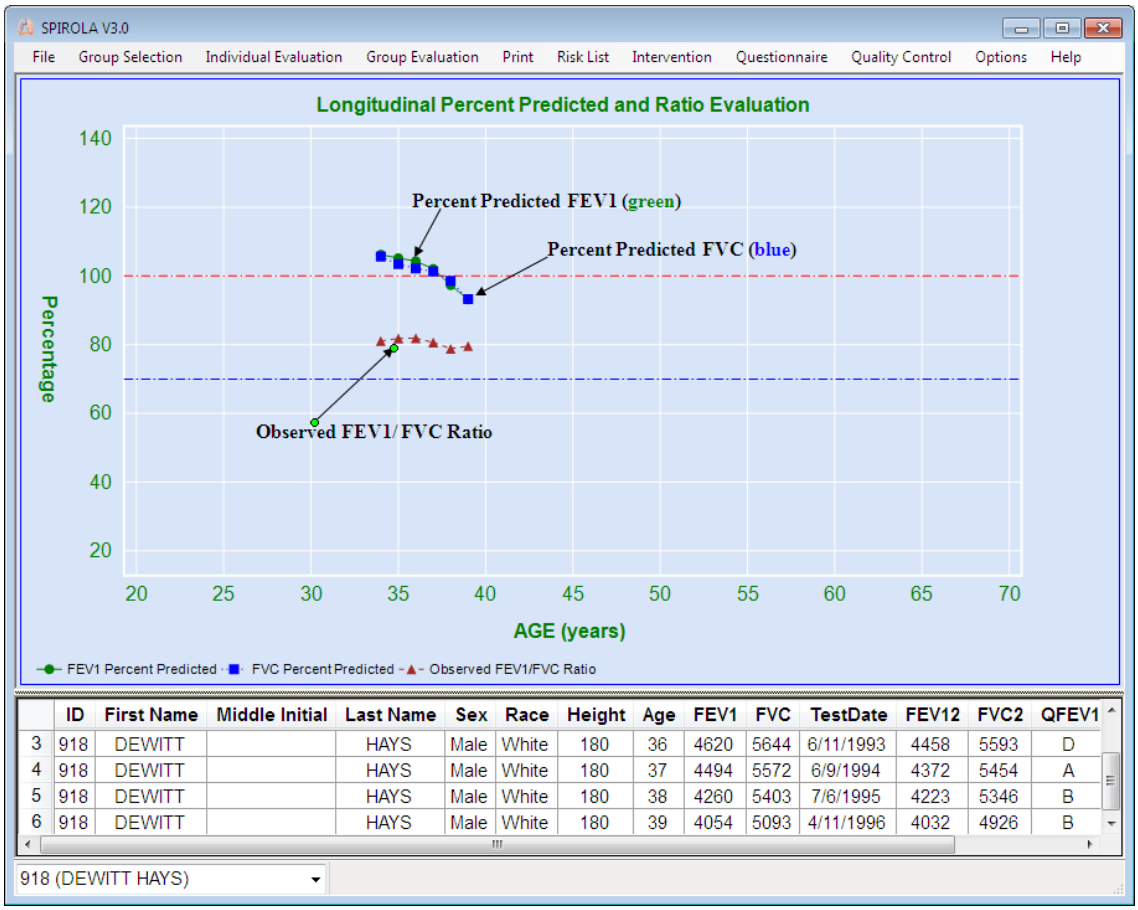


	ID	First Name	Middle Initial	Last Name	Sex	Race	Height	Age	FEV1	FVC	TestDate	FEV12	FVC2	QFEV1	QFVC	Oper
▸1	918	DEWITT		HAYS	Male	White	180	34	4757	5867	11/7/1991	4727	5715	A	B	YYK
2	918	DEWITT		HAYS	Male	White	180	35	4686	5728	3/25/1992	4656	5638	B	B	AA
3	918	DEWITT		HAYS	Male	White	180	36	4620	5644	6/11/1993	4458	5593	D	A	YYK

The individual FVC chart shows: the observed FVC values (green dots) plotted against age; the linear regression line (green line) fitted to the observed FVC data (when at least 4 years of follow-up data are available); and cross-sectional lower limit of normal (LLN) (purple line) and lower 0.1th percentile (yellow line) (comparable to 60% predicted), based on U.S. population-based reference equations.[9] Longitudinal limit LLDr (blue line) is also provided. Individuals whose most recent measurements fall below LLDr or LLN can be identified using the Risk List. The information should be evaluated as to whether the decline represents data or spirometry quality issue or true decline.

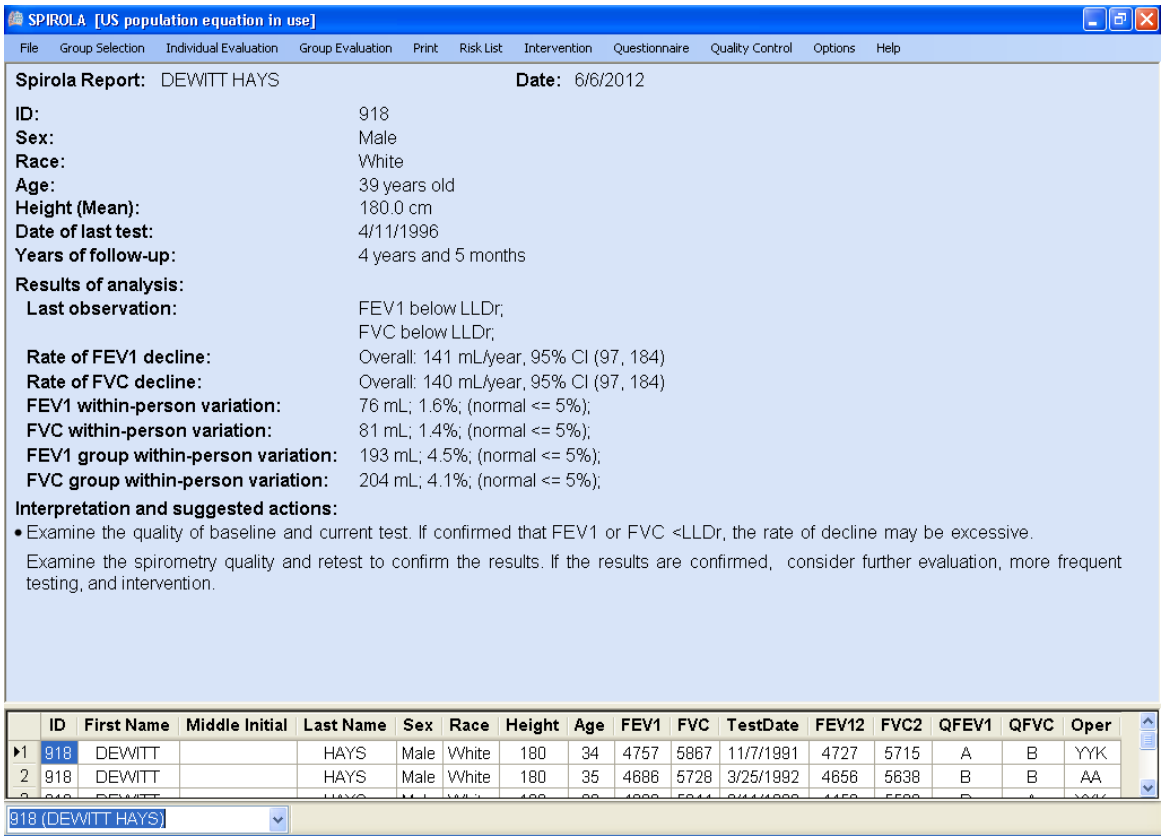
Monitor percent predicted values in an individual

1. On the **Individual Evaluation** menu click **Percent Predicted** to obtain a chart with percent predicted values for an individual person, as shown below.
2. Click the arrow next to combo box (ID box) on the left bottom corner to select an ID. Alternatively, type the ID into the **Search for a Participant** box.



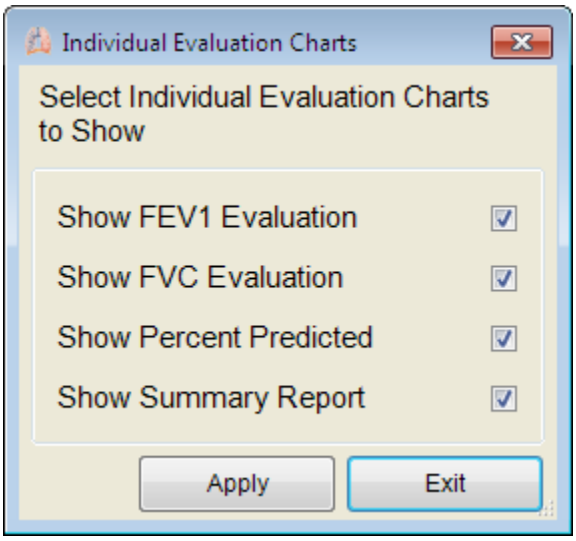
Display summary report

1. On the **Individual Evaluation** menu click **Summary Report** to view results of an individual's data analysis and suggested course of action, as shown below (see Section 9 on evaluation methods).
2. Click **Print** to print the Summary Report.

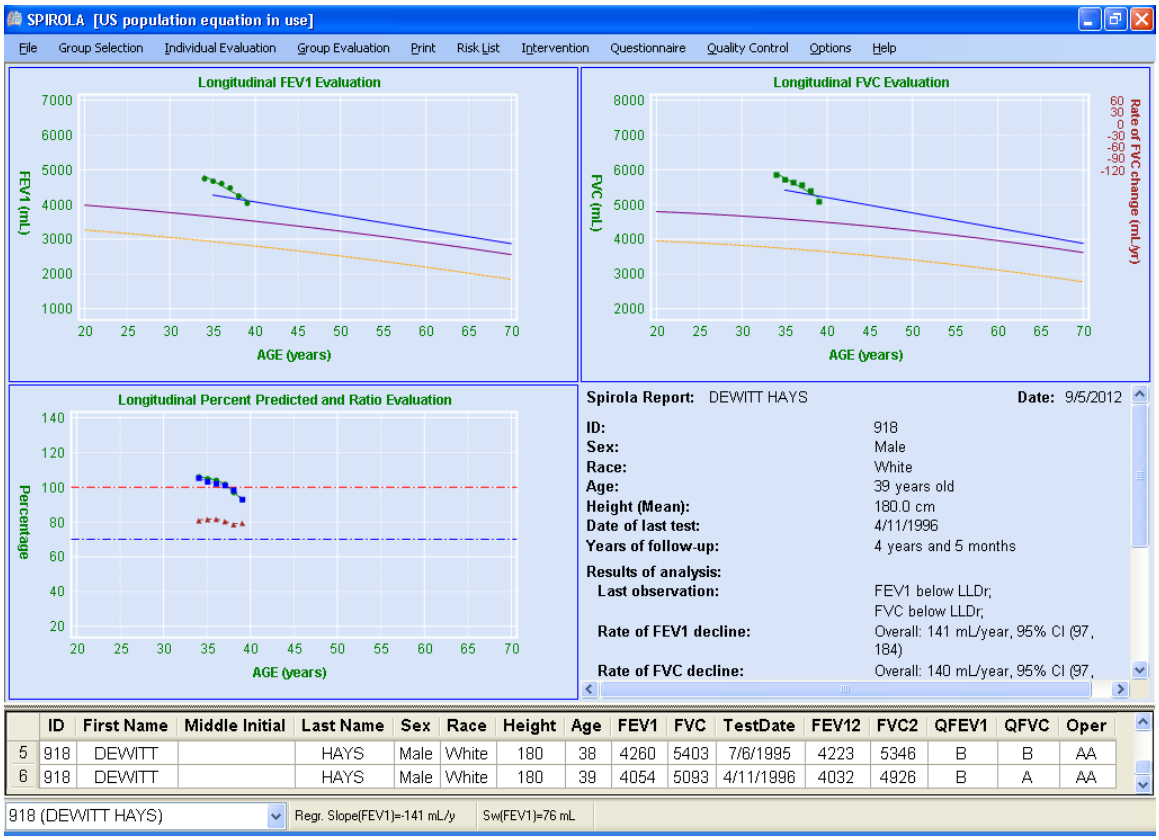


Display multiple charts

1. On the **Individual Evaluation** menu click **Multiple Charts** and **Chart Options.** Select charts to be displayed together, as shown below, and click **Apply** and **Exit**.

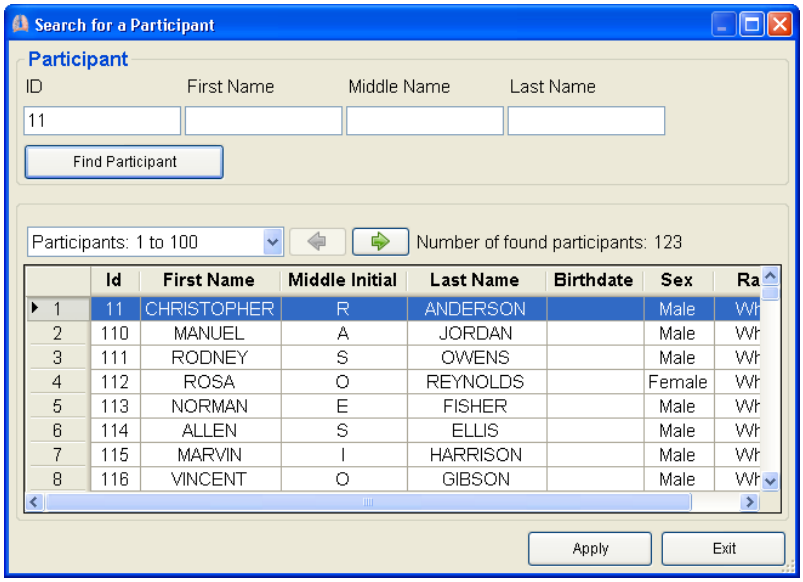


2. On the **Individual Evaluation** menu click **Multiple Charts** and **View Charts** to display multiple charts, as shown below.



Search for an individual by name or identity number

1. On **Individual Evaluation** menu click on **Search for a Participant**, as shown below.
2. Type the person's name or identity number and click on **Find Participant,** or click on **Find Participant**, to list all individuals. Select an individual and click **Apply**.



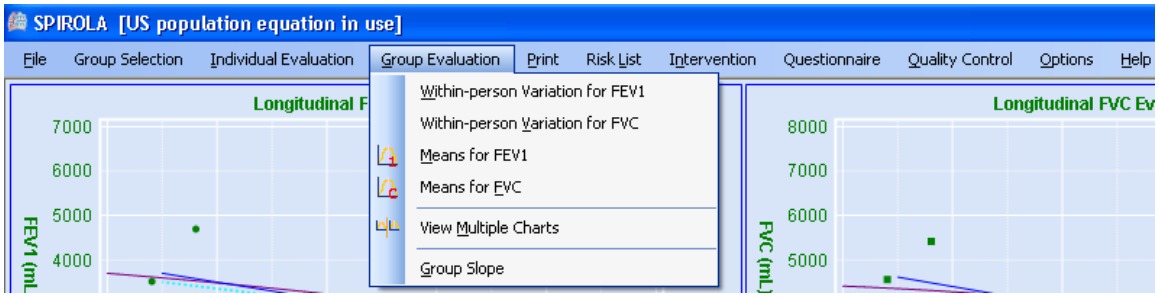
Display data values and remove outliers on a chart

1. To display values on a chart, place the cursor on any data point, and then right click. A small tooltip label will show coordinates.
2. To remove outliers, on the chart, place the cursor on any data point(s) which you want to remove while processing the data, and then right click. The data point(s) will be crossed out, and the regression line and other curves will be recalculated and redrawn. To reload a data point, right click and include the observation in the analysis. SPIROLA will remember the deletion and indicate it by a cross.

Note: The deleted data points are not deleted from the dataset and can be reinstated back into the data analysis by clicking on the data point and including it in the data analysis. To permanently correct data values, changes need to be done in the source database.

4.3 Group Evaluation Menu

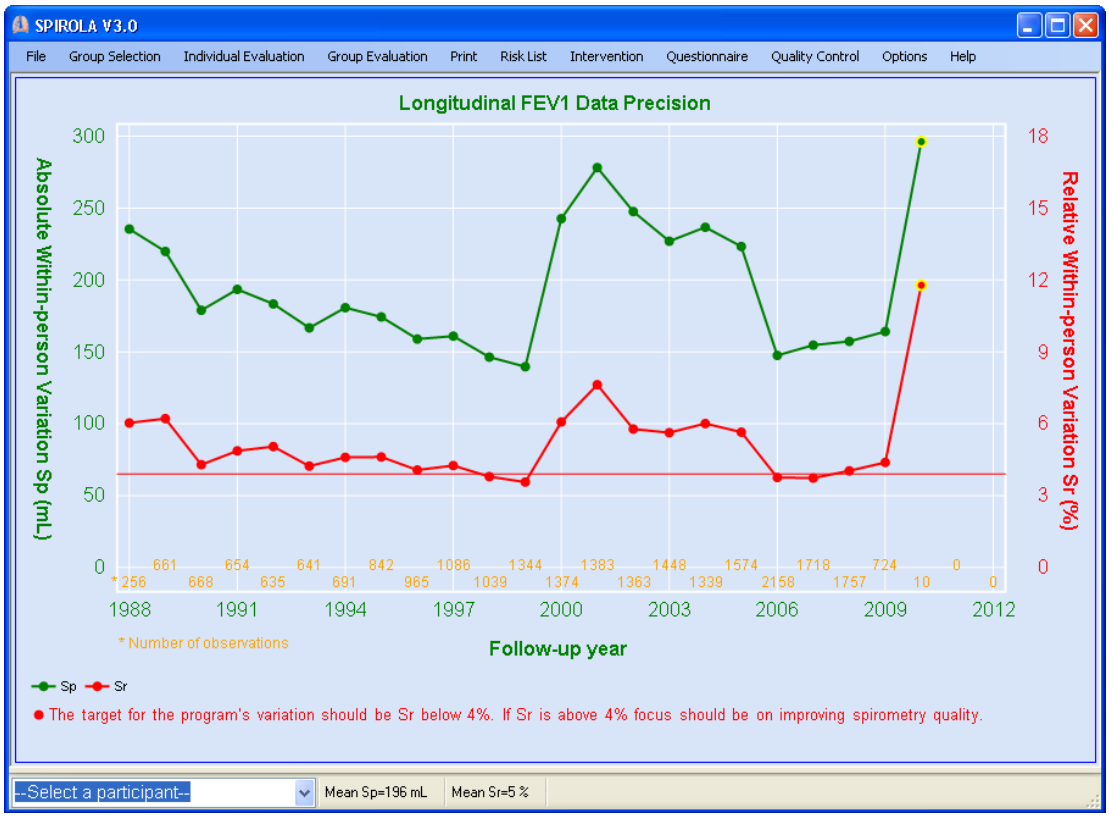
Group evaluation menu (see below) helps the user to monitor over time the following outcomes: group longitudinal FEV_1 and FVC data variability (i.e., the pair-wise within-person variation); group means for FEV_1 and FVC; and the mean slopes of decline for FEV_1. All four charts can be displayed in one window in Multiple Charts. The group evaluation can be done for all participants or for sub-groups identified by the Risk List menu (i.e., those with abnormal spirometry findings or those selected for intervention).



Monitor longitudinal data precision in a group

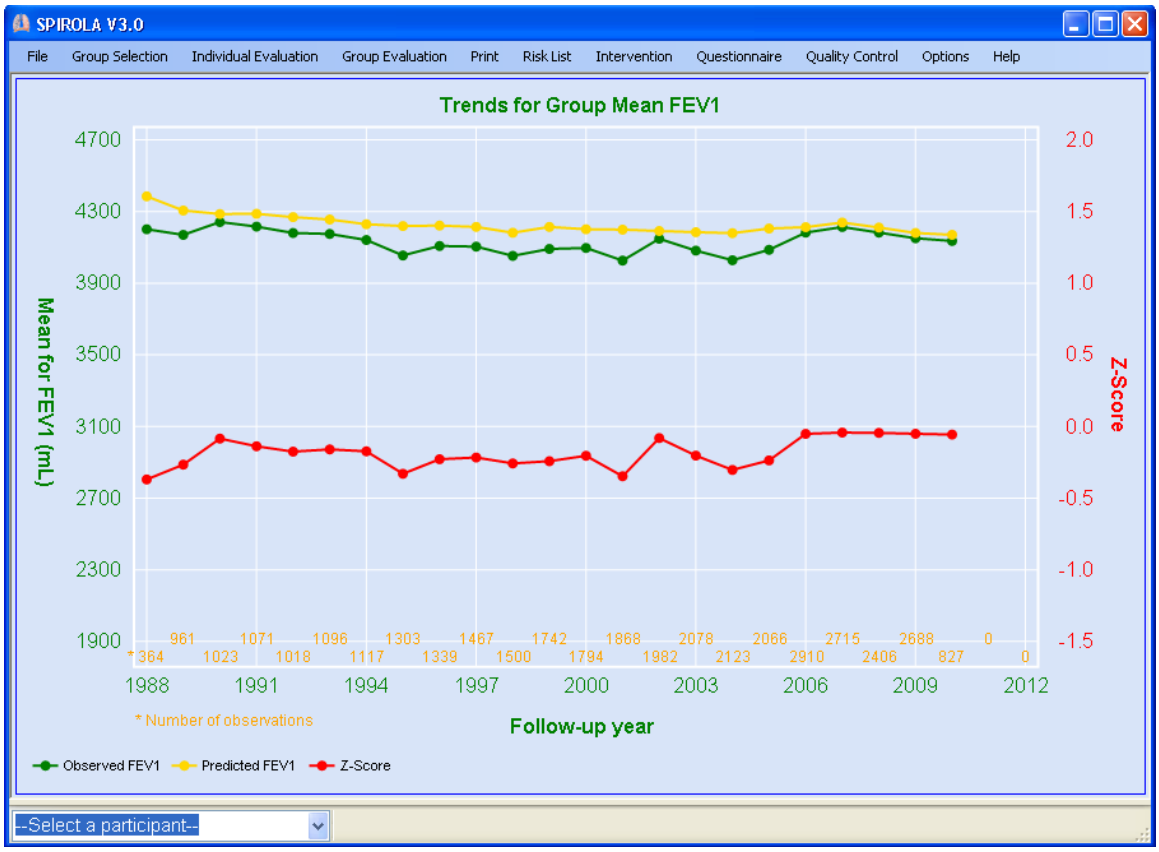
1. On the **Group Evaluation** menu click on **Within-person Variation for FEV_1** or **FVC** to show the yearly values of the pair-wise within-person variation s_p (absolute) and s_r (relative), as shown below. The annual s_p and s_r values are calculated using FEV_1 or FVC measurements repeated within 18 months. The yellow numbers along the bottom axis show the number of repeated observations used in the calculation; only one pair-wise observation per person is included. If the number of repeated observations is small (<50) in any one year, the s_p and s_r values are circled in yellow to indicate that the estimate may not be reliable. The red horizontal line corresponds to the desirable level of relative within-person variation of 4%. The legend at the bottom of the screen shows the mean s_p and s_r values over all the year. These values can be used to determine what longitudinal limit is appropriate (see Section 8.1:

Define longitudinal limits for FEV_1 or FVC). If spirometry is done less frequently, the measure of average within-person variation can be obtained from **Group Slope**.



Monitor mean FEV_1 and FVC values in a group

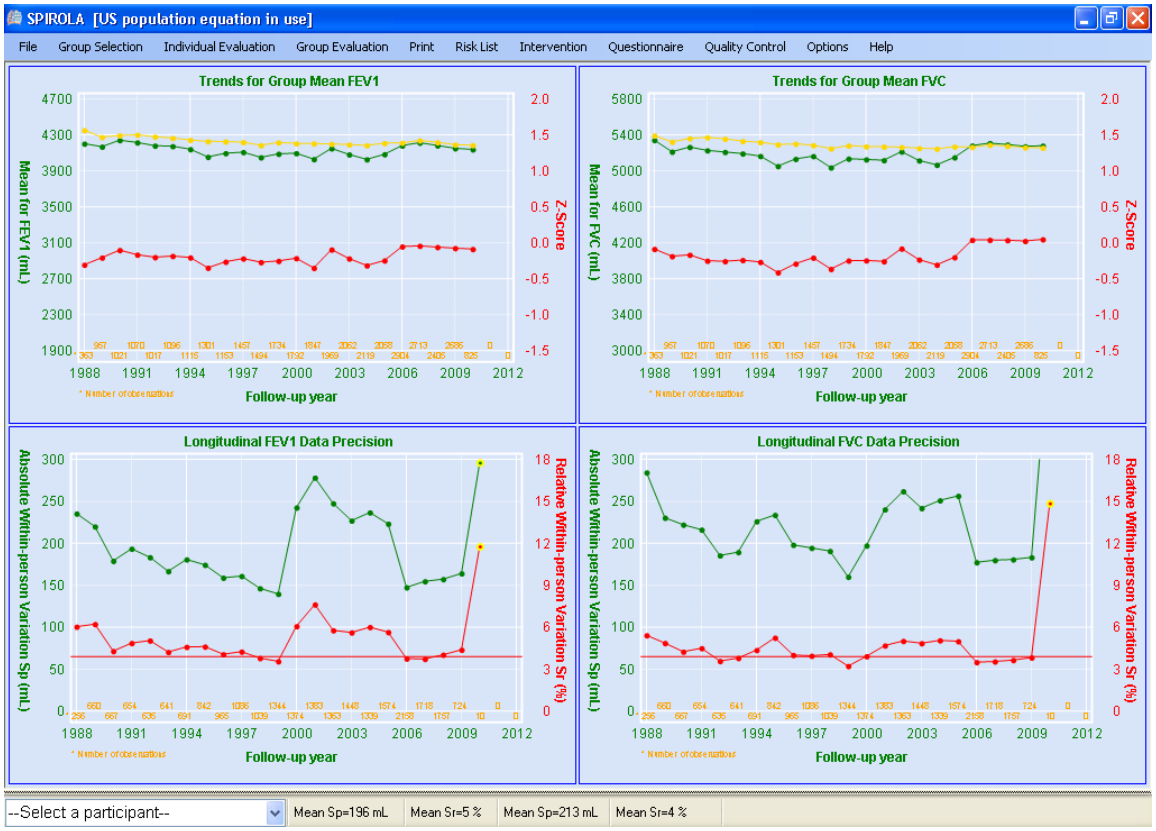
1. On the **Group Evaluations** menu click **Means for FEV_1** (or **FVC**) to display yearly group means for observed, predicted, and z-score (standard deviation units from the predicted value) as shown below for FEV_1.



The mean FEV_1 chart shows group means for predicted (yellow), observed (green), and z-score (red) values. Same applies for FVC chart. The predicted values are derived from prediction equations that take into account age, height, sex, and race/ethnic background, and are based on nationally representative healthy never-smokers.[9] Irregular deviations of observed mean values from predicted values may be due to changes in measurement procedures, or due to effects of occupational exposure or interventions. Monitoring group means can help to identify systematic effects taking place at a group level.

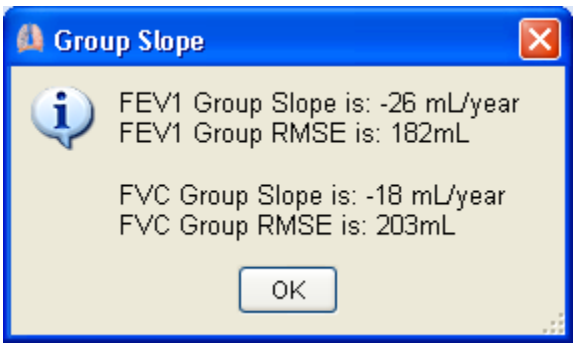
Display multiple charts

1. On the **Group Evaluations** menu, click **View Multiple Charts** to display the three group evaluation charts together (see example below). This allows the user to review changes in a group FEV_1 and FVC means in relation to data precision.



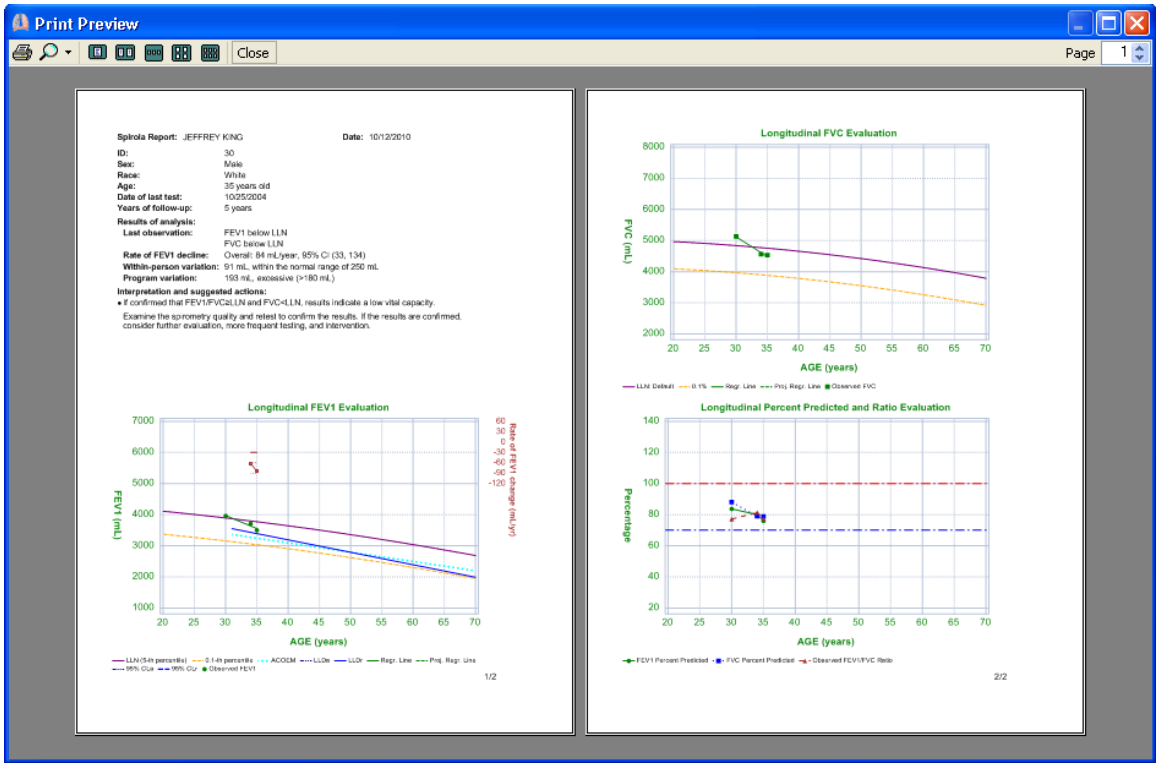
Display mean slope and within-person variation

1. On the **Group Evaluations** menu, click **Group Slope** to display the mean slope and within-person variation for the group, for FEV_1 and FVC. The mean statistics are calculated from the regression analyses conducted on individuals who have four or more years of spirometry follow-up.



4.4 Print Menu

1. To print a current plot, click **Print**, or **Quick Print** on the **Print** menu.
2. Results summarized in a report can be printed as individual charts or in the Multiple Chart option (see example below).
3. To preview the report, click **Print Preview** on the **Print** menu. Click one or two page display on the upper picture menu, as shown below.

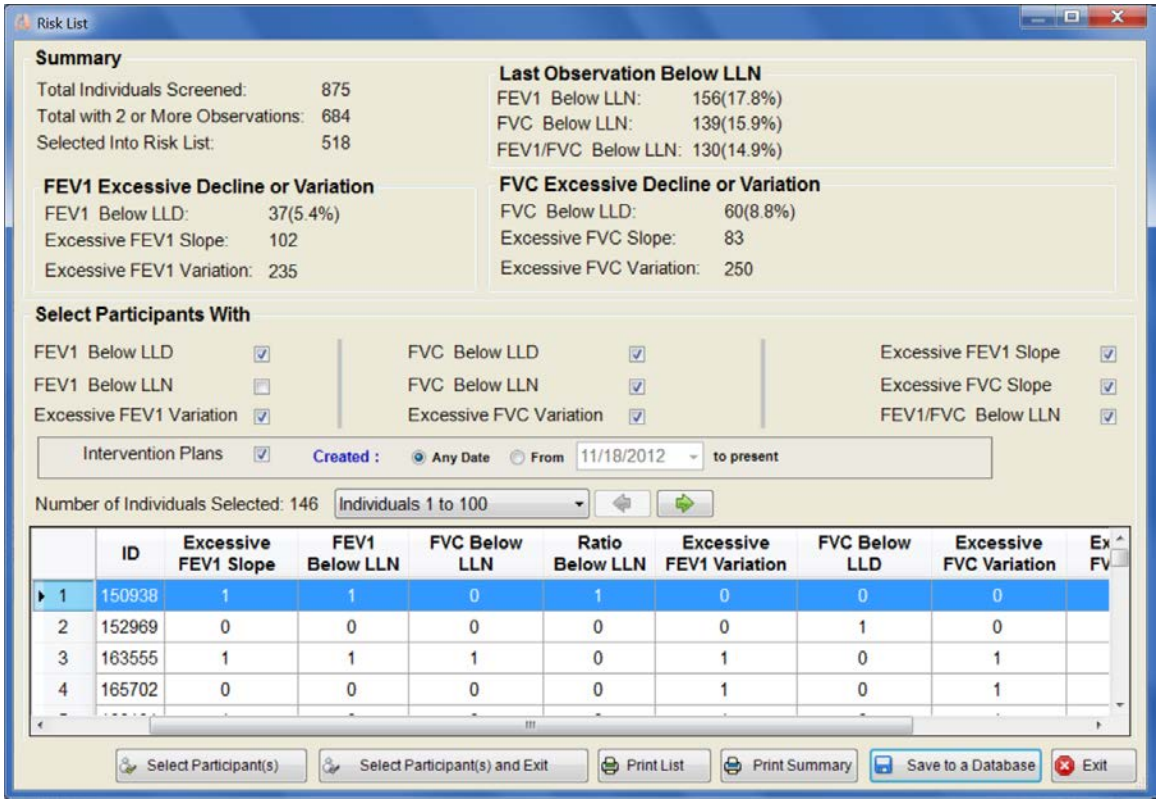


4.5 Risk List Menu

The Risk List menu screens for individuals whose most recent lung function test results are abnormal, or whose decline in lung function or variation in the longitudinal lung function data are excessive. In addition, the menu enables to select individuals who have been previously assigned an intervention plan. The subsequent lung function evaluation can be done on both individual and group level. The group evaluation thus enables the user to evaluate the effect of the various abnormalities, or interventions, on the group mean lung function values (FEV_1 and FVC). The group pairwise within-person may not be as useful, unless spirometry is done on annual basis for a large number of individuals.

Screen for individuals at risk of developing respiratory impairment

1. On the **Risk List** menu, click **Show Risk List Summary** to obtain a list of individuals whose rate of decline or within person variation in FEV_1 or FVC has been identified as excessive, or whose most recent lung function values (FEV_1, FVC, or the FEV_1/FVC ratio) are below LLN. See figure below for the selection criteria.
2. The results from Risk List show the number of individuals screened and the numbers with each type of outcome. Click on **Print Summary** to print the summary statistics.
3. To evaluate a subset of individuals with a specific outcome and/or with an intervention plan, select the appropriate outcome(s) shown under **Select Participants With**.
4. If the **Intervention** menu has been used to assign intervention plans, use the **Intervention Plans** function to select individuals who were assigned an intervention plan, or individuals whose plans were created from a specified data to the present (i.e., current date).
5. Click on **Select Participant(s)** to select the individuals for evaluation. Alternatively, to select a particular individual, scroll down the list, and click on a particular record and on **Select Participant(s)**. To see the lung function results without closing the **Risk List** screen, click on the top blue frame of the **Risk List** and drag the screen to the left bottom side and drag it up again when needed. If needed, click on Maximize or Restore Down function at the top right corner of the **Risk List** screen to change the size of the screen.
6. Click on **Print List** to print the list.
7. Click on **Select Participant(s) and Exit** to display lung function results and exit the Risk List.
8. To exit from the Risk List click on **Exit**.



Interpretation and suggested actions

1. Individuals' lung function data evaluation

The tables below summaries "Result of the analysis" and "Interpretation and suggested actions" as provided in the **Summary Report**. Individuals whose lung function is categorized as abnormal based on the definitions below are selected into **Risk List**.

Cross-sectional evaluation using the most recent spirometry results

Result of the analysis	**Interpretations and suggested action(s)**
If any of the results below:	Examine spirometry quality and retest to confirm the results.
FEV_1<LLN	If confirmed that FEV_1<LLN, the person has FEV_1 value that has only 5% probability of being normal. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
FEV_1/FVC<LLN	If confirmed that FEV_1/FVC<LLN, results indicate airflow obstruction. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
FEV_1/FVC≥LLN and FVC<LLN†	If confirmed that FEV_1/FVC≥LLN and FVC<LLN, results indicate a low vital capacity. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.
FEV_1<0.1^{th} percentile	If confirmed that FEV_1<0.1^{th} percentile, the person has FEV_1 value that has only 0.1% probability of being normal. If the results are confirmed, consider referral for clinical evaluation, more frequent testing, and intervention.

Changes in FEV_1 and FVC over time, with <8 years of follow-up

Result of the analysis	Interpretations and suggested action(s)
FEV_1 or FVC <LLDr	Examine the quality of baseline and current test. If confirmed that the current FEV_1 or FVC <LLDr, the rate of decline may be excessive.
Rate of decline in FEV_1 and FVC	Prior to 8 years of follow-up, excessive decline is evaluated using the LLDr limit. The rate of decline is provided as additional information from 4 years of follow-up, but is not used in SPIROLA's decision making.
Within-person variation in FEV_1 or FVC >5%	The within-person variation >5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase FEV_1 variability.

Changes in FEV_1 and FVC over time, with 8 or more years of follow-up

Result of the analysis	Interpretations and suggested action(s)
FEV_1 or FVC values < 95%CL (derived from the regression line)	If confirmed that FEV_1 or FVC <95%CL for the regression line, consider re-testing in near future.
Rate of decline FEV_1 or FVC >90 mL/y.[5]	If a rate decline in FEV_1 or FVC >90 mL/y is confirmed, results indicate excessive decline. Consider further evaluation, more frequent testing, and intervention.
Within-person variation >5%	The within-person variation >5% can be due to lack of spirometry quality control. Consider correcting data errors before interpretation. Occupational exposure, asthma, or personal factors can increase FEV_1 variability.
Projected FEV_1 or FVC declines to 0.1^{th} percentile before 70 years of age.	If projected FEV_1 regression line declines to 0.1^{th} percentile (≈60% predicted), results indicate increased risk of developing moderate impairment. If the results are confirmed, consider further evaluation, more frequent testing, and intervention.

2. Group data evaluation

Users may also want to evaluate those selected into the Risk List at a group level.

1. To evaluate a group of individuals with a specific outcome, and/or individuals assigned an intervention plan, in the **Risk List** select the appropriate outcome(s) shown under **Select Participants With**.

2. Click **Select Participant(s) and Exit**.

3. Under the **Group Selection** menu select **Participants in the Risk List**, and then select the desired chart from the **Group Evaluation** menu.

Figure A Figure B

This procedure allows the user to monitor group means for all participants as well as for sub-groups selected into the Risk List based on various selection criteria. For example, the two figures above compare trends for the mean FEV1 values for all participants (Figure A) and for participants selected into the Risk List (Figure B). Notice those selected into the Risk List have much lower observed mean FEV1 values (green line) compared to predicted mean values (yellow line) than all participants.

Suggested Risk List evaluation procedure

The **Risk List** identifies individuals who fulfill any of the criteria listed in the above table (see, Individuals' lung function data evaluation). In addition, if the Intervention menu is used to assign intervention plans, individuals with assigned plans can be also selected. The following evaluation procedure is recommended.

1. **Examination of the individual's existing data**
   a. Examine the longitudinal demographic, FVC, and FEV_1 data shown below the FEV_1 chart, to make sure that the data are reasonable.
   b. If a data point appears to be an outlier, temporarily exclude the point by right clicking on it and then evaluate the new results on the chart and in the report.
   c. If a single data point appears to be an outlier and causes the individual's selection into the risk list, check for possible data errors. The first (baseline) observation may sometimes be lower due to the learning effect. When this happens, exclusion of the baseline value may improve precision of the interpretation.
   d. If a data error is found, correct the data in the .mdb database using Microsoft Access software, re-run SPIROLA, and review the new **Summary Report**.

2. **Examination of the individual's spirometry data quality**
   a. Examine the original spirometry tracings using the ATS standardization criteria of: (a) acceptability (extrapolated volume, cough in first second, end of test criteria, obstructed mouthpiece, extra breath, cessation of airflow); and (b) repeatability (≤150 mL).[9]
   b. If an acceptability error is found, consider removing data for that test from the dataset, correct the SPIROLA .mdb file using Microsoft Access, and then re-run SPIROLA to produce a new **Summary Report** for the individual.
   c. Provide feedback to the spirometry technician(s) on the spirometry errors found.

3. **Re-test the individual**

After the first two steps have been completed and SPIROLA still identifies the person as being at risk, consider re-testing the person within six months from the most recent test. If the re-tested spirometry values confirm the original interpretation, consider the suggested actions in the new **Summary Report**.

Suggested intervention measures

When spirometry quality issues are satisfied and re-testing confirms that a person has impairment or is at increased risk of developing respiratory disease, further clinical evaluation, implementation of more frequent testing, and intervention measures should be considered. The severity of existing impairment and the rate of lung function decline should be considered when deciding on the type of intervention(s).

Interventions on an individual level:
Discussing lung function results with a worker can motivate the individual and can help to determine what course of action is acceptable to the individual to prevent further excessive lung function loss. Decreasing inhalation of noxious particulates and gases is usually the most important intervention. The most important risk factor for excessive decline in lung function is often tobacco smoking, for which nicotine replacement therapy may provide best results for smoking cessation.[10] Studies show that complete smoking cessation is needed to halt excessive lung function decline.[11] Occupational exposures to respiratory hazards also represent an important risk.[12] Evaluation of individual occupational exposures should be done. Where possible, hazardous exposures should be reduced or eliminated through engineering controls (e.g., substitution of less hazardous materials, process enclosure, workplace ventilation). Administrative controls (e.g., revised work practices) may also help limit hazardous occupational exposures. Finally, use of effective personal protective equipment (e.g., respirators) should be recommended when other measures are not feasible or insufficient by themselves. The potential synergistic effect of smoking and occupational exposure on lung function should be explained to individuals who are exposed to both hazards. Weight gain can also contribute to lung function decline due to loss of fitness and difficulty in performing the spirometry test at full lung capacity. Body mass index (BMI) greater than 25 kg/m^2 associated with abdominal obesity can cause increased decline in lung function.

Interventions at a company level:
Management commitment to an integrated worksite health and safety program provides a key foundation for success in maintaining a healthy workforce. Programs are likely to be more effective when they are based on management's understanding of workers' concerns about health risks on the job. By identifying workers' priorities, smoking (for example) can be addressed in the broader context of worksite safety. Intervention at the individual level is then more likely to be successful.

Evaluation of the effect of intervention(s):
To determine the effect of individual intervention on the rate of FEV_1 decline using SPIROLA, use the small rate of decline chart shown on the FEV_1 and FVC charts. To determine the effect of an integrated worksite health and safety program using SPIROLA, assess trends on the FEV_1 and FVC means for the whole group and or at-risk subgroup.

The **Intervention** menu (Section 5) allows the provider to design an intervention program for a group of workers, and to plan, record and evaluate an intervention for an individual worker. The **Questionnaire** menu (Section 6) enables to conduct periodic

questionnaire surveys, and to integrate the questionnaire data with the spirometry and intervention data.

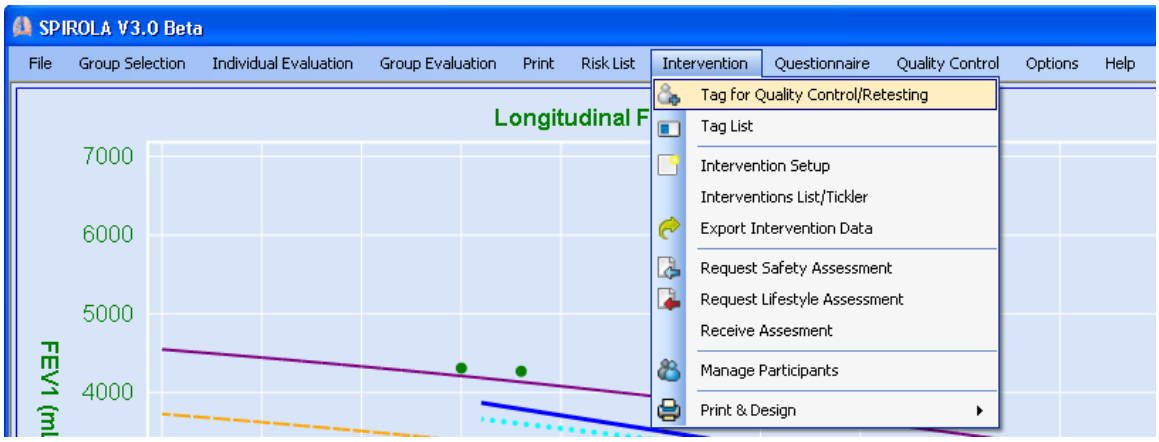
5. Intervention Menu

The intervention and questionnaire modules have been created in collaboration with an existing occupational safety and wellness program, to address the need of the program.[16] Users can redesign the intervention or questionnaire forms using the design templates provided in Sections 5.4 and 6.2, respectively.

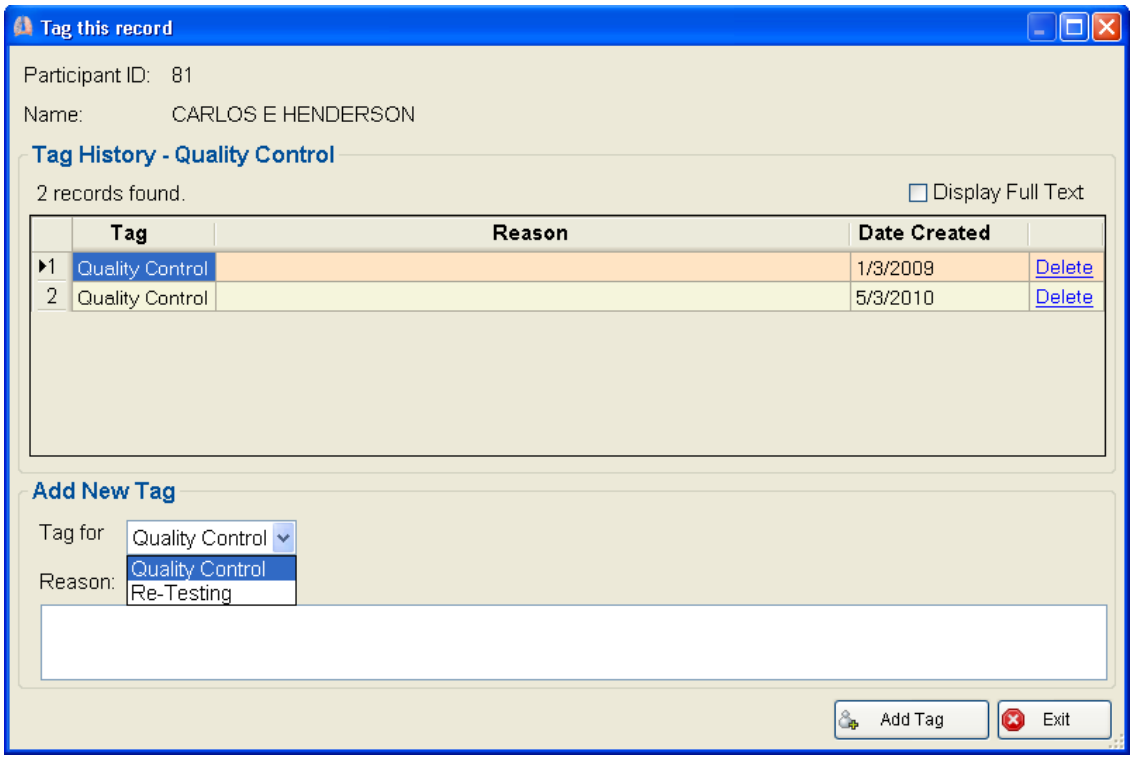
The information created by the Intervention or Questionnaire modules is stored in the administrative database **SPIROLA_Admin.mdb**. To avoid data loss, the administrative database, as well as the spirometry database, should be kept in a secured location that is regularly backed-up (see Section 9 on the administrative database management).

5.1 Tag Individuals for Spirometry Quality Control or Retesting

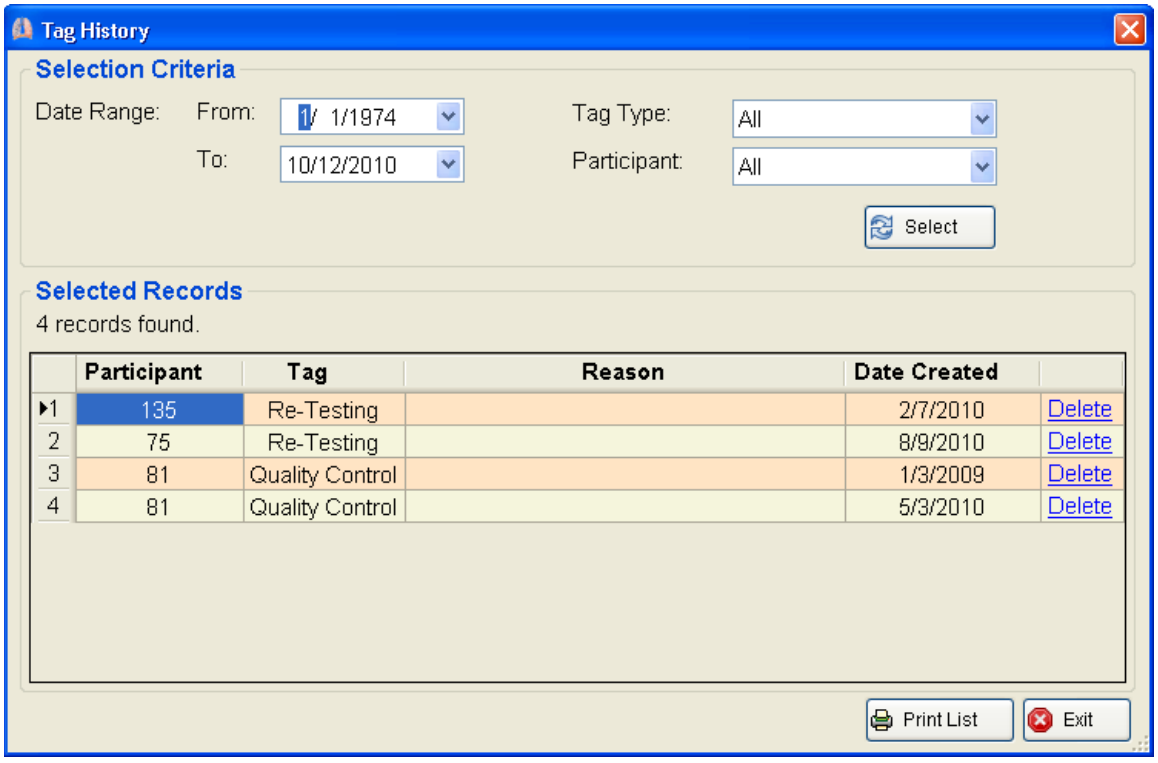
1. On the **Intervention** menu, click on **Tag for Quality Control/Retesting**.



2. Add a new tag for **Quality control** or **Re-Testing**, this adds individual to a **Tag List** (see below).



3. To display the Tag List, on the **Intervention** menu click on **Tag List** (see below).

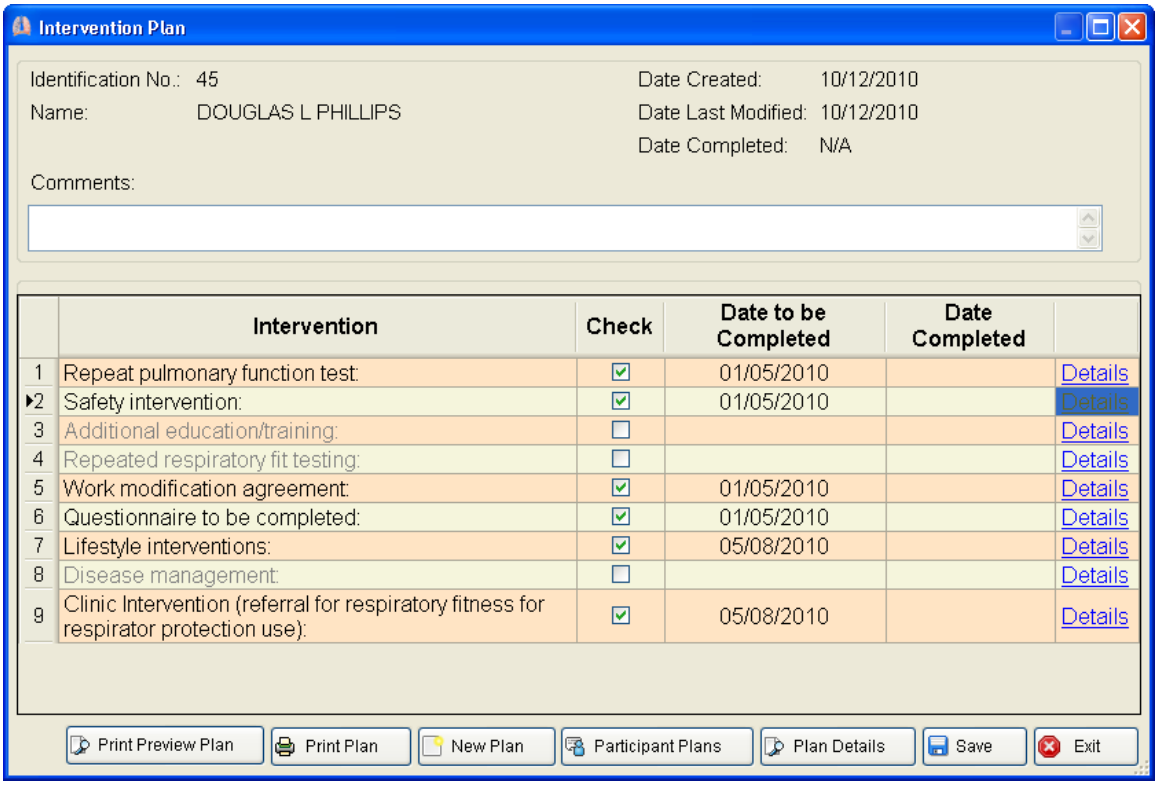


5.2 Setup and Evaluate Intervention Plan for Individuals

SPIROLA provides a generalized intervention plan which currently includes workplace safety evaluation, lifestyle intervention, and disease management plan. Section 5.5 describes how to customize the intervention forms.

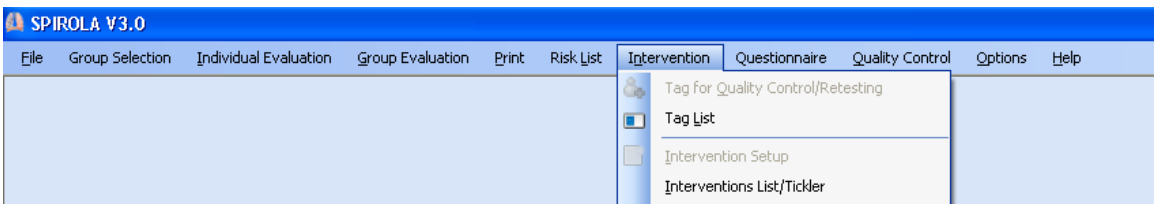
Setup intervention plan

1. On the **Intervention** menu, click on **Intervention Setup** to create an intervention plan for an individual.
2. To develop the plan, check checkboxes under column **Check** (see picture below).
3. Click on **Details**, **Plan Details**, or **Participants Plans** buttons at the bottom of the form, to view the current or previous plans, and complete the intervention plan setup.
4. Click on **Save** button to save the intervention plan in the administrative database.

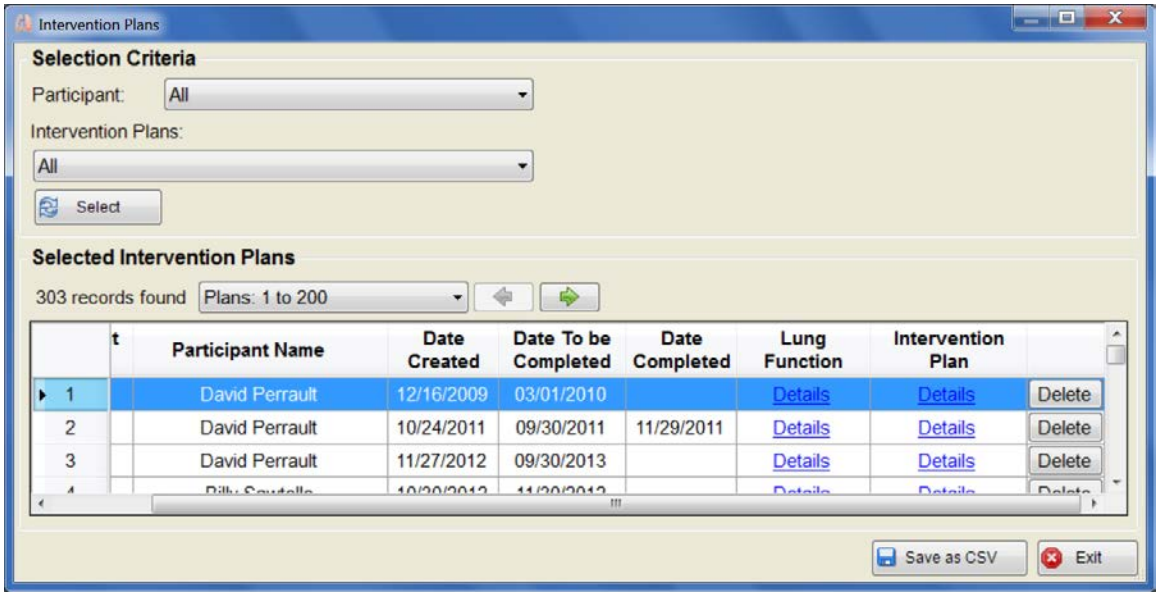


Evaluate or modify interventions

1. On the **Intervention** menu, click **Interventions List/Tickler** to view interventions set for an individual or a group of individuals (see below).



2. On the **Selected Intervention Plans** section (see below), click on **Details** to view or modify an intervention plan for an individual.
3. Use the **Selection Criteria** section and **Select** button to specify criteria (including dates) to select a specific subset of intervention plans.
4. Use **Delete** function provided on each intervention plan record to delete an intervention plan permanently.
5. To print the list of interventions, save the list to a .csv file and print from there.



5.3 Methods of Implementing Interventions

After intervention plans for individuals are setup by a healthcare provider using **Intervention Setup** menu, the intervention forms can be completed using responses from either: (i) participants; (ii) workplace safety officers; (iii) wellness coaches; or (iv) others who are involved in the intervention program.

The information can be entered into SPIROLA using one of the following techniques:

1. Type answers directly into SPIROLA intervention forms. On **Individual Evaluation** menu click on **Search for a Participant** to select an individual. Next, on **Intervention** menu click **Interventions List/Tickler** to show the intervention plan(s) created previously for the individual. Click on **Detail** and fill in the form.
2. Save an individual intervention plan and click on the **Print Plan** button. Print the intervention plans (Safety or Lifestyle) and after the forms are completed, type the answers into SPIROLA as above. Alternatively, the plans can be printed as a PDF file and send by e-mail for completion.
3. Electronically (e.g., by e-mail), send batches of intervention plans to a worksite to request safety assessment or to a wellness coach to request lifestyle assessment, and to implement the intervention. The safety officers and wellness coaches use

SPIROLA interface software to monitor the intervention. On completion, they send the file back to the physician's office to be read into SPIROLA (see below).

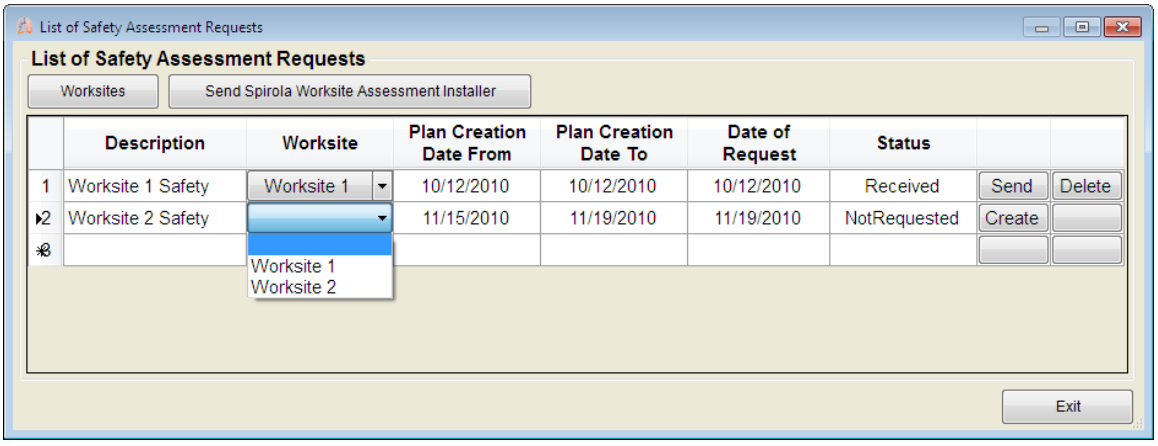
5.4 Electronic Safety or Lifestyle Assessment at Worksite

The section describes how to send electronically intervention plans to worksites or to wellness coaches who then use SPIROLA interface software **SPIROLA_Request** to implement the intervention. On completion, or at certain intervals, the responses are sent back to the physician office to be read into SPIROLA for individual or group evaluation.

Creating safety or lifestyle assessment request

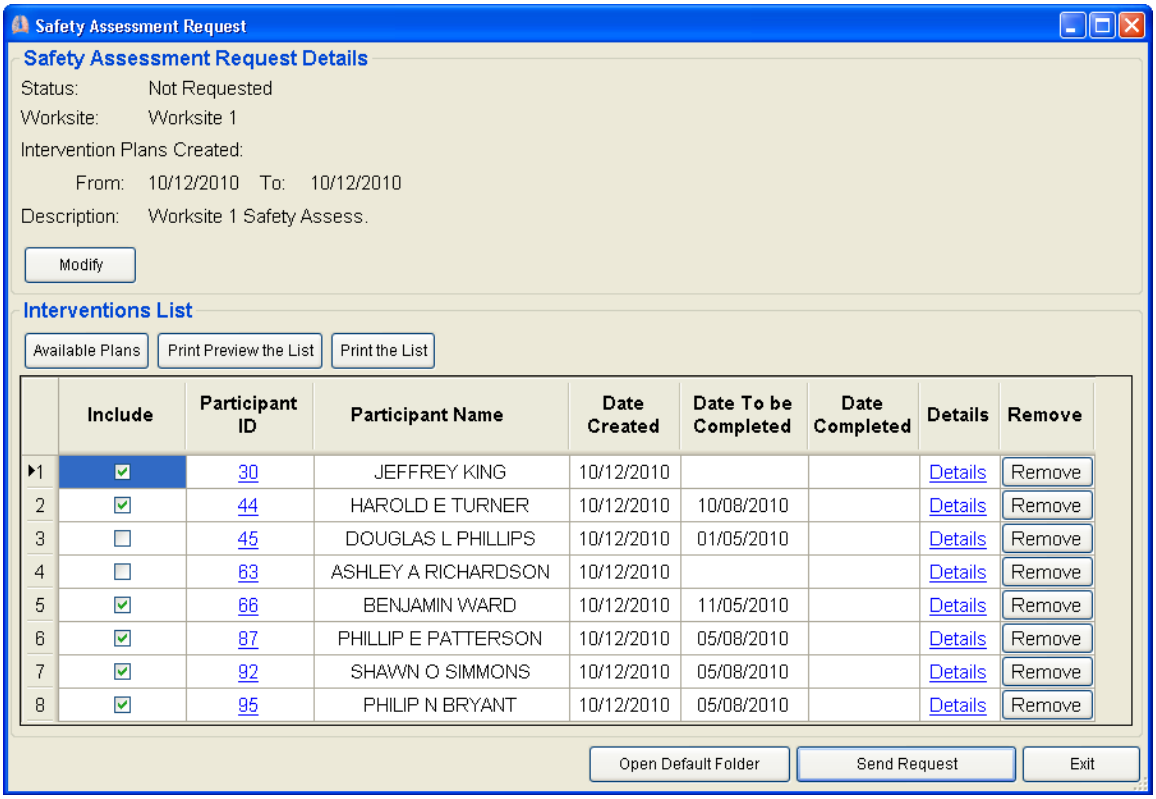
1. On the **Intervention** menu, click on **Request Safety Assessment** or **Request Lifestyle Assessment**.
2. In the opened form (see below) click on **Send Request Installation Package**. Send the self installing package **SPIROLA_Request_Setup.msi** to worksites or health coaches. This needs to be done only once at the beginning.
3. To create an intervention request, fill the **Description**, **Worksite**, **Plan Creation Date From** and **Plan Creation Date To** fields (see below). Use the button Worksites at the top of the form, to create a list of worksites. SPIROLA will add only intervention plans which were created between **Creation Date From** and **Plan Creation Date To** inclusively.
4. Click on the **Create** button to save the safety assessment request or lifestyle assessment request in the administrative database.

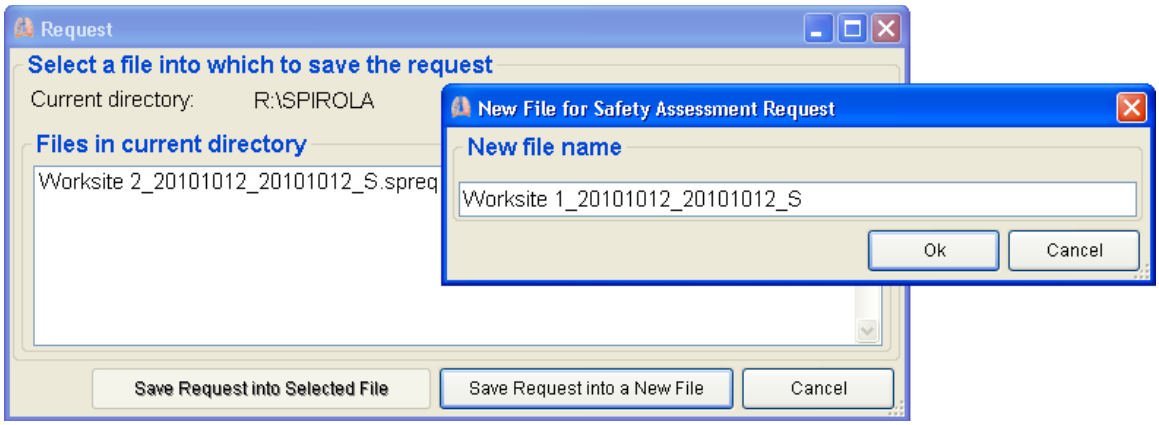
   Note: Safety assessment requests include only intervention plans for which at least one safety related question is checked (i.e., questions 1 through 6 in **Intervention Plan** form). Lifestyle assessment requests include only intervention plans for which at least one lifestyle related question was checked (i.e., questions 7 through 9 in **Intervention Plan** form).



Sending safety or lifestyle assessment request to worksite

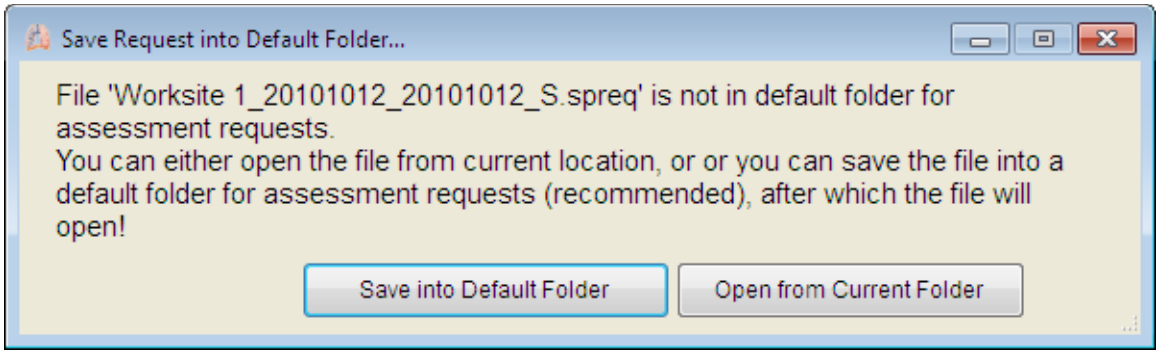
1. On the **List of Safety Assessment Requests** (see picture above) click **Send** button located next to a specific request. This opens an individual **Safety Assessment Request** form to allow the user to prepare it for sending (see picture below).
2. To make changes to the request, use the **Modify** button to modify request settings (including the dates), the **Available Plans** button to include intervention plan(s) which were previously deleted or created after the request has been created, or the **Include** column or the **Remove** button to exclude plans from a request but not the administrative database.
3. Click on **Send Request** button to generate a file with the selected intervention plans.
4. Next, click on **Save Request into Selected File** to select an existing file name where the request is to be saved. Alternatively, click on **Save Request into a New File** to specify a new file name, and e-mail the file. The created file with SPREQ extension is located in the directory where the administrative database is located, in folders **\SentRequests\SafetyRequests** or **\SentRequests\HealthyLifestyleRequests**. Alternatively, to find the location of the file, click on **Open Default Folder**.



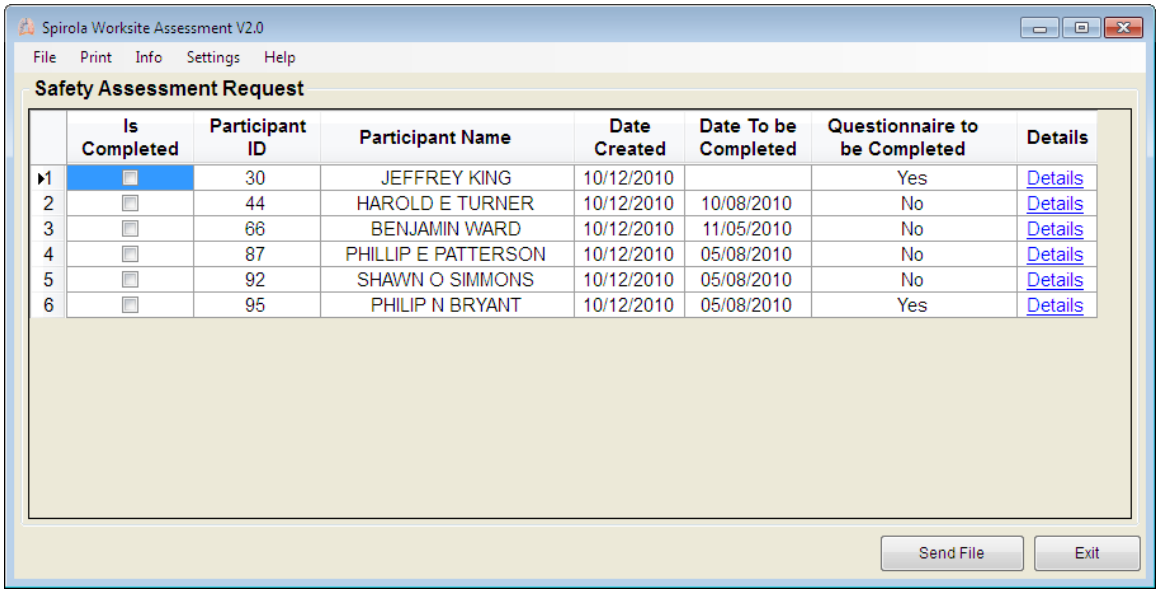


Completing safety or lifestyle assessment request at worksites

1. Install software called **Spirola Worksite Assessment** on a computer, if not already installed, by clicking on the installation file **Spirola_Worksite_Assessment_Setup_V2.0.msi**.
2. Double-click on the assessment request file (i.e., a file with SPREQ extension) received from the physician's office. If the file is not currently in a **Spirola Worksite Assessment**'s default directory, a message shown below will be displayed.
3. Click on **Save into Default Folder** button, alternatively open from a current folder.



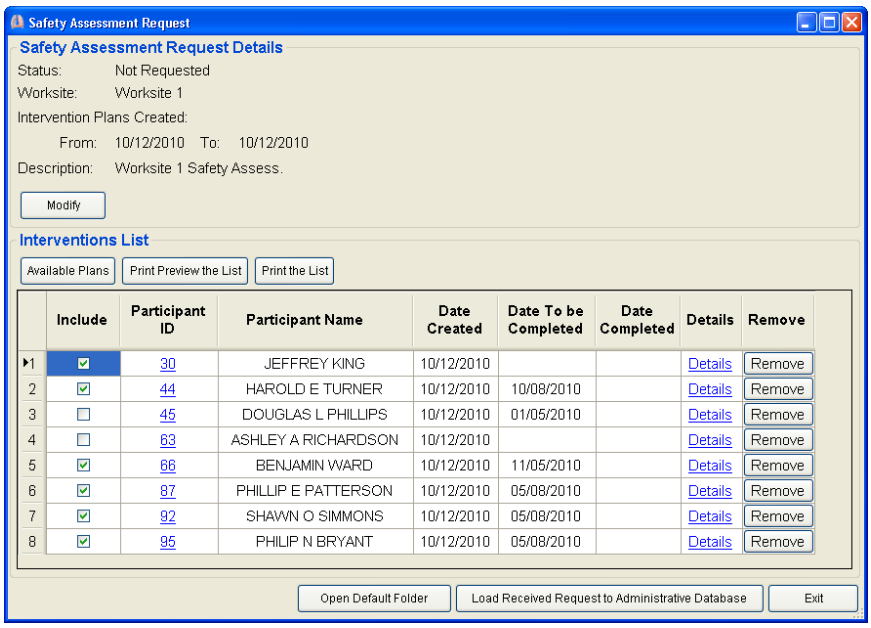
4. **Spirola Worksite Assessment** will open up with the list of intervention plans created by the physician (see picture below).
5. Click on **Details** links, to implement an intervention plan. After completing an intervention plan, check the checkbox in a column **Is Completed** (see picture above). The checkboxes are reminders on which intervention plans have been completed.
6. After the intervention plans are completed, click on **Send File** button (see picture above). SPIROLA Requests will open a directory which contains the file (i.e., SPREQ extension file) with completed intervention plans. Send the file back to the physician's office. This is the same file that was received from the physician's office.
7. If **Questionnaire to be Completed** is marked as 'Yes', print a copy of a questionnaire and ask a participant to complete it and send to the physician's office. Obtain the questionnaire PDF file from the physician's office.



	Is Completed	Participant ID	Participant Name	Date Created	Date To be Completed	Questionnaire to be Completed	Details
▶1	☐	30	JEFFREY KING	10/12/2010		Yes	Details
2	☐	44	HAROLD E TURNER	10/12/2010	10/08/2010	No	Details
3	☐	66	BENJAMIN WARD	10/12/2010	11/05/2010	No	Details
4	☐	87	PHILLIP E PATTERSON	10/12/2010	05/08/2010	No	Details
5	☐	92	SHAWN O SIMMONS	10/12/2010	05/08/2010	No	Details
6	☐	95	PHILIP N BRYANT	10/12/2010	05/08/2010	Yes	Details

Loading completed safety or lifestyle assessment requests to SPIROLA

1. Download a assessment request file (i.e., SPREQ extension file), received from a worksite or health coach (e.g., e-mailed), into a directory.
2. Start SPIROLA and on the **Intervention** menu, click on **Receive Assessment**.
3. In the file dialog select an SPREQ extension file with received assessment.
4. In the opened form (see picture below) check the requests made and click on **Load Received Requests to Administrative Database**. Intervention plans, for which **Include** checkboxes are checked (see picture below), will be modified with data in the received safety or lifestyle assessment request file (i.e., SPREQ extension file).

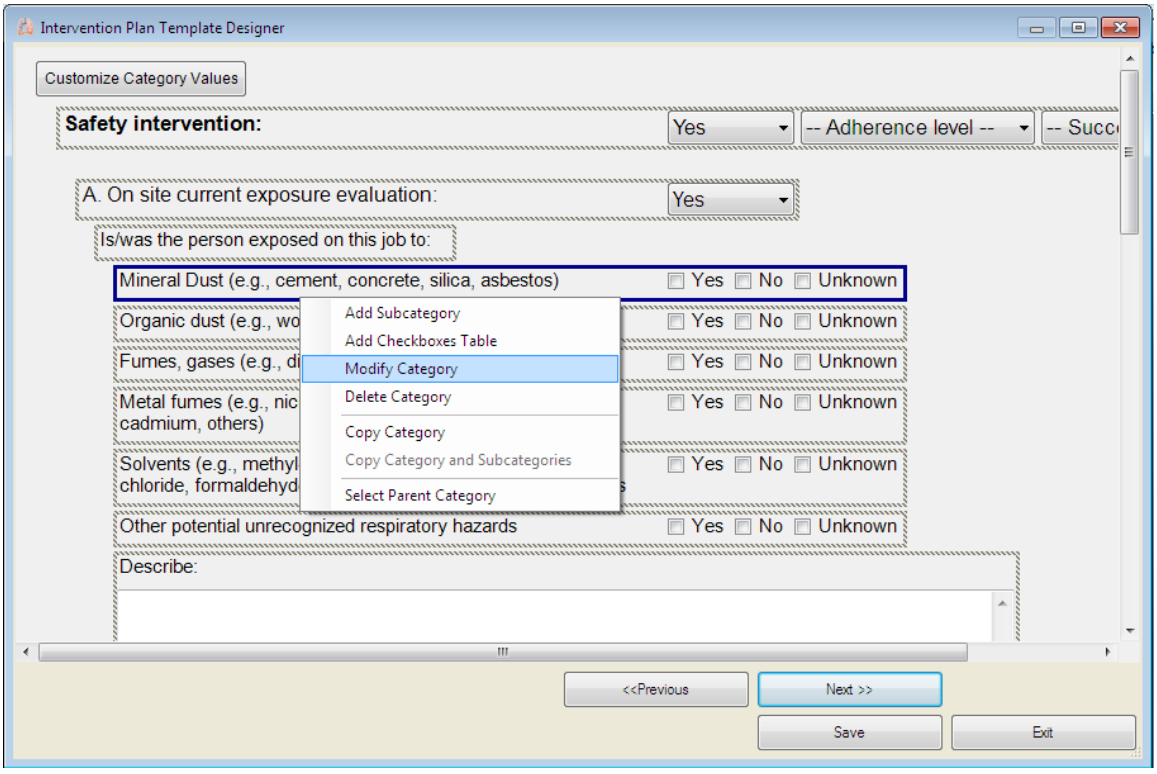


	Include	Participant ID	Participant Name	Date Created	Date To be Completed	Date Completed	Details	Remove
▶1	☑	30	JEFFREY KING	10/12/2010			Details	Remove
2	☑	44	HAROLD E TURNER	10/12/2010	10/08/2010		Details	Remove
3	☐	45	DOUGLAS L PHILLIPS	10/12/2010	01/05/2010		Details	Remove
4	☐	63	ASHLEY A RICHARDSON	10/12/2010			Details	Remove
5	☑	66	BENJAMIN WARD	10/12/2010	11/05/2010		Details	Remove
6	☑	87	PHILLIP E PATTERSON	10/12/2010	05/08/2010		Details	Remove
7	☑	92	SHAWN O SIMMONS	10/12/2010	05/08/2010		Details	Remove
8	☑	95	PHILIP N BRYANT	10/12/2010	05/08/2010		Details	Remove

5.5 Design Intervention Plan Template

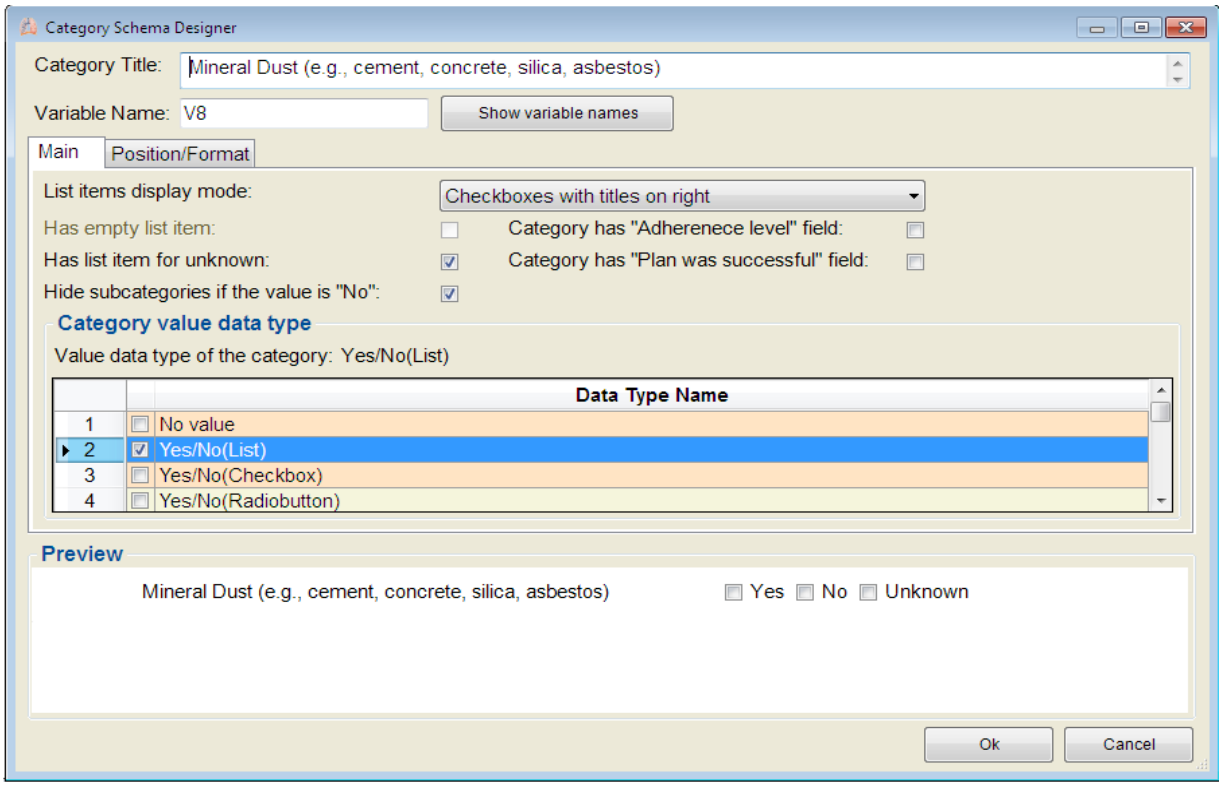
SPIROLA allows modifying the intervention forms. Changes to the intervention forms should be done at the planning stage of the intervention program. Changes made once the data collection has started will make interpretation difficult. All changes made to the plan template will be saved permanently in the administrative database, which needs to be safeguarded and regularly backed-up (see Section 9).

1. To modify the intervention plan template, on the **Intervention** menu click on **Print & Design**, and then click on **Design Intervention**.
2. In the form that opens next (see picture below) right click on a particular item (e.g., **Mineral Dust**) and select from the following menus:
   - Click on **Add Subcategory** menu, to add new sub-question(s).
   - Click on **Add Checkboxes Table** menu, to add checkboxes table.
   - Click on **Modify Category** menu, to modify the text and characteristics of the response. A form **Category Schema Designer** (displayed below) will appear and allow the user to make desired changes.
   - Note SPIROLA automatically generates unique value for the **Variable Name** field, which identifies each question and is used when exporting intervention data for use by other software. The name can be changed by the user, as discussed in Section 5.6.



   - Click on **Delete Category** menu, to permanently delete a selected question and all its sub-questions.

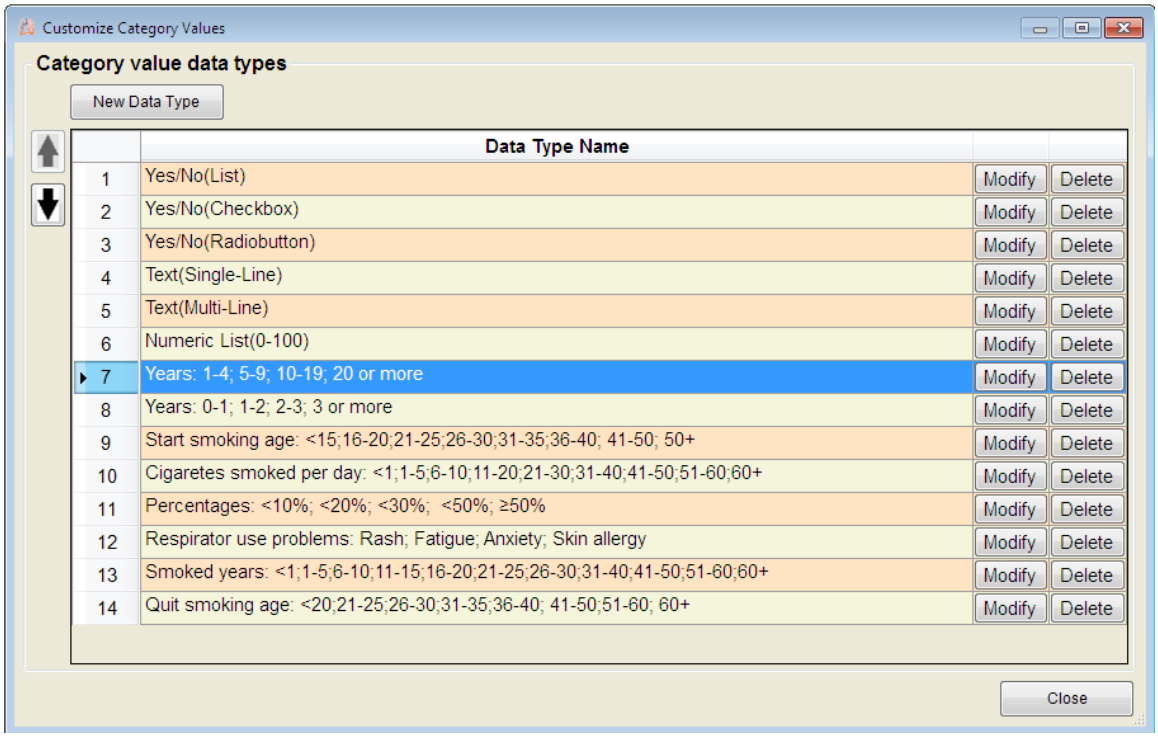
- Click on **Copy Category** menu, to copy the question, without copying the values of the question.
- Click on **Copy Category and Subcategories** menu, to copy question and all its sub-questions, without copying the values.
- Click on **Select Parent Category** menu, to highlight the parent question of the selected question.



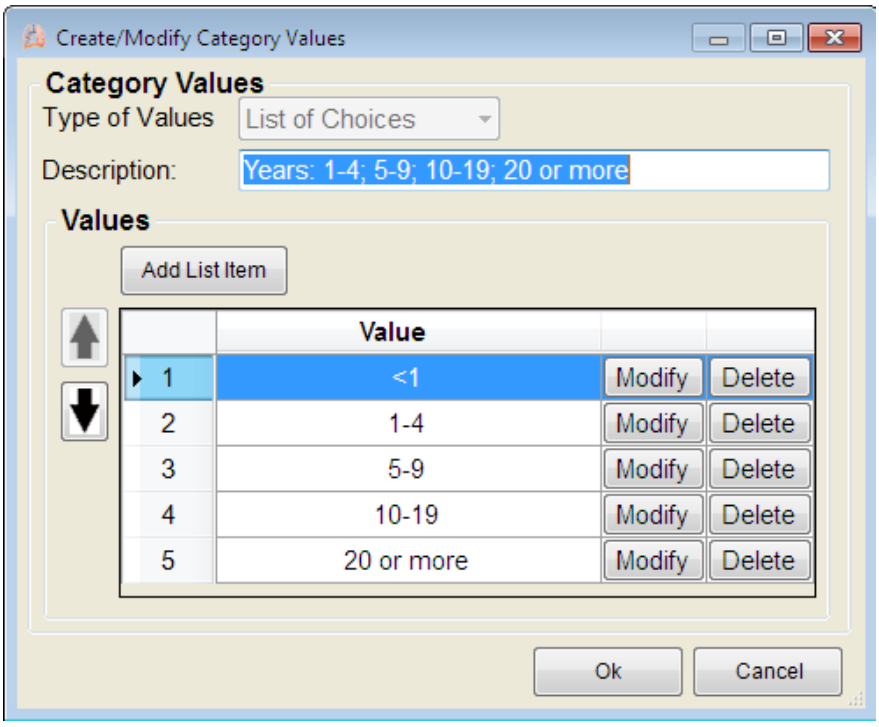
Create or modify choices of responses

SPIROLA allows creating or modifying choices of responses that can be used with each question. To create or modify choices of responses do the following:

1. On the **Intervention** menu, click on **Print & Design**, and then on **Design Intervention**.
2. In the opened form click on **Customize Category Values** at the top of the form.
3. In the form which opens next (see picture below), click on **New Data Type**, **Modify**, or **Delete** buttons to create, modify, or delete the types of responses.



For example if **Modify** button is clicked next to the **Years: 1-4; 5-9; 10-19; 20 or more** item in the picture above, a form called **Create/Modify Category Values** will open as shown in picture below, which can be used to modify or delete the choices.



5.6 Export Intervention Data

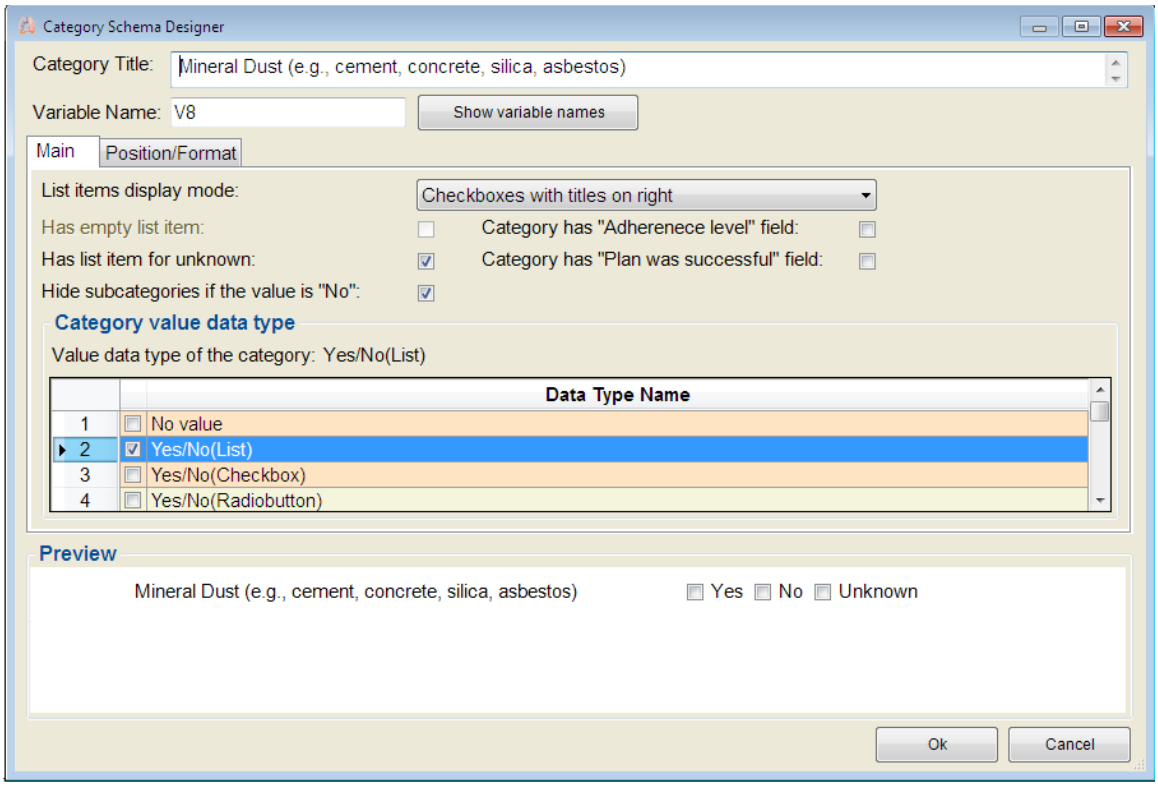
SPIROLA provides a function for exporting intervention data stored in the administrative database to a CSV file in a simple tabular format. The CSV file can be analyzed by statistical software (e.g., SAS, SPSS) or opened by Microsoft Office Excel.

1. On the **Intervention** menu, click on **Export Intervention Data** and in the opened file dialog (see picture below) select a directory and type a file name where the intervention data should be saved.
   SPIROLA creates two files: CSV extension file and XML extension file. For example, if the user types **Interventions.csv**, SPIROLA will create files **Interventions Variables.xml** and **Interventions.csv** in the selected directory.
   a. **CSV** extension file (**Interventions.csv** in this example) includes all the intervention plans in administrative database (i.e., a row per plan). The first row contains variable names, and the following rows contain the values. Picture below is an example of CSV file, opened using Microsoft Office Excel application.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	
1	ParticipantId	ParticipantId_Spirola	FirstName	LastName	PlanId	DateCreated	DateCompleted	V1	V2	V3	V4	V5	V6	V6_AdherenceLevel	V6_
2	87	634225644893255000	PHILLIP	PATTERSON	6.34226E+17	10/12/2010	10/20/2010	1	1	0		0	1		
3	92	634225644893255000	SHAWN	SIMMONS	6.34226E+17	10/12/2010	10/20/2010	1	1	0		0	1		
4	95	634225644893411000	PHILIP	BRYANT	6.34226E+17	10/12/2010	10/20/2010	1	1	0		0	1		
5	30	634224888710763000	JEFFREY	KING	6.34225E+17	10/12/2010	10/20/2010	1	1	0		0	1		
6	44	634224810444853000	HAROLD	TURNER	6.34225E+17	10/12/2010	10/20/2010	1	1	0		0	1		
7	45	634224950998403000	DOUGLAS	PHILLIPS	6.34225E+17	10/12/2010	10/20/2010	1	1	0		0	1		
8	63	634225041706304000	ASHLEY	RICHARDSON	6.34225E+17	10/12/2010	10/20/2010	1	1	0		0	1		
9	66	634225041706304000	BENJAMIN	WARD	6.34225E+17	10/12/2010	10/20/2010	0		0		0	1		
10	10	634225654826565000	THOMAS	TAYLOR	6.34226E+17	10/13/2010	10/20/2010	1	1	0		0	1		
11															
12															

   Note, variable names V1, V2, V3, V4, V5, and V6 in this example are variable names automatically assigned to questions in intervention plan by SPIROLA. To change the variable name for a specific question:
   - On **Intervention** menu click on **Print & Design**, and then on **Design Intervention**. Next, right click on a question, and select **Modify** menu.
   - In the form **Category Schema Designer**, which opens next (see picture below), type a new variable name in the **Variable Name** field.

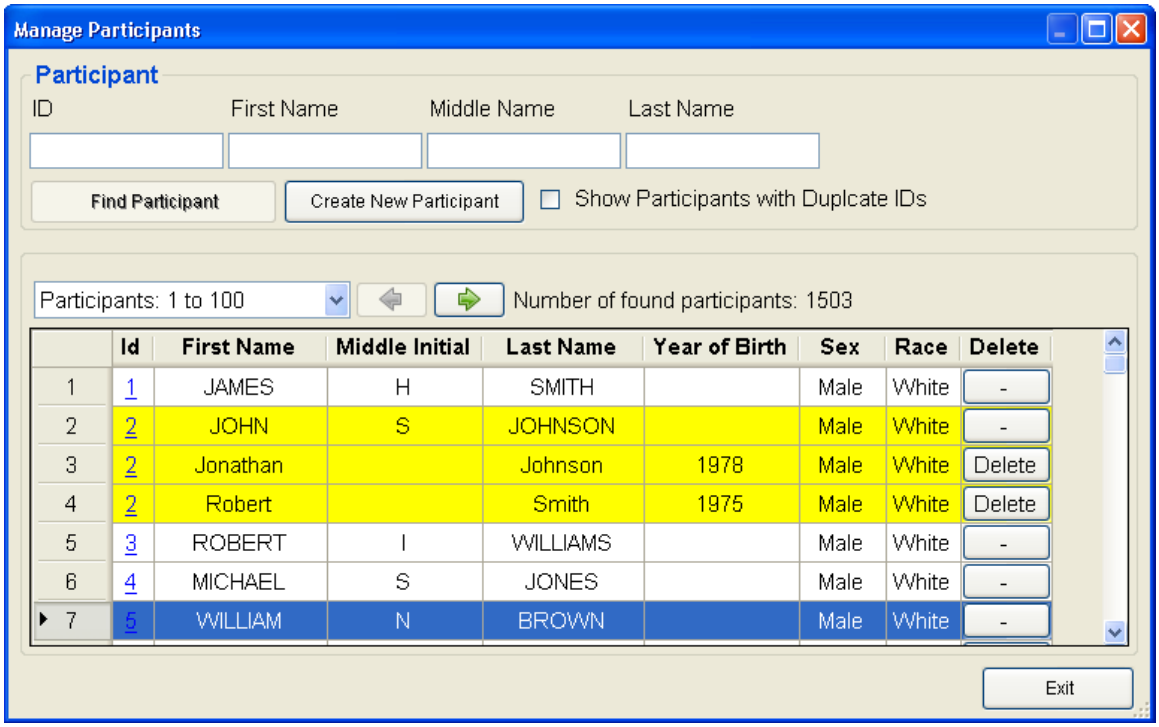
   b. XML extension file (**Interventions Variables.xml** in this example) includes information about variables, and the possible values of variables. This is a simple text file, which can be viewed by Notepad application, which is included in Windows 2000 or later (go to Start->All Programs->Accessories->Notepad to open Notepad application), or by web browsers, such as Internet Explorer or Firefox (i.e., normally this can be done by double clicking on the file).



5.7 Manage Participants Menu

When the user tags participant for farther evaluation, or creates an intervention plan for a participant (See sections 5.2), SPIROLA saves the intervention data in the administrative database. To manage participants in the administrative database follow the steps below.

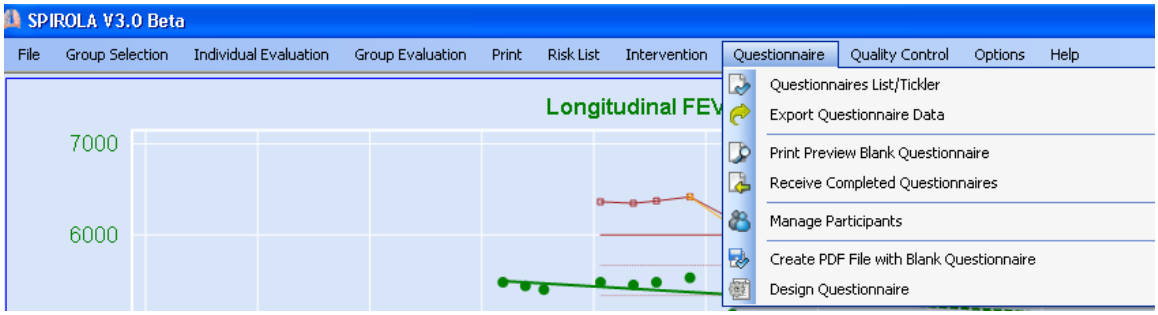
1. On the **Intervention** menu, click on **Manage Participants**. The form that opens next (see picture below), lists all participants in the current spirometry database and participants in administrative database.
   Note, Manage Participants form allows creating and modifying participants' data in administrative database, but not in the spirometry database. Therefore, if a participant's data is modified using the Manage Participants form, the same participant's data should be modified in the spirometry database.
2. Click on button **Create New Participant** (see picture below) to create a new participant in administrative database.
3. Click on a link in **Id** column (see picture below), to modify participant's data in administrative database.
4. Click on **Delete** button to delete a participant from the administrative database.



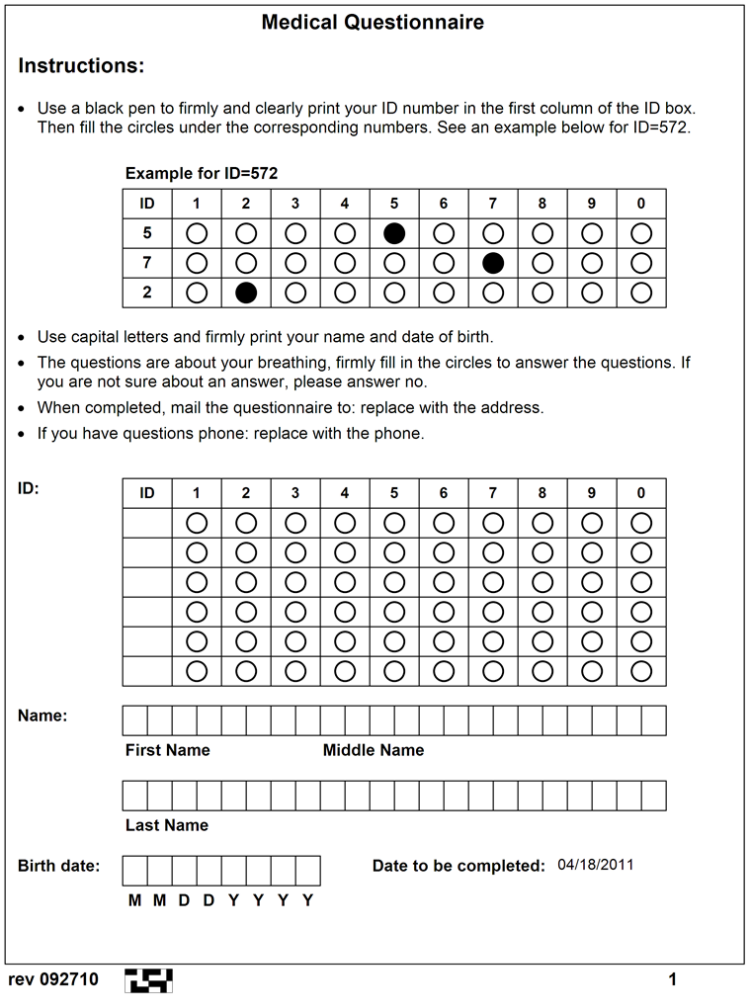
SPIROLA highlights participants with duplicate IDs in yellow, and also allows filtering out participants with duplicate IDs (i.e., click on **Show Participants with Duplicate IDs** checkbox). Once participants with duplicate IDs are identified, they can be deleted. SPIROLA will prompt if interventions and questionnaires, associated with the participant being deleted should be deleted as well, or if they should be assigned to another participant.

6. Questionnaire Menu

The **Questionnaire** menu (see picture below) allows the user to design and manage questionnaire surveys. The questionnaire forms are similar to the intervention forms (Section 5) except that questionnaire includes a cover page (see below) to enable electronic processing (i.e., scanning) of the questionnaires. The questionnaire design and some of the details of the cover page can be customized.



Questionnaire cover page:



Medical Questionnaire

Instructions:

- Use a black pen to firmly and clearly print your ID number in the first column of the ID box. Then fill the circles under the corresponding numbers. See an example below for ID=572.

Example for ID=572

ID	1	2	3	4	5	6	7	8	9	0
5	○	○	○	○	●	○	○	○	○	○
7	○	○	○	○	○	○	●	○	○	○
2	○	●	○	○	○	○	○	○	○	○

- Use capital letters and firmly print your name and date of birth.
- The questions are about your breathing, firmly fill in the circles to answer the questions. If you are not sure about an answer, please answer no.
- When completed, mail the questionnaire to: replace with the address.
- If you have questions phone: replace with the phone.

ID:

ID	1	2	3	4	5	6	7	8	9	0
	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○
	○	○	○	○	○	○	○	○	○	○

Name:

First Name **Middle Name**

Last Name

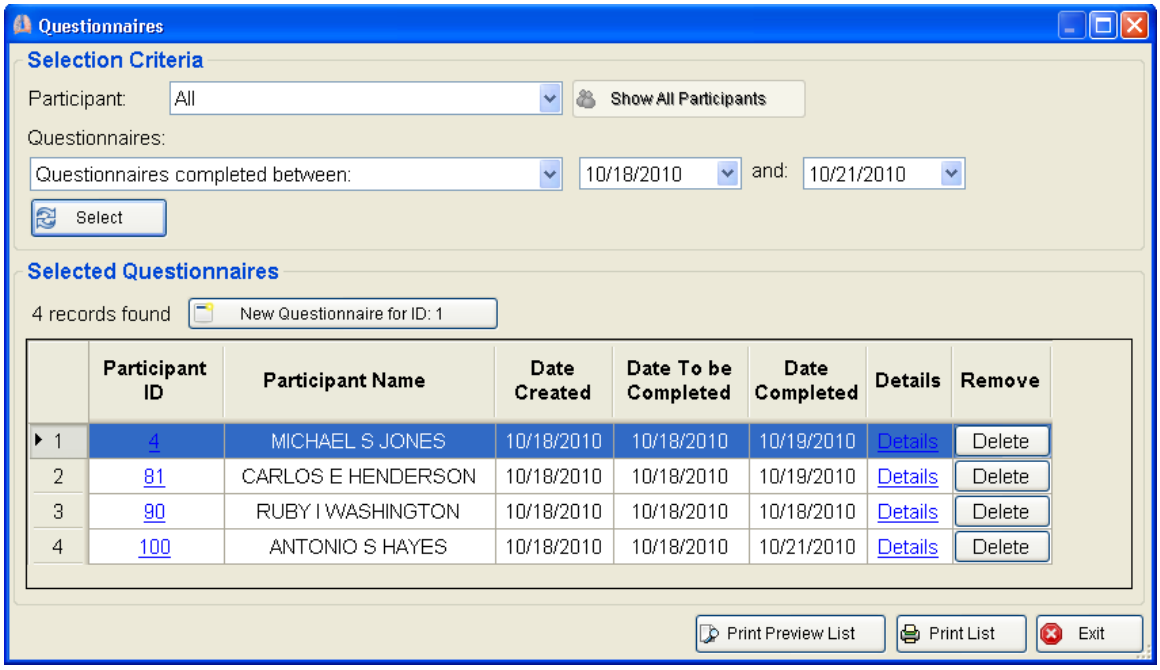
Birth date: M M D D Y Y Y Y

Date to be completed: 04/18/2011

rev 092710 **1**

6.1 View or modify questionnaires

1. On the **Questionnaire** menu, click on **Questionnaires List/Tickler** to view questionnaires created for individuals (see picture below).
2. Click on **Details** links, to view or modify/fill in questionnaire.
3. Use section **Selection Criteria** and **Select** button, to specify selection criteria to be applied to display a list of completed or to be completed questionnaires.
4. Click on **New Questionnaire for ID: Id** (see picture below) button to create questionnaire for a participant, currently selected in SPIROLA, e.g., by using the **Individual Evaluation** menu.



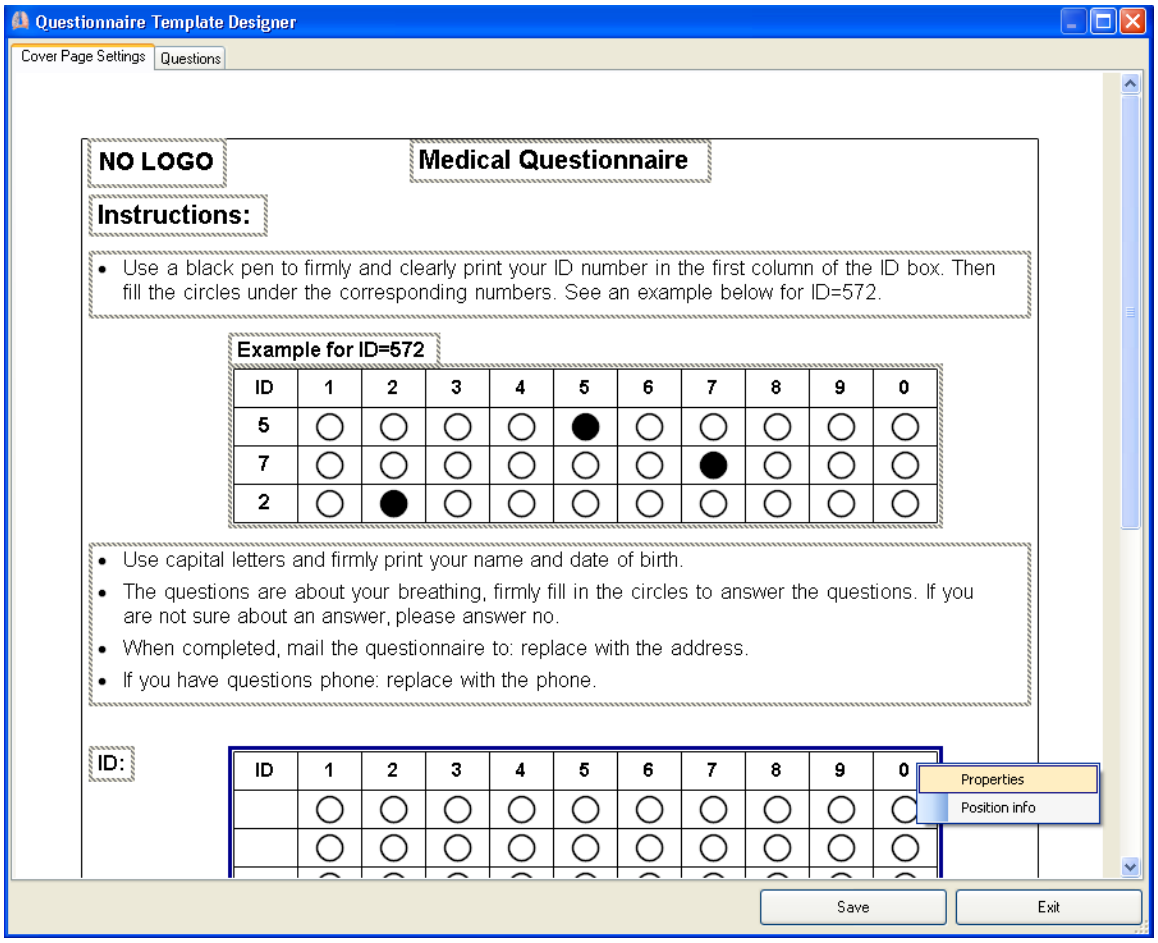
6.2 Design Questionnaire Template

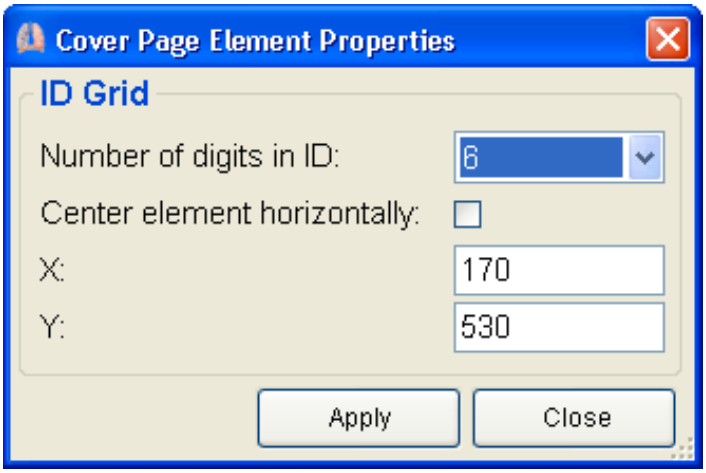
SPIROLA allows the user to modify the default questionnaires template, similar to designing the intervention plan template (see Section 5.5). Some details of the cover page can be also modified. Changes to the templates are best done at the planning stage of the intervention program. Changes made once the data collection has started will make interpretation difficult. Changes made to the questionnaire template will be saved permanently in the administrative database, which needs to be safeguarded.

Design questionnaire cover page

1. On the **Questionnaire** menu, click on **Design Questionnaire**.
2. In the form, that opens next (see picture below) select **Cover Page Settings** tab.
3. Right-click on a specific element on the cover page and select **Properties** menu.

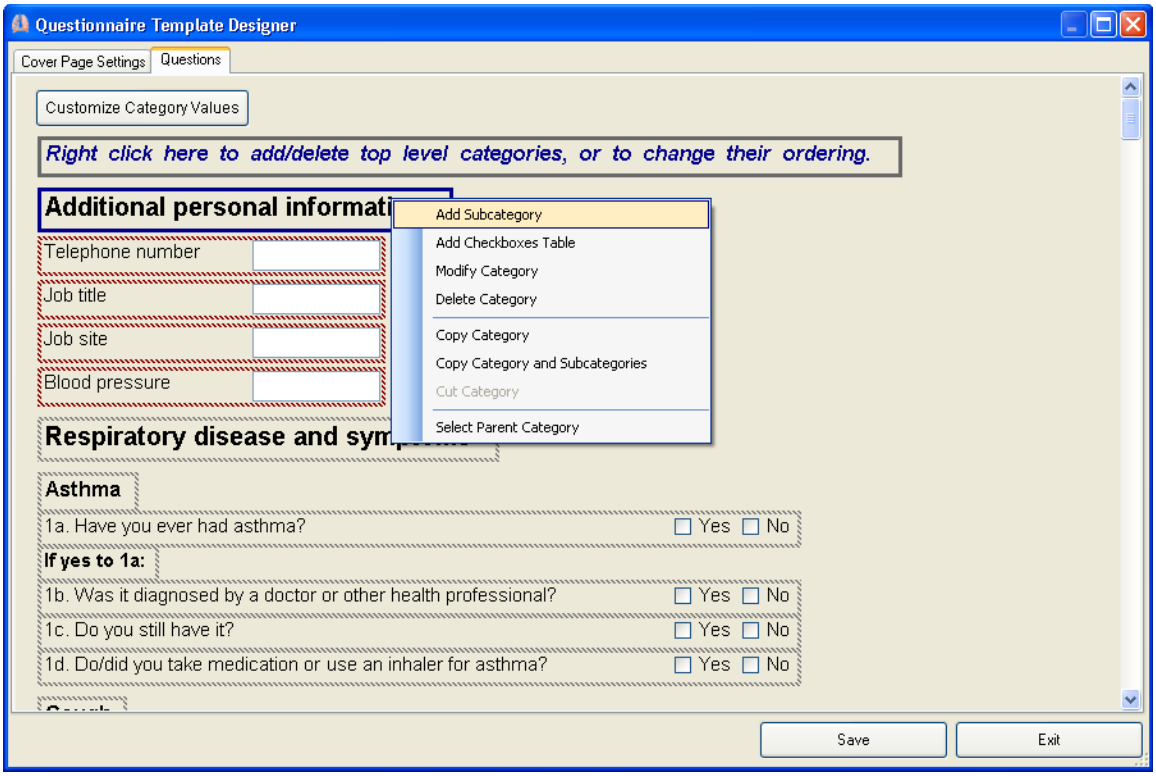
4. In the properties form, which opens next select the properties related to the selected element. For example properties form for ID grid (see picture below) allows selecting number of digits in participant ID and controlling the location of the grid on the page. **Note**: Different elements have different properties, but usually the properties form allows modifying element's text (any language can be used) and element's location.





Design questionnaire questions

1. On the **Questionnaire** menu, click on **Design Questionnaire**.
2. In the next form (see picture below) select **Questions** tab.
3. Right-click on a specific question and select options to modify the question (see picture below). Modifying questionnaire template is similar to modifying intervention plan template, therefore refer to Section 5.5 for more details.
4. Once the questionnaire is designed, on the **Questionnaire** menu, click on **Print**.
5. **Preview Blank Questionnaire** to view how the questionnaire will look when printed. Make sure that all questions fit within the bounding frame on the page.



Save blank questionnaire to PDF file

1. On the **Questionnaire** menu, click on **Create PDF File with Blank Questionnaire**.
2. In the dialog which opens next, specify a date, by which questionnaire should be completed (by default, SPIROLA sets this date to six months from the current date) and click on **Ok** button.
3. In the file dialog, which opens next select a directory where the PDF file should be saved and type a name for the PDF file.

6.3 Perform Questionnaire Survey

The questionnaire responses can be typed into SPIROLA directly (see Section 6.1).

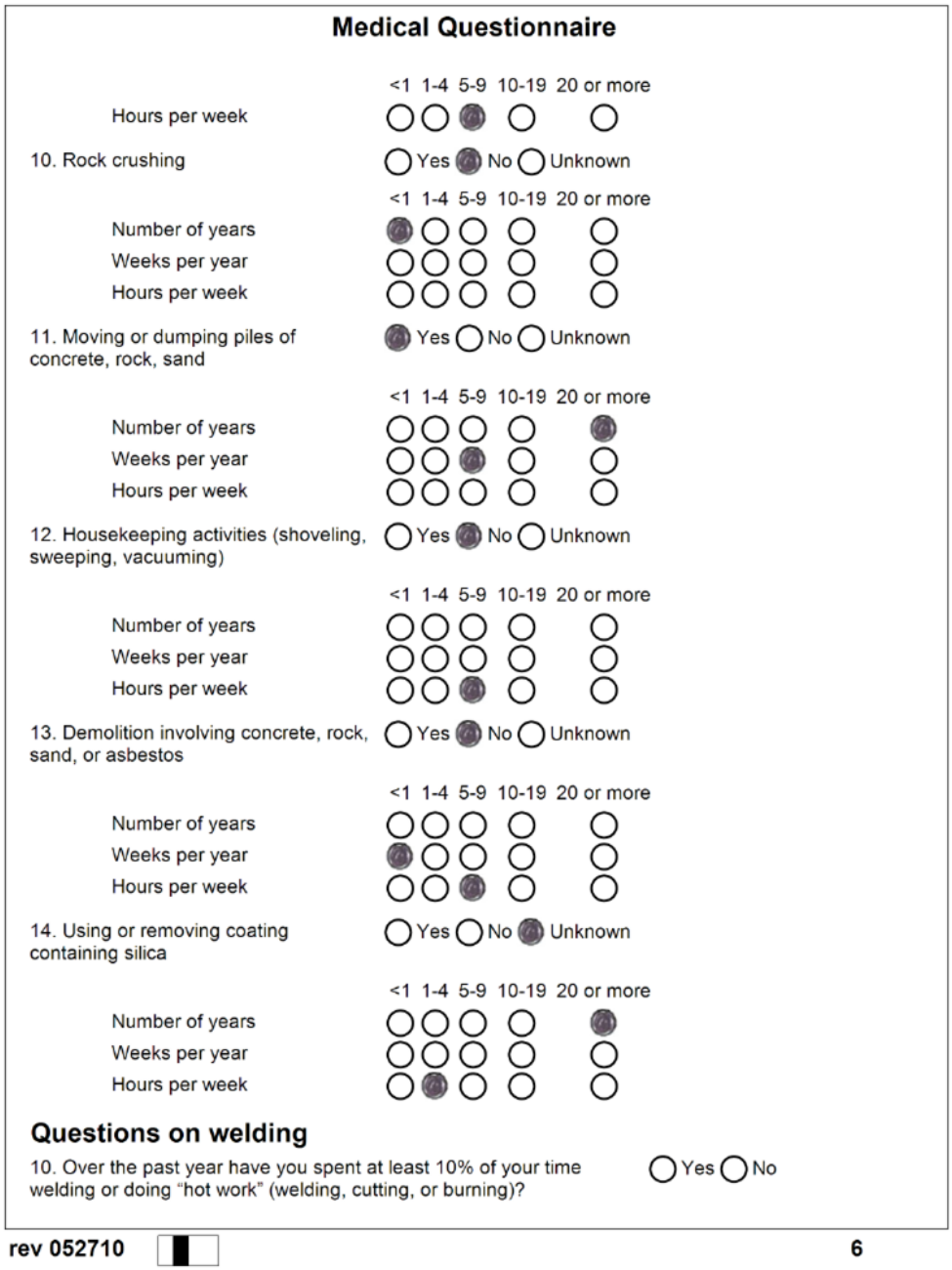
Alternatively, SPIROLA allows electronic processing of the questionnaires by following the steps below:

1. Save a blank questionnaire to a PDF file using SPIROLA (see Section 6.2).
2. Send the PDF file to worksites to be printed at worksites and to be distributed to participants. Alternatively, the PDF file can be printed at physician's office and sent to worksites or participants. Note, the blank questionnaires should be printed on a letter format paper (8.5'' X 11'' paper), which is a very common paper format.
3. Mail completed questionnaires back to the physician's office. It is important that participants mail unfolded questionnaires. Faxed questionnaires usually do not produce good quality printouts and might have extra text added to the margins.
4. Scan the received questionnaires into one or several PDF files. If the number of received questionnaires is large, scan the questionnaires into several PDF files (e.g., 100 questionnaires per file). Note: A questionnaire cannot be split into two PDF files.

Important points to consider:

- The questionnaire template should not be modified after the survey has started and until all the questionnaires are received from participants and loaded into SPIROLA. If the questionnaire template is modified after questionnaires are received, the answers should be typed into SPIROLA using the menu **Questionnaire -> Questionnaires List/Tickler** explained in Section 6.1.
- The questionnaires should be printed on letter format (8.5'' X 11'' paper) and scanned, using good quality printers and scanners.
- Participants should use black or blue ink pen to firmly fill the questionnaire circles. Usually, crossing out the circles will work as well, but the reliability of data, parsed by SPIROLA, will be the highest if the circles are filled in.
- Participants should not write anything outside the bounding frame.
- The pages scanned into the PDF file may be slightly rotated, but the horizontal and vertical sides of the bounding frames should be perpendicular.
- The bounding frame, page numbers, and the symbols on the bottom of questionnaire pages should be clearly visible.

The picture below is an example of a good quality questionnaire page in a PDF file, which SPIROLA will successfully parse. The page is clean, boundaries are well aligned, and the symbols at the bottom page are clearly visible.



Medical Questionnaire

	<1	1-4	5-9	10-19	20 or more
Hours per week	○	○	●	○	○

10. Rock crushing ○ Yes ● No ○ Unknown

	<1	1-4	5-9	10-19	20 or more
Number of years	●	○	○	○	○
Weeks per year	○	○	○	○	○
Hours per week	○	○	○	○	○

11. Moving or dumping piles of concrete, rock, sand ● Yes ○ No ○ Unknown

	<1	1-4	5-9	10-19	20 or more
Number of years	○	○	○	○	●
Weeks per year	○	○	●	○	○
Hours per week	○	○	○	○	○

12. Housekeeping activities (shoveling, sweeping, vacuuming) ○ Yes ● No ○ Unknown

	<1	1-4	5-9	10-19	20 or more
Number of years	○	○	○	○	○
Weeks per year	○	○	○	○	○
Hours per week	○	○	●	○	○

13. Demolition involving concrete, rock, sand, or asbestos ○ Yes ● No ○ Unknown

	<1	1-4	5-9	10-19	20 or more
Number of years	○	○	○	○	○
Weeks per year	●	○	○	○	○
Hours per week	○	○	●	○	○

14. Using or removing coating containing silica ○ Yes ○ No ● Unknown

	<1	1-4	5-9	10-19	20 or more
Number of years	○	○	○	○	●
Weeks per year	○	○	○	○	○
Hours per week	○	●	○	○	○

Questions on welding

10. Over the past year have you spent at least 10% of your time welding or doing "hot work" (welding, cutting, or burning)? ○ Yes ○ No

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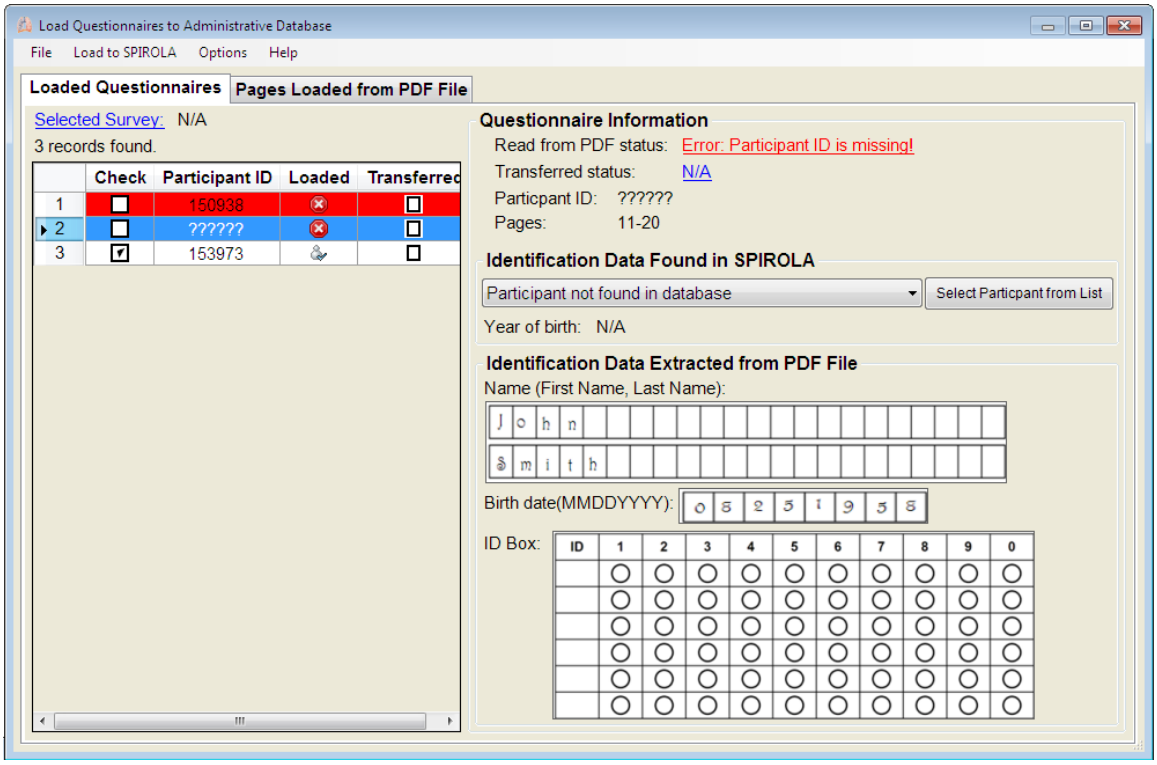
Check questionnaires for errors

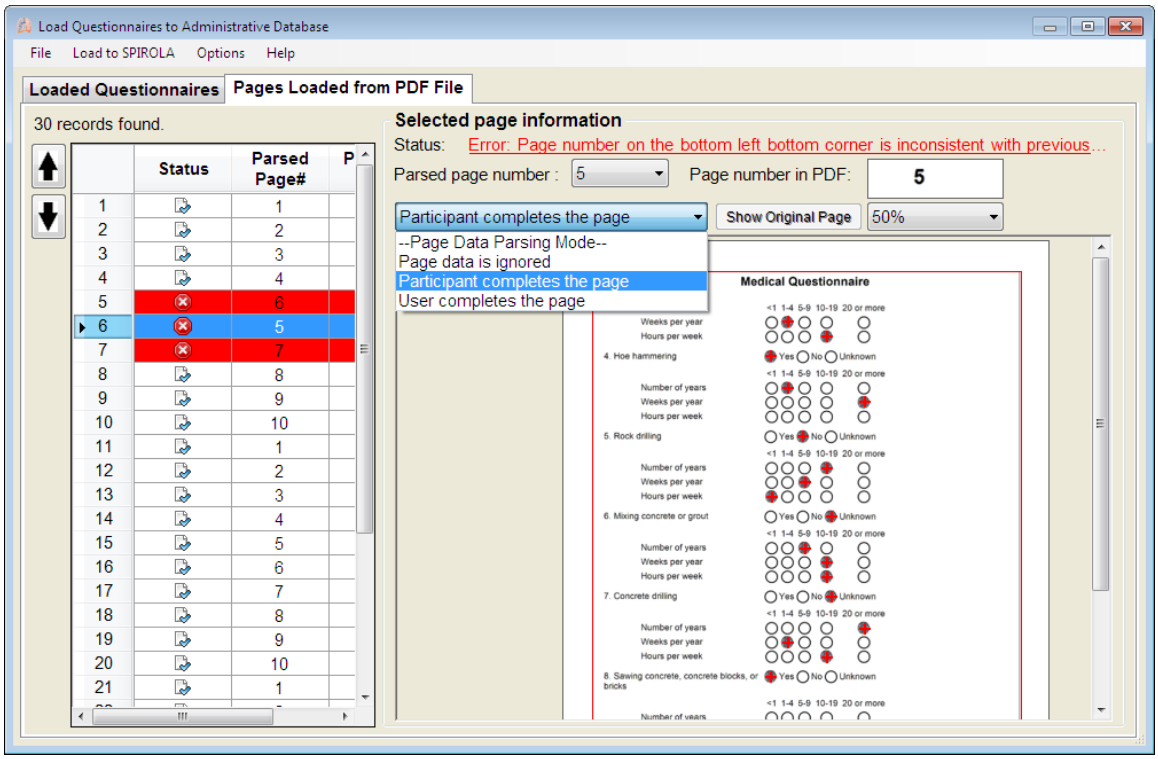
SPIROLA enables the user to screen questionnaires for errors before loading the data into the administrative database. The first step is to open the PDF file and check the questionnaires for problems and try to fix these problems. Note, even if some questionnaires are not successfully parsed, SPIROLA will process the rest of questionnaires.

1. On the **Questionnaire** menu, click on **Receive Completed Questionnaires**.

2. On the next form, click on **File** menu and **Open PDF File with Questionnaires**.
3. In the file dialog select the received PDF file with questionnaires. SPIROLA will display the list of questionnaires in the PDF file (see picture below).
4. Click on **Loaded Questionnaires** tab, and select a questionnaire in the table on the left side of the form. SPIROLA will show the details about the selected questionnaire, in section **Questionnaire Information** on right side of the form (see picture below).
5. Click on **Pages Loaded from PDF File** tab (see picture below) to see the loaded status of each page in the PDF file, as well as to fix errors (see second picture below).



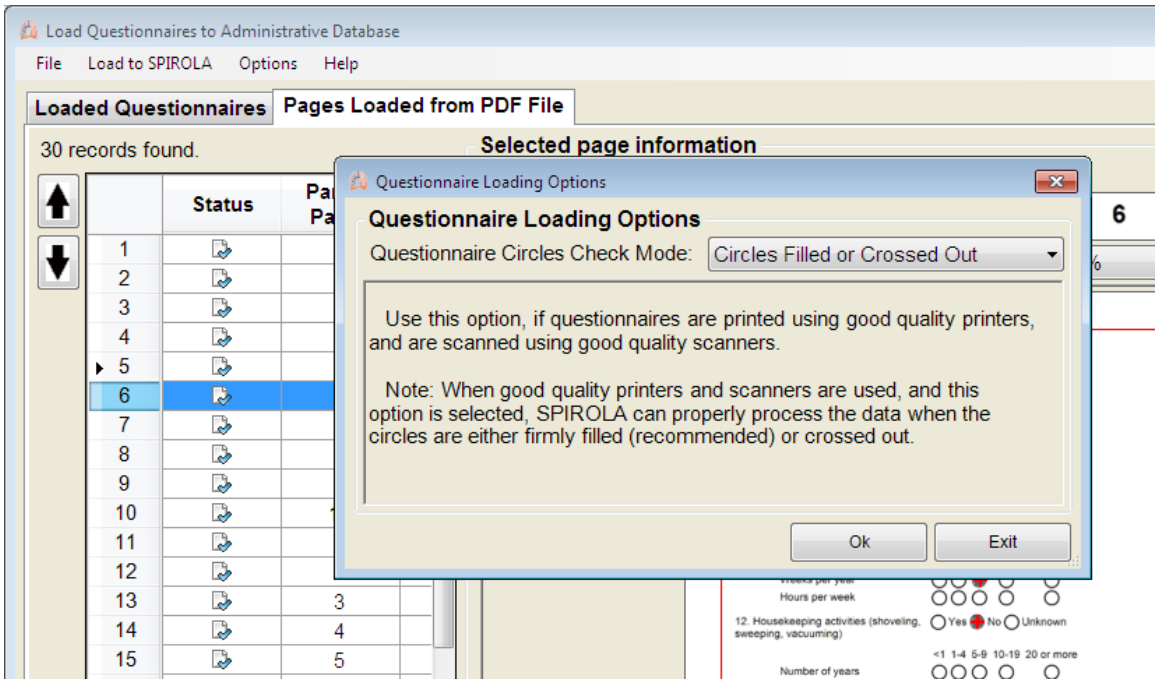
6. Correct the errors. The two pictures (above and below) illustrate an example of loading a PDF file with three questionnaires:
   - The first questionnaire (i.e., questionnaire for participant with ID 150938) was not successfully loaded, since SPIROLA found some errors on some pages of the questionnaire (see the second picture above). To fix this problem user can select the 5-th page and click on the button, with an arrow pointing down (see top-left side of the form in the picture above). By doing this, the pages 5 and 6 will be switched, after which the problems with questionnaire pages will be fixed.
   - The second questionnaire pages were successfully loaded; however, Participant ID box was not completed (see the first picture). To fill in the ID, click on **Select Participant from List** and in the **Select Participant** form select a participant John Smith, if this participant is listed in this form, or create a new participant John Smith, by clicking on **Create New Participant** button in the opened form. After these steps, the questionnaire will be assigned to a selected participant.
   - The third questionnaire (ID 153973) was successful loaded.



Note: SPIROLA uses red crosses, to show the checked checkboxes (see picture above), that SPIROLA was able to identify in the PDF file. If the quality of scanned questionnaire pages is bad, or if participant filled more than one checkbox, then SPIROLA might interpret the data incorrectly. To make sure, that invalid data is not saved into Administrative database, the user should click on each page on the left side in picture above, and make corrections if necessary, by clicking twice on the checkboxes that should be checked. In other words, the selections originally identified by SPIROA can be changed by the user.

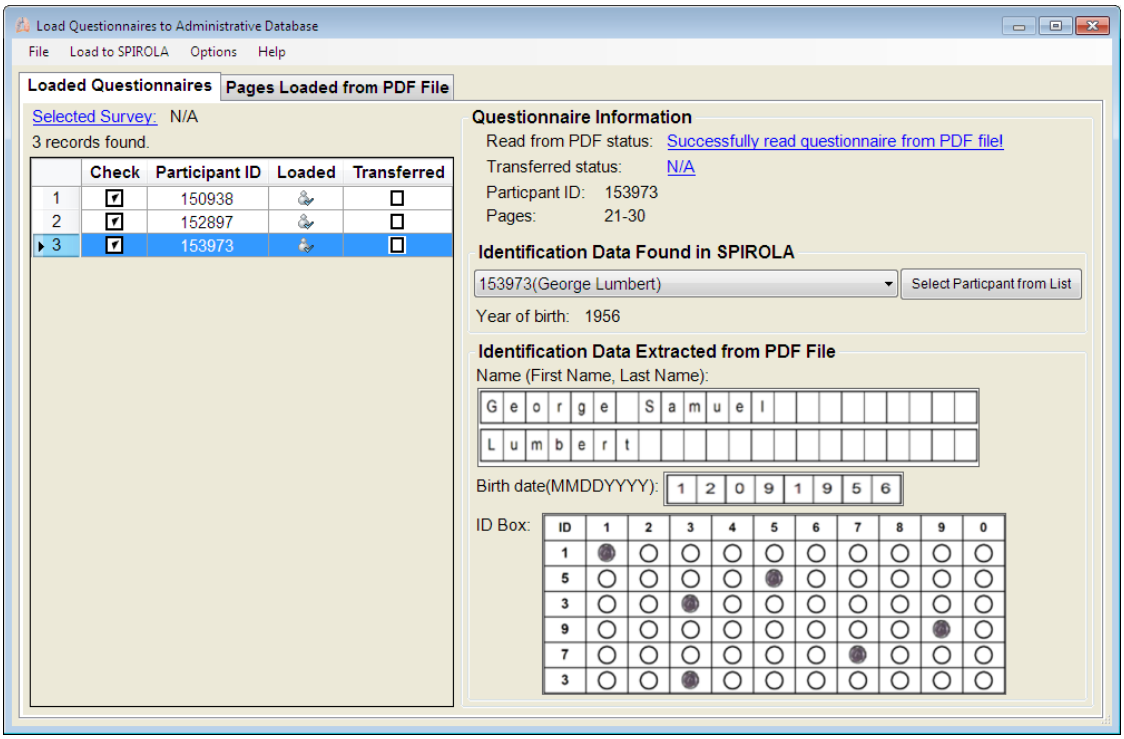
Note: When the selected page is blank or should not be considered as one of the pages in questionnaire, the user should select **Page data is ignored** item in the drop down list (see picture above). Also, if the page quality is bad and the bounding frame could not be found by SPIROLA, then the user should select the item **User completes the page** item in the drop down list and a page number in the list **Parsed page number** (see picture above). SPIROLA will fail to find the bounding frame in very rare situations.

Note: By default SPIROLA assumes that the circles on questionnaire pages are firmly filled, when processing the data. If it is known that the printers and scanners used to produce the loaded PDF file are of good quality, than SPIROLA can be configured to correctly (in most cases) interpret selections on questionnaire pages, when participants either firmly fill or cross out the circles. To do this, click on **Option** menu and then on **Questionnaire Loading**, and in the opened form select the appropriate setting (see picture below).



Load questionnaires into SPIROLA

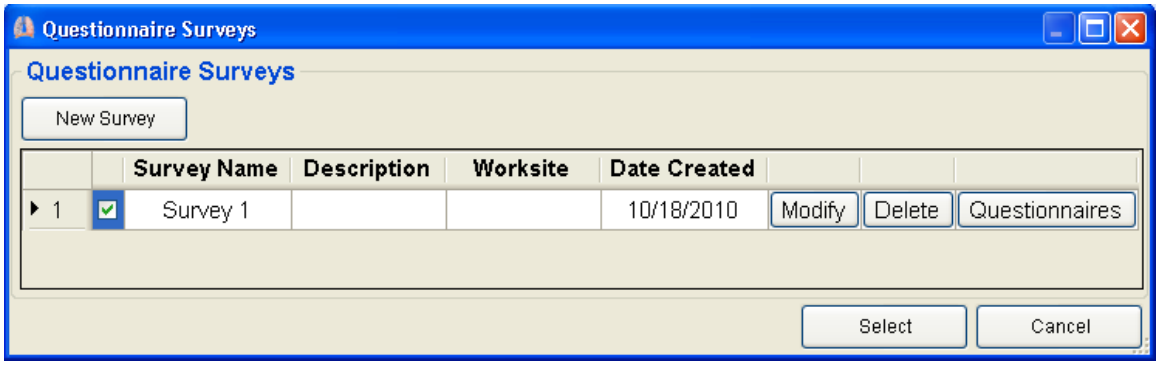
1. Questionnaires that have checkboxes under **Check** column checked, can be transferred to the administrative database (the checkboxes are checked by default).



2. Click on **Selected Survey** link on the top-left side in picture above, and on the form that opens next select a survey (see picture below), or create a new survey if

necessary. After a survey is selected, click on **Select** button (see picture below), to close the **Questionnaire Surveys** form.

Note: Surveys help organize questionnaires in several PDF file together. In other words, once the questionnaires are loaded into SPIROLA administrative database, the user can open different PDF file with questionnaires, and select the same survey. To view or edit the questionnaires in a survey, click on **Questionnaires** button in **Questionnaire Surveys** form (see picture below).



3. On the **Load to SPIROLA** menu (see second picture above) click on **Load Selected Questionnaires to SPIROLA Database** to transfer the questionnaires to the administrative database.

6.4 Export Questionnaire Survey Data

SPIROLA allows exporting questionnaire data from the administrative database to a CSV file in a simple tabular format. The CSV file generated can be analyzed by statistical software (e.g., SAS, SPSS) and by Microsoft Office Excel application.

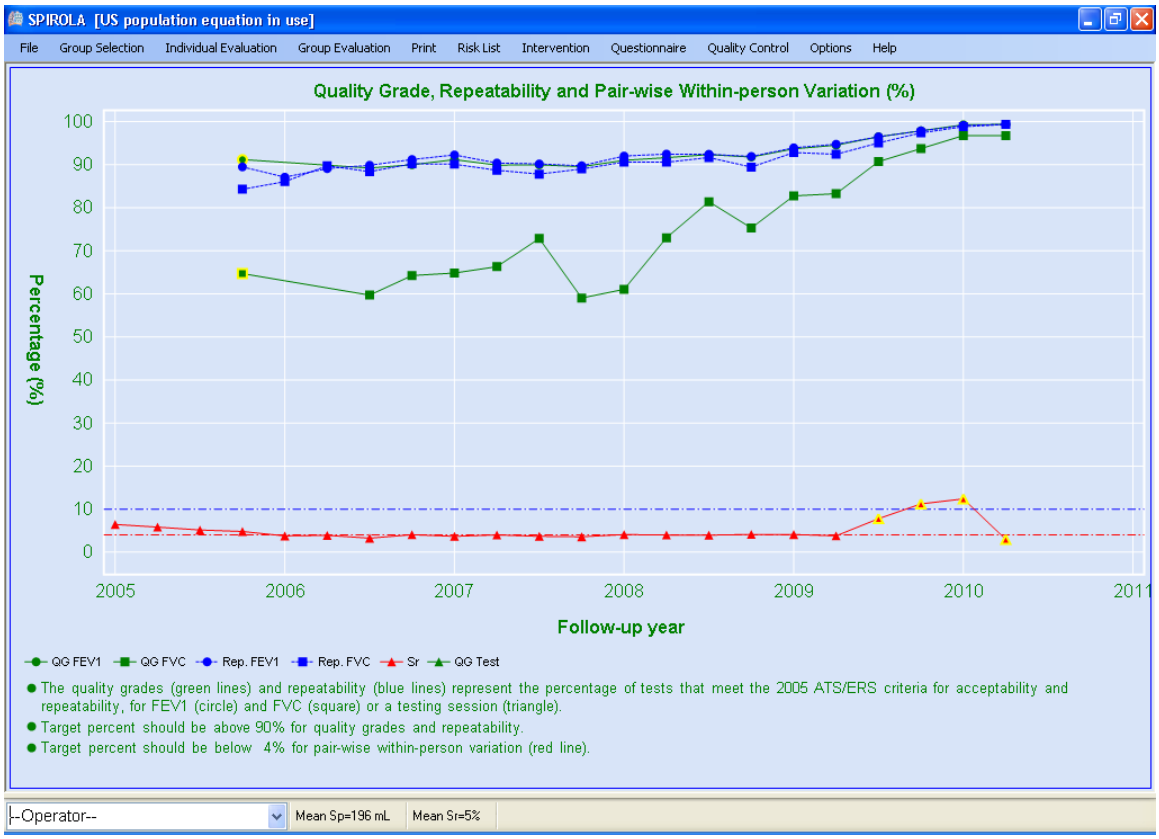
1. On the **Questionnaire** menu, click on **Export Questionnaire Data**, and in the opened file dialog select a directory, and type a file name, where the interventions should be saved. Exporting questionnaires is similar to exporting intervention plans, therefore refer to Section 5.6 for details.

6.5 Manage Participants Menu

To manage participants in administrative database refer to Section 5.7. When a participant who is not currently in an administrative database fills in a questionnaire, the name needs to be added into the database using this menu.

7. Spirometry Quality Control Menu

1. On the **Quality Control** menu, click on **Quality Control Indices**, to obtain charts that evaluate quality grades assigned from each test session by a spirometer. The Quality Control charts are provided only if the quality grades are included in the SPIROLA database (see Section 3.2). The example below is from an ongoing monitoring program and shows: the percentage of FVC (green line, square symbol) and FEV_1 (green line, circle symbol) tests that meet the ATS/ERS acceptability and repeatability criteria; the percentage of the tests that meet the ATS/ERS repeatability criteria for FVC and FEV_1 (blue lines); and the pair-wise within-person variation based on tests repeated within 18 months. The chart can be also requested for individual operators (see bottom of the following chart).



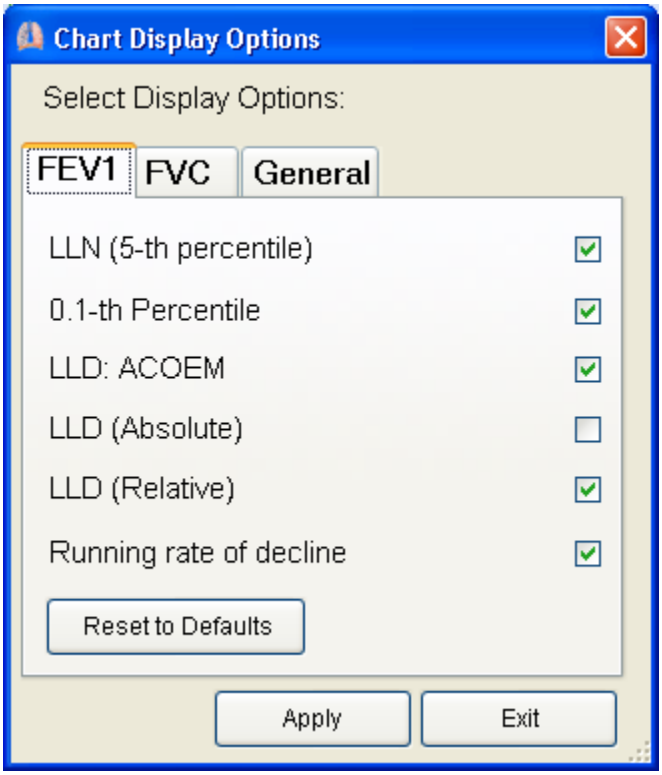
8. Options Menu

The **Option** menu (see picture below) allows the user to change the following default values:

1) The display on an individual's chart
2) Longitudinal limits definitions for FEV_1 and FVC
3) Cross-sectional limits – reference equations to be used

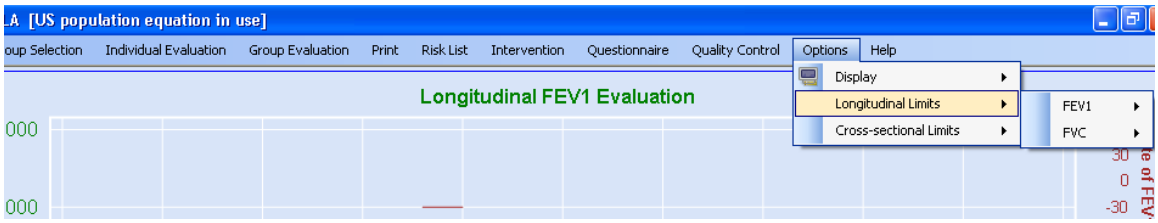
8.1 Display—Critical limit curves

1. On the **Options** menu, click **Display**, and then click **Curves.** A new dialog window will appear, as shown below.
2. To enable or disable display of a critical limit curve for FEV_1 or FVC charts, click the check box next to the name of each critical limit curve. By default, all curves are checked except A**bsolute LLD** and **Show projected regression line**.
3. Click **Apply** to confirm the selections and Exit to exit this window.



8.1 Define longitudinal limits for FEV_1 or FVC

The **Longitudinal Limits** option allows changing definition of the longitudinal limits for FEV_1 and FVC, see below.



Click on FEV1 or FVC and the **Referential Rate of Decline** and **Within-person Variation** options appear:

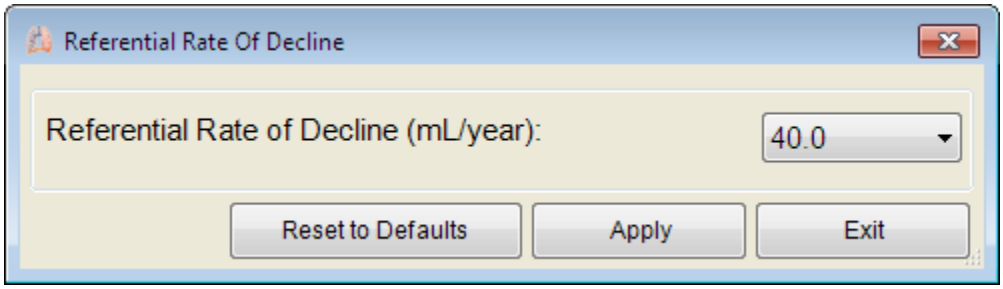
The **Referential Rate of Decline** option allows changing the default referential rate of FEV_1 decline of 40 mL/y used in the calculation of the limit of longitudinal decline (LLDr). Studies indicate that the mean rate of FEV_1 decline in healthy never-smokers is about 30 mL/y. To achieve greater specificity of LLD for moderate impairment of lung function, a referential rate of decline based on an average working population regardless of smoking status, is used. For guidance, SPIROLA calculates the mean rate of decline for the group using all individuals with four or more years of follow-up and shows the result on the bottom margin of individual FEV_1 and FVC charts. Using the mean rate of decline as the referential rate of decline together with the program's average within-person variation will result in identifying about 5% of declines as excessive.[5]

The **Within-person Variation** option allows the user to change the value of the LLDr limit used for decision making by SPIROLA. The default is based on the relative within-person standard deviation s_r of 4% which corresponds to LLDr of $\approx$10% for the first year (see Section 10). This limit assumes relatively high longitudinal data precision. When ATS/ERS recommendations on quality control are followed, workplace monitoring programs can achieve comparable data precision.[15]

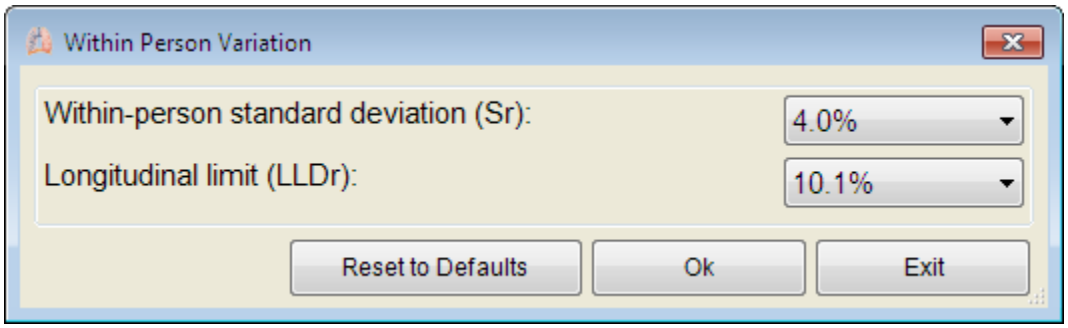
The ACOEM recommended longitudinal limit based on an annual decline of 15% can be specified for decision-making be selecting a referential rate of decline of 30 mL/y and within-person standard deviation of 6%.

To change the longitudinal limit LLDr that SPIROLA uses for decision making:

1. Click **Referential Rate of Decline** and a dialog window will appear, as shown below. Select a desired value from the list box, click **Apply** and **Exit**. To reset back to default value of 40 ml/y, click on **Reset to Defaults**.



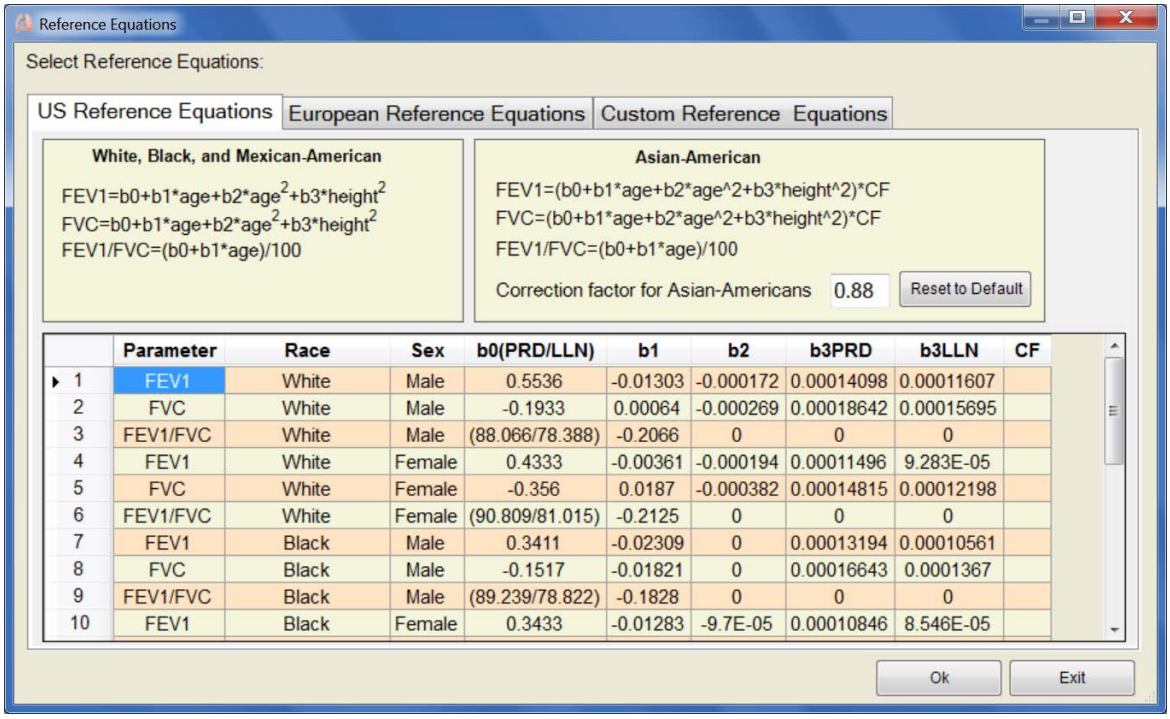
2. Click **Within-person Variation,** and then click **Relative Value** or **Absolute Value** and a new dialog window will appear, as shown below.
3. Click the arrow button of **Within-person standard deviation** or **Longitudinal limit,** and click on a desired value. If a desired value is not in the list box, enter the value.
4. Click the **OK** button to confirm the selection and **Exit**.



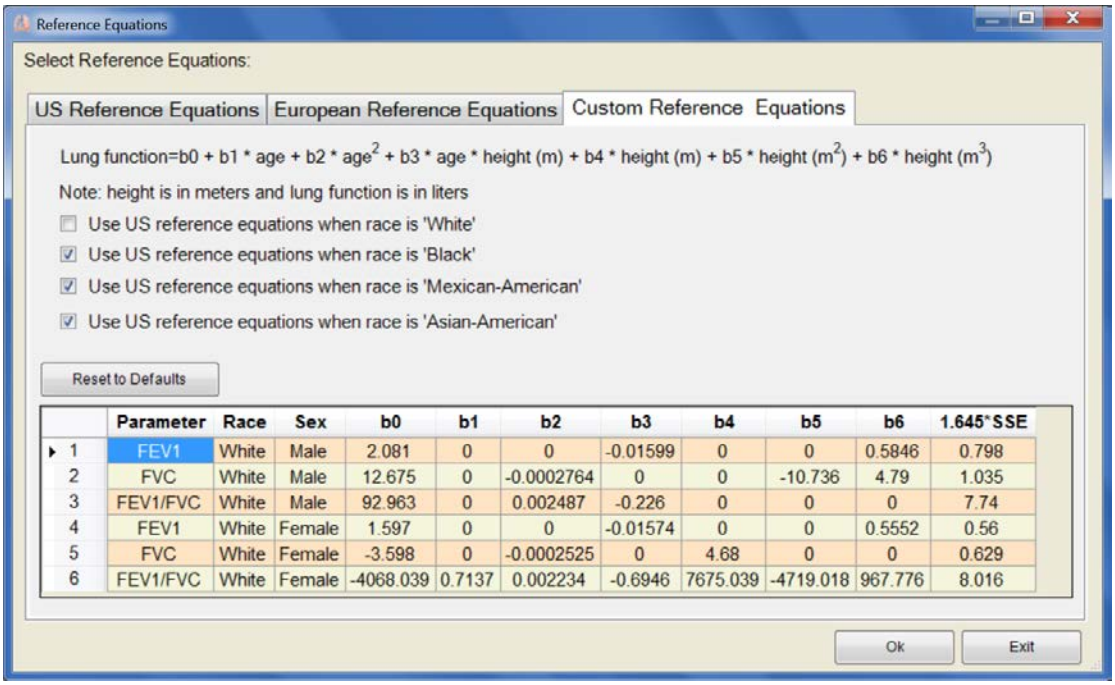
8.4 Cross-sectional evaluation—Customize reference equations

The **Cross-sectional Limits** and **Reference Equations** option allows the user to change the reference equations to be used in the determination of whether the most recent FEV_1 or FVC values are within the normal limits as determined by the reference equations. The **Height Option** allows selection of the height values to be used in the reference equations.

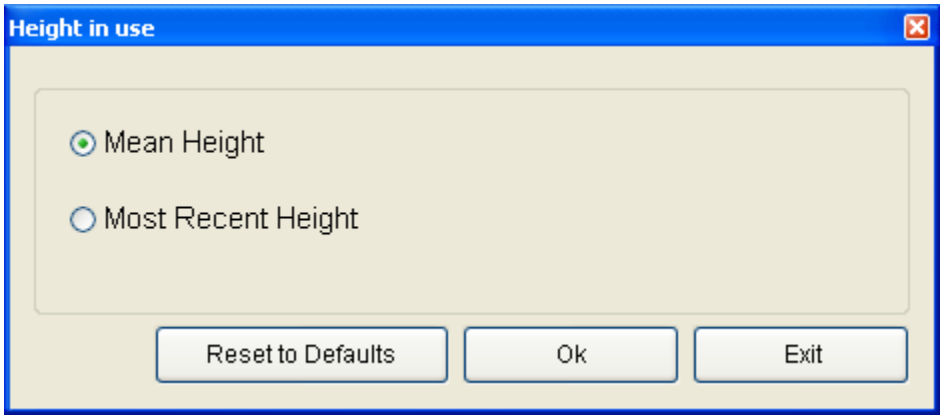
1. Click **Reference Equations** to display a reference equations window (see below). By default, SPIROLA uses U.S. population-based reference equations based on NHANES III data.[7]
2. Select one of the following tab pages: US Reference Equations, European Reference Equations, or Custom Reference Equations.



3. If **Custom Reference Equations** page is selected, user can customize the reference equations, by typing into the table user-specific regression coefficients that correspond to those provided in the equation above the table. If the equation does not include some specific parameters (e.g., weight), let us know. If equations for some race are not known, check the checkboxes above the table, to use US reference equations for all individuals of specific race. For example if the setting for custom reference equations are as shown below, SPIROLA will use custom reference equations for all individuals with Caucasians and Mexican Americans, and SPIROLA will use US Reference Equations for all African Americans.
4. Clock **Ok** and **Exit** to apply and save the new values



The **Cross-sectional Limits** and **Height Option** allows to select whether the mean height or the most recent height reported in the SPIROLA database for an individual is to be used in the reference equations (see below).



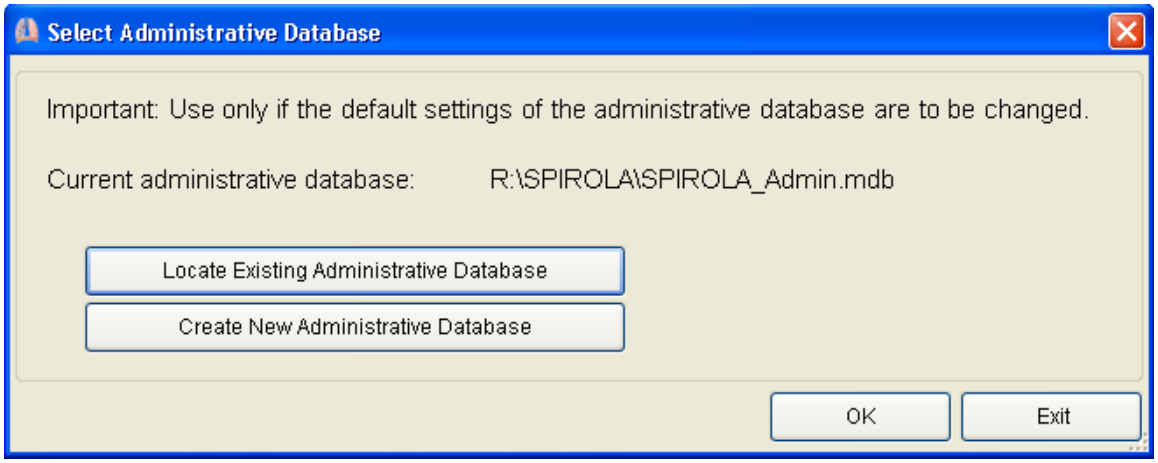
9. Administrative Database Management

Administrative database **SPIROLA_Admin.mdb** stores questionnaire results and intervention plans (i.e., records created using the **Intervention** and **Questionnaire** menus). To avoid data loss, the administrative database, as well as the spirometry database, should be kept in a secured location that is regularly backed-up.

By default, when installing SPIROLA, the **SPIROLA_Admin.mdb** database is created in the installation folder. Therefore, when installing or uninstalling SPIROLA, the user should safeguard an existing **SPIROLA_Admin.mdb** database that contains questionnaire or intervention data. This can be done by copying or moving **SPIROLA_Admin.mdb** to another folder or by renaming the administrative database (e.g., SPIROLA_Admin_Copy.mdb). When re-installing a SPIROLA V2.0 or higher, the existing administrative database will be kept.

Note: the administrative database should be stored in a protected folder, so that only authorized users have read/write permissions on the database file, since the database might contain sensitive data.

1. To locate the current administrative database, on the **File** menu click on **Select Administrative Database**. A window will inform the user of the current location of the administrative database (see below).



2. To select a different administrative database, click on **Locate Existing Administrative Database** button. For example, this function is useful when an administrative database needs to be stored on a shared disk space or in a secured location and all users need to point to it. To share administrative database:

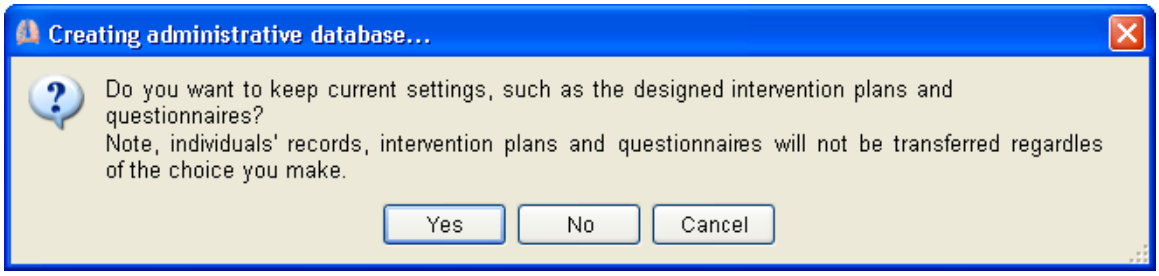
    a) Copy the existing administrative database into a shared folder using Window Explorer.

b) Click on **Locate Existing Administrative Database** button and select the copied administrative database. Note: the located administrative database will became the current administrative database.

3. To create a new administrative database, click on **Create New Administrative Database** and select a new location and a file name for newly created administrative database. Note: the created administrative database will become the current administrative database, used by SPIROLA. Before creating a new administrative database, SPIROLA prompts the user, if questionnaires and intervention plans designed by the user should be migrated to the new administrative database (see figure below).

c) If the user clicks on **Yes** button, the structure of questionnaires and intervention plans designed by the user will be migrated to the new administrative database. Individuals' records (i.e., intervention plans and questionnaires related to specific individuals), however will not be migrated to the new administrative database.

d) If the user clicks on **No** button, SPIROLA copies the default **SPIROLA_Admin.mdb** file from the **Template_Files** under SPIROLA installation folder into the specified folder. The new administrative database will have general questionnaires and intervention plans, provided by SPIROLA.



10. Theoretical Background

The use of SPIROLA may help to preserve lung function by:

(i) Maintaining spirometry quality and longitudinal data precision at high level.

(ii) Identifying individuals with excessive decline in lung function using limits of longitudinal decline (LLDr) based on default criteria (i.e., s_r=4% or LLDr=10%) or the ACOEM longitudinal limit criteria (i.e., s_r=6% or LLDr=15%);

(iii) Identifying individuals who already have lung function impairment using ATS/ERS criteria based on cross-sectional data evaluation;

(iv) Identifying when an individual's lung function warrants individualized intervention measures;

(v) Evaluating the effects of intervention at the individual level and the group level.

10.1 Evaluation of FEV_1 precision in a group

Monitoring a program's data precision on an annual basis can help to identify and address data quality problems soon after these occur and this way achieve and maintain high data precision. To monitor data precision, SPIROLA calculates and charts yearly values of the *absolute within-person standard deviation* s_p and the *relative within-person standard deviation* s_r (see Section 4: Group Evaluation menu).[4-6] These statistics are calculated on a yearly basis as the difference between FEV_{11i} and FEV_{12i} measured within 18 months of each other and summed over $i = 1,..,n$ individuals. (**Note**: this is not within testing session variance.) The year of the first measurement determines the assigned year. A sample of about 50 individuals with repeated measurements is needed to obtain a reliable estimate of yearly FEV_1 variation.

The absolute within-person standard deviation s_p for a specific year is defined as:

$$s_p = \sqrt{\frac{1}{2n}\sum_{i=1}^{n}(FEV_{1_{1i}} - FEV_{1_{2i}})^2}$$

The relative within person standard deviation s_r adjusts for each individual's FEV_1 size and for a specific year is defined as:

$$s_r = \sqrt{\frac{1}{2n}\sum_{i=1}^{n}\left(\frac{FEV_{1_{1i}} - FEV_{1_{2i}}}{(FEV_{1_{1i}} + FEV_{1_{2i}})/2}\right)^2}$$

The average values $\bar{s}_p = (1/kN)\sum(s_p n)$ and $\bar{s}_r = (1/kN)\sum(s_r n)$ are calculated by summing the yearly weighted s_p and s_r values over all years of follow-up and then dividing by the total number of repeated observations *N*. These values represent the average program-specific absolute and relative within-person variation, respectively. The $\bar{s}_p$ and $\bar{s}_r$ values are shown at the bottom of SPIROLA's Group Within-person Variation

chart as 'Mean s_p' and 'Mean s_r'. The mean within-person standard deviations $\bar{s}_p$ and $\bar{s}_r$ can be used to derive the program-specific *limits of longitudinal decline* (LLD) by substituting these for the default values on the **Options** menu under **Within-person Variation** option. When annual measurements are not available, SPIROLA provides the group average within-person variation *Group* s_w estimated from the linear regression analysis done on each individual's data from 4 years of follow-up. Generally there is good agreement between these two methods of estimation.

Note: If the sample of measurements repeated within 18 months is less than 50, the s_p and s_r values are considered unreliable and are indicated by a yellow color. If $\bar{s}_p$ and $\bar{s}_r$ values are not displayed or are based on a sparse sample, the user could use the default LLD_r value of 10% or change the default to LLD_r of 15% as based on the ACOEM limit.

10.2 Estimation of limits of longitudinal decline for an individual

Because of inherent variability in the lung function data, it takes approximately 5-8 years of follow-up to obtain a reliable estimate of the rate of decline in FEV_1 or FVC in an individual.[4-6] To identify individuals with an excessive lung function decline within the first 8 years of follow-up, SPIROLA uses by default the relative limit of longitudinal decline (LLD_r),[6] but the absolute limit (LLD_a) or the ACOEM limit based on 15% can also be used. These limits are applied to determine whether the lung function decline between the baseline FEV_1 or FVC value (or a mean of the first two observations, if the first value is lower than the second one) and each follow-up FEV_1 or FVC is excessive. Observations that fall below the LLD warrant concern. The absolute or relative longitudinal limits are calculated using a default value based on 10% annual decline. The user may change this to reflect the average within-person FEV_1 variability for the group or the ACOEM limit based on 15%.

The absolute limit of longitudinal decline LLD_a (mL/yr) is defined as a one-sided 95% confidence limit:

$$LLD_a = t \times (b + 1.645 \times SE(b))$$

where t is the duration of follow-up in years and b is either the referent slope of decline (up to 8 years of follow-up) or the individual's estimated regression slope (beginning with 8 years of follow-up). SPIROLA uses a default referent slope of decline of 40 mL/yr based on an analysis evaluating performance characteristics of the limit with respect to sensitivity and specificity for long-term excessive decline in FEV_1 of $\geq$90 mL/yr and FEV_1 $\leq$60% predicted. The standard error of the slope b is defined as

$$SE(b) = \sigma_w \sqrt{12(P-1)} / t\sqrt{P(P+1)} \qquad (1)$$

where t is the duration of follow-up in years, P=2 represents two repeated measurements done during the follow-up time t (the baseline and last observation), and σ_w is the within-person standard deviation. By substituting the program-specific pair-wise

estimate of the within-person standard deviation $\bar{s}_p$ for the within-person variation σ_w in equation (1), one can estimate program-specific absolute LLD_a.

The relative limit of longitudinal decline LLD_r (%) standardizes for the magnitude of FEV_1 and is defined as:

$$LLD_r = t \times (b/\overline{FEV}_{1b} + 1.645 \times SE_r(b)) \quad (2)$$

where $\overline{FEV}_{1b}$ is the program-specific mean baseline FEV_1, and $SE_r(b)$ is the approximate standard error of $b/\overline{FEV}_{1b}$ calculated by substituting the program-specific relative within-person standard deviation $\bar{s}_r$ for σ_w in equation (1).

The limit for the actual value of FEV_1 (mL) below which an individual's FEV_1 should not decline after *t* years of follow-up without raising concern can be calculated in terms of the individual's baseline FEV_{1b} value and LLD_a or LLD_r, as follows:

$$FEV_1 = FEV_{1b} - LLD_a \quad \text{or} \quad FEV_1 = FEV_{1b} - FEV_{1b} \times LLD_r$$

SPIROLA's default value for the relative within-person variation $\bar{s}_r$ is 4%, which corresponds to LLD_r of 10% for t=1 (i.e., annual follow-up). The LLD_r of 15% for t=1, which corresponds to the ACOEM limit, is based on $\bar{s}_r$ of 6%. The longitudinal limit for FVC is calculated in the same way. To change the default value, on the **Options** menu use the **Within-person Variation** option. Beginning with 8 years of follow-up, the interpretation of excessive decline is based on an individual's regression slope and the lower 95% confidence limit around the regression line calculated as above. Here *b* represents the estimated regression slope and the individual's baseline measurement FEV_{1b} is replaced by the individual's predicted FEV_1 value.

Cross-sectional evaluation to identify respiratory impairment

SPIROLA evaluates and reports for the most recent spirometry test whether the FEV_1, FVC, or FEV_1/FVC ratio values are below the respective "cross-sectional" lower limit of normal (LLN) values or whether the FEV_1 value is below 0.1^{th} percentile. This approach defines the individual's value in terms of the probability of being normal based on population distribution for individual's characteristics (*i.e.*, age, height, gender, ethnicity or race). By default, the LLN values and the predicted values are calculated using the U.S. population-based reference equations estimated separately for Caucasians, African-Americans, and Mexican-Americans.[7] However, user-defined reference equations for FEV_1, FVC, and the FEV_1/FVC ratio can be specified.

11. References

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Appendix A: Software requirements to run SPIROLA

- Microsoft Windows XP/Vista/Windows 7
- Microsoft .NET Framework 3.5 and Database engine. In most cases these software packages are already installed on the user's computer.
- Microsoft Access 2003/2007/2010 for viewing or editing data in Microsoft Access format.
- SPIROLA only supports 32-bit versions of Microsoft Office

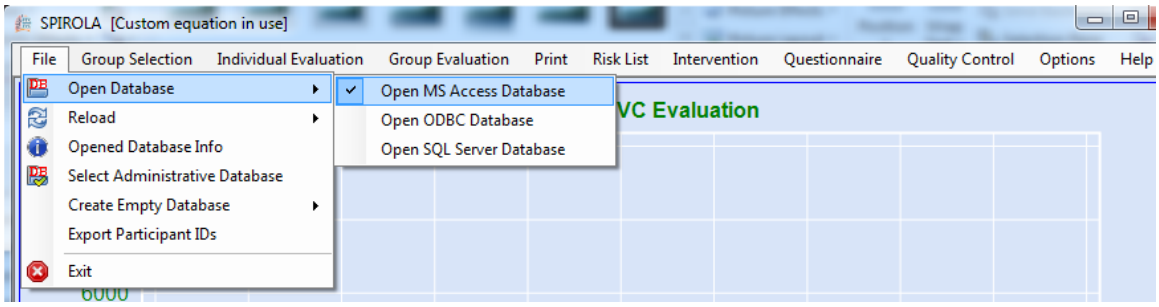
If the .NET Framework version 3.5 redistributable package is not already installed on the computer, it can be obtained as a free download and installed from the following link: http://go.microsoft.com/fwlink/?linkid=118076

If you do not have Microsoft Access 2007 or a newer version installed, download and install the 32-bit version of the Microsoft Access 2010 runtime from the following link:
http://www.microsoft.com/en-us/download/details.aspx?id=10910

Appendix B: Open different types of spirometry datasets

This appendix describes in more detail how to open different types of SPIROLA datasets.

To open SPIROLA dataset click on **File** menu and then on **Open Database** (see picture below), and select one of the menu items: **Open MS Access Database**, **Open ODBC Database**, or **Open SQL Server Database**.

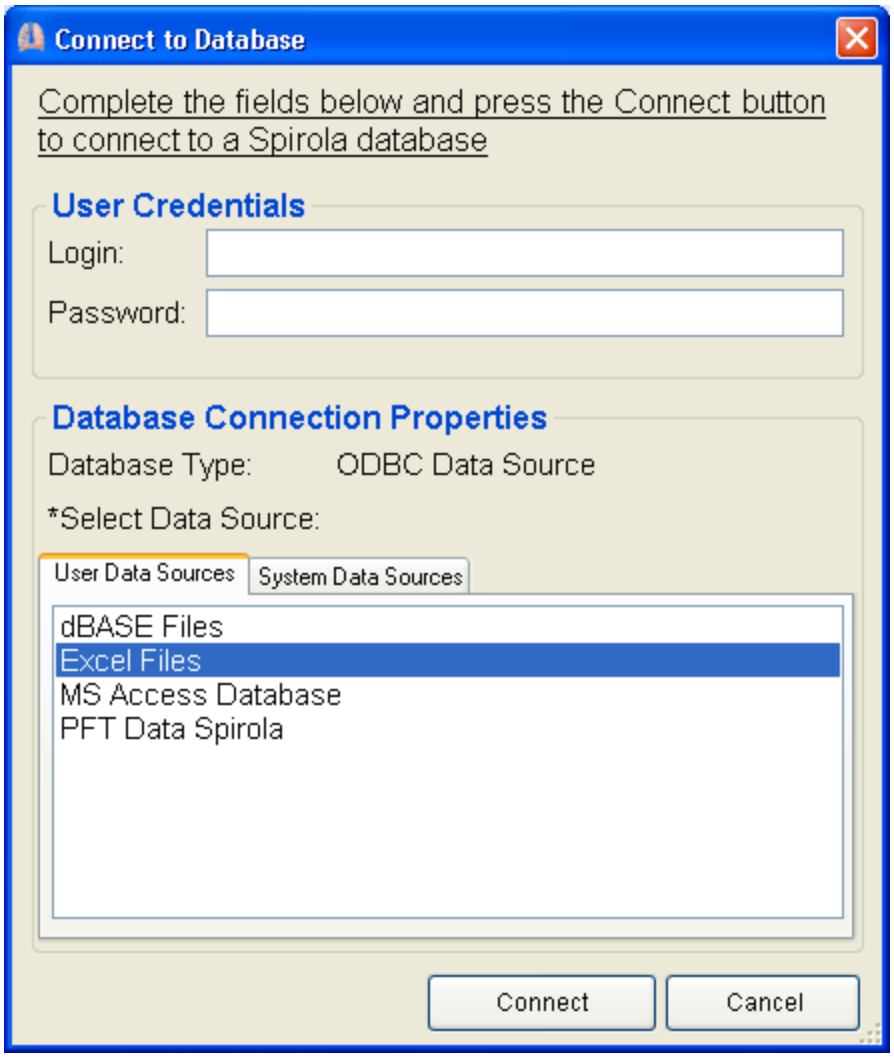


Using the above menus, the following databases can be read into SPIROLA:

a) **Open MS Access Database** menu opens Microsoft Access database. In the file dialog window that appears the user should select the desired .MDB extension file (for example, DemoDataSet.mdb) and click **Open** to proceed.
   i) If **Connect to Database** window appears the Microsoft Access database might require a password that was assigned by the user, or an incorrect Microsoft Access database has been selected. The .accdb file format requires Access 2007 or newer. See Appendix A.

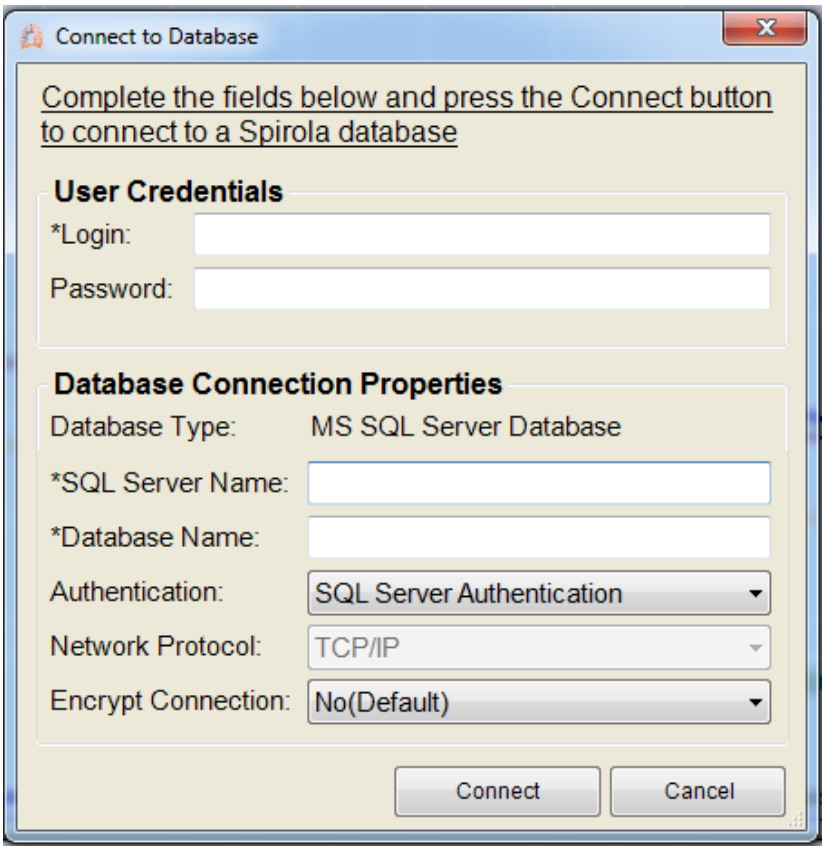
b) **Open ODBC Database** menu opens the following databases: Microsoft Excel files, text files, SAS files, Oracle databases, MS Access database, MS SQL Server databases, and other types of files and database supported by the ODBC system. If the database to be opened is not a Microsoft Access database or Microsoft SQL Server database use ODBC. Firstly, the user needs to create an ODBC data source (a link) using instructions provided in Appendix E: Create ODBC data source for Excel 2007.

   After the ODBC data source is created, select **Open ODBC Database** menu. In the window shown below select a data source either from the **User Data Sources** or **System Data Sources** lists and click on **Connect** button (some data sources might require completing **Login** and **Password** fields). The created data source names should appear in the list of sources.



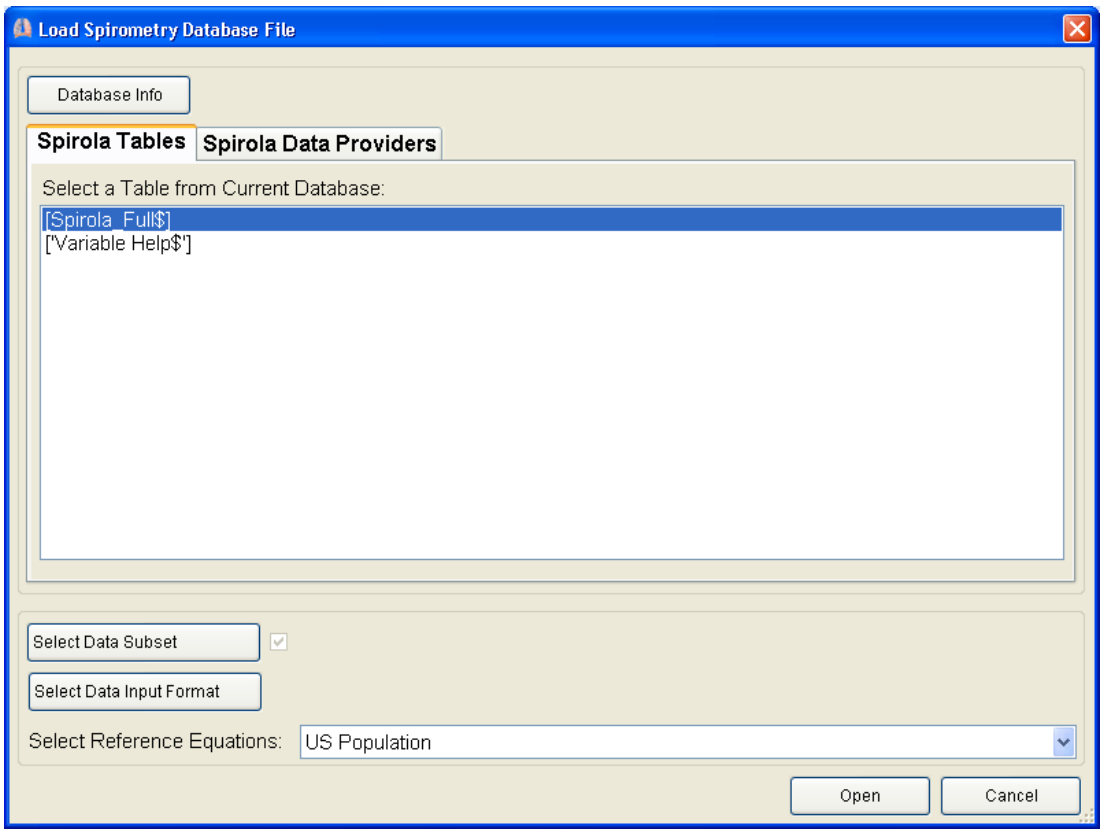
c) **Open SQL Server Database** menu opens Microsoft SQL Server database. Window will appear as shown below. Type in the information provided by SQL Server administrator. After all the necessary fields are completed, click on **Connect** button.

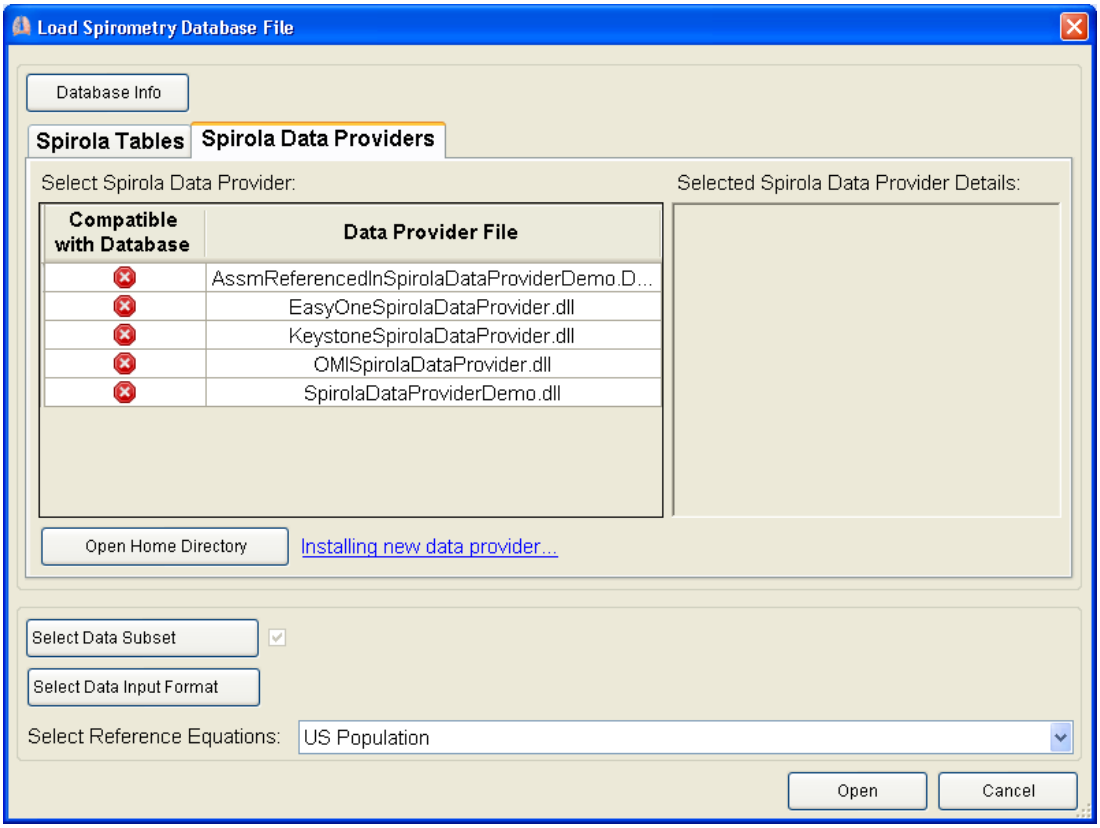
Note: **Authentication** field can have two values: **Windows Authentication** or **SQL Server Authentication**. Authentication method to use will be determined by SQL Server administrator, but using **Windows Authentication** simplifies things, since in that case there is no need to complete **Login** and **Password** fields (SPIROLA uses the login and password of the user currently logged into computer).



Select data table or data provider and input options

1. In the window which opens next, click on a desired data table listed under **Spirola Tables** as shown below (table **Spirola_Full** in this example).
2. Alternatively, if Spirola data provider is installed for the selected database, the user can click on **Spirola Data Providers** tab and select a Spirola data provider for the selected database (see picture below).


Load Spirometry Database File
Database Info
Spirola Tables
Spirola Data Providers
Select a Table from Current Database:
[Spirola_Full$]
['Variable Help$']
Select Data Subset
Select Data Input Format
Select Reference Equations:
US Population
Open
Cancel


Load Spirometry Database File
Database Info
Spirola Tables
Spirola Data Providers
Select Spirola Data Provider:
Selected Spirola Data Provider Details:
Compatible with Database
Data Provider File
AssmReferencedInSpirolaDataProviderDemo.D...
EasyOneSpirolaDataProvider.dll
KeystoneSpirolaDataProvider.dll
OMISpirolaDataProvider.dll
SpirolaDataProviderDemo.dll
Open Home Directory
Installing new data provider...
Select Data Subset
Select Data Input Format
Select Reference Equations:
US Population
Open
Cancel

Appendix C: Installing new Spirola data provider

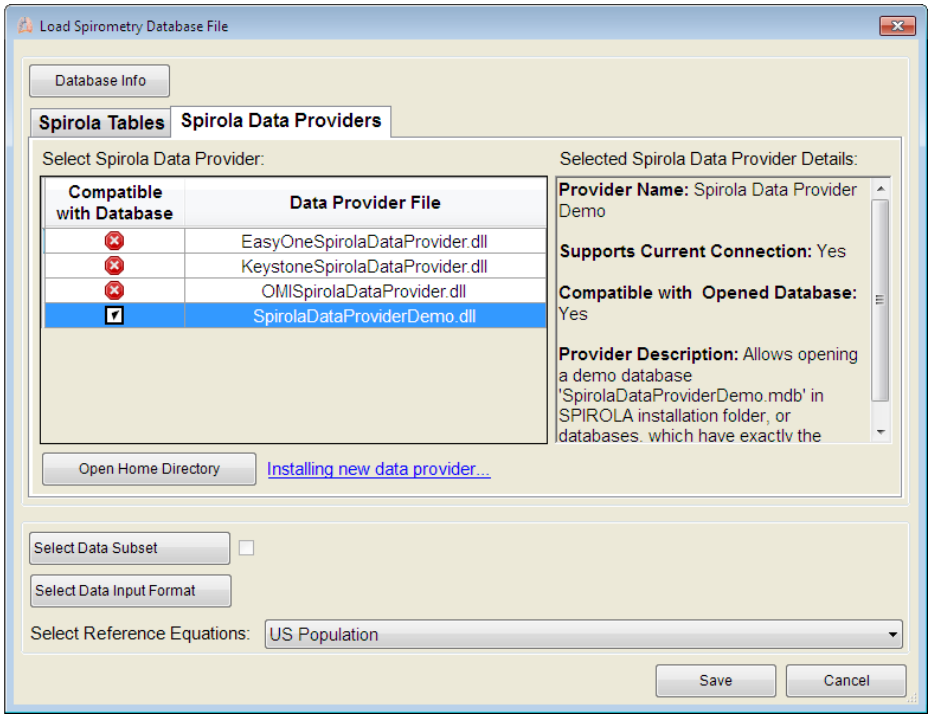
1. On the **File** menu click on **Open Database** menu, and then on **Open MS Access Database**.
2. Select any MS Access database, for example the file **SpirolaDataProviderDemo.mdb** in SPIROLA installation folder.
3. In the form that opens next (see picture below) click on the **Spirola Data Providers** tab, and then on button **Open Home Directory**, to open the directory, where Spirola data provider files are saved.
4. Save the new data provider file (i.e., DLL or EXE extension file) to the directory opened in Step 3.
5. If Spirola data provider file has dependent files, such as other DLL extension files or image files, that the data provider is using, then do the following:

    a) Create a new directory in the directory opened in Step 3, and rename the new directory so that its name is similar to the Spirola data provider file name without the extension.

    For example if the Spirola data provider file name is MyDataProvider.dll, then the new directory should have a name MyDataProvider

    b) Copy the dependent files into the directory, created in Step a.

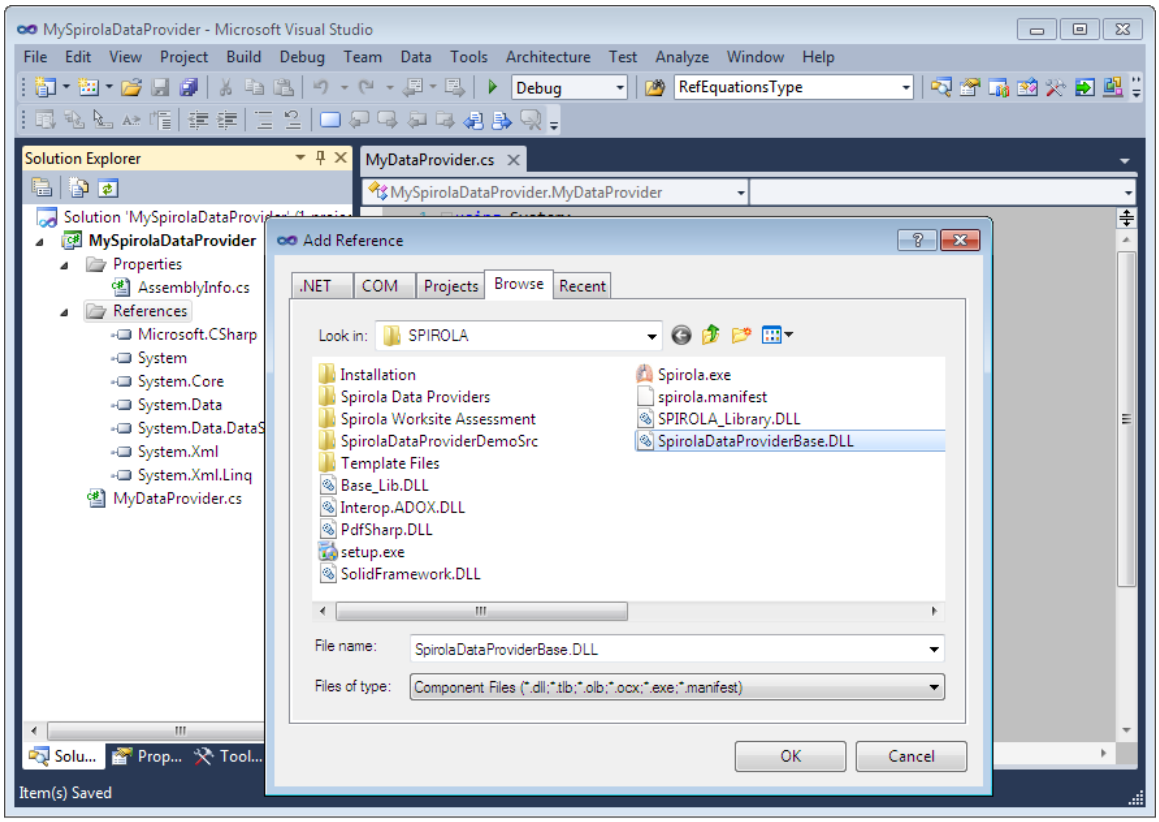
6. Restart Spirola.



Appendix D: Note to .NET Developers on Programming Spirola Data Provider

The steps below describe creating Spirola Data Provider using C#.NET and Visual Studio 2010. Other languages or compiles can be used as well, following these steps.

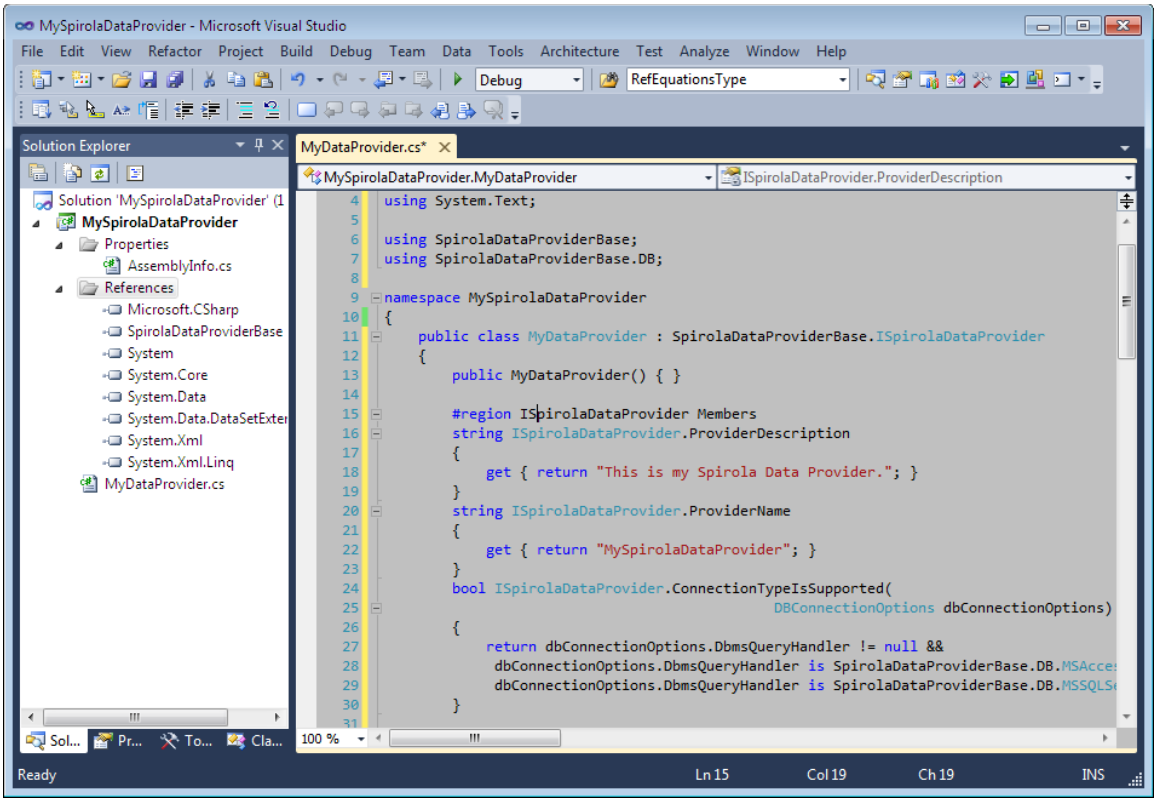
1. Install SPIROLA V3.0.2.
2. Start a Visual Studio 2010 and create a C# Class Library class project (project is named **MySpirolaDataProvider** in this example).
3. Right click on **References** item in the created Visual Studio project (see picture below), and in the menu click on **Add Reference…** menu.
4. In the window that opens next click on **Browse** tab, and select the file **SpirolaDataProviderBase.DLL** from the folder, from the SPIROLA installation directory (see picture below).



5. Create a class (named **MyDataProvider** in picture below) and do the following:

    a) Add **using SpirolaDataProviderBase** and **using SpirolaDataProviderBase.DB** statements, to be able to use classes in namespaces SpirolaDataProviderBase and SpirolaDataProviderBase.DB in the referenced assembly **SpirolaDataProviderBase.DLL**.

b) Add a constructor to the created class, which does not require any arguments (see picture below).
c) Make sure that class, created in Step 5 implements the interface **SpirolaDataProviderBase.ISpirolaDataProvider** (see picture below). To quickly implement the interface, right click on **SpirolaDataProviderBase.ISpirolaDataProvider** text and click on **Implement Interface** menu.



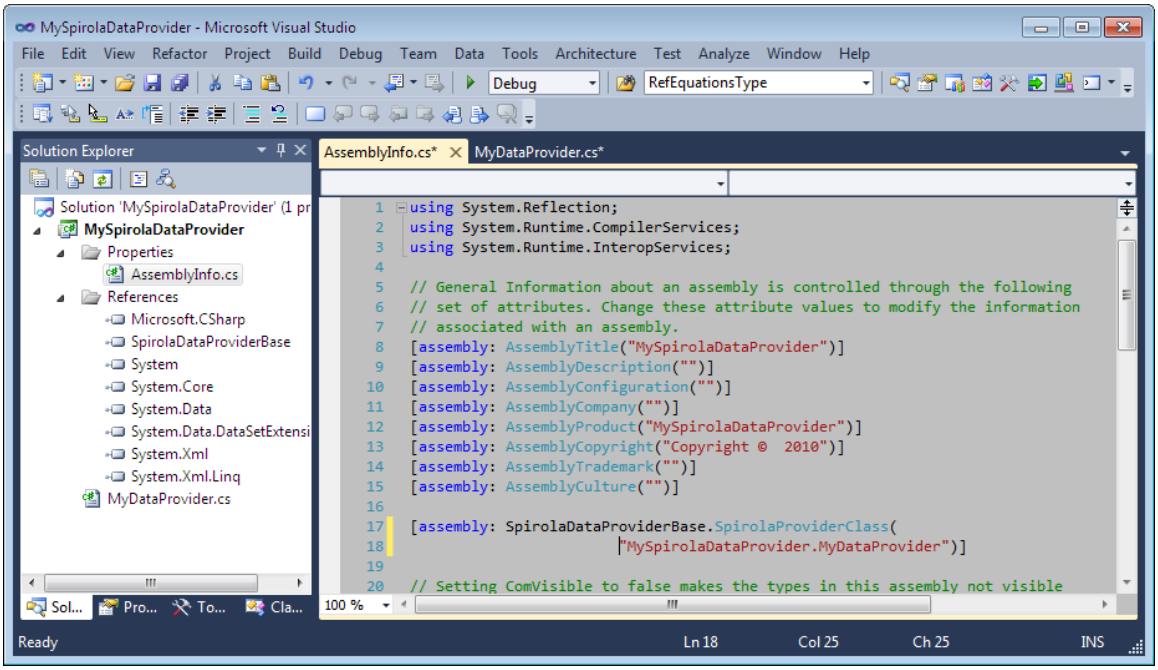
6. Click on **Properties** and then double-click on **AssemblyInfo.cs** file (see picture below) and in the opened editor add line

[assembly: SpirolaDataProviderBase.SpirolaProviderClass(
"Type the full name of the class, which implements the interface
SpirolaDataProviderBase.ISpirolaDataProvider")]

In our example, the added line is:
[assembly:SpirolaDataProviderBase.SpirolaProviderClass(
"MySpirolaDataProvider.MyDataProvider")]

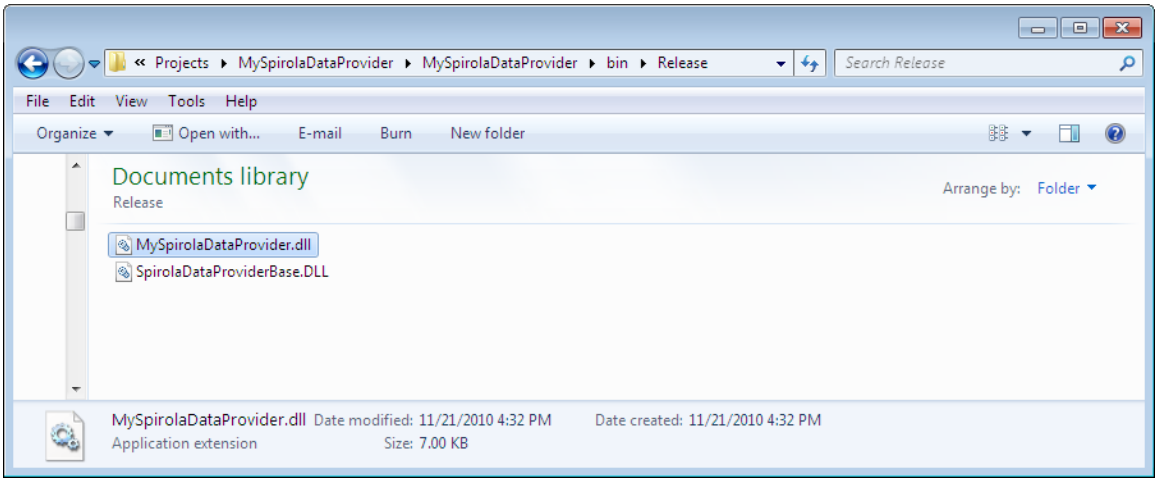
The full name of the class, which implements the interface **SpirolaDataProviderBase.ISpirolaDataProvider** is **MySpirolaDataProvider.MyDataProvider** in this example, therefore the added line in this example should be

[assembly:SpirolaDataProviderBase.SpirolaProviderClass(
"MySpirolaDataProvider.MyDataProvider")].



7. Compile the project to obtain the DLL file (MySpirolaDataProvider.dll in this example), which should be copied to the special directory for installed Spirola data providers, discussed in Appendix C above.

   Note: File **SpirolaDataProviderBase.DLL** should not be copied, since this file is already in SPIROLA installation directory.



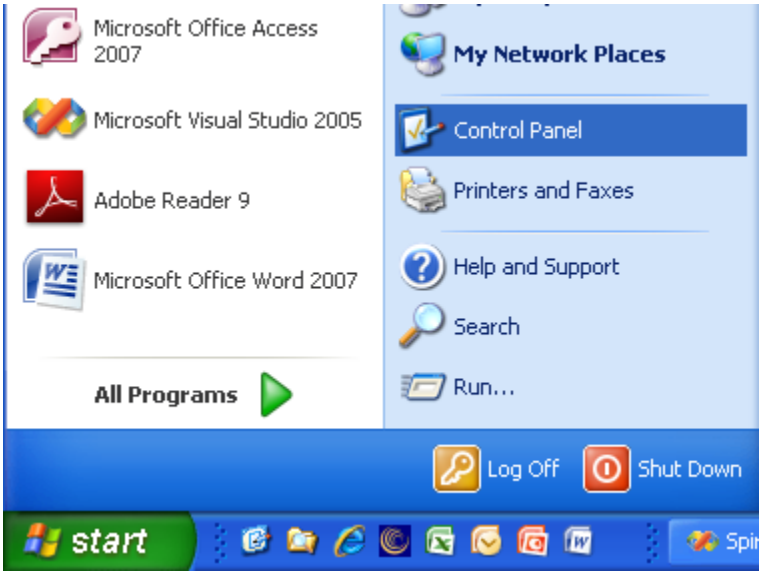
   For a complete example of programming Spirola data providers, refer to a directory SpirolaDataProviderDemoSrc in SPIROLA installation directory. This directory includes two zipped files:

a) File **SpirolaDataProviderDemo.zip**, which includes source code for the **SpirolaDataProviderDemo.DLL** demo Spirola Data Provider, which is automatically installed with SPIROLA.

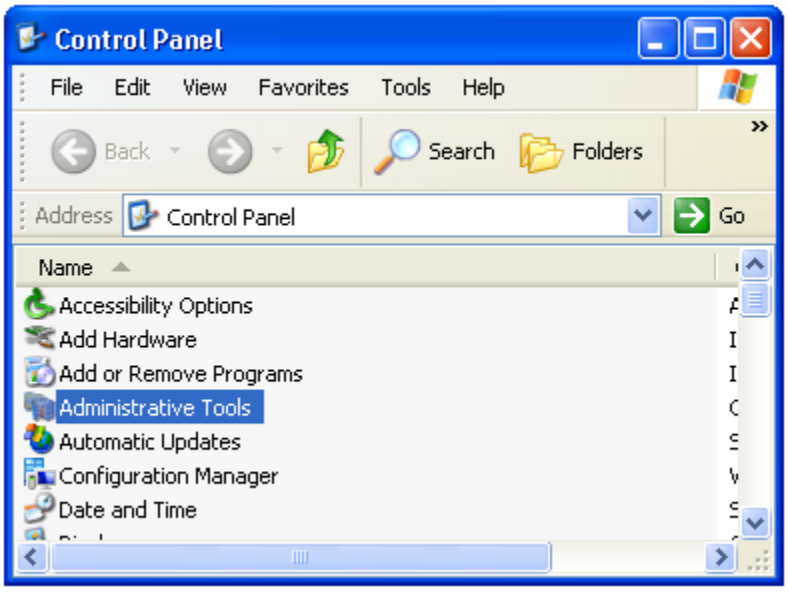
File **SpirolaDataProviderBase.zip**, which includes source code for the **SpirolaDataProviderBase.DLL** assembly, which should be added to the list references in Visual Studio project, when programming Spirola data provider (see Step 3 above).

Appendix E: Create ODBC data source for Excel 2007

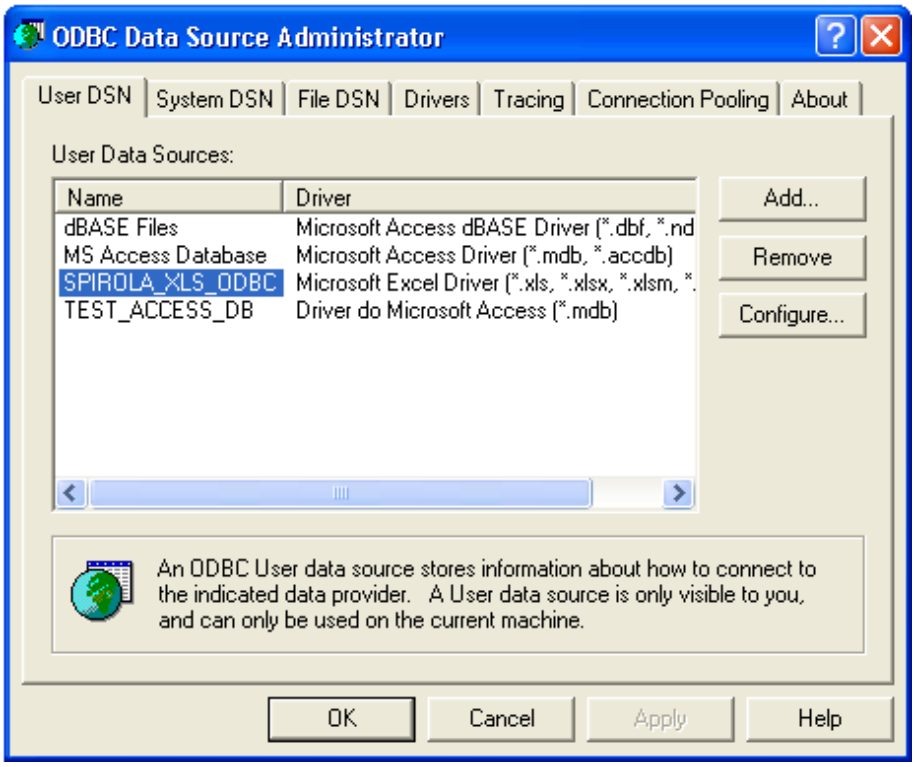
1) Click on the **start button on the left bo**ttom side of the screen and select **Control Panel** (see picture below).



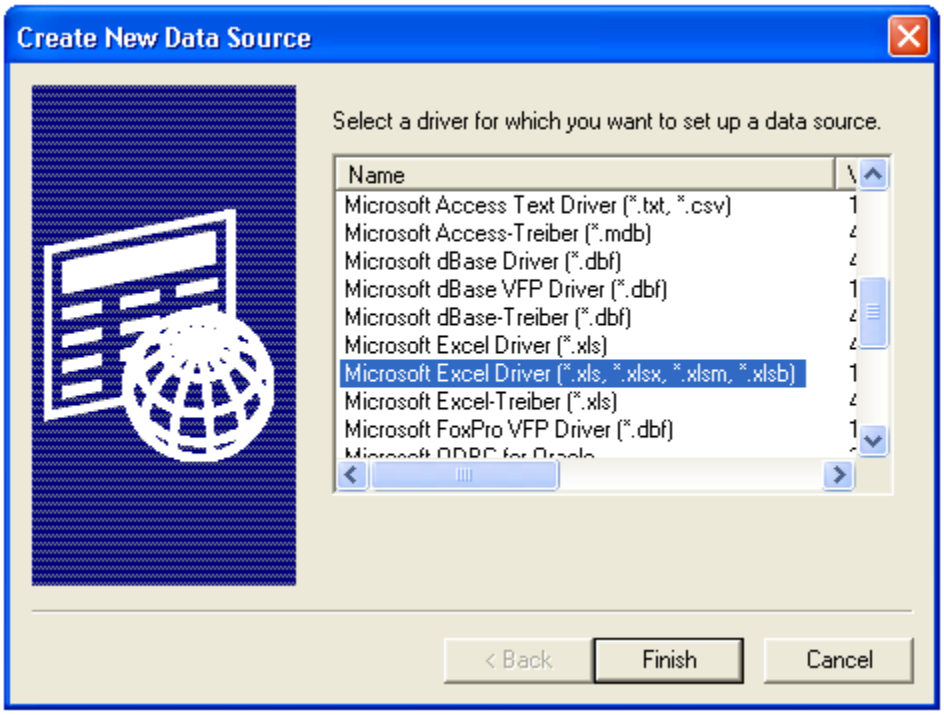
2) In the opened folder double-click on **Administrative Tools** (see picture below). In the next opened window double-click on **Data Sources (ODBC)**.



3) After a window called **ODBC Data Source Administrator** opens, select either **User DSN** tab or System DSN tab and click on the **Add** button (see picture below).



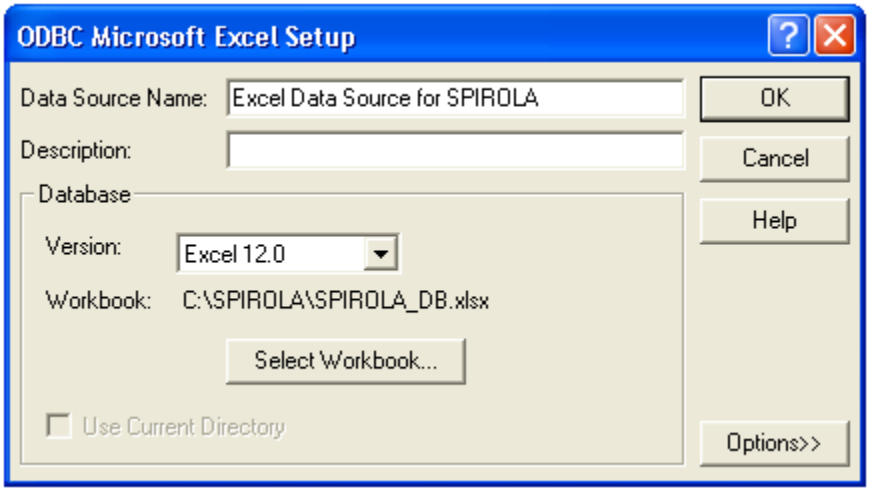
4) In the window called **Create New Data Source** that opens next scroll to **Microsoft Excel Driver** and press the **Finish** button (see picture below)



5) Window called **ODBC Microsoft Excel Setup** will open next (see picture below).

In this window:

- Type some name for the data source (e.g., **Excel Data Source for SPIROLA**).
- Click on the **Select Workbook…** button and select Microsoft Excel 2007 file which has spirometry records in SPIROLA format (see **Spirometry Database Format** in Section 3.2).
- Click on the Ok button.



Picture below shows an example of Microsoft Excel 2007 file, selected in **ODBC Microsoft Excel Setup** window above (i.e., file C:\SPIROLA\SPIROLA_DB.xlsx) in a required format.

	A	B	C	D	E	F	G	H	I	J	K	L
1	ID	First_Name	Middle_Initial	Last_Name	SEX	RACE	HEIGHT	AGE	TESTDATE	FEV1	FVC	
2	86	Ernest		Long	M	W	172	35	7/20/1994	4702	5545	
3	87	Phillip	E	Patterson	M	W	177	24	10/16/1990	4208	5272	
4	87	Phillip	E	Patterson	M	W	177	27	3/29/1994	4027	4997	
5	87	Phillip	E	Patterson	M	W	178	29	6/23/1995	3948	4883	
6	87	Phillip	E	Patterson	M	W	180	30	8/14/1996	3885	4819	
7	87	Phillip	E	Patterson	M	W	178	33	7/20/1999	3493	4348	
8	88	Todd	E	Hughes	M	W	183	47	7/9/1999	4230	5460	
9	88	Todd	E	Hughes	M	W	183	50	4/25/2002	3805	5092	
10	88	Todd	E	Hughes	M	W	183	51	9/2/2003	4100	5050	
11	89	Jesse	E	Flores	M	W	175	43	10/20/1994	3598	4953	
12	89	Jesse	E	Flores	M	W	173	44	11/8/1995	3467	4674	
13	89	Jesse	E	Flores	M	W	175	45	10/8/1996	3428	4607	
14												

Appendix F: Starting SPIROLA from Third Party Applications

Like any other Windows application, SPIROLA can be started from other software. SPIROLA can be started in a normal mode (when all individuals' test results in current SPIROLA database are loaded), or in a single individual mode, when only test results for specific individual are loaded.

To start SPIROLA in a single individual mode

1. Start SPIROLA and select a SPIROLA database on each computer, where SPIROLA is installed (see Section 3.3 above). This step needs to be done only once, so that SPIROLA remembers, from where to load the spirometry data the next time SPIROLA starts.

   SPIROLA stores the settings (including database settings) in **app.config** file under some folder, which is specific to each Windows user. For example if currently logged in Windows user is John, the **app.config** file on Windows XP system will normally be stored in directory **C:\Documents and Settings\John\Local Settings\Application Data\SPIROLA**. Therefore, to automate the Step 1, do Step 1 once, and copy the file **C:\Documents and Settings\John\Local Settings\Application Data\SPIROLA\ app.config** to the appropriate directory on each computer.

   For example, **app.config** should be copied to directory **C:\Documents and Settings\John Smith\Local Settings\Application Data\SPIROLA**, for the windows user John Smith.

2. Start SPIROLA using a batch file (i.e., .bat extension text file), which has the following line:

   "C:\Program Files\Spirola\Spirola.exe" "ParticipantId=ID" .

   Notes:
   - Instead of using .BAT file, SPIROLA can be started programmatically using VB Script or .NET language, as long as the parameter "ParticipantId=ID" is specified, where ID should be replaced with some individual's identity number.
   - Double parenthesizes may be omitted, as long as ParticipantId=ID text does not contain any spaces.

Appendix G: Import an Excel spreadsheet into the newly created Access database using Microsoft Access 2003

- From the **File** menu of Access, navigate to ***Get External Data*** and select ***Import***.
- Using the ***Files of type*** pull-down menu, select Microsoft Excel (*.xls).
- Navigate to the file location of your formatted Excel file ***YourSpirometerData.xls***, select file, and click on the Import button.
- Using the Import Spreadsheet Wizard, highlight the Show Worksheets radio button and select the worksheet containing your spirometer data records; click Next >.
- Check the "***First Row Contains Column Headings"*** box and click ***Next >***.
- Since this is a new database, highlight the ***In a New Table*** button for the question of where to store data and click ***Next >***.
- ***"Field Options Dialog Box"***: Verify that field names and records follow the formatting conventions described in the user manual on page 5; if not, field names can be renamed here and data fields that are not being imported into dataset can be excluded by checking the "***Do not import field (skip)***" box.
- **Indexed:** If you have an ***ID*** field in your data sheet, choose "***Yes (no duplicates)"*** for that column. All other fields should be left with the default ***Indexed*** choice of ***No***. (*Note- you will need to highlight each category to verify the selection.*) When data field verification is complete, click ***Next >***.
- In the "***Import to Table"*** box, type the name ***"FullDataset"* or "*StandardDataset"***; click ***Finish*** and then ***OK*** to complete the import process.
- Save and Exit Access

Appendix H: Import an Excel spreadsheet into the newly created Access database using Microsoft Access 2007

- Open newly created empty access database.
- Click on the "***External Data"*** tab.
- Under the "***Import & Link"*** section click on ***Excel***.
- The "***Get External Data-Excel Spreadsheet"*** window will open.
- Using the "***Browse***" button navigates to the Excel file you want to import.
- In the "***File Open"*** window select the file and click on the ***Open*** button.
- You will return to the "***Get External Data-Excel Spreadsheet"*** window.
- Select the option "***Append a copy of the records to the table"***.
- Select ***"FullDataset"*** or "***StandardDataset"*** from the dropdown.
- Click on the OK button.
- The "***Import Spreadsheet Wizard***" will open and guide you through the steps necessary to import the Excel spreadsheet.
- Select "***Spirola_Full***" worksheet, if initial excel spreadsheet was created using SPIROLA Empty database option otherwise select the worksheet that contains the data and press ***Next***>.
- Check "***First Row Contains Column Headings***" check box.
- In the "***Import to Table"*** box, type the name ***"FullDataset"*** **or** "***StandardDataset"***; click ***Finish*** and then ***OK*** to complete the import process.
- Save and Exit Access